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, 2024

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 001-40800

TYRA BIOSCIENCES, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**83-1476348**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2656 State Street	
Carlsbad, California	**92008**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (619) 728-4760

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, $0.0001 par value per share	**TYRA**	**The Nasdaq Global Select 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, smaller reporting company, or an emerging growth company. See the 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 Exchange Act). YES ☐ NO ☒

The aggregate market value of registrant's common stock held by non-affiliates of the registrant, computed by reference to the closing price as of the last business day of the registrant's most recently completed second fiscal quarter, June 28, 2024, was approximately $337.8 million.

As of March 25, 2025, the registrant had 53,089,957 shares of common stock ($0.0001 par value) outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain sections of the registrant's definitive proxy statement for the 2024 annual meeting of stockholders to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Form 10-K are incorporated by reference into Part III of this Form 10-K.

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PART I

FORWARD-LOOKING STATEMENTS AND MARKET DATA

This Annual Report on Form 10-K (Annual Report) contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). All statements other than statements of historical facts contained in this Annual Report, including statements regarding our future results of operations and financial position, business strategy, research and development plans, the anticipated timing and phase of development, costs, design and conduct of our ongoing and planned preclinical studies and clinical trials for our product candidates, the potential benefits of regulatory designations, the timing and likelihood of regulatory filings and approvals for our product candidates, the potential to develop product candidates and the safety and therapeutic benefits of our product candidates, our ability to commercialize our product candidates, if approved, the pricing and reimbursement of our product candidates, if approved, the timing and likelihood of success, plans and objectives of management for future operations, and future results of anticipated product development efforts, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that 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. This Annual Report also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

In some cases, you can identify forward-looking statements by terms such as “anticipate,” “believe,” “continue” “could,” “contemplate,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will” or "would" or the negative of these terms or other similar expressions. The forward-looking statements in this Annual Report are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Annual Report and are subject to a number of risks, uncertainties and assumptions, including, without limitation, the risk factors described in Part I, Item 1A, “Risk Factors.” The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

This Annual Report includes trademarks, tradenames and service marks that are the property of other organizations. Solely for convenience, trademarks and tradenames referred to in this Annual Report appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or that the applicable owner will not assert its rights, to these trademarks and tradenames.

We maintain a website at www.tyra.bio, to which we regularly post copies of our press releases as well as additional information about us. Our filings with the Securities and Exchange Commission (SEC) are available free of charge through our website as soon as reasonably practicable after being electronically filed with or furnished to the SEC. Information contained in our website does not constitute a part of this report or our other filings with the SEC.

Item 1. Business.

Overview

We are a clinical-stage biotechnology company focused on developing next-generation precision medicines for large opportunities in targeted oncology and genetically defined conditions, with an initial focus on Fibroblast Growth Factor Receptor (FGFR) biology.

Our in-house precision medicine platform, SNÅP, enables rapid and precise drug design through iterative molecular SNÅPshots that help us design and predict which product candidates may demonstrate the highest potency, selectivity and tolerability in the clinic. We have initially leveraged our SNÅP approach to develop TYRA-300, TYRA-200 and TYRA-430: three clinical-stage, novel small molecules designed to overcome the toxicity and resistance liabilities of first generation pan-FGFR inhibitors.

Our FGFR3 Programs—TYRA-300 for Bladder Cancer and Skeletal Conditions

Mutations in the protein receptor FGFR3 are a key driver in two indications with large market opportunities: bladder cancer and skeletal conditions. In bladder cancer, uncontrolled activation of FGFR3 on the cell surface stimulates cellular proliferation. In skeletal conditions, increased activity of FGFR3 expressed in growth plate chondrocytes (cartilage cells) results in excessive limitation of long bone growth.

Our lead program, TYRA-300, was designed to be more selective for FGFR3 over FGFR1, FGFR2, and FGFR4 to minimize off-target side effects, providing potential clinical advantages over less selective first-generation compounds and potentially addressing key unmet needs across both bladder cancer and skeletal conditions.

TYRA-300 is to be evaluated in three Phase 2 studies: SURF301, for the treatment of metastatic urothelial carcinoma (mUC); SURF302, for the treatment of non-muscle invasive bladder cancer (NMIBC); and BEACH301, for the treatment of pediatric achondroplasia (ACH).

SURF301 for mUC: This ongoing study is an international, multi-center, open label Phase 1/2 clinical trial that was designed to determine the optimal and maximum tolerated doses (MTD), and the recommended Phase 2 dose (RP2D) of TYRA-300, as well as to evaluate the preliminary antitumor activity of TYRA-300. In late October 2024, we reported interim data that in patients with FGFR3+ mUC who received doses ≥ 90 mg once daily (QD), 6 out of 11 (54.5%) patients achieved a confirmed partial response (PR). Preliminary data, as of the August 15, 2024 data cutoff, suggested TYRA-300 was generally well-tolerated, with infrequent FGFR2- and FGFR1-associated toxicities. Dose optimization is ongoing in this study.

SURF302 for NMIBC: This study is an open-label Phase 2 clinical trial evaluating the efficacy and safety of TYRA-300 at lower doses (50 and 60mg QD) in participants with FGFR3-altered low-grade, intermediate risk (IR) NMIBC. We expect to dose the first patient in this study in the second quarter of 2025.

BEACH301 for ACH: This study is an open-label, Phase 2 dose-escalation/dose-expansion trial evaluating TYRA-300 at lower doses (0.125, 0.25, 0.375, 0.50 mg/kg) in children ages 3 to 10 with ACH with open growth plates. Prior to initiation of the first two cohorts, the study will enroll a safety sentinel cohort of up to 3 treatment-naïve participants per dose level in children ages 5 to 10. We expect to dose the first child in this study in the second quarter of 2025.

Our FGFR2 Program- TYRA-200 for Intrahepatic Cholangiocarcinoma

FGFR2 is a protein receptor present on the cell surface that promotes cellular proliferation and transformation upon binding of fibroblast growth factor. Activating gene alterations of FGFR2 have been implicated in the tumorigenesis of multiple solid tumor types, with pan-FGFR inhibitors approved for intrahepatic cholangiocarcinoma (ICC).

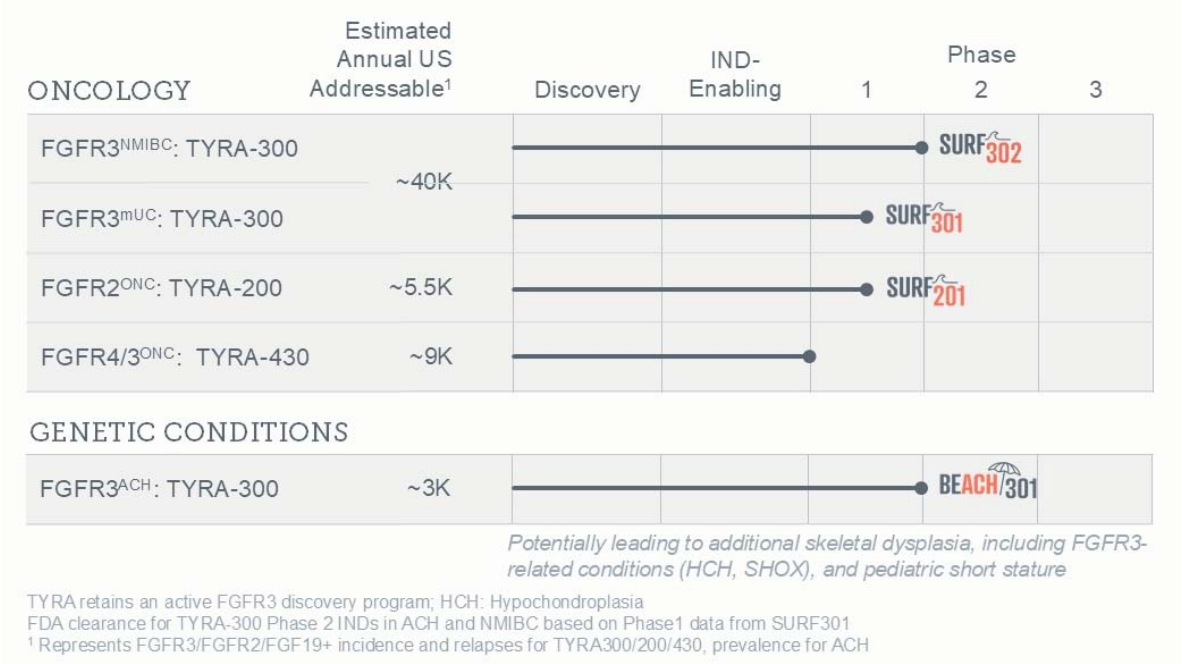
TYRA-200 is an FGFR1/2/3 inhibitor designed to be active against nearly all of the clinically identified acquired resistant mutations that arise during treatment with pan-FGFR inhibitors, which we believe is necessary to address the problem of disease progression due to polyclonal resistance. TYRA-200 is currently being evaluated in a multi-center, open label Phase 1 clinical study, SURF201 that is designed to evaluate the safety, tolerability, and pharmacokinetics (PK) of TYRA-200, determine the optimal dose for further development and the MTD and RP2D, and evaluate preliminary antitumor activity, with a focus on achieving proof-of-concept in a cohort of FGFR2-driven ICC resistant to previous FGFR inhibitors.

Our FGF19+ Program- TYRA-430 for Hepatocellular Carcinoma

Fibroblast growth factor 19 (FGF19) is a post-prandial enterohepatic hormone that signals through FGFR4 and its associated co-receptor Klotho Beta (KLB) to exert its normal cellular functions. In certain cancers, FGF19 is aberrantly expressed due to focal chromosomal amplifications or epigenetic mechanisms, promoting tumor cells to become dependent on the FGFR4/KLB/FGF19 oncogenic axis. Recent insights into FGF/FGFR signaling in HCC have indicated an important bypass mechanism in FGFR3, which shares the KLB coreceptor.

TYRA-430 was designed to be biased for FGFR4 and FGFR3 over the FGFR1 and FGFR2 isoforms specifically to address the FGF19 signaling pathway, while also potentially limiting side effects due to inhibition of FGFR1 and FGFR2, as well as to address acquired resistance mutations that have limited the efficacy of previous FGFR4-specific inhibitors. TYRA-430 will be initially studied in SURF431, a global Phase 1 multicenter, open-label, study in advanced HCC and other solid tumors with activating FGF/FGFR pathway aberrations (SURF431). We expect to dose the first patient in this study in the second quarter of 2025.

Our Pipeline



Our Strategy

Our mission is to improve outcomes for patients living with cancer and genetically defined conditions. We are executing on our mission by focusing on our three strategic pillars: a novel SNÅP platform; an expanding and advancing pipeline; and building a leading company around FGFR biology. With this strategy, our goal is the discovery, development and commercialization of next-generation precision small molecules against clinically validated targets to treat a wide range of indications currently lacking adequate treatment options.

The elements of our strategy to achieve this goal are to:

1. Advance our lead product candidate, TYRA-300, in bladder cancer and skeletal conditions;

2. Advance our early-stage clinical pipeline and maintain our position as a leader in our initial focus area of FGFR biology; and

3. Harness the power of our SNÅP platform to expand our pipeline of next-generation precision medicines for oncology and rare disease indications within FGFR biology and potentially other target areas of interest.

All of our assets have been developed in-house and we retain full development and commercialization rights for our pipeline. We intend to maximize the value of our pipeline by retaining development and commercialization rights to our product candidates, indications and geographies that we believe we can ultimately commercialize successfully on our own if they are approved. We will seek to collaborate on product candidates or indications that we believe have promising utility in disease areas or patient populations that are better served by the resources or specific expertise of larger biopharmaceutical companies.

Our SNÅP Platform

Our proprietary SNÅP platform enables rapid and precise drug design through iterative molecular SNÅPshots that help us design and predict which product candidates will demonstrate the highest potency, selectivity and tolerability in the clinic. Through this approach, we have developed next-generation precision small molecule candidates with novel structures designed to inhibit the target while avoiding off-target toxicities and resistance mutations.

Our SNÅP platform is driven by our ability to generate iterative data rapidly and concurrently from the following three key pillars.

1. **Protein crystallography**. We have developed proprietary protein crystallography techniques that enable us to determine the co-crystal structures of newly synthesized compounds in target proteins in as little as three days. This enables weekly generation of detailed structural insights on the precise interactions and conformational changes that occur when our potential product candidates bind to a particular target, creating opportunities to further refine the structural design.

2. **Cell-based assays**. We assess inhibitor potency directly in in vitro target-specific anti-proliferation assays, in addition to enzymatic assays, to enable us to simultaneously understand target potency and cell penetration as well as target-specific cell killing. Our process allows us to generate data on newly synthesized compounds in as little as two days.

3. **In vivo models**. Our direct structural insights and in vitro datasets are complemented by in vivo pharmacologic data generated through in-house animal models that provide us with bioavailability, PK data and anti-tumor activity in as little as five days.

Together, these three pillars of our platform provide a molecular SNÅPshot for our compound candidates. At this time, we are able to generate a molecular SNÅPshot for a compound candidate within one week. We believe that a sharp focus on efficiently generating these three key empirical datasets for compound candidates enables us to

balance speed with the robust identification of pivotal insights to rapidly and precisely iterate the design of our novel molecular structures.

Overcoming First Generation FGFR Inhibitor Liabilities

We have initially leveraged our SNÅP approach to develop novel small molecules designed to overcome the toxicity and resistance liabilities of prior generation pan-FGFR inhibitors. Four FGFR targeted therapies have been approved by the FDA for oncology: erdafitinib for locally advanced or mUC, or bladder cancer, and pemigatinib, infigratinib, and futibatinib for ICC with FGFR2-fusions or gene rearrangements (infigratinib was later withdrawn from the market effective March 31, 2023). These inhibitors have demonstrated clinical responses, however response rates and duration of response are limited and come with toxicities driven by the inhibition of FGFR receptors 1, 2 and 4. FGFR1 is expressed in kidney cells where it regulates phosphate and calcium reabsorption, and consequently, inhibition of FGFR1 results in hyperphosphatemia. Inhibition of FGFR2 can result in toxicities that significantly impact quality of life, such as skin and nail toxicities (e.g., onycholysis and hand-foot syndrome), stomatitis, and ocular toxicities such as keratitis and blurred vision. Inhibition of FGFR4 disrupts bile acid metabolism and can result in diarrhea and elevated liver enzymes (AST and ALT). Hyperphosphatemia was a dose-limiting toxicity (DLT) of erdafitinib and was reported in over 70% of patients in the Phase 3 clinical trial conducted in mUC. Overall, Phase 3 adverse events resulted in 72% dose interruptions, 69% dose reductions, and 14% treatment discontinuations. By way of example, we believe the safety and tolerability profile of erdafitinib is a key limitation to its efficacy, as demonstrated by the dosing instructions to start at a daily 8 mg dose, and only increase to 9 mg if hyperphosphatemia is not observed. A similarly high rate of FGFR-related toxicities has been reported in clinical trials of other non-isoform selective FGFR inhibitors including pemigatinib, infigratinib and futibatinib in pivotal studies for ICC. In addition to being limited by toxicity, patients can develop acquired drug resistance, ultimately resulting in disease progression and discontinuation of therapy.

Our FGFR3 Program for Bladder Cancer

TYRA-300 for mUC and NMIBC

FGFR3 is a protein receptor expressed on the cell surface that stimulates cellular proliferation upon binding of fibroblast growth factor. Uncontrolled activation of FGFR3 has been implicated in the oncogenesis of multiple solid tumor types, including bladder cancer.

TYRA-300 was designed to be more selective for FGFR3 over FGFR1, FGFR2, and FGFR4, to minimize side effects resulting from inhibition of these related proteins and achieve greater potency against the FGFR3 driver mutation. TYRA-300 is currently being studied in the global Phase 1/2 SURF301 trial in patients with mUC; TYRA-300 will also be evaluated in the global Phase 2 SURF302 trial in patients with IR NMIBC, expected to initiate in the second quarter of 2025.

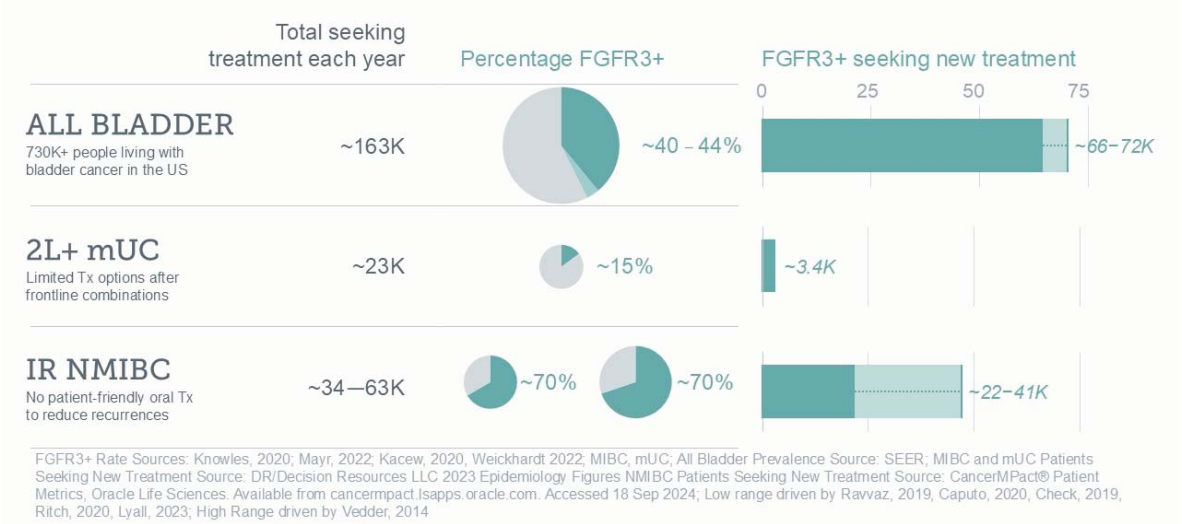
Disease background

Urothelial cancer (UC) is one of the most common malignancies of the genitourinary system, with over 730,000 people living with bladder cancer in the United States in 2021. Bladder cancer is classified into three broad categories: NMIBC where the cancer is restricted to surface lining of the bladder, MIBC, which is a cancer that has grown deeper into the bladder wall, and mUC in which cancer has spread beyond the bladder. NMIBC comprises the largest population of bladder cancer patients, representing 70-75% of cases diagnosed annually in the United States. NMIBC can be categorized as low, intermediate and high risk for recurrence or progression, with a significant proportion categorized as intermediate and high risk. Whereas between 2014 to 2020, the five-year survival for early stage NMIBC was 97.2%, it was 8.8% for mUC.

The incidence of activating FGFR3 mutations in bladder cancer has been estimated to be between 60-80% of IR NMIBC and between 10-20% of mUC, making FGFR3 an attractive target for development.

We estimate that in 2023, across NIMBC, MIBC and mUC, approximately 163,000 patients were seeking therapy for first-time treatment or to address a recurrence. Applying FGFR3 alteration incidence to these estimates,

we believe that approximately 66,000-72,000 FGFR3+ patients are addressable across intermediate and high risk NMIBC, MIBC and mUC in the United States alone. The majority of FGFR3+ patients are estimated to be IR, ranging from 22-41,000, and approximately 3,400 patients are estimated to be addressable in the post-frontline setting of mUC.



Potential bladder cancer patient populations for our FGFR3 inhibitor

Current 2/3L+ mUC treatment landscape and unmet need

The shift in frontline mUC standard of care from chemotherapy combinations to Padcev in combination with Keytruda has created an unmet need in the post-frontline setting, where Padcev and Keytruda were initially approved as monotherapies. For FGFR3+ mUC patients who have received frontline Padcev and Keytruda, erdafitinib is a second-line treatment option, offering a 35.3% overall response rate (ORR), a median progression free survival (PFS) of 5.6 months and overall survival (OS) of 12.1 months, outperforming single agent chemotherapy. Erdafitinib uptake has been limited by tolerability, including 13% serious treatment-related adverse events (TRAE), 45.9%, grade 3/4 TRAE and 66% TRAE leading to dose reduction. Other available options include chemotherapy combinations, for which no randomized controlled trial data is available to date. There continues to be a high unmet need for improvements in both efficacy and toxicity in the 2/3L+ setting.

Current NMIBC treatment landscape and unmet need

NMIBC is one of the most recurrent of all cancers and current standard of care treatment comes with drawbacks. For low grade lesions, Transurethral Resection of Bladder Tumor (TURBT) with or without adjuvant intravesical chemotherapy is the standard of care, whereas high risk lesions should be treated with either adjuvant BCG or radical cystectomy. TURBT comes with risks and burden to patients, including the need to undergo general anesthesia and potential for adverse events such as bladder perforation. Within the first two years of initial standard of care treatment, intermediate and high risk NMIBC recurrence rates are as high as 40% and 30%, respectively. No novel therapy has been approved for IR NMIBC, with only intravesical therapies remaining in development. For high risk NMIBC, primarily intravesical treatments have been approved only for patients with carcinoma in situ (CIS) and multiple intravesical therapies are in Phase 3 development.

Phase 2 data for erdafitinib in NMIBC suggest the potential for FGFR inhibitors in this indication. Oral erdafitinib demonstrated a preliminary 83% complete response (CR) rate in IR patients presented at SUO 2023, 77% recurrence free survival (RFS) in high-risk papillary patients presented at ESMO 2023 and 73% 6-month CR rate in high-risk CIS patients presented at SUO 2023. The safety and tolerability results were generally consistent with that known for erdafitinib, despite using a lower 6mg daily dose in these studies. TAR-210, an erdafitinib-containing

device implanted every three months via the urethra, also demonstrated a 90% CR rate in IR patients and 90% RFS in high-risk papillary patients as presented at AUA 2024. Johnson & Johnson has initiated a Phase 3 study for TAR-210 in low grade, IR patients and has not indicated plans to develop oral erdafitinib further in this setting.

Our solution, TYRA-300 in mUC and NMIBC

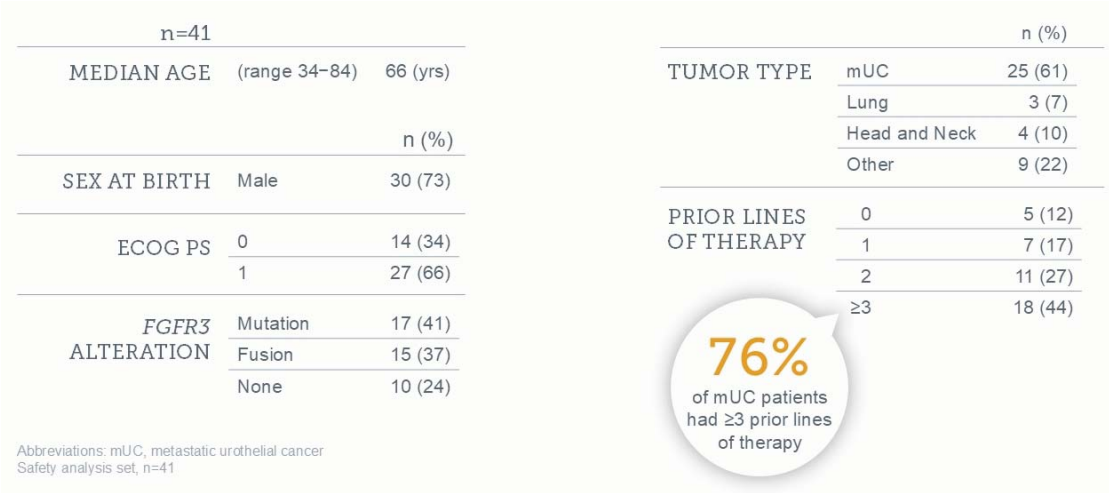
We believe an orally administered, highly specific FGFR3-directed inhibitor, with minimal effects from other FGFR-related toxicities, has the potential to be highly efficacious and tolerable and represents a potentially large future market opportunity for our product candidate in patients with FGFR3+ mUC and NMIBC.

Designing inhibitors that bind to the ATP-binding site and that can selectively differentiate between FGFR3 and FGFR1 is challenging due to the near-identical amino acid sequence in this site. We utilized the differentiated approach of our SNÅP platform to generate compounds, including TYRA-300, that capitalize on subtle conformational differences between FGFR3 and FGFR1 to obtain greater than ten-fold selectivity for FGFR3 versus FGFR1. In comparison, other FGFR inhibitors that are approved or in clinical development such as erdafitinib, pemigatinib, futibatinib and infigratinib, have demonstrated low or no selectivity for FGFR3 over FGFR1 and FGFR2.

Clinical development and data generated to date for TYRA-300 in oncology

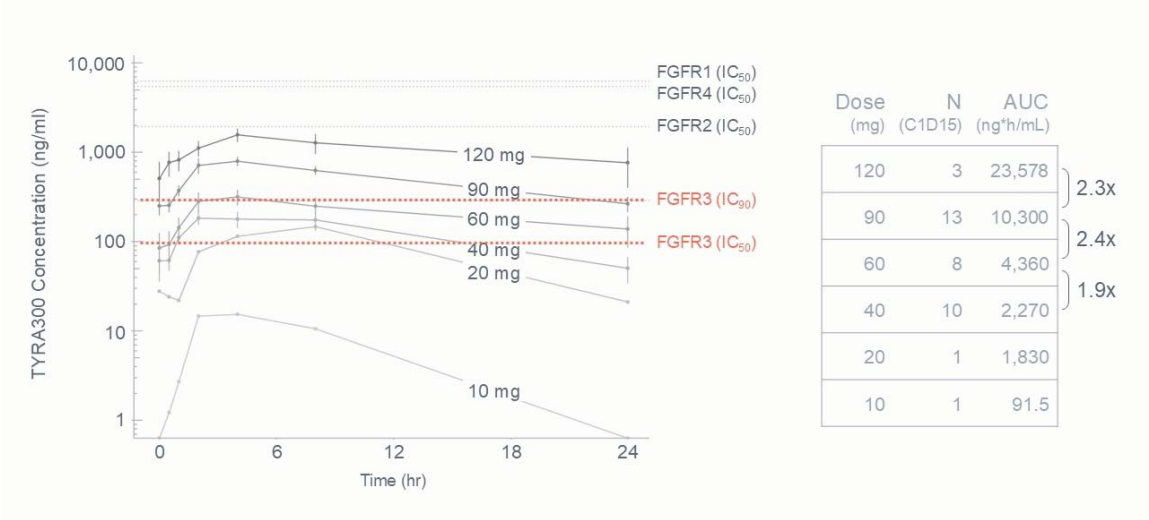
In November 2022, we initiated our Phase 1 clinical trial of TYRA-300, SURF301, an international, multi-center, open label study designed to determine the optimal dose, MTD and the RP2D of TYRA-300, as well as to evaluate the preliminary antitumor activity of TYRA-300. SURF301 is currently enrolling adults with locally advanced or mUC and other advanced solid tumors with FGFR3 gene alterations. As of March 2024, the Part A Phase 1 portion of SURF301 completed dose escalation up to 120mg without determining an MTD, and is currently evaluating doses below 120mg, including 100mg in preparation for initiating the Phase 2 portion of the study.

In October 2024, we announced interim clinical proof-of-concept data for TYRA-300 in patients with mUC from the SURF301 study. These data were presented in a late-breaking oral presentation at the 36th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics in Barcelona, Spain. As of the August 15, 2024 data cutoff, 41 patients were enrolled in the Phase 1 portion of the SURF301 Phase 1/2 study. Eligible participants were adults with advanced malignancies with or without FGFR3 alterations, including those previously treated with erdafitinib. The enrolled patient population was heavily pre-treated, with 44% of patients receiving ≥ 3 lines of therapy prior to receiving TYRA-300, and 76% of FGFR3+ mUC patients receiving ≥ 3 lines of therapy. Treatment with TYRA-300 was evaluated across six dose levels, ranging from 10 mg-120 mg QD.



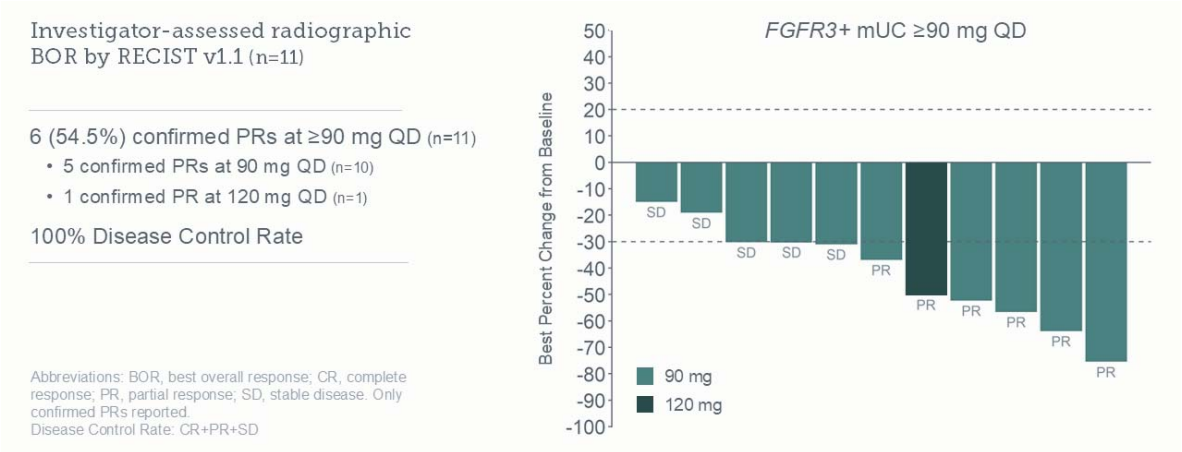
The study population was older and heavily pre-treated

In the preliminary PK/pharmacodynamics analysis in 41 patients as of the data cutoff, TYRA-300 plasma concentrations indicated adequate target coverage at ≥90 mg QD, with further PK characterization ongoing.



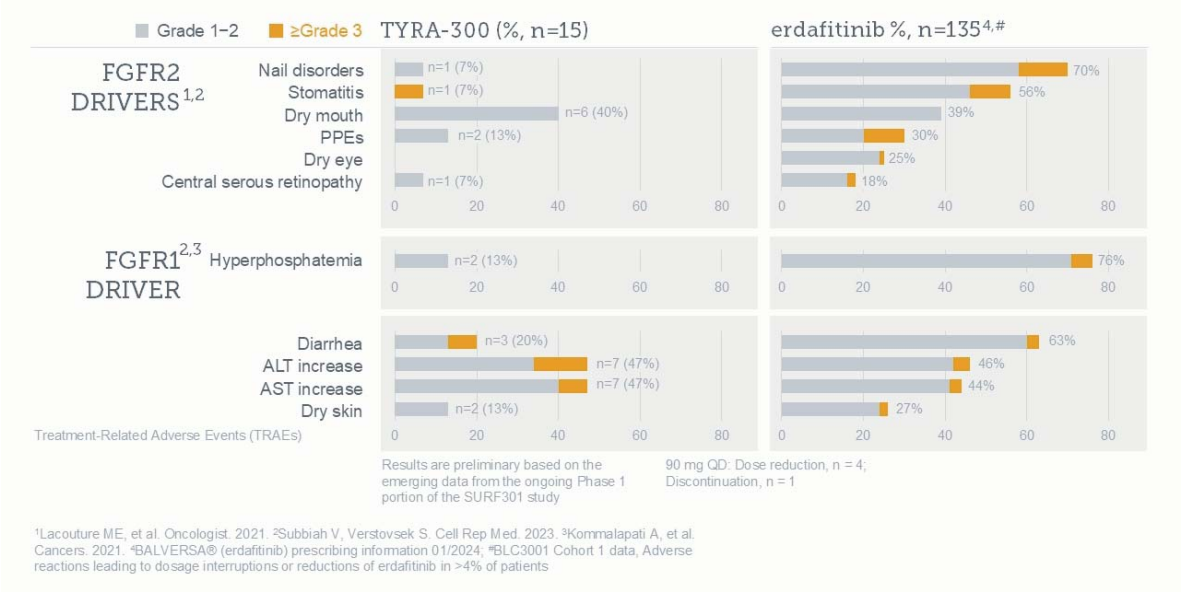
Exposure at doses ≥90 mg exceeded FGFR3 IC_{90} target coverage

In patients with FGFR3+ mUC who received doses ≥ 90 mg QD, anti-tumor activity was observed in all patients: (i) 6 out of 11 (54.5%) patients at ≥ 90 mg QD achieved a confirmed PR, 3 of which are still ongoing; (ii) 5 out of 10 (50%) patients at 90 mg QD achieved a PR; (iii) 1 out of 1 (100%) patient at 120 mg QD achieved a PR; and (iv) a 100% disease control rate (DCR) was achieved for all patients at ≥ 90 mg QD (PR + stable disease).



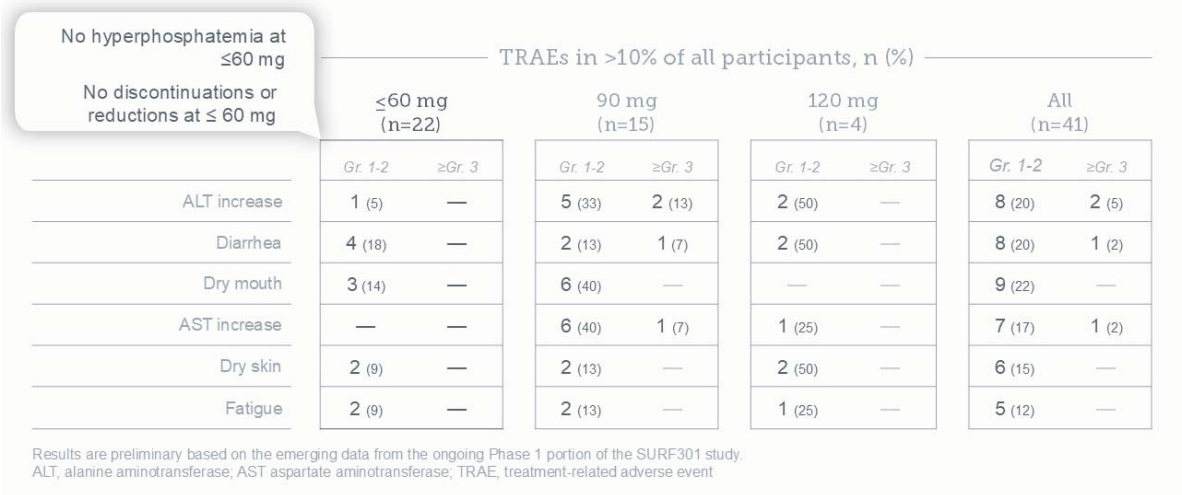
Anti-tumor activity was observed in all *FGFR3*+ mUC patients treated at ≥90 mg QD

TYRA-300 demonstrated favorable interim safety results as of the data cutoff date: (i) preliminary data has shown TYRA-300 was generally well-tolerated, with infrequent FGFR2- and FGFR1-associated toxicities; (ii) in doses from 10 mg up to 120 mg QD, there were 4 (10%) serious adverse events related to TYRA-300, 1 DLT of grade (Gr) 3 diarrhea at 90 mg QD, and 1 TRAE leading to discontinuation of treatment (Gr3 ALT, 90 mg QD); (iii) there were no ≥ Gr4 TRAEs; and (iv) the 120 mg QD dose was the highest dose evaluated with no DLTs reported.



At 90mg QD, improved tolerability was observed with TYRA-300 as compared to erdafitinib

At dose levels lower than 60mg, including target dose levels for NMIBC and skeletal conditions, TYRA-300 exhibited favorable interim safety results as of the data cutoff date. No hyperphosphatemia, discontinuation or dose reductions were reported at doses equal to or below 60mg.



FGFR-related toxicities were infrequent at lower doses

Future clinical development plans for TYRA-300 in mUC and NMIBC

We believe that the full development potential for TYRA-300 may cover the entire spectrum of disease in UC, and may represent a large opportunity relative to other drug targets given the high prevalence of FGFR3 mutations and the potential to treat earlier disease.

The Phase 2 portion of SURF301 will test two doses of TYRA-300. We plan to include cohorts of mUC patients naïve to FGFR inhibitors as well as a small cohort of mUC patients who have received an FGFR inhibitor

previously and have developed resistance to that inhibitor due to an FGFR3 mutation, such as the gatekeeper V555M.

In January 2025, we announced that the FDA cleared our Investigational New Drug application (IND) for TYRA-300 to proceed with a Phase 2 clinical trial of TYRA-300 in low-grade, IR NMIBC (SURF302). SURF302 will be an open-label Phase 2 clinical study evaluating the efficacy and safety of TYRA-300 in participants with FGFR3-altered low-grade, IR NMIBC. The study will enroll up to 90 participants at multiple sites primarily in the United States. Participants will be randomized initially to treatment with TYRA-300 at 50 mg QD (Cohort 1) or treatment with TYRA-300 at 60 mg QD (Cohort 2). Following a review of efficacy and safety, an additional dosing cohort may be evaluated. The primary endpoint is CR rate at three months. Secondary endpoints include time to recurrence, the median duration of response, RFS, PFS, safety and tolerability. We expect to dose the first patient in this study in the second quarter of 2025.

Our future plans may include potential combination studies with approved or novel agents across all stages of bladder cancer where the risk of overlapping toxicities may be diminished when combined with TYRA-300.

Our FGFR3 Program for Skeletal Conditions

TYRA-300 for ACH and Skeletal Conditions

Mutations in FGFR3 are implicated in skeletal conditions due to its role in regulating bone and cartilage formation. We believe that there is a significant opportunity to develop TYRA-300 to potentially address the long-term complications associated with these skeletal conditions including ACH, hypochondroplasia (HCH), Short Stature Homeobox (SHOX) deficiency, other FGFR3-driven genetic syndromes and idiopathic short stature.

Disease background

FGFR3 is expressed in growth plate chondrocytes (cartilage cells) where it functions in signaling pathways to limit growth. The G380R mutation in FGFR3, which causes an estimated 99% of ACH, as well as other activating mutations, increases FGFR3 activity, resulting in excessive limitation of growth in the long bones, vertebral bodies and skull base. In children with ACH, the most common form of dwarfism, these growth differences can result in life-long health complications such as sleep apnea, obesity, recurrent ear infections, and bowed legs. The most serious sequelae include spinal stenosis (narrowing of the spinal canal); up to 20% of infants require surgery to address narrowing at the base of the skull (foramen magnum stenosis), which can be life-threatening; in adults, spinal stenosis of the lower back results in chronic pain, necessitating surgery and long-term pain management.

ACH is an autosomal dominant condition that occurs in approximately 1 in 15,000 to 40,000 newborns worldwide, and it is estimated that there are approximately 3,000 affected individuals under the age of 18 in the United States and approximately 23,000 addressable, affected individuals under the age of 18 worldwide. Approximately 80% of ACH cases arise through a spontaneous mutation of FGFR3, whereas 20% of cases are familial.

FGFR3 is implicated in multiple additional skeletal conditions, including HCH, which is most commonly caused by the N540K mutation (~70-80%) in the FGFR3 gene, as well as SHOX Deficiency, where SHOX is a transcription factor for FGFR3.

Current treatment landscape and unmet need

ACH had been managed primarily through surgical and physical therapy intervention until the accelerated approval of Voxzogo (vosoritide) in 2021. Voxzogo is a daily injected C-natriuretic peptide (CNP) analog, which acts downstream of FGFR3. In a pivotal study, children treated with 15mg/kg of Voxzogo achieved 5.66cm/year in average height velocity (AHV), a 1.40cm improvement over 4.26cm baseline. Children in the Phase 2 trial treated with 15mg/kg achieved 5.91cm/year AHV, 1.87cm improvement over 4.04cm baseline. Children treated with 30mg/kg saw a lower change from baseline, suggesting the CNP pathway activity is potentially dose-limited in

FGFR3-driven conditions. TransCon CNP, a prodrug of CNP administered to children with ACH by injection on a weekly basis, showed similar efficacy in Phase 3 and a New Drug Application (NDA) filing is expected in the first quarter of 2025. BridgeBio is developing infigratinib, a daily oral, low-dose FGFR1/2/3 inhibitor, which achieved 6.0 cm/yr AHV and a 2.51 cm/yr improvement over 3.51cm/yr baseline for the 0.25 mg/kg cohort in Phase 2 studies. BridgeBio previously published that doses above 0.33mg/kg are limited by hyperphosphatemia and they have communicated they do not plan to exceed the 0.25 mg/kg dose in pediatric skeletal conditions. BioMarin disclosed that prolonged treatment with Voxzogo could result in a final adult height improvement of 17cm or more in ACH, potentially 29cm less than average height for adult males without ACH, pointing to remaining unmet need.

Our solution, TYRA-300 in ACH

By engaging FGFR3 selectively at higher, safe doses, TYRA-300 may have the potential to meaningfully improve height, health and functional outcomes beyond what can be achieved with current therapies in development for children with ACH, HCH, SHOX deficiency, other FGFR3-driven genetic syndromes and idiopathic short stature.

In the Imagine Institute's FGFR3Y367C/+ preclinical model, TYRA-300 administered daily at a 1.2 mg/kg dose for 15 days, increased body length in mice by 17.9% compared to the vehicle ($p<0.0001$) and increased the length of the femur (+22.6%), tibia (+33.0%) and L4-L6 (+23.5%) in mice ($p<0.0001$). 1.2mg/kg in mice roughly equates to a 0.5mg/kg dose in children and a 40mg dose in adults. TYRA-300 also demonstrated increases in long bone length in the Imagine Institute's HCH mouse model.

Development plans for TYRA-300 in ACH

In October 2024, we announced that the FDA cleared the Company's IND for TYRA-300 to proceed with a Phase 2 clinical trial of TYRA-300 for children with ACH (BEACH301). BEACH301 will be a Phase 2, multicenter, open-label, dose-escalation/dose-expansion study evaluating TYRA-300 in children ages 3 to 10 with ACH with open growth plates. The study will enroll children who are treatment-naïve (Cohort 1) and those who have received prior growth-accelerating therapy (Cohort 2) at multiple sites across the globe. Each of these cohorts is expected to enroll up to 10 participants per dose level (0.125, 0.25, 0.375, 0.50 mg/kg) for up to 12 months. Prior to initiation of Cohorts 1 and 2, the study will enroll a safety sentinel cohort of up to 3 treatment-naïve participants per dose level in children ages 5 to 10. The primary objectives of the study will be to assess safety and tolerability in children with ACH and evaluate change from baseline in annualized growth velocity to determine the dose(s) for further development. Secondary objectives will include evaluating change from baseline in height z-score, proportionality and PK. We are also planning exploratory assessments of clinical outcomes such as functional improvements, changes in the spine, and quality of life measures. The Company expects to dose the first child with ACH in the BEACH301 study in the second quarter of 2025.

In July 2023 and January 2024, the FDA granted orphan drug designation and rare pediatric disease designation to TYRA-300, respectively, for the treatment of ACH.

Our FGFR2 Program

TYRA-200 for ICC

FGFR2 is a protein receptor present on the cell surface that promotes cellular proliferation and transformation upon binding of fibroblast growth factor. Activating gene alterations of FGFR2 have been implicated in the tumorigenesis of multiple solid tumor types.

TYRA-200 is an investigational, oral, FGFR1/2/3 inhibitor designed to be active against activating FGFR2 gene alterations, as well as clinically important molecular brake and gatekeeper resistance mutations, and selective for FGFR4. We are focusing initial Phase 1 development of TYRA-200 in FGFR2-driven ICC resistant to treatment with prior FGFR inhibitors.

Disease background

ICC is a form of cancer that originates in the bile ducts, which are a series of thin vessels that transport bile from liver cells to the small intestine. The median OS for all patients diagnosed with ICC is reported to be 16.1 months. The median OS for patients diagnosed with late-stage disease is less than one year. Approximately 15-20% of patients with ICC have genetic alterations in FGFR2, which are primarily gene rearrangements and activating mutations. In addition to ICC, FGFR2 drives an estimated 7-16% of endometrial cancers and 0.8% of other solid tumors.

ICC is a rare tumor, accounting for an estimated 10-20% of intrahepatic biliary cancers and an estimated ~11% of cancers of unknown primary origin. We estimate that in 2023, approximately 1,000 second-line FGFR2+ ICC patients are addressable for treatment with an FGFR2 inhibitor and approximately 500 FGFR2+ ICC patients are addressable in the FGFR-resistant setting in the United States. We also estimate that approximately 1,000 and 3,000 FGFR2+ patients with late-stage endometrial cancer and other solid tumors, respectively, may be addressable with FGFR2 inhibitors.

Current treatment landscape and unmet need

Currently, surgical recession is the only curative option available to ICC patients. However, only up to one-third of patients are eligible for surgery at diagnosis and up to 70% of patients experience a recurrence largely within the first two years following surgery. Patients with unresectable tumors are typically treated with frontline immunotherapy in combination with cisplatin-based chemotherapy which have shown 12.7-12.8 month OS. Upon disease progression, patients with somatic alternations in FGFR2 are eligible to be treated with approved pan-FGFR inhibitors including Pemazyre (pemigatinib) and Lytgobi (futibatinib) which have generated ORR of 36-42% and mean duration of response of 9.1-9.7 months. The investigational FGFR2-specific inhibitor lirafugratinib has reported ~80% response rates in a small dataset of patients who have not received an FGFR inhibitor previously, though showed limited activity in patients whose tumors have developed these acquired resistance mutations.

The currently approved pan-FGFR inhibitors as well as several investigational agents are not active against the entire spectrum of clinically important acquired resistance mutations that develop in response to FGFR inhibition. Polyclonal resistance (multiple resistance mutations that occur in the same patient) is a common feature in this patient population, with one dataset showing Over 50% of patients who recur on FGFR therapy have gatekeeper and molecular brake mutations. We believe the ability to demonstrate clinically beneficial activity in the FGFR inhibitor-resistant setting will provide proof of concept and validate the design principles behind TYRA-200.

Our solution, TYRA-200 in ICC

We believe the critical unmet need for patients with FGFR2 fusion or FGFR2-altered ICC is balancing the potency for the wild type and the numerous on-target resistance mutations that confer resistance to the currently approved FGFR inhibitors. We believe maintaining potency against all of these clinically important mutations as well as wild-type FGFR2 could potentially improve efficacy and duration of response. Additionally, we designed TYRA-200 with greater selectivity for FGFR1-3 versus FGFR4 to potentially improve upon tolerability of pan-FGFR inhibitors that are potent for FGFR4.

In preclinical models, TYRA-200 has demonstrated potency in FGFR2-driven Ba/F3 cells similar to erdafitinib, pemigatinib, futibatinib or infigratinib, while reducing or eliminating the decrease in potency observed with N550K/H/D and E566A molecular brake, V565F/L/I gatekeeper, and K660E/N A-loop activator resistance mutations. In a preclinical allograft model of an FGFR2-driven Ba/F3 cell line with the V565F gatekeeper mutation, we observed 96% and 98% tumor growth inhibition by TYRA-200 versus 62% tumor growth inhibition in an allograft treated with futibatinib.

Development plans for TYRA-200 in ICC

In December 2023, we commenced our Phase 1 clinical trial of TYRA-200, SURF201, a multi-center, open label study designed to evaluate the safety, tolerability, and PK of TYRA-200 and determine the optimal dose for further development, the MTD and RP2D, as well as evaluate preliminary antitumor activity. SURF201 is currently enrolling participants with ICC with acquired kinase domain mutations. Positive data in this setting, where other FGFR inhibitors have not succeeded, would potentially provide confidence in our belief that addressing acquired resistance may prolong the duration of responses, and ultimately PFS, in the FGFR-naive setting.

Beyond FGFR-resistant and FGFR-naive ICC, there is potential for TYRA-200 to extend into metastatic endometrial carcinoma as well as advanced colorectal, breast, ovarian, gastric, and lung cancer.

Our FGF19+ Program

TYRA-430 for Hepatocellular Carcinoma

FGF19 is a post-prandial enterohepatic hormone that signals through FGFR4 and its associated co-receptor KLB to exert its normal cellular functions. In a subset of certain cancers, such as HCC, gastric adenocarcinoma, and squamous esophageal carcinoma, FGF19 is aberrantly expressed due to focal chromosomal amplifications or epigenetic mechanisms, promoting tumor cells to become dependent on the FGFR4/KLB/FGF19 oncogenic axis.

An experiment run by Tao et al (2022) demonstrated a greater dependence of HCC JHH-7 cells on KLB, the common co-receptor for FGFR3 and FGFR4, than on either receptor alone. This is also consistent with the results of the double knock down of FGFR3 and 4 being more deleterious than knock down of either receptor alone, suggesting the need for dual inhibition of FGFR3 or FGFR4.

TYRA-430 is an investigational FGFR4/3 biased inhibitor for FGF19+/FGFR4-driven cancers that is designed to be agnostic to acquired resistance mechanisms originating from the V550 gatekeeper and the C552 mutations. In August 2024, we announced that the FDA cleared our IND to proceed with the global Phase 1 SURF431 clinical trial of TYRA-430 in advanced HCC and other solid tumors with activating FGF/FGFR pathway aberrations.

Disease background

Liver cancer is the third leading cause of cancer related mortality worldwide (Bray et al). Abnormal activation of FGF19 has been implicated as an oncogenic driver in approximately 30% of HCC. Data suggests that in this subtype, excessive FGF19 may over-activate the receptor tyrosine kinases FGFR4 and FGFR3 thus drive cancer cell proliferation, survival, and resistance to apoptosis.

We estimate that in 2022, approximately 6,000 frontline FGFR19+ HCC patients were addressable for treatment with an FGFR4/3 inhibitor and over 3,000 FGFR19+ HCC patients were addressable in the post-frontline setting in the United States.

Current treatment landscape and unmet need

Between 2014 and 2020, the five-year relative survival for liver cancer patients in the US was 21.7%. Most HCC patients are diagnosed with unresectable disease and are not eligible for potentially curable treatments, including surgery, transplant or ablation. For patients with advanced, unresectable HCC, immunotherapies have become standard of care in the frontline since the 2020 approval of Tecentriq/Avastin (atezolizumab/bevacizumab), based on a 28% ORR and 6.8 month PFS, with follow up analysis in the intent to treat population showing a 19.2 month OS. Promising phase 2 datasets have been released for agents in development as part of a triplet combination regimen atezolizumab/bevacizumab.

In the post-frontline setting, non-targeted approaches including multi-kinase inhibitors approved for the second and third lines have shown modest therapeutic benefit. Bayer's Stivarga (regorafenib), Exilixis' Cabometyx

(cabozantinib) and Eli Lilly's ramucirumab have been approved in this setting based on ORR ranging from 4-7%, PFS ranging from 2.5-5.2 months and OS ranging from 8.5-10.6 months. Use of sorafenib and lenvatinib, initially approved for treatment-naïve patients, is anticipated to rise in the second line, but randomized data is not available for these agents in this setting. Several FGFR4-selective inhibitors have been developed and achieved clinical proof of concept with ORR of 17%-21%, in FGF19+ patients. However, FGFR4-specific approaches have shown limited durability, potentially due to an FGFR3-mediated bypass mechanism as well as acquired drug resistance in some cases. We believe TYRA-430 has the potential to address the shortcomings of prior FGFR4-specific approaches as well as the overall unmet need in FGF19+ HCC, where no biomarker-driven, targeted therapy has been approved.

Our Solution, TYRA-430 in HCC

TYRA-430 was selected for development based in part on its bias for FGFR4 and FGFR3 over the FGFR1 and FGFR2 isoforms specifically to address the aberrant FGF19 signaling pathway, while also potentially limiting side effects due to inhibition of FGFR1 and FGFR2. In addition to the activity toward FGFR3, TYRA-430 is further distinguished from the highly specific FGFR4 inhibitors by its relative resistance to clinically observed mutations at the gatekeeper (550) and cysteine (552) positions.

In preclinical models, TYRA-430 demonstrated bias for FGFR4 and FGFR3 over FGFR1 and FGFR2 isoforms in Ba/F3 cells. Additionally, in a JHH7 FGF19+ HCC xenograft, TYRA-430 (28 mg/kg BID), demonstrated 99% tumor growth inhibition while roblitinib (FGFR4-specific inhibitor, 100 mg/kg BID) and lenvatinib (30 mg/kg QD) demonstrated 86% and 53% tumor growth inhibition, respectively.

Development plans for TYRA-430 in HCC

In August 2024, we announced that the FDA cleared our IND to proceed with a Phase 1 clinical trial of TYRA-430. SURF431 will be a Phase 1, multicenter, open-label, first-in-human study of TYRA-430 in advanced HCC and other solid tumors with activating FGF/FGFR pathway aberrations. We believe TYRA-430 has the potential to address a significant unmet need in HCC, where there are no approved biomarker-driven, targeted therapies. We expect to dose the first patient in this study in the second quarter of 2025.

Our Discovery Engine

We continue to leverage the SNÅP platform in the discovery and development of additional, undisclosed preclinical programs. These efforts are focused in the field of FGFR biology as well as other targets that are important drivers for opportunities across precision oncology and genetically defined conditions.

Competition

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition, and a strong emphasis on proprietary products. While we believe that our technology, technical expertise, and drug development experience provide us with competitive advantages, we face increasing competition from many different sources, including pharmaceutical and biotechnology companies, academic institutions, governmental agencies, and public and private research institutions. Product candidates that we successfully develop and commercialize may compete with existing and/or new therapies that may become available in the future.

Many of our competitors, either alone or with their collaborators, have significantly greater financial resources, established presence in the market, expertise in manufacturing, R&D, pre-clinical activities and clinical trial conduct. Additionally, many of our competitors are commercial-stage entities with experience in obtaining regulatory approvals and reimbursement for marketed approved products. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with larger and/or established companies. Additional mergers and acquisitions may result in even more resources being concentrated in our competitors.

Our commercial potential could be reduced or eliminated if our competitors develop and commercialize products that are more effective, have a more favorable safety profile, and are more convenient or less expensive than products that we may develop. Our competitors also may obtain FDA or other foreign regulatory approval(s) for their products more rapidly than us, which could result in our competitors establishing a strong market position before we are able to enter the market or could otherwise make our development more complicated. We believe the key competitive factors affecting the success of all of our programs are likely to be efficacy, including duration of human response and breadth of coverage, safety and patient convenience.

There are numerous companies developing or marketing treatments for cancer, including many major pharmaceutical and biotechnology companies. These treatments consist of small molecule drug products, biologics, cellular therapies, and traditional chemotherapy.

For TYRA-300 in post-frontline mUC, approved competitors include Janssen Pharmaceutical's Balversa (erdafitinib), chemotherapy agents and immunotherapy or Padcev for patients not exposed in the frontline. Therapies in development include Eli Lilly's LOXO-435, an oral, FGFR3-specific inhibitor, as well as multiple next-generation Nectin4-targeted therapies.

For TYRA-300 in IR NMIBC, no agents beyond intravesical BCG or chemotherapy have been approved. Urogen's UGN-102, a hydrogel reformulation of mitomycin C, has a PDUFA date scheduled for June 2025. Additional agents in Phase 3 development include Janssen Pharmaceutical's TAR-210, CG Oncology's crestostimogene grenadenorepvec and Ferring's nadofaragene firadenovec.

For TYRA-300 in high risk NMIBC, beyond Intravesical BCG and chemotherapy instillations, Merck's Keytruda, ImmunityBio's Anktiva in combination with BCG and Ferring's Adstiladrin are approved in BCG-unresponsive high risk NMIBC with CIS, with or without papillary tumors. Additional agents in Phase 3 development include Janssen Pharmaceutical's TAR-200, CG Oncology's crestostimogene grenadenorepvec and PD–(L)1 inhibitors including Pfizer's sasanlimab.

For TYRA-300 in ACH, BioMarin's Voxzogo is approved for children of any age with open growth plates. Ascendis has disclosed an intent to file an NDA and MAA for TransCon CNP in 2025 and BridgeBio's infigratinib is still in Phase 3 development. BioMartin is studying BMN-333, a long-acting CNP in Phase 1 development.

For TYRA-300 in HCH, BioMarin's vosoritide is in Phase 3 development, BridgeBio's infigratinib has initiated a run-in for a Phase 2 study and Ascendis has disclosed plans to initiate a clinical study in 2025. BioMarin has also initiated a Phase 2 basket trial for vosoritide in children with Turner Syndrome, SHOX Deficiency and Noonan Syndrome without sufficient response to human growth hormone, in addition to a Phase 2 study for children with idiopathic short stature.

For TYRA-200 in ICC, there are two pan-FGFR inhibitors available in the United States that are indicated for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a FGFR2 fusion or other rearrangement: Incyte Corporation's Pemazyre and Taiho Oncology's Lytgobi. Additional inhibitors in development include Elevar's Lirafugratinib, TransThera's tinengotinib and Cogent's CGT-4859.

For TYRA-430 in HCC, several multi-kinase inhibitors have been approved for the treatment of HCC, but there are currently no approved FGFR4-specific inhibitors approved. In the late line setting, approved, non-targeted treatment options include Bayer's Stivarga, Exelixis' Cabometyx, Eli Lilly's Cyramza, Merck's Keytruda and BMS' Opdivo combined with Yervoy. There are a number of FGFR4 clinical stage programs, with most of the development focused in China, including CStone Pharmaceuticals and Blueprint Medicine's BLU-554 (fisogatinib), Everest Medicine's FGF401 and Abbisko Therapeutics' ABSK-011.

Intellectual Property

We strive to protect the intellectual property and proprietary technology that we consider important to our business through a variety of methods, including seeking and maintaining patents intended to cover our product

candidates and compositions, their methods of use and processes for their manufacture, and any other inventions that are important to our business. We rely on know-how and continuing technological innovation to develop and maintain our proprietary position. We also rely on trade secrets and know-how that may be important to the development of our business. We seek to obtain domestic and international patent protection and endeavor to promptly file patent applications for new commercially valuable inventions to expand our intellectual property portfolio.

We are building a patent portfolio and have substantial confidential know-how relating to our product candidates and SNÅP platform. As of March 15, 2025, our intellectual property portfolio consists of one granted U.S. patent, 14 pending U.S. provisional applications, 10 pending U.S. nonprovisional applications, 90 pending foreign patent applications, one granted foreign patent and 10 patent applications pursuant to the Patent Cooperation Treaty (PCT) all of which are solely owned by us. We do not license any material patent rights from any third party. Collectively, our patent rights relate to various aspects of our product candidates.

We continually assess and refine our intellectual property strategy as we develop new product candidates and improvements to our SNÅP platform. To that end, we are prepared to file additional patent applications in any appropriate fields if our intellectual property strategy requires such filings, or where we seek to adapt to competition or seize business opportunities. Further, we are prepared to file patent applications, as we consider appropriate under the circumstances, relating to the new technologies that we develop.

We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications we may own or license in the future, nor can we be sure that any patents we may own or license in the future will be useful in protecting our technology. Please see the section entitled "Risk Factors—Risks Related to Our Intellectual Property" for additional information on the risks associated with our intellectual property strategy and portfolio.

Intellectual Property Relating to Our FGFR3 Program

With regard to our FGFR3 product candidates, as of March 15, 2025, we own 11 pending U.S. provisional applications, five pending U.S. nonprovisional applications, one granted U.S. patent, five pending PCT patent applications, 44 pending foreign applications and one granted foreign patent. These patent rights relate to the FGFR3 product candidates' compositions of matter, formulations containing them, methods of manufacturing, and methods of treating diseases, using our FGFR3 product candidates. Specifically, we have one granted U.S. patent, one granted foreign patent and 30 pending foreign patent applications directed to the composition matter of our leading candidate in the FGFR3 program. We expect any patents issued from these applications to expire between 2040 and 2046 without accounting for any patent term adjustment or extension that may be available.

Intellectual Property Relating to Our FGFR2 Program

With regard to our FGFR2 program, as of March 15, 2025, we own two pending U.S. nonprovisional applications, one pending PCT patent application and 16 pending foreign applications. These patent rights relate to the FGFR2 program's compositions of matter, formulations containing them, methods of manufacturing, and methods of treating diseases. Specifically, we have one pending U.S. nonprovisional and 15 pending foreign patent applications directed to the composition matter of our leading candidate in the FGFR2 program. We expect any patents issued from these applications to expire between 2040 and 2044 without accounting for any patent term extension that may be available.

Intellectual Property Relating to Other Programs

With regard to our other programs, including the FGFR4 program, as of March 15, 2025, we own three pending U.S. provisional patent application, three pending U.S. nonprovisional application, three pending PCT patent applications and 28 pending foreign applications. These patent rights relate to these other programs' compositions of matter, formulations containing them, methods of manufacturing, and methods of treating diseases. We expect any patents issued from these applications to expire between 2042 and 2045 without accounting for any patent term extension that may be available.

Scope and Duration of Intellectual Property Protection

The term of individual patents depends upon the laws of the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing of a non-provisional patent application. However, the term of United States patents may be extended for delays incurred due to compliance with the FDA requirements or by delays encountered during prosecution that are caused by the USPTO. For example, for drugs that are regulated by the FDA under the Hatch-Waxman Act, the FDA is permitted to extend the term of a patent that covers such drug for up to five years beyond the normal expiration date of the patent, provided that the extended patent term may not exceed fourteen years after the date of approval of the marketing application. In the future, if and when our product candidates receive FDA approval, we expect to apply for patent term extensions on any issued U.S. patents covering those product candidates. We intend to seek patent term extensions for our current and future issued patents in jurisdictions where these are available; however, there is no guarantee that the applicable authorities, including the USPTO and FDA, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions. Our issued patent and any patents issuing from our pending patent applications are expected to expire on dates ranging from 2040 to 2046, without accounting for potentially available patent term extensions or patent term adjustments.

However, the actual protection afforded by a patent varies on a product-by-product basis, from country-to-country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. No consistent policy regarding the scope of claims allowable in patents in the field of oncology therapy has emerged in the United States. The patent situation outside of the United States is even more uncertain. Changes in the patent laws and rules, either by legislation, judicial decisions, or regulatory interpretation in the United States and other countries may diminish our ability to protect our inventions and enforce our intellectual property rights, and more generally could affect the value of our intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell, importing or otherwise commercializing any of our patented inventions, either directly or indirectly, will depend in part on our success in obtaining, defending and enforcing patent claims that cover our technology, inventions, and improvements. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our current or future patents will be commercially useful in protecting our product candidates and the methods used to manufacture them. Moreover, our current or future patents may not guarantee us the right to practice our technology in relation to the commercialization of our product candidates.

The area of patent and other intellectual property rights in biotechnology is an evolving one with many risks and uncertainties, and third parties may have blocking patents that could be used to prevent us from commercializing our product candidates and practicing our proprietary technology. Our current or future patents may be challenged, narrowed, circumvented or invalidated, which could limit our ability to stop competitors from marketing related product candidates or limit the length of the term of patent protection that we may have for our product candidates. In addition, the rights granted under our current or future issued patents may not provide us with protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies. For these and other reasons, we may have competition for our product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before any product candidate can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any protection afforded by the patent. For this and other risks related to our proprietary technology, inventions, improvements, SNÅP platform and product candidates, please see the section entitled “Risk Factors—Risks Related to Our Intellectual Property.”

We have filed applications for trademark registrations in connection with our product candidates in various jurisdictions, including the United States. We have filed for trademark protection of the TYRA and TYRA BIOSCIENCES marks with the United States Patent and Trademark Office and certain foreign patent and trademark organizations. We have registered trademarks in the United States and other jurisdictions.

We also rely on trade secret protection for our confidential and proprietary information. Although we take steps to protect our confidential and proprietary information as trade secrets, including through contractual means with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements under 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 individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In many cases our confidentiality and other agreements with consultants, outside scientific collaborators, sponsored researchers and other advisors require them to assign or grant us licenses to inventions they invent as a result of the work or services they render under such agreements or grant us an option to negotiate a license to use such inventions. Despite these efforts, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for such breaches.

We also seek to preserve the integrity and confidentiality of our proprietary technology and processes by maintaining physical security of our premises and physical and electronic security of our information technology systems. Although we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. To the extent that our employees, contractors, consultants, collaborators and advisors use intellectual property owned by others in their work for us, disputes may arise as to the rights in relation to the resulting know-how or inventions. For more information, please see the section entitled "Risk Factors—Risks Related to Our Intellectual Property."

Commercialization

We intend to retain significant development and commercial rights to our product candidates and, if marketing approval is obtained, to commercialize our product candidates on our own, or potentially with a partner, in the United States and other regions. We currently have no sales, marketing or commercial product distribution capabilities. We intend to build the necessary infrastructure and capabilities over time for the United States, and potentially other regions, following further advancement of our product candidates. Clinical data, the size of the addressable patient population, the size of the commercial infrastructure and manufacturing needs may all influence or alter our commercialization plans.

Manufacturing

We do not have any manufacturing facilities or personnel. We currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates undergoing preclinical testing, as well as for subsequent clinical testing and commercial manufacture if our product candidates receive marketing approval. We believe this strategy allows us to focus our expertise and resources on the development of our product candidates by eliminating the need for us to invest in our own manufacturing facilities, equipment and personnel.

We plan to put agreements in place with contract manufacturing organizations for the necessary quantities of active pharmaceutical ingredients (API) and drug product for each of our product candidates, on a project-by-project basis, based on our development needs.

As we advance our product candidates through development, we will explore adding backup suppliers for the API and drug product for each of our product candidates to protect against any potential supply disruptions.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing and export and import of drug products. A new drug must be approved by the FDA through the New Drug Application (NDA) process before it may be legally marketed in the United States. We, along with any 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 of our products and product candidates. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

U.S. Drug Development Process

In the United States, the FDA regulates drugs under the federal Food, Drug, and Cosmetic Act (the FDCA) and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of certain preclinical laboratory tests, animal studies and formulation studies in accordance with FDA's GLP requirements and other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent Institutional Review Board (IRB) or ethics committee at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices (GCPs) to establish the safety and efficacy of the proposed drug for its intended use;
- preparation of and submission to the FDA of an NDA after completion of all pivotal trials;
- a determination by the FDA within 60 days of its receipt of an NDA to file the application for review;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current Good Manufacturing Practice (cGMP) or similar foreign requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- satisfactory completion of potential FDA audit of select clinical trial sites to assure compliance with GCP; and
- FDA review and approval of the NDA to permit commercial marketing of the product for particular indications for use in the United States.

Prior to beginning the first clinical trial with a product candidate in the United States, a sponsor must submit an IND to the FDA. An IND is a request for allowance from the FDA to administer an investigational drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and in vitro studies assessing the toxicology, PK, pharmacology, and PD characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. 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 allowance 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 GCPs, which include among other things, the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, 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. While the IND is active, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or in vitro testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

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 study until completed. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial. The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1: The product candidate is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution 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 product candidate 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.

- Phase 3: The product candidate 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 labeling.

In some cases, the FDA may require, or sponsors may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These clinical trials, sometimes referred to as Phase 4 studies, may be used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP or similar foreign requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. In addition, 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.

U.S. Review and Approval Process

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, including results from preclinical and other non-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of the use of the product, or from a number of alternative sources, including studies initiated by independent investigators. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA conducts a preliminary review of an NDA within the first 60 days after submission, before accepting it for filing, to determine whether it is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once filed, the FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality and purity. Under the Prescription Drug User Fee Act guidelines that are currently in effect, the FDA has a goal of ten months from the filing date to complete a standard review of an NDA for a drug that is a new molecular entity. This review typically takes twelve months from the date the NDA is submitted to the FDA because the FDA has approximately two months to make a "filing" decision after the application is submitted.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, 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 and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs.

After the FDA evaluates an NDA and conducts any necessary inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter (CRL). An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A CRL usually describes all of the deficiencies that the FDA has identified and may require additional clinical data, such as an additional clinical trial or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. When the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the CRL without first conducting required inspections and/or reviewing proposed labeling. If a CRL is issued, the sponsor must resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the NDA with a Risk Evaluation and Mitigation Strategy (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 medicine 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. The FDA may also require one or more post-market studies 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 studies.

In addition, the Pediatric Research Equity Act (PREA) requires a sponsor to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs and supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates. For example, the Fast Track program is intended to expedite or facilitate the process for reviewing new product candidates that are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a Fast Track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the application may be eligible for priority review. An NDA for a Fast Track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for Breakthrough Therapy designation to expedite its development and review. A product candidate can receive Breakthrough Therapy designation if preliminary clinical evidence indicates that the product candidate, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing

therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the Fast Track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior managers.

Any marketing application for a drug submitted to the FDA for approval, including a product candidate with a Fast Track designation and/or Breakthrough Therapy designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as priority review. An NDA is eligible for priority review if the product candidate is designed to treat a serious or life-threatening disease or condition, and if approved, would provide a significant improvement in safety or effectiveness compared to available alternatives for such disease or condition. For new-molecular-entity NDAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date.

Additionally, depending on the design of the applicable clinical trials, product candidates studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled confirmatory clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit, and may require that such confirmatory studies be underway prior to granting any accelerated approval. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required confirmatory studies in a timely manner or if such studies fail to verify the predicted clinical benefit. In addition, the FDA requires pre-approval of promotional materials as a condition of accelerated approval, which could adversely impact the timing of the commercial launch of the product.

Fast Track designation, Breakthrough Therapy designation, priority review, and accelerated approval do not change the standards for approval, but may expedite the development or approval process. Even if a product candidate qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 individuals in the United States and when there is no reasonable expectation that the cost of developing and making available the drug in the United States will be recovered from sales in the United States for that drug. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA.

If a product that has orphan drug designation subsequently receives the first FDA approval for the drug and disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, to market the same drug for the same disease or condition for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA application user fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the disease or condition for which it received orphan designation. In addition, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially

defective or, as noted above, if a second applicant demonstrates that its product is clinically superior to the approved product with orphan exclusivity or the manufacturer of the approved product 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

In 2012, the U.S. Congress authorized the FDA to award priority review vouchers to Sponsors of certain rare pediatric disease product applications. This program 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 priority review of a subsequent marketing application for a different product. The Sponsor of a rare pediatric disease drug product receiving a priority review voucher 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 priority review voucher 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 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 diseases or conditions within the meaning of the Orphan Drug Act. Under the current statutory sunset provisions, as amended by the Continuing Appropriations and Extensions Act, 2025, the FDA may only award a voucher for an approved rare pediatric disease product application if the Sponsor has rare pediatric disease designation for the drug, and that designation was granted by December 20, 2024. After September 30, 2026, FDA may not award any Rare Pediatric Disease Priority Review Voucher.

Post-approval Requirements

Drug 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 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, annual program fees for any marketed products. Drug 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 NDA holders and product 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. 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 adverse events 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 studies 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 the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters, or untitled letters;
- clinical holds on clinical studies;

- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of drug products. A company can make only those claims relating to safety and efficacy, purity and potency 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, in their independent professional medical judgment, legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. 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. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labelling.

Marketing Exclusivity

Non-patent regulatory exclusivity provisions authorized under the FDCA can delay the submission or the approval of certain marketing applications. The FDCA provides a five-year period of non-patent data exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not approve or even accept for review an abbreviated new drug application (ANDA) or an NDA submitted under Section 505(b)(2) (505(b)(2) NDA) submitted by another company for another drug containing the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder.

The FDCA alternatively provides three years of non-patent exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to any preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of marketing exclusivity available in the United States. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to another period of regulatory exclusivity or existing patent term if a sponsor conducts clinical trials in children in response to a written request

from the FDA and meets other conditions. The issuance of a written request does not require the sponsor to undertake the described clinical trials. In addition, orphan drug exclusivity, as described above, may offer a seven-year period of marketing exclusivity, except in certain circumstances.

FDA Regulation of Companion Diagnostics

If safe and effective use of a drug depends on an in vitro diagnostic, then the FDA may require approval or clearance of that diagnostic, known as a companion diagnostic, at the same time that the FDA approves the therapeutic product. In August 2014, the FDA issued final guidance clarifying the requirements that will apply to approval of therapeutic products and in vitro companion diagnostics. According to the guidance, if FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, FDA may will not approve the drug or new indication if the companion diagnostic device is not also approved or cleared for that indication. Approval or clearance of the companion diagnostic device will ensure that the device has been adequately evaluated and has adequate performance characteristics in the intended population. The review of in vitro companion diagnostics in conjunction with the review of our product candidates will, therefore, likely involve coordination of review by the FDA's Center for Drug Evaluation and Research and the FDA's Center for Devices and Radiological Health Office of In Vitro Diagnostics and Radiological Health.

Under the FDCA, in vitro diagnostics, including companion diagnostics, are regulated as medical devices. In the United States, the FDCA and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance.

Unless an exemption applies, each medical device commercially distributed in the United States generally requires either FDA clearance of a 510(k) premarket notification, or approval of a premarket approval (PMA) application. Under the FDCA, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to ensure its safety and effectiveness. While most Class I devices—devices that generally pose a low risk to users—are exempt from the 510(k) premarket notification requirement, manufacturers of most Class II devices are required to submit to the FDA a premarket notification under Section 510(k) of the FDCA requesting permission to commercially distribute the device. The FDA's permission to commercially distribute a device subject to a 510(k) premarket notification is generally known as 510(k) clearance. Devices deemed by the FDA to pose the greatest risks, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are automatically placed in Class III, requiring approval of a PMA unless down-classified in accordance with the "de novo" process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device.

To obtain 510(k) clearance, a manufacturer must submit to the FDA a premarket notification demonstrating that the proposed device is "substantially equivalent" to a predicate device already on the market. A predicate device is a legally marketed device that is not subject to premarket approval, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was found substantially equivalent through the 510(k) process. If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device. If the FDA determines that the device is "not substantially equivalent" to a previously cleared device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements or request down-classification of the device through the "de novo" process.

The PMA process is more demanding than the 510(k) premarket notification process, and can take several years or longer. It involves a rigorous premarket review during which the applicant must prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing and labeling. PMA applications are subject to an application fee. In addition, PMAs for certain devices must generally include the results from extensive preclinical and adequate and well-controlled clinical trials to establish the safety and effectiveness of the device for each indication for which FDA approval is sought. As part of the PMA review, the FDA will typically inspect the

manufacturer's facilities for compliance with the QSR, which imposes elaborate testing, control, documentation and other quality assurance requirements.

If the FDA's evaluation of the PMA application is favorable, the FDA typically issues an approvable letter requiring the applicant's agreement to specific conditions, such as changes in labeling, or specific additional information, such as submission of final labeling, in order to secure final approval of the PMA. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and then the data submitted in an amendment to the PMA. If the FDA concludes that the applicable criteria have been met, the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the applicant. The PMA can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution. Once granted, PMA approval may be withdrawn by the FDA if compliance with post-approval requirements, conditions of approval or other regulatory standards are not maintained or problems are identified following initial marketing.

After a device is placed on the market, it remains subject to significant regulatory requirements. Medical devices may be marketed only for the uses and indications for which they are cleared or approved. Device manufacturers must also establish registration and device listings with the FDA. A medical device manufacturer's manufacturing processes and those of its suppliers are required to comply with the applicable portions of the QSR, which currently cover the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging and shipping of medical devices. Domestic facility records and manufacturing processes are subject to periodic unscheduled inspections by the FDA. The FDA also may inspect foreign facilities that export products to the United States.

Other U.S. Healthcare Laws

Pharmaceutical companies like us are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such regulation and enforcement may constrain the financial arrangements and relationships through which we research, develop, and ultimately, sell, market and distribute any products for which we obtain marketing approval. Such laws include, without limitation, federal and state anti-kickback, fraud and abuse, and false claims laws, such as the federal Anti-Kickback Statute and the federal civil False Claims Act, as well as federal and state transparency laws and regulations with respect to drug pricing and payments and other transfers of value made by pharmaceutical manufacturers to physicians and other health care providers, such as the federal Physician Payments Sunshine Act.

Violation of any of such laws or any other governmental regulations that apply may result in significant criminal, civil and administrative penalties including damages, fines, imprisonment, disgorgement, additional reporting requirements and oversight if we become subject to a Corporate Integrity Agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, disgorgement, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations.

U.S. Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidate for which we may seek regulatory approval. Sales in the United States will depend, in part, on the availability of sufficient coverage and adequate reimbursement from third-party payors, which include government health programs such as Medicare, Medicaid, TRICARE and the Veterans Administration, as well as managed care organizations and private health insurers. Prices at which we or our customers seek reimbursement for our product candidates can be subject to challenge, reduction or denial by third-party payors. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs.

The process for determining whether a third-party payor will provide coverage for a product is typically separate from the process for setting the reimbursement rate that the payor will pay for the product. In the United States, there is no uniform policy among payors for coverage or reimbursement. Decisions regarding whether to cover any of a product, the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies, but also have their own methods and approval processes. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that can require manufacturers to provide scientific and clinical support for the use of a product to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product that receives approval. Third-party payors may not consider our product candidates to be medically necessary or cost-effective compared to other available therapies, or the rebate percentages required to secure favorable coverage may not yield an adequate margin over cost or may not enable us to maintain price levels sufficient to realize an appropriate return on our investment in drug development. Additionally, decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product.

Moreover, as a condition of participating in, and having products covered under, certain federal healthcare programs, such as Medicare and Medicaid, we may become subject to federal laws and regulations that require pharmaceutical manufacturers to calculate and report certain pricing metrics to the government, including the Average Manufacturer Price (AMP) and Best Price under the Medicaid Drug Rebate Program, the Medicare Average Sales Price, the 340B Ceiling Price, and Non-Federal AMP reported to the Department of Veteran Affairs, and with respect to Medicaid, pay statutory rebates on utilization of manufacturers' products by Medicaid beneficiaries. Compliance with these laws and regulations will require significant resources and may have a material adverse effect on our revenues.

U.S. Healthcare Reform

In the United States, there has been, and continues 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 profitable sale of product candidates.

Among policy makers and payors in the United States, 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 United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the ACA, was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly affected the pharmaceutical industry. Among other changes, the ACA increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1%; required collection of rebates for drugs paid by Medicaid managed care organizations; required manufacturers to participate in a coverage gap discount program, which was replaced by a new manufacturer discount program on January 1, 2025 (as discussed below), in which manufacturers were required to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain "branded prescription drugs" to specified federal government programs; implemented a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected; expanded eligibility criteria for Medicaid programs; created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare and Medicaid Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial and political challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA.

In addition, other legislative changes have been adopted since the ACA was enacted. Most recently, in March 2021, Congress enacted the American Rescue Plan Act of 2021, which, among other things, eliminated the statutory cap on drug manufacturers' Medicaid Drug Rebate Program rebate liability, effective January 1, 2024. Drug manufacturers' Medicaid Drug Rebate Program rebate liability was previously capped at 100% of the average manufacturer price for a covered outpatient drug. Other changes included aggregate reductions to Medicare payments to providers, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect into 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. This has resulted in several Congressional inquiries and proposed and enacted federal and state regulations designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products. On August 16, 2022, the Inflation Reduction Act of 2022 (IRA) came into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023), and replaces the Part D coverage gap discount program with a new discounting program (which began in 2025). The IRA permits the Secretary of the Department of Health and Human Services to implement many of these provisions through guidance, as opposed to regulation, for the initial years. CMS has published the negotiated prices for the initial ten drugs, which will first be effective in 2026, and has published the list of the subsequent 15 drugs that will be subject to negotiation. Each year thereafter, more Part B and Part D products will become subject to the HHS price negotiation program, although the program is currently subject to legal challenges. For that and other reasons, it is currently unclear how the IRA will be effectuated.

Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical 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, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which drugs and suppliers will be included in their healthcare programs. Furthermore, there has been increased interest by third party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

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 products once approved or additional pricing pressures. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates.

Foreign Regulation

To market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials, marketing authorization (MA), commercial sales and distribution of our products. The foreign regulatory approval process includes all of the risks associated with FDA approval set forth above, as well as additional country-specific regulation.

Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the

product in those countries. Approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions. The approval process varies from country to country, can involve additional testing beyond that required by FDA, and may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing, promotion, and reimbursement vary greatly from country to country.

Non-clinical Studies and Clinical Trials in the EU

Similarly to the United States, the various phases of non-clinical and clinical research in the European Union (EU) are subject to significant regulatory controls.

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical (pharmaco-toxicological) studies must be conducted in compliance with the principles of good laboratory practice (GLP), as set forth in EU Directive 2004/10/EC (unless otherwise justified for certain particular medicinal products, e.g., radio-pharmaceutical precursors for radio-labeling purposes). In particular, non-clinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), guidelines on Good Clinical Practices (GCP), as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. If the sponsor of the clinical trial is not established within the EU, it must appoint an EU entity to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and in most EU member states, the sponsor is liable to provide 'no fault' compensation to any study subject injured in the clinical trial.

The regulatory landscape related to clinical trials in the EU has been subject to recent changes. The EU Clinical Trials Regulation (CTR), which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. Unlike directives, the CTR is directly applicable in all EU member states without the need for member states to further implement it into national law. The CTR notably harmonizes the assessment and supervision processes for clinical trials throughout the EU via a Clinical Trials Information System, which contains a centralized EU portal and database.

While the EU Clinical Trials Directive required a separate clinical trial application (CTA) to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, much like the FDA and IRB respectively, the CTR introduces a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The CTA must include, among other things, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed.

The CTR transition period ended on January 31, 2025, and all clinical trials (and related applications) are now fully subject to the provisions of the CTR.

Medicines used in clinical trials must be manufactured in accordance with Good Manufacturing Practice (GMP). Other national and EU-wide regulatory requirements may also apply.

Marketing Authorization in the EU

In order to market our product candidates in the EU and many other foreign jurisdictions, we must obtain separate regulatory approvals. More concretely, in the EU, medicinal product candidates can only be commercialized after obtaining a MA. To obtain regulatory approval of a product candidate under EU regulatory systems, we must submit a MA application (MAA). The process for doing this depends, among other things, on the nature of the medicinal product. There are two types of MAs:

- "Centralized MAs" are issued by the European Commission through the centralized procedure based on the opinion of the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) and are valid throughout the EU. The centralized procedure is compulsory for certain types of medicinal products such as (i) medicinal products derived from biotechnological processes, (ii) designated orphan medicinal products, (iii) advanced therapy medicinal products (ATMPs) (such as gene therapy, somatic cell therapy and tissue engineered products) and (iv) medicinal products containing a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative diseases or autoimmune diseases and other immune dysfunctions, and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the EU, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.
- "National MAs" are issued by the competent authorities of the EU member states, only cover their respective territory, and are available for product candidates not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in an EU member state, this national MA can be recognized in another member state through the mutual recognition procedure. If the product has not received a national MA in any member state at the time of application, it can be approved simultaneously in various member states through the decentralized procedure. Under the decentralized procedure an identical dossier is submitted to the competent authorities of each of the member states in which the MA is sought, one of which is selected by the applicant as the reference member state.

Under the centralized procedure the maximum timeframe for the evaluation of an MAA by the EMA is 210 days, excluding clock stops. Under the above described procedures, in order to grant the MA, the EMA or the competent authorities of the EU member states make an assessment of the risk benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy. MAs have an initial duration of five years. After these five years, the authorization may be renewed on the basis of a reevaluation of the risk-benefit balance.

Data and Marketing Exclusivity in the EU

In the EU, new products authorized for marketing (*i.e.*, reference products) generally receive eight years of data exclusivity and an additional two years of market exclusivity upon MA. If granted, the data exclusivity period prevents generic and biosimilar applicants from relying on the preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar MA in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until ten years have elapsed from the initial MA of the reference product in the EU. The overall ten-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those ten years, the MA holder obtains an authorization for one or more new therapeutic indications, which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical or biological entity, and products may not qualify for data exclusivity.

Orphan Medicinal Products in the EU

The criteria for designating an "orphan medicinal product" in the EU are similar in principle to those in the United States. A medicinal product can be designated as an orphan if its sponsor can establish that: (1) the product is intended for the diagnosis, prevention or treatment of a life threatening or chronically debilitating condition (2)

either (a) such condition affects not more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from the orphan status, would not generate sufficient return in the EU to justify the necessary investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized for marketing in the EU or, if such method exists, the product will be of significant benefit to those affected by that condition.

Orphan designation must be requested before submitting an MAA. An EU orphan medicinal product designation entitles a party to incentives such as reduction of fees or fee waivers, protocol assistance, and access to the centralized procedure. Upon grant of a MA, orphan medicinal products are entitled to ten years of market exclusivity for the approved indication, which means that the competent authorities cannot accept another MAA, or grant a MA, or accept an application to extend a MA for a similar medicinal product for the same indication for a period of ten years. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed pediatric investigation plan (PIP). No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan medicinal product designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The orphan exclusivity period may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for which it received orphan designation, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, MA may be granted to a similar product for the same indication at any time if (i) the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior; (ii) the applicant consents to a second orphan medicinal product application; or (iii) the applicant cannot supply enough orphan medicinal product.

Pediatric Development

In the EU, MAAs for new medicinal products have to include the results of studies conducted in the pediatric population, in compliance with a PIP agreed with the EMA's Pediatric Committee (PDCO). The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the product candidate for which MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data is not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all the EU member states and study results are included in the product information, even when negative, the product is eligible for six months' supplementary protection certificate extension (if any is in effect at the time of approval) or, in the case of orphan medicinal products, a two year extension of the orphan market exclusivity is granted.

The aforementioned EU rules are generally applicable in the European Economic Area (EEA), which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland.

Failure to comply with EU and member state laws that apply to the conduct of clinical trials, manufacturing approval, MA of medicinal products and marketing of such products, both before and after grant of the MA, manufacturing of pharmaceutical products, statutory health insurance, bribery and anti-corruption or with other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant MA, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the MA, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

Regulation of Companion Diagnostics in the EU

In the EU, *in vitro* diagnostic medical devices (IVD MDs), were regulated by the EU Directive on *in vitro* diagnostic medical devices (Directive No. 98/79/EC, as amended) (IVDD), which regulated the placing on the

market, the European Conformity (CE) marking, the essential requirements, the conformity assessment procedures, the registration obligations for manufacturers and devices as well as the vigilance procedure. IVD MDs had to comply with the requirements provided for in the IVDD, and with further requirements implemented at national level (as the case may be).

The regulation of companion diagnostics is subject to further requirements since Regulation (EU) No 2017/746 (IVDR) became applicable on May 26, 2022. Following subsequent legislative changes, European institutions adopted a "progressive" roll-out of the IVDR to prevent disruption in the supply of in vitro diagnostic medical devices. Therefore, the IVDR applies since May 26, 2022, but there is a tiered system extending the grace period for many devices (depending on their risk classification) before they have to be fully compliant with the regulation. The IVDR introduced a new classification system for companion diagnostics which are now specifically defined as diagnostic tests that support the safe and effective use of a specific medicinal product, by identifying patients that are suitable or unsuitable for treatment. Companion diagnostics will have to undergo a conformity assessment by a notified body. Before it can issue an EU certificate, the notified body must seek a scientific opinion from the EMA on the suitability of the companion diagnostic to the medicinal product concerned if the medicinal product falls exclusively within the scope of the centralized procedure for the authorization of medicines, or the medicinal product is already authorized through the centralized procedure, or a MAA for the medicinal product has been submitted through the centralized procedure. For other substances, the notified body can seek the opinion from national competent authorities or the EMA.

The aforementioned EU rules are generally applicable in the EEA.

Data Privacy & Security

Numerous state, federal and foreign laws, regulations and standards govern the collection, 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 United States, 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.

Human Capital

As of March 25, 2025, we had 60 full-time employees, including a total of 16 employees with M.D. or Ph.D. degrees. Of these full-time employees, 44 employees are engaged in research and development.

None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards. We value our employees and regularly benchmark total rewards we provide, such as short and long-term compensation, 401(k) plan participation, health, welfare and quality of life benefits, paid time off and personal leave, against our industry peers to ensure we remain competitive and attractive to potential new hires.

Available Information

Our internet address is www.tyra.bio. Our investor relations website is located at https://tyrabio.investorroom.com. We make available free of charge on our investor relations website under "SEC Filings" our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, our

directors' and officers' Section 16 reports and any amendments to those reports as soon as reasonably practicable after filing or furnishing such materials to the SEC. They are also available for free on the SEC's website at www.sec.gov.

We use our investor relations website as a means of disclosing material non-public information and for complying with our disclosure obligations under Regulation FD. Investors should monitor such website, in addition to following our press releases, SEC filings and public conference calls and webcasts. Information relating to our corporate governance is also included on our investor relations website The information in or accessible through the SEC and our website are not incorporated into, and are not considered part of, this filing.

Item 1A. Risk Factors.

You should carefully consider the following risk factors, together with the other information contained in this Annual Report, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before making a decision to purchase or sell shares of our common stock. We cannot assure you that any of the events discussed in the risk factors below will not occur. These risks could have a material and adverse impact on our business, results of operations, financial condition and growth prospects. If that were to happen, the trading price of our common stock could decline. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations or financial condition. In this section, we first provide a summary of the principal risks and uncertainties we face and then provide a full set of risk factors and discuss them in greater detail.

Summary of Risks Related to Our Business

- We are early in our development efforts, have a limited operating history, have not completed any clinical trials, and have no products approved for commercial sale, which may make it difficult for investors to evaluate our current business and likelihood of success and viability.
- We have incurred significant net losses in each period since our inception, and we expect to continue to incur significant net losses for the foreseeable future.
- Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve our objectives relating to discovery, development and commercialization of our product candidates.
- We will require substantial additional capital to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our development programs, commercialization efforts or other operations.
- We are early in our development efforts, with three product candidates in clinical development, and our other development programs in the preclinical or discovery stage. If we are unable to successfully develop, obtain marketing approval and ultimately commercialize product candidates, or experience significant delays in doing so, our business will be materially harmed.
- As an organization, we have never completed any clinical trials or submitted an application for marketing approval and may be unable to do so for any of our product candidates.
- Preclinical and clinical development involves a lengthy and expensive process with an uncertain outcome, and the results of preclinical studies and early clinical trials are not necessarily predictive of future results. Our product candidates may not have favorable results in clinical trials, if any, or receive marketing approval on a timely basis, if at all.
- If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

- Use of our product candidates could be associated with side effects, adverse events or other properties or safety risks, which could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon a product candidate, limit the commercial profile of an approved label or result in other significant negative consequences that could severely harm our business, prospects, operating results and financial condition.

- We intend to rely on third parties for the manufacture of our product candidates for preclinical and clinical development. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

- We rely on third parties to conduct our clinical trials and some of our preclinical studies. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, our development programs and our ability to seek or obtain marketing approval for or commercialize our product candidates may be delayed.

- We face significant competition, and, if our competitors develop technologies or product candidates more rapidly than we do or their technologies are more effective, our business and our ability to develop and successfully commercialize products may be adversely affected.

- If we are unable to obtain and maintain patent protection for our product candidates and other proprietary technologies we develop, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our product candidates and other proprietary technologies we may develop may be adversely affected.

- The trading price of the shares of our common stock could be highly volatile, and purchasers of our common stock could incur substantial losses.

Risks Related to Our Limited Operating History, Financial Position and Capital Requirements

We are early in our development efforts, have a limited operating history, have not completed any clinical trials, and have no products approved for commercial sale, which may make it difficult for investors to evaluate our current business and likelihood of success and viability.

Investment in drug development is a highly speculative undertaking and involves a substantial degree of risk. We are a biopharmaceutical company formed in 2018 with a limited operating history upon which you can evaluate our business and prospects. We have three product candidates in clinical development. Our other development programs are either in preclinical development or in the drug discovery stage. To date, we have focused primarily on organizing and staffing our company, business planning, raising capital, research and development activities including development of our proprietary SNÅP platform and identifying potential product candidates, establishing our intellectual property portfolio, conducting research and preclinical studies and clinical trials, and providing general and administrative support to these operations. Our approach to the discovery and development of product candidates based on our proprietary SNÅP platform is unproven, and we do not know whether we will be able to develop any product candidates that are successful in clinical development or products of commercial value.

As an organization, we have not yet completed any clinical trials, obtained regulatory approvals, manufactured a commercial-scale product, or arranged for a third party to do so on our behalf, or conducted sales and marketing activities necessary for successful product commercialization. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing biopharmaceutical products.

We have incurred significant net losses in each period since our inception, and we expect to continue to incur significant net losses for the foreseeable future.

We have incurred significant operating losses since our inception. Our net losses were $86.5 million and $69.1 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of $251.3 million. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. TYRA-300, TYRA-200, TYRA-430 and any of our other product candidates will require substantial additional development time and resources before we are able to apply for, or receive, marketing approval and begin generating revenue from product sales. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase substantially as we continue our development of, and seek marketing approval for, and potentially commercialize any of our product candidates and as we seek to discover, develop and market additional potential product candidates.

Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve our objectives relating to discovery, development and commercialization of our product candidates.

To generate revenue and achieve profitability, we must succeed in developing and eventually commercializing product candidates that generate significant revenue. This will require us to be successful in a range of challenging activities, including identifying lead product candidates, completing preclinical studies and clinical trials of our product candidates, discovering additional product candidates, obtaining marketing approval for these product candidates and manufacturing, marketing and selling any products for which we may obtain marketing approval. We are only in the preliminary stages of many of these activities. We may never succeed in these activities and, even if we succeed in commercializing one or more of our product candidates, we may never generate revenues that are significant or large enough to achieve profitability. In addition, we have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical industry.

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. Even if we obtain marketing approval for one or more of our product candidates and achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable may have an adverse effect on the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product candidates or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We will require substantial additional capital to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our development programs, commercialization efforts or other operations.

The development of biopharmaceutical product candidates is capital-intensive. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct our ongoing and planned clinical trials and preclinical studies for our product candidates and other development programs and seek marketing approval for our current product candidates and any future product candidates we may develop. If we obtain marketing approval for any of our product candidates, we also expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Because the outcome of any preclinical study or clinical trial is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in

connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

Based upon our current operating plan, we believe that our existing cash, cash equivalents and marketable securities will enable us to fund our operations through at least 2027. We have based these estimates on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our operating plans and other demands on our cash resources may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other capital sources, including potentially additional collaborations, licenses and other similar arrangements. In addition, we may seek additional capital due to favorable market conditions or liquidity or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. For example, in October 2022, we entered into an ATM Sales Agreement (the Sales Agreement) with Virtu Americas LLC (the Agent), pursuant to which we may, from time to time, sell shares of our common stock having an aggregate offering price of up to $150 million in "at the market" offerings through or to the Agent, as sales agent or principal. However, there can be no assurance that the Agent will be successful in consummating future sales based on prevailing market conditions or in the quantities or at the prices that we deem appropriate. In addition, the Sales Agreement may be terminated by us or the Agent at any time upon specified notice to the other party, or by the Agent at any time in certain circumstances, including the occurrence of a material adverse change. Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop our product candidates.

Our future capital requirements will depend on many factors, including, but not limited to:

- the type, number, scope, progress, expansions, results, costs and timing of, discovery, preclinical studies and clinical trials of our product candidates which we are pursuing or may choose to pursue in the future;
- the costs and timing of manufacturing for our product candidates and commercial manufacturing if any product candidate is approved;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights;
- our efforts to enhance operational, compliance, and quality systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal controls over financial reporting;
- the costs associated with hiring additional personnel and consultants as our preclinical and clinical activities increase;
- the costs and timing of establishing or securing sales and marketing capabilities if any product candidate is approved for commercial sale;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;
- changes in laws or regulations applicable to our product candidates, including but not limited to clinical trial requirements for approval;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements; and

- costs associated with any products or technologies that we may in-license or acquire.

Because we do not expect to generate commercial revenues, if any, from sales of products that we do not expect to be commercially available for many years, if at all, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all, including as a result of financial and credit market deterioration or instability, market-wide liquidity shortages, geopolitical events or otherwise.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through equity offerings, debt financings, or other capital sources, including potential collaborations, licenses and other similar arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Any future debt financing and preferred equity financing, if available, may involve, agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, selling or licensing our assets, making capital expenditures, declaring dividends or encumbering our assets to secure future indebtedness. Such restrictions could adversely impact our ability to conduct our operations and execute our business plan.

If we raise additional funds through future collaborations, licenses and other similar arrangements, we may have to relinquish valuable rights to our future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us and/or that may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed or on terms acceptable to us, we would be required to delay, limit, reduce, or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Our portfolio of investments or bank deposits may be subject to market, interest and credit risk that may reduce their value and adversely affect our business, results of operations and financial condition.

The value of our investments may decline due to increases in interest rates, downgrades of the bonds and other securities included in our commercial money market account portfolio and instability in the global financial markets that reduces the liquidity of securities included in our portfolio. In addition, in the past, the closure of financial institutions and their placement into receivership with the Federal Deposit Insurance Corporation (FDIC) created bank-specific and broader financial institution liquidity risk and concerns. Future adverse developments with respect to specific financial institutions or the broader financial services industry may impair our ability to access capital needed to support near-term working capital needs, whether from our existing investment and deposit accounts and credit facilities or otherwise, and may lead to market-wide liquidity shortages and create additional market and economic uncertainty. Furthermore, possible recession and rising inflation concerns have adversely affected and may continue to adversely affect the financial markets in some or all countries worldwide. Each of these events may cause us to record charges to reduce the carrying value of our investment portfolio or sell investments for less than our acquisition cost. Although we attempt to mitigate these risks through diversification of our investments, the value of our investments may nevertheless decline, and our ability to fund our near-term and long-term working capital needs to support our business and clinical development plans may be adversely affected. In addition, any decline in available funding or access to our cash and liquidity resources could also result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws.

Risks Related to the Discovery, Development and Marketing Approval of Our Product Candidates

We are early in our development efforts, with three product candidates in clinical development, and our other development programs in the preclinical or discovery stage. If we are unable to successfully develop, obtain marketing approval and ultimately commercialize product candidates, or experience significant delays in doing so, our business will be materially harmed.

We are in the early stages of our research and development efforts and all of our development programs are either in early clinical development or the preclinical or drug discovery stage. We have invested substantially all of our efforts to date in developing our proprietary SNÅP platform, developing TYRA-300, TYRA-200 and TYRA-430, identifying other potential product candidates and conducting preclinical studies. We are relatively early in our clinical trials of our product candidates and will need to progress our other development programs through additional preclinical studies to enable us to submit INDs with the FDA and receive allowance from the FDA to proceed with initiating their clinical development. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend on the successful development and eventual commercialization of our product candidates. The success of our product candidates will depend on several factors, including the following:

- successful completion of preclinical studies with favorable results, including those compliant with Good Laboratory Practice (GLP) such as toxicology studies, biodistribution studies and minimum effective dose studies in animals;
- acceptance by the FDA of INDs or of similar regulatory submissions by comparable foreign regulatory authorities for the conduct of clinical trials of our product candidates and our proposed design of future clinical trials;
- successful identification of appropriate patients eligible to enroll, and enrollment of such patients, in clinical trials and completion of clinical trials with favorable results;
- successful identification of new product candidates utilizing our SNÅP platform;
- demonstrating safety and efficacy to the satisfaction of applicable regulatory authorities;
- making arrangements with our third-party manufacturers for, or establishing, commercial manufacturing capabilities;
- receipt of marketing approvals from applicable regulatory authorities, including new drug applications (NDAs), from the FDA and maintaining such approvals;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- establishing and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates;
- maintaining an acceptable safety profile of our products following marketing approval, including acceptable results from any post-approval studies or clinical trials agreed to by us or required by the FDA; and
- maintaining and growing an organization of people who can develop and commercialize our product candidates.

The FDA or comparable foreign regulatory authorities can refuse to accept INDs or similar regulatory submissions for many reasons, including negative or ambiguous results from our preclinical studies or disagreement with our interpretation of data from preclinical studies. If we are unable to develop, obtain marketing approval for,

or, if approved, successfully commercialize our product candidates, we may not be able to generate sufficient revenue to continue our business.

As an organization, we have never completed any clinical trials or submitted an application for marketing approval and may be unable to do so for any of our product candidates.

We are early in our development efforts for our product candidates and we will need to successfully complete our ongoing and planned clinical trials and later-stage and pivotal clinical trials, in order to obtain marketing authorization from the FDA or comparable foreign regulatory authorities to market TYRA-300, TYRA-200, TYRA-430, as well as complete IND-enabling studies for our development programs in the preclinical or discovery stage. Carrying out clinical trials and the submission of a successful NDA is a complicated process. As an organization, while we have commenced clinical trials for certain of our product candidates, we have not previously completed any clinical trials, have limited experience as a company in preparing and submitting marketing applications and have not previously submitted an NDA or other comparable foreign regulatory submission for any product candidate. In addition, we have had limited interactions with the FDA and cannot be certain how many clinical trials of TYRA-300, TYRA-200, TYRA-430 or any other product candidates will be required or how such trials should be designed. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to regulatory submission and approval of any of our product candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining marketing approvals of product candidates that we develop. Failure to commence or complete, or delays in, our ongoing or planned clinical trials, could prevent us from, or delay us in submitting NDAs for, and commercializing our product candidates.

Preclinical and clinical development involves a lengthy and expensive process with an uncertain outcome, and the results of preclinical studies and early clinical trials are not necessarily predictive of future results. Our product candidates may not have favorable results in clinical trials, if any, or receive marketing approval on a timely basis, if at all.

Preclinical and clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain. We cannot guarantee that any preclinical studies or clinical trials will be conducted as planned or completed on schedule, if at all, and delay or failure can occur at any time during the preclinical study or clinical trial process, including due to factors that are beyond our control. Further, we may not be able to meet expected timeframes for data readouts. Despite promising preclinical or clinical results, any biopharmaceutical company's product candidate can unexpectedly fail at any stage of preclinical or clinical development, and regulators, such as the FDA or comparable foreign regulatory authorities, may not accept the results as demonstrating the product candidate's safety and efficacy. The historical failure rate for product candidates in our industry is high.

The results from preclinical studies or clinical trials of a product candidate may not predict the results of later clinical trials of the product candidate, and interim, topline, or preliminary results of a clinical trial are not necessarily indicative of final results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed through preclinical studies and initial clinical trials. In particular, while we have conducted certain preclinical studies of our product candidates , we do not know whether our current product candidates or other potential product candidates will perform in current or future clinical trials as they have performed in these prior studies. The positive results we have observed for our product candidates in preclinical animal models may not be predictive of our current or future clinical trials in humans. In addition, while we reported interim results from our ongoing SURF301 trial, they are not necessarily indicative of final results or results from future trials, It is not uncommon to observe results in clinical trials that are unexpected based on preclinical studies and early clinical trials, and many product candidates fail in clinical trials despite very promising early results. If unexpected observations or toxicities are observed in our ongoing or planned trials, or in IND-enabling studies for any of our other product candidates, such results could delay and possibly prevent or limit

clinical trials for our product candidates. Moreover, preclinical and clinical data may be susceptible to varying interpretations and analyses. A number of companies in the biopharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies. Such setbacks have occurred and may occur for many reasons, including, but not limited to: clinical sites and investigators may deviate from clinical trial protocols, whether due to lack of training or otherwise, and we may fail to detect any such deviations in a timely manner; patients may fail to adhere to any required clinical trial procedures, including any requirements for post-treatment follow-up; our product candidates may fail to demonstrate effectiveness or safety in certain patient subpopulations, which has not been observed in earlier trials due to limited sample size, lack of analysis or otherwise; or our clinical trials may not adequately represent the patient populations we intend to treat, whether due to limitations in our trial designs or otherwise, such as where one patient subgroup is overrepresented in the clinical trial. There can be no assurance that we will not suffer similar setbacks despite the data we observed in earlier or ongoing studies. Based upon negative or inconclusive results, we or any future collaborator may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials, which would cause us to incur additional operating expenses and delays and may not be sufficient to support regulatory approval on a timely basis or at all.

For the foregoing reasons, we cannot be certain that our ongoing and planned preclinical studies and clinical trials will be successful. In addition, any safety concerns observed in any one of our clinical trials in our targeted indications could impair the development, marketing approval or commercial prospects of our product candidates in those and other indications, such as TYRA-300 for oncology and achondroplasia, which could have a material adverse effect on our business, financial condition and results of operations.

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the European Union (EU) recently evolved. The EU Clinical Trials Regulation (CTR) which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the EU Clinical Trials Directive required a separate clinical trial application (CTA) to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. The CTR transition period ended on January 31, 2025, and all clinical trials (and related applications) are now fully subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as contract research organizations (CROs), may impact our developments plans.

In oncology, our discovery and preclinical development activities are focused on the development of targeted therapeutics for patients with genomically defined cancers, which is a rapidly evolving area of science, and the approach we are taking to discover and develop drugs based on our SNÅP platform is novel and unproven and may never lead to approved products of commercial value.

The discovery and development of targeted therapeutics for patients with genomically defined cancers is an emerging field, and the scientific discoveries that form the basis for our efforts to discover and develop product candidates are relatively new. Although we believe, based on our preclinical work in oncology, that the genomic alterations targeted by our programs are oncogenic drivers, clinical results may not confirm this hypothesis or may only confirm it for certain alterations or certain tumor types. In addition, even if our approach is successful in showing clinical benefit for acquired resistance mutation-driven cancers for our TYRA-300, TYRA-200, or TYRA-

430 product candidates, we may never successfully identify additional oncogenic alterations for other receptor tyrosine kinases using our SNÅP platform, or succeed in identifying additional product candidates to address such alterations. Any product candidates we do discover and advance based on scientific approach may be later shown to have harmful side effects or may have other characteristics that may necessitate additional clinical testing, or make the product candidates unmarketable or unlikely to receive marketing approval. Therefore, we do not know if our approach of discovering and developing product candidates to treat patients with genomically defined cancers will be successful, and if our approach is unsuccessful, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operation.

Any difficulties or delays in the commencement or completion, or termination or suspension, of our clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

Before we can initiate clinical trials for our product candidates, we must submit the results of preclinical studies to the FDA or comparable foreign regulatory authorities along with other information, including information about product candidate chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an IND or similar regulatory filing required for regulatory allowance before proceeding with clinical development. The FDA or comparable foreign regulatory authorities may require us to conduct additional preclinical studies for any product candidate before it allows us to initiate clinical trials under any IND or similar regulatory filing, which may lead to delays and increase the costs of our preclinical development programs. Moreover, even if these trials begin, issues may arise that could cause regulatory authorities to suspend or terminate such clinical trials. Any such delays in the commencement or completion of our ongoing or planned clinical trials for TYRA-300, TYRA-200, TYRA-430 or any other product candidate, could significantly affect our product development timelines and development costs.

We do not know whether our planned trials will begin on time or be completed on schedule, if at all. The commencement, data readouts and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- inability to generate sufficient preclinical, toxicology, or other *in vivo* or in vitro data to support the initiation or continuation of clinical trials;
- obtaining regulatory allowance or authorization to commence a trial or reaching a consensus with regulatory authorities on trial design;
- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- any failure or delay in reaching an agreement with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- failure to reach an agreement with diagnostic companies for the development and use of liquid biopsy companion diagnostic tests in our clinical trials;
- obtaining approval from one or more institutional review boards (IRBs) (or ethics committees);
- IRBs (or ethics committees) refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional patients, or withdrawing their approval of the trial;
- changes to clinical trial protocol;

- identifying sufficient appropriately qualified investigators and other professionals to conduct the clinical trials;
- clinical sites deviating from trial protocol or dropping out of a trial;
- manufacturing sufficient quantities of product candidates for use in clinical trials;
- patients failing to enroll or remain in our trials at the rate we expect, or failing to return for post-treatment follow-up;
- patients choosing alternative treatments for the indications for which we are developing our product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trials;
- patients experiencing severe or unexpected drug-related adverse effects;
- occurrence of serious adverse events in clinical trials of the same class of agents conducted by other companies;
- selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data;
- a facility manufacturing our product candidates or any of their components suspending or limiting manufacturing due to violations of cGMP, or other applicable requirements, including infections or cross-contaminations of product candidates in the manufacturing process, or the facility being subject to other enforcement by the FDA or comparable foreign regulatory authorities that result in temporary or permanent manufacturing shut downs or product supply limitations;
- any changes to our manufacturing process that may be necessary or desired;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials or being suspended or disqualified by the FDA or comparable foreign regulatory authorities, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, GCPs, or other regulatory requirements;
- third-party contractors not performing data collection or analysis in a timely or accurate manner; or
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or comparable foreign regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which our trials are being conducted, by a Data Safety Monitoring Board for our trial or by the FDA or comparable foreign regulatory authorities. These authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols and to make the appropriate required records, inspection of the clinical trial operations or trial site by the FDA or comparable foreign 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 clinical trial drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Further, conducting clinical trials in foreign countries, as we may do for our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of investigators or enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks, including war, relevant to such foreign countries.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues.

Our proprietary SNÅP platform is innovative and unproven, and we do not know whether we will be able to develop any product candidates that are successful in clinical development or products of commercial value.

The success of our business depends primarily upon our ability to identify, develop and commercialize products based on our proprietary SNÅP platform, which is designed to efficiently identify and selectively target vulnerabilities in the mutant proteins that commonly eliminate or reduce the effectiveness of standard-of-care therapies. We have not yet succeeded and may not succeed in demonstrating efficacy and safety for any product candidates in clinical trials or in obtaining marketing approval thereafter. Our product candidates are in the early stages of development and we have not yet completed any clinical trials for any product candidate. Our SNÅP platform utilizes the rapid generation of precise molecular SNÅPshots to continually gain deeper insights into the structure of inhibitor binding sites and how commonly occurring resistance mutations lead to acquired drug resistance to existing therapies, which we believe aids in the prediction of amino acid residues most likely to cause resistance to specific existing therapies. This innovative process may never be successful in identifying additional product candidates with innovative structures that are able to inhibit the target while avoiding those specific residues. Further, because all of our product candidates and discovery programs are based on our SNÅP platform, adverse developments with respect to one of our programs may have a significant adverse impact on the actual or perceived likelihood of success and value of our other development programs.

In addition, the biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies. Our future success will depend in part on our ability to maintain a competitive position with our innovative approach to compound identification. If we fail to stay at the forefront of technological innovation in utilizing our SNÅP platform, we may be unable to compete effectively.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may not be able to complete clinical trials for our product candidates if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or comparable foreign regulatory authorities. Patient enrollment for our clinical trials may be affected by many factors, including:

- the size and nature of the patient population;
- severity of the disease or condition under evaluation;
- the proximity of patients to clinical sites;
- the eligibility and exclusion criteria for the trial;
- the design of the clinical trial;

- the risk that enrolled patients will not complete a clinical trial;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience; and
- competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating as well as any product candidates under development.

We will be required to identify and enroll a sufficient number of patients for each of our clinical trials. The patient populations for our product candidates are limited to those with specific target alterations and may not be completely defined but are substantially smaller than the general treated cancer population, and we will need to screen and identify these patients with targeted alterations. Successful identification of patients is dependent on several factors, including achieving certainty as to how specific alterations respond to our product candidates and the ability to identify such alterations. Furthermore, even if we are successful in identifying patients, we cannot be certain that the resulting patient populations for each mutation will be large enough to allow us to successfully obtain approval for each mutation type and commercialize our product candidates and achieve profitability. We may not be able to initiate or continue clinical trials if we are unable to locate a sufficient number of eligible patients to participate in the clinical trials required by the FDA or comparable foreign regulatory authorities. In addition, the process of finding and diagnosing patients may prove costly.

The timing of our clinical trials depends, in part, on the speed at which we can recruit patients to participate in our trials, as well as completion of required follow-up periods. The eligibility criteria of our clinical trials, once established, will further limit the pool of available trial participants. If patients are unwilling to participate in our trials for any reason, including the existence of concurrent clinical trials for similar patient populations or the availability of other therapies, or we otherwise have difficulty enrolling a sufficient number of patients, the timeline for recruiting patients, conducting clinical trials and obtaining marketing approval of our product candidates may be delayed. Additionally, because our initial clinical trials will be in patients with relapsed/refractory cancer, these patients are typically in the late stages of their disease and may experience disease progression independent from our product candidates, making them unevaluable for purposes of the clinical trial and requiring additional patient enrollment. Our inability to enroll a sufficient number of patients for any of our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. In addition, we expect to rely on CROs and clinical trial sites to ensure proper and timely conduct of our clinical trials and, while we intend to enter into agreements governing their services, we will have limited influence over their actual performance.

We cannot assure you that our assumptions used in determining expected clinical trial timelines are correct or that we will not experience delays in enrollment, which would result in the delay of completion of such trials beyond our expected timelines.

Use of our product candidates could be associated with side effects, adverse events or other properties or safety risks, which could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon a product candidate, limit the commercial profile of an approved label or result in other significant negative consequences that could severely harm our business, prospects, operating results and financial condition.

We have not completed the evaluation of any of our product candidates in human clinical trials. It is impossible to predict when or if any product candidates we may develop will prove safe in humans. As is the case with biopharmaceuticals generally, and treatments for cancer and rare diseases in particular, it is likely that there

may be side effects and adverse events associated with the use of our product candidates. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or comparable foreign regulatory authorities. If adverse events or other side effects are observed in any of our clinical trials, we may have difficulty recruiting patients to our clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether. Any of these occurrences may harm our business, financial condition and prospects significantly.

Moreover, if our product candidates are associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may elect to abandon their development or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial expectations for the product candidate if approved. Any such undesirable side effects observed in one of our clinical trials in our targeted indications could impair the development, marketing approval or commercial prospects of our product candidates in those and other indications. We, the FDA or other applicable regulatory authorities, or an IRB, may suspend or terminate future clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Many compounds that initially showed promise in early-stage testing have later been found to cause side effects that prevented further development of the compound. In addition, regulatory authorities may draw different conclusions or require additional testing to confirm these determinations.

It is possible that as we test our product candidates in larger, longer and more extensive clinical trials, including with different dosing regimens, or as the use of these product candidates becomes more widespread if they receive marketing approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, may be reported by patients. If such side effects become known later in development or upon approval, if any, such findings may harm our business, financial condition and prospects significantly.

Patients treated with our products, if approved, may experience previously unreported adverse reactions, and it is possible that the FDA or comparable foreign regulatory authorities may ask for additional safety data as a condition of, or in connection with, our efforts to obtain approval of our product candidates. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus other therapies. If safety problems occur or are identified after our products, if any, are available for commercial sale and use, we may make the decision, or be required by regulatory authorities, to amend the labeling of our product candidates, recall our product candidates or even withdraw approval for an approved product.

In addition, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw, suspend or limit approvals of such product, or seek an injunction against its manufacture or distribution;
- we may be required to recall a product or change the way such product is administered to patients;
- regulatory authorities may require additional warnings on the label, such as a “black box” warning or a contraindication;

- we may be required to implement a Risk Evaluation and Mitigation Strategy (REMS) or create a medication guide outlining the risks of such side effects for distribution to patients;

- we may be required to change the way a product is distributed, conduct additional clinical trials or change the labeling of a product or be required to conduct additional post-marketing studies or surveillance;

- we could be sued and held liable for harm caused to patients; or

- sales of the product may decrease significantly or the product could become less competitive and our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

Our product candidates are subject to extensive regulation and compliance, which is costly and time consuming, and such regulation may cause unanticipated delays or prevent the receipt of the required approvals to commercialize our product candidates.

The clinical development, manufacturing, labeling, packaging, storage, record-keeping, advertising, promotion, import, export, marketing, distribution and adverse event reporting, including the submission of safety and other information, of our product candidates are subject to extensive regulation by the FDA in the United States and by comparable foreign regulatory authorities in foreign markets. In the United States, we are not permitted to market our product candidates until we receive marketing approval from the FDA. The process of obtaining marketing approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications and patient population. Approval policies or regulations may change, and the FDA has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, marketing approval is never guaranteed. Neither we, nor any future collaborator, is permitted to market any of our product candidates in the United States until we receive marketing approval from the FDA.

Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we or our collaborators must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities, as the case may be, may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or post-approval, or may object to elements of our clinical development program.

The FDA or comparable foreign regulatory authorities can delay, limit or deny approval of a product candidate for many reasons, including:

- such authorities may disagree with the design or implementation of our, or our any of our potential future collaborators' clinical trials;

- negative or ambiguous results from our clinical trials or results may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for marketing approval;

- serious and unexpected drug-related side effects may be experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;
- such authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the United States;
- we, or any of our potential future collaborators may be unable to demonstrate that a product candidate is safe and effective, and that product candidate's clinical and other benefits outweigh its safety risks;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- such authorities may not agree that the data collected from clinical trials of our product candidates are acceptable or sufficient to support the submission of an NDA or other submission or to obtain marketing approval in the United States or elsewhere, and such authorities may impose requirements for additional preclinical studies or clinical trials;
- such authorities may disagree regarding the formulation, labeling and/or the specifications of our product candidates;
- such authorities may require additional information, data, qualification, or validation of our manufacturing and testing processes as part of the chemistry, manufacturing, and controls information we submit as part of our application;
- approval may be granted only for indications that are significantly more limited than what we apply for and/or with other significant restrictions on distribution and use;
- such authorities may find deficiencies in the manufacturing processes, approval policies or facilities of our third-party manufacturers with which we or any of our current or future collaborators contract for clinical and commercial supplies;
- regulations of such authorities may significantly change in a manner rendering our or any of our potential future collaborators' clinical data insufficient for approval; or
- such authorities may not accept a submission due to, among other reasons, the content or formatting of the submission.

Any delays in the marketing approval of our product candidates may negatively impact our ability to successfully position the product candidate in the market or the product candidate may face additional competition from other products.

With respect to foreign markets, marketing approval procedures vary among countries and, in addition to the foregoing risks, may involve additional product testing, administrative review periods and agreements with pricing authorities. In addition, events raising questions about the safety of certain marketed biopharmaceuticals may result in increased cautiousness by the FDA or comparable foreign regulatory authorities in reviewing new drugs based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining marketing approvals. Any delay in obtaining, or inability to obtain, applicable marketing approvals would prevent us or any of our potential future collaborators from commercializing our product candidates.

If we are unable to successfully develop companion diagnostics for biomarkers that enable patient selection, or experience significant delays in doing so, we may not be able to commercialize the product candidate and our ability to generate revenue will be materially impaired.

A key component of our strategy includes the use of companion diagnostics to guide patient selection of our product candidates. We do not have the ability to develop such tests on our own, and so we plan to rely on third

parties for the design, development and manufacture of companion diagnostic tests for any of our product candidates that may require such tests. If we enter into such collaborative agreements, we will be dependent on the sustained cooperation and effort of our future collaborators in developing and obtaining approval, certification or clearance for these companion diagnostics. To be successful in developing and commercializing product candidates in combination with these companion diagnostics, we and our future collaborators will need to address a number of scientific, technical, regulatory and logistical challenges.

According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared at the same time the product candidate is approved. To date, the FDA has generally required premarketing approval for companion diagnostic tests for use with cancer therapies. Various foreign regulatory authorities also regulate in vitro companion diagnostics as medical devices and, under those regulatory frameworks, will likely require the conduct of clinical trials to demonstrate the safety and effectiveness of these companion diagnostics, which we expect will require separate regulatory clearance or approval prior to commercialization.

The approval, certification or clearance of a companion diagnostic as part of the therapeutic product's labeling limits the use of the therapeutic product to only those patients who express certain biomarkers or the specific genomic alteration that the companion diagnostic was developed to detect. If the FDA or comparable foreign regulatory authorities require approval or clearance of a companion diagnostic for any of our product candidates, whether before or concurrently with marketing approval of the product candidate, we and/or our collaborators, may encounter difficulties in developing and obtaining approval, certification or clearance for these companion diagnostics. Any delay or failure by us or potential future collaborators to develop or obtain regulatory approval or clearance of a companion diagnostic could delay or prevent approval, certification or continued marketing of our related product candidates.

Indeed, approval, certification or clearance of companion diagnostics may be subject to further legislative or regulatory reforms notably in the EU. On May 25, 2017, the new In Vitro Medical Devices Regulation (IVDR) entered into force. The IVDR repeals and replaces the EU In Vitro Diagnostic Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EU member states, regulations are directly applicable, i.e., without the need for adoption of EU member states laws implementing them, in all EU member states and are intended to eliminate current differences in the regulation of medical devices among EU member states. The IVDR, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EU for medical devices and ensure a high level of safety and health while supporting innovation. The IVDR became applicable on May 26, 2022. Following subsequent legislative changes, European institutions adopted a "progressive" roll-out of the IVDR to prevent disruption in the supply of in vitro diagnostic medical devices. Therefore, the IVDR applies since May 26, 2022, but there is a tiered system extending the grace period for many devices (depending on their risk classification) before they have to be fully compliant with the regulation.

The regulation of companion diagnostics is subject to further requirements since the IVDR became applicable as it introduced a new classification system for companion diagnostics which are now specifically defined as diagnostic tests that support the safe and effective use of a specific medicinal product, by identifying patients that are suitable or unsuitable for treatment. Companion diagnostics will have to undergo a conformity assessment by a notified body. Before it can issue an EU certificate, the notified body must seek a scientific opinion from the European Medicine Agency (EMA) on the suitability of the companion diagnostic to the medicinal product concerned if the medicinal product falls exclusively within the scope of the centralized procedure for the authorization of medicines, or the medicinal product is already authorized through the centralized procedure, or a marketing authorization application for the medicinal product has been submitted through the centralized procedure. For other substances, the notified body can seek the opinion from national competent authorities or the EMA. These

modifications may make it more difficult and costly for us to obtain regulatory clearances, approvals or certification for our companion diagnostics or to manufacture, market or distribute our products after clearance, approval or certification is obtained.

In addition, in January 2024, the FDA announced its intention to initiate the process to reclassify most in vitro diagnostic tests (IVDs) that are currently Class III into Class II, including companion diagnostic IVDs. If such reclassification efforts occur, any companion diagnostics that are the subject of the down- classification may no longer require premarket approval, but rather may be marketed pursuant to the generally less burdensome 510(k) clearance process. However, there is no assurance that any companion diagnostic required for our pharmaceutical development programs will benefit from any reclassification, or that such reclassification, even if it does occur, will result in a shorter timeline to development or marketing of the companion diagnostic.

We may also be required to conduct additional studies to support a broader claim. Also, to the extent other approved diagnostics are able to broaden their labeling claims to include our approved drug products, we may be forced to abandon any partnered companion diagnostic development plans we undertake or we may not be able to compete effectively upon marketing approval, which could adversely impact our ability to generate revenue from the sale of our approved products and our business operations.

Moreover, even if data from preclinical studies and early clinical trials appear to support development of a companion diagnostic for a product candidate, data generated in later clinical trials may fail to support the analytical and clinical validation of the companion diagnostic. We and our future collaborators may encounter difficulties in developing, obtaining regulatory approval, certification or clearance for, manufacturing and commercializing companion diagnostics similar to those we face with respect to our product candidates themselves, including issues with achieving regulatory clearance or approval, production of sufficient quantities at commercial scale and with appropriate quality standards, and in gaining market acceptance. If we are unable to successfully develop companion diagnostics for our product candidates, or experience delays in doing so, the development of our product candidates may be adversely affected, our product candidates may not obtain marketing approval, and we may not realize the full commercial potential of any of our product candidates that obtain marketing approval. As a result, our business, results of operations and financial condition could be materially harmed. In addition, a diagnostic company with whom we contract may decide to discontinue selling or manufacturing the companion diagnostic test that we anticipate using in connection with development and commercialization of product candidates or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our product candidates.

We may expend our limited resources to pursue a particular product candidate and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on specific product candidates, development programs and specific indications. As a result, we may forgo or delay pursuit of opportunities with other product candidates that could have had greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable potential commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaborations, licenses and other similar arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

We may not be able to obtain or maintain orphan drug designations for any of our product candidates, and we may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs or biologics for relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA may designate a product as an orphan product if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or a patient population of greater than 200,000 individuals in the United States, but for which there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the EU, the European Commission grants orphan designation after receiving the opinion of the EMA's Committee for Orphan Medicinal Products. In the EU, a medicinal product can be designated as an orphan if its sponsor can establish that: (1) the product is intended for the diagnosis, prevention or treatment of a life threatening or chronically debilitating condition (2) either (a) such condition affects not more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from the orphan status, would not generate sufficient return in the EU to justify the necessary investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized for marketing in the EU or, if such method exists, the product will be of significant benefit to those affected by that condition.

We have received orphan drug designation from the FDA for TYRA-300 for the treatment of ACH, and we may seek additional orphan drug designations in the United States and/or the EU for TYRA-300 and our other product candidates in qualified patient populations. There can be no assurance that the FDA or European Commission will grant orphan designation for any indication for which we apply, or that we will be able to maintain such designation.

In the United States, orphan designation entitles a party to financial incentives such as opportunities for grant funding toward clinical trial costs, tax advantages and user-fee waivers. In addition, if a product candidate that has orphan designation subsequently receives the first FDA approval for the disease or condition 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, including an NDA, to market the same product for the same disease or condition for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity. In the EU, orphan designation entitles a party to financial incentives such as reduction of fees, fee waivers, protocol assistance, and access to the centralized marketing authorization procedure. Moreover, upon grant of a marketing authorization and assuming the requirement for orphan designation are also met at the time the marketing authorization is granted, orphan medicinal products are entitled to a ten-year period of market exclusivity for the approved therapeutic indication. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed Pediatric Investigation Plan. The European exclusivity period can be reduced to six years, if, at the end of the fifth year a drug no longer meets the criteria for orphan designation (i.e. the prevalence of the condition has increased above the orphan designation threshold or it is judged that the product is sufficiently profitable so as not to justify maintenance of market exclusivity).

Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same disease or condition. Even after an orphan drug is approved, the FDA or comparable foreign regulatory authorities can subsequently approve the same drug for the same disease or condition if such regulatory authority concludes that the later drug is clinically superior because it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusivity may also be lost if the FDA later determines that the initial request for designation was materially defective. In addition, orphan drug exclusivity does not prevent the FDA from approving competing drugs for the same or similar disease or condition containing a different active ingredient. In addition, if a subsequent drug is

approved for marketing for the same or a similar disease or condition as any of our product candidates that receive marketing approval, we may face increased competition and lose market share regardless of orphan drug exclusivity. Orphan drug designation 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.

If we successfully develop our product candidates, we may seek Breakthrough Therapy designation or Fast Track designation by the FDA for one or more of our product candidates, but we may not receive such designation, and even if we do, such designation may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek Breakthrough Therapy or Fast Track designation for some of our 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 or biologics, to treat a serious or life- threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs or biologics that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. An NDA for a Breakthrough Therapy-designated product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

If a product candidate is intended for the treatment of a serious or life-threatening condition and clinical or preclinical data demonstrate the potential to address unmet medical needs for this condition, the sponsor may apply for Fast Track Designation. The sponsor of a Fast Track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and an NDA for a Fast Track product candidate may also be eligible for rolling review.

Whether to grant Breakthrough Therapy or Fast Track Designation is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for these designations, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of either of these designations for a product candidate may not result in a faster development process, review or approval compared to product candidates considered for approval under non-expedited FDA review procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify for either of these designations, the FDA may later decide that the product candidate no longer meet the conditions for qualification.

We have obtained a rare pediatric disease designation for TYRA-300 for the treatment of ACH, however, there is no guarantee that any FDA approval of TYRA-300 will result in issuance of a priority review voucher.

In 2012, Congress authorized the FDA to award priority review vouchers to sponsors of certain rare pediatric disease product applications. This program 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" (RPD) that meets certain criteria 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 RPD drug product receiving a priority review voucher 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 priority review voucher if the RPD drug for which the voucher was awarded is not marketed in the U.S. within one year following the date of approval.

We have obtained a RPD designation for TYRA-300 for the treatment of ACH, however, there is no guarantee that we will be able to obtain a priority review voucher, even if TYRA-300 is approved by the FDA for use in ACH patients. For example, the FDA may determine that an NDA, even if ultimately approved, does not meet the eligibility criteria for a priority review voucher, including for the following reasons:

- the product no longer meets the definition of a RPD;
- the product contains an active ingredient (including any ester or salt of the active ingredient) that has been previously approved in another marketing application;
- the application does not rely on clinical data derived from studies examining a pediatric population and dosages of the drug intended for that population; or
- the application is approved for a different adult indication than the RPD for which the product is designated

Moreover, Congress included a sunset provision in the statute authorizing the RPD priority review voucher program. Under the current statutory sunset provisions, after September 30, 2024, the FDA may only award a voucher for an approved RPD product application if the sponsor has RPD designation for the product candidate, and that designation was granted by December 20, 2024. After September 30, 2026, FDA may not award any RPD priority review vouchers.

We have conducted, and may continue to conduct, clinical trials for certain of our product candidates outside of the United States. However, the FDA and other foreign equivalents may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business.

We have conducted, and may continue to conduct, one or more of our clinical trials for our product candidates outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA. Where data from foreign clinical trials are intended to as the sole basis for marketing approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless those data are applicable to the U.S. population and U.S. medical practice; the trials 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. For trials that are conducted only at sites outside of the United States and not subject to an IND, the FDA requires the clinical trial to have been conducted in accordance with GCP and the FDA must be able to validate the data from the clinical trial through an on-site inspection if it deems such inspection necessary. For such trials not subject to an IND, the FDA generally does not review the clinical protocols for the trials, and therefore there is an additional potential risk that the FDA could determine that the trial design or protocol for a non-U.S. clinical trial was inadequate, which could require us to conduct additional clinical trials.

In addition, such foreign trials would be subject to the applicable local laws of the foreign regulatory and legal requirements where the trials are conducted. There can be no assurance the FDA will accept data from clinical trials conducted outside of the United States. If the FDA does not accept data from our clinical trials of our product candidates, it would likely result in the need for additional clinical trials, which would be costly and time consuming and delay or permanently halt our development of our product candidates.

Interim, topline and preliminary data from our preclinical studies and clinical trials that we may announce or publish from time to time 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 preliminary, interim or topline data from our preclinical studies and clinical trials, such as the interim data we reported regarding the SURF301 trial in October 2024. These interim updates are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. For example, we may report responses in certain patients that are unconfirmed at the time and which do not ultimately result in confirmed responses to treatment after follow-up evaluations. 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 topline results that we report may differ from future results of the same studies or trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse changes between interim data and final data could significantly harm our business and prospects. Further, additional disclosure of interim data by us or by our competitors in the future could result in volatility in the price of our common stock.

In addition, the information we choose to publicly disclose regarding a particular study or trial is typically selected from a more extensive amount of available information. Investors may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the interim, topline or preliminary data that we report differ from late, final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, any of our product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects.

We may attempt to secure approval from the FDA through the use of the accelerated approval pathway. If we are unable to obtain such approval, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw any accelerated approval we have obtained.

We may in the future seek accelerated approval for our one or more of our product candidates. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit.

The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional confirmatory studies to verify and describe the drug's clinical benefit. If such post-approval studies fail to confirm the drug's clinical benefit or are not completed in a timely manner, the FDA may withdraw its approval of the drug on an expedited basis. In addition, in December 2022, President Biden signed an omnibus appropriations bill to fund the U.S. government through fiscal year 2023. Included in the omnibus bill is the Food and Drug Omnibus Reform Act of 2022, which among other things, provided the FDA new statutory authority to mitigate potential risks to patients from continued marketing of ineffective drugs previously granted accelerated approval. Under these provisions, the FDA may require a sponsor of a product seeking accelerated approval to have a confirmatory trial underway prior to such approval being granted. In December 2024, the FDA further issued draft guidance for industry regarding the accelerated approval of drugs and biologics, which among other things, set forth the FDA's current expectations for accelerated approval endpoints and confirmatory trials as well as the process for withdrawing accelerated approval. The FDA may continue to develop guidance or otherwise change its policies with respect to the accelerated approval pathway that may make it more difficult to seek accelerated approval of any of our product candidates.

Prior to seeking accelerated approval for any of our product candidates, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA for accelerated approval or any other form of expedited development, review or approval. Furthermore, if we decide to submit an application for accelerated approval for our product candidates, there can be no assurance that such application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidate would result in a longer time period to commercialization of such product candidate, if any, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and comparable foreign regulatory activities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, the FDA's and comparable foreign regulatory activities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's and comparable foreign regulatory activities' ability to perform routine functions. Average review times at the FDA and comparable foreign regulatory activities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and comparable foreign regulatory activities may also slow the time necessary for new drugs and biologics or modifications to approved drugs and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points.

If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA or comparable foreign regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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

As product candidates progress through preclinical studies and clinical trials to marketing 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 safety, efficacy, yield and manufacturing batch size, minimize costs and achieve consistent quality and results. Similarly, in the future we may introduce an alternative formulation of one or more of our product candidates during the course of our ongoing or planned clinical trials. 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 ongoing, planned or future clinical trials conducted with the altered materials. This could delay initiation or completion of clinical trials, require the conduct of bridging studies or clinical trials or the repetition of one or more studies or clinical trials, increase development costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates, if approved, and generate revenue.

Risks Related to Our Reliance on Third Parties

We intend to rely on third parties for the manufacture of our product candidates for preclinical and clinical development. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not own or operate manufacturing facilities and have no plans to develop our own clinical or commercial-scale manufacturing capabilities. We plan to rely, and expect to continue to rely, on third parties for the manufacture of our product candidates and related raw materials for preclinical and clinical development, as well as for commercial manufacture if any of our product candidates receive marketing approval. The facilities used by third-party manufacturers to manufacture our product candidates must be approved by the FDA or comparable foreign regulatory authorities for the manufacture of our product candidates pursuant to inspections that will be conducted after we submit an NDA to the FDA or any comparable filing to a foreign regulatory authority. We do not control the manufacturing process of, and are completely dependent on, third-party manufacturers for compliance with cGMP or similar foreign requirements for manufacture of products. If these third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or any comparable foreign regulatory authority, they will not be able to secure and/or maintain marketing approval for their manufacturing facilities. In addition, we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance, qualified personnel, and accurate and complete recordkeeping. If the FDA or comparable foreign regulatory authorities does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us or the third-party manufacturers, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

Our or a third party's failure to execute on our manufacturing requirements on commercially reasonable terms and in compliance with cGMP or similar foreign requirements (where applicable) could adversely affect our business in a number of ways, including:

- an inability to initiate clinical trials of our product candidates under development;
- delay in submitting regulatory applications, or receiving marketing approvals, for our product candidates;
- subjecting third-party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease development or to recall batches of our product candidates; and
- in the event of approval to market and commercialize our product candidates, an inability to meet commercial demands for our product candidates or any other future product candidates.

In addition, we do not have any long-term commitments or supply agreements with our third party manufacturers. We may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms, which increases the risk of timely obtaining sufficient quantities of our product candidates or such quantifies at an acceptable cost. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- failure of third-party manufacturers to comply with regulatory requirements and maintain quality assurance;
- breach of the manufacturing agreement by the third party;
- failure to manufacture our product according to our specifications;
- failure to manufacture our product according to our schedule or at all;
- misappropriation of our proprietary information, including our trade secrets and know-how; and
- termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Our product candidates and any products that receive marketing approval may compete with the product candidates and products of other companies for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP and similar foreign regulations and that might be capable of manufacturing for us. This could lead to a delay in the manufacture of our product candidates or any products that receive marketing approval, and negatively impact the supply of such product candidates or products for clinical trials or commercialization.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval, and any related remedial measures may be costly or time consuming to implement. We do not currently have arrangements in place for redundant supply or a second source for all required raw materials used in the manufacture of our product candidates. If our existing or future third-party manufacturers cannot perform as agreed, we may be required to replace such manufacturers and we may be unable to replace them on a timely basis or at all. In particular, any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third-party and a feasible

alternative may not exist. In addition, certain of our product candidates and our own proprietary methods have never been produced or implemented outside of our company, and we may therefore experience delays to our development programs if and when we attempt to establish new third-party manufacturing arrangements for these product candidates or methods.

In addition, we currently and may in the future rely on contract manufacturers in China. Such foreign contract manufacturers may be subject to U.S. legislation, sanctions, tariffs, trade restrictions and other foreign regulatory requirements which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material or have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies. For example, in January 2024, there was Congressional activity, including the introduction of the BIOSECURE Act (H.R. 7085) in the House of Representatives and a substantially similar Senate bill (S.3558). The BIOSECURE Act was passed by the House of Representatives in September 2024. If these bills or similar laws become law, they could have the potential to restrict the ability of U.S. biopharmaceutical companies like us to purchase services or products from certain Chinese biotechnology companies of concern without losing the ability to contract with, or otherwise receive funding from, the U.S. government.

In addition, changes by the U.S. and foreign governments in trade policies including the imposition of higher tariffs on imports into the United States and other governmental regulations affecting trade between the United States and other countries where we, our contract manufacturers and/or our CROs conduct business, and any retaliatory actions by other governments, could increase costs, impact the supply of materials and adversely impact our business, financial condition and results of operations.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

Our reliance on third parties requires us to share our confidential information, which increases the possibility that confidential information will be misappropriated or disclosed.

Because we currently plan to rely on third parties to manufacture our product candidates and to perform quality testing, we must, at times, share our proprietary technology and confidential information with them. We seek to protect our proprietary technology, in part, by entering into confidentiality agreements, and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information. Despite the contractual provisions employed when working with third parties, the need to share confidential information increases the risk that such trade secrets become known by our competitors, are intentionally or inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and confidential information and despite our efforts to protect our confidential information, a competitor's discovery of our proprietary technology and confidential information or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business, financial condition, results of operations and prospects.

We may seek to enter into collaborations, licenses and other similar arrangements and may not be successful in doing so, and even if we are, we may relinquish valuable rights and may not realize the benefits of such relationships.

We may seek to enter into collaborations, joint ventures, licenses and other similar arrangements for the development or commercialization of our product candidates, due to capital costs required to develop or

commercialize the product candidate or manufacturing constraints. We may not be successful in our efforts to establish such collaborations for our product candidates because our research and development pipeline may be insufficient, our product candidates may be deemed to be at too early of a stage of development for collaborative effort or third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy or significant commercial opportunity. In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process can be time-consuming and complex. We may have to relinquish valuable rights to our future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us, as part of any such arrangement, and such arrangements may restrict us from entering into additional agreements with other potential collaborators. We cannot be certain that, following a collaboration, license or strategic transaction, we will achieve an economic benefit that justifies such transaction.

Even if we are successful in our efforts to establish such collaborations, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such collaborations if, for example, the development or approval of a product candidate is delayed, the safety of a product candidate is questioned or the sales of an approved product candidate are unsatisfactory.

In addition, any potential future collaborations may be terminable by our strategic partners, and we may not be able to adequately protect our rights under these agreements. Furthermore, strategic partners may negotiate for certain rights to control decisions regarding the development and commercialization of our product candidates, if approved, and may not conduct those activities in the same manner as we do. Any termination of collaborations we enter into in the future, or any delay in entering into collaborations related to our product candidates, could delay the development and commercialization of our product candidates and reduce their competitiveness if they reach the market, which could have a material adverse effect on our business, financial condition and results of operations.

We rely on third parties to conduct our clinical trials and some of our preclinical studies. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, our development programs and our ability to seek or obtain marketing approval for or commercialize our product candidates may be delayed.

We are dependent on third parties to conduct our clinical trials and some of our preclinical studies. Specifically, we have used and relied on, or intend to use and rely on, medical institutions, clinical investigators, CROs, contract development and manufacturing organizations, and consultants to conduct some of our preclinical studies and to conduct clinical trials in accordance with our clinical protocols and regulatory requirements. These CROs, investigators and other third parties play a significant role in the conduct and timing of these preclinical studies and clinical trials and subsequent collection and analysis of data. While we have and will have agreements governing the activities of our CROs, investigators and other third-party contractors, we have limited influence over their actual performance. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on our CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GLP and GCP requirements, which are regulations and guidelines enforced by the FDA or comparable foreign regulatory authorities for all of our product candidates in preclinical and clinical development. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, principal investigators, trial sites, and other third parties. If we or any of our CROs, trial sites or other third parties fail to comply with applicable GLP or GCP or other requirements, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional preclinical studies or clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with products produced under cGMP regulations or similar foreign requirements. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the marketing approval process.

There is no guarantee that any of our CROs, investigators or other third parties will devote adequate time and resources to such trials or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, or otherwise performs in a substandard manner, our clinical trials may be extended, delayed or terminated. In addition, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other development activities that could harm our competitive position. In addition, principal investigators for our clinical trials may also serve as scientific advisors or consultants to us from time to time and may 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, or the FDA concludes that the financial relationship may have affected the interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA of any NDA we submit. Any such delay or rejection could prevent us from commercializing our product candidates.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if we make a general assignment for the benefit of our creditors or if we are liquidated. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms or at all. Switching or adding additional CROs, investigators and other third parties involves additional cost and requires our management's time and focus. In addition, there is a natural transition period when a new CRO, investigator or other third party contractor commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, investigators and other third parties, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

Risks Related to Commercialization of Our Product Candidates

Even if we receive marketing approval for any product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions on marketing or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any of them are approved.

Following potential approval of any our product candidates, the FDA may impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly and time consuming post-approval studies, post-market surveillance or clinical trials to monitor the safety and efficacy of the product, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS, as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export recordkeeping, and other activities relating to our products will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP (and similar requirements outside the United States) and GCP requirements for any clinical trials that we conduct post- approval. Manufacturers of approved products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP or similar foreign regulations and standards. Later discovery

of previously unknown problems with our products, including additional adverse events or adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or product recalls;
- restrictions on product distribution or use, or requirements to conduct post-marketing studies or clinical trials;
- fines, restitutions, disgorgement of profits or revenues, civil money penalties, warning letters, untitled letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of our products; and
- injunctions or the imposition of civil or criminal penalties.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

In addition, if any of our product candidates are approved, our product labeling, advertising and promotion will be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about drug products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless, in their independent medical judgment, prescribe it to their patients in a manner that is inconsistent with the approved label. The FDA does not regulate the behavior of physicians in their choice of treatments but the FDA does restrict manufacturer's communications on the subject of off-label use of their products. If we are found to have promoted such off-label uses, we may become subject to significant liability. The FDA, the Department of Justice, and other governmental authorities 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 sanctions. For example, the federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into corporate integrity agreements, consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay marketing approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we

may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

The commercial success of our product candidates will depend upon the degree of market acceptance of such product candidates by physicians, patients, healthcare payors and others in the medical community.

Our product candidates may not be commercially successful. Even if any of our product candidates receive marketing approval, they may not gain market acceptance among physicians, patients, healthcare payors or the medical community. The commercial success of any of our current or future product candidates will depend significantly on the broad adoption and use of the resulting product by physicians and patients for approved indications. The degree of market acceptance of our products will depend on a number of factors, including:

- demonstration of clinical efficacy and safety compared to other more-established products;
- the indications for which our product candidates are approved;
- the limitation of our targeted patient population and other limitations or warnings contained in any FDA-approved labeling;
- acceptance of a new drug for the relevant indication by healthcare providers and their patients;
- the pricing and cost-effectiveness of our products, as well as the cost of treatment with our products in relation to alternative treatments and therapies;
- our ability to obtain and maintain sufficient third-party coverage and adequate reimbursement from government healthcare programs, including Medicare and Medicaid, private health insurers and other third-party payors;
- the willingness of patients to pay all, or a portion of, out-of-pocket costs associated with our products in the absence of sufficient third-party coverage and adequate reimbursement;
- any restrictions on the use of our products, and the prevalence and severity of any adverse effects;
- potential product liability claims;
- the timing of market introduction of our products as well as competitive drugs;
- the effectiveness of our or any of our current or potential future collaborators' sales and marketing strategies; and
- unfavorable publicity relating to the product.

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors or patients, we may not generate sufficient revenue from that product and may not become or remain profitable. Our efforts to educate the medical community and third-party payors regarding the benefits of our products may require significant resources and may never be successful.

We currently have no marketing and sales organization and have no experience as a company in commercializing products, and we may have to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our products, we may not be able to generate product revenue.

We have no internal sales, marketing or distribution capabilities, nor have we commercialized a product. If any of our product candidates ultimately receives marketing approval, we must build a marketing and sales

organization with technical expertise and supporting distribution capabilities to commercialize each such product in major markets, which will be expensive and time consuming, or collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. We have no prior experience as a company in the marketing, sale and distribution of biopharmaceutical 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 and distribution capabilities would adversely impact the commercialization of these products. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenues and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we are not successful in commercializing our products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

The successful commercialization of our product candidates, if approved, will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and favorable pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our products could limit our ability to market those products and decrease our ability to generate revenue.

The availability of coverage and the adequacy of reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as our product candidates, if approved. Our ability to achieve coverage and acceptable levels of reimbursement for our products by third-party payors will have an effect on our ability to successfully commercialize those products. Moreover, we are initially developing TYRA-300 for the treatment of mUC, pediatric ACH and NMIBC, TYRA-200 for FGFR2-driven ICC resistant to previous FGFR inhibitors and TYRA-430 for advanced HCC and other solid tumors with activating FGF/FGFR pathway aberrations. Some of these indications target a small patient population. In order for products that are designed to treat smaller patient populations to be commercially viable, the reimbursement for such products must be higher, on a relative basis, to account for the lack of volume. Accordingly, we will need to implement a coverage and reimbursement strategy for any approved product candidate with a smaller patient population that accounts for the smaller potential market size. Even if we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. We cannot be sure that coverage and reimbursement in the United States, the EU or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Obtaining and maintaining reimbursement status is time consuming, costly and uncertain. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. However, no uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement

change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

Third-party payors increasingly are challenging prices charged for biopharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third-party payor may consider our products as substitutable and only offer to reimburse patients for the less expensive product. Even if we are successful in demonstrating improved efficacy or improved convenience of administration with our products, pricing of existing drugs may limit the amount we will be able to charge for our products. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates and may not be able to obtain a satisfactory financial return on products that we may develop, once approved. In addition, in the event that we or third parties develop companion diagnostic tests for use with our product candidates, if approved, such companion diagnostic tests will require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement applicable to pharmaceutical or biological products will apply to companion diagnostics tests.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries has and will continue to put pressure on the pricing and usage of our products, once approved. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our products. Accordingly, in markets outside the United States, the reimbursement for our products, once approved, may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our products, once approved. We expect to experience pricing pressures in connection with the sale of any of our products due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

We face significant competition, and if our competitors develop technologies or product candidates more rapidly than we do or their technologies are more effective, our business and our ability to develop and successfully commercialize products may be adversely affected.

The biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary and novel products and product candidates. Our competitors have developed, are developing or may develop products or product candidates competitive with our product candidates. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we may attempt to develop product candidates. In particular, there is intense competition in the precision oncology field. Our competitors include larger and better-funded pharmaceutical,

biopharmaceutical, biotechnological and therapeutics companies. Moreover, we may also compete with universities and other research institutions who may be active in the indications we are targeting and could be in direct competition with us. We also compete with these organizations to recruit management, scientists and clinical development personnel, which could negatively affect our level of expertise and our ability to execute our business plan. We will also face competition in establishing clinical trial sites, enrolling patients for clinical trials and in identifying and in-licensing new product candidates. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

We expect to face competition from existing products and products in development for each of our product candidates. There are three currently marketed pan-FGFR inhibitors: Incyte Corporation's Pemazyre (pemigatinib), Taiho's Lytgobi (futibatinib) approved in FGFR2 gene rearrangements in cholangiocarcinoma, and Janssen Biotech, Inc.'s Balversa (erdafitinib), approved in specific FGFR3 gene alterations. There are a number of other isoform-specific FGFR inhibitors such as Elevar Therapeutics' and Relay Therapeutics, Inc.'s lirafugratinib (RLY-4008), Cogent Biosciences' CGT4859, TransThera's tinengotinib and Lilly's Loxo Oncology's isoform-selective FGFR3 inhibitor compound, LOXO-435 (LOX-24350). There are currently no approved FGFR4 inhibitors, but there remain a number of FGFR4 programs in clinical development in China, including Abbisko's ABSK011. BioMarin Pharmaceutical's Voxzogo, a once daily injectable C-natriuretic peptide (CNP) analog is approved in the United States for children with ACH. There are a number of other experimental therapies in development for ACH, including Ascendis' CNP pro-drug (TransCon CNP) and QED Therapeutics' low dose pan-FGFR inhibitor (infigratinib).

Many of our competitors have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we do. If we successfully obtain marketing approval for any product candidate, we will face competition based on many different factors, including the safety and effectiveness of our products, the ease with which our products can be administered and the extent to which patients accept relatively new routes of administration, the timing and scope of marketing approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, more convenient, less expensive or marketed and sold more effectively than any products we may develop. Competitive products or technological approaches may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our product candidates. If we are unable to compete effectively, our opportunity to generate revenue from the sale of our products we may develop, if approved, could be adversely affected.

If the market opportunities for our product candidates are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer.

The precise incidence and prevalence for all the conditions we aim to address with our product candidates are unknown. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new trials may change the estimated incidence or prevalence of these indications. The total addressable market across all of our product candidates will ultimately depend upon, among other things, the diagnosis criteria included in the final label for each of our product candidates which receives marketing approval for these indications, the availability of alternative treatments and the safety, convenience, cost and efficacy of our product candidates relative to such alternative treatments, acceptance by the medical community and patient access, drug pricing and reimbursement. The number of patients in the United States and other major markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our product candidates 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. Further, even if we obtain significant market share for our product candidates, because some of our potential target populations are very small, we may never achieve profitability despite obtaining such significant market share.

Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to develop and commercialize our product candidates in foreign markets. We are not permitted to market or promote any of our product candidates before we receive marketing approval from applicable regulatory authorities in foreign markets, and we may never receive such marketing approvals for any of our product candidates. To obtain separate marketing approval in many other countries we must comply with numerous and varying regulatory requirements regarding safety and efficacy and governing, among other things, clinical trials, commercial sales, pricing and distribution of our product candidates. If we obtain marketing approval of our product candidates and ultimately commercialize our products in foreign markets, we would be subject to additional risks and uncertainties, including:

- different regulatory requirements for approval of drugs in foreign countries;
- reduced protection for intellectual property rights;
- the existence of additional third-party patent rights of potential relevance to our business;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, political instability or war in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- foreign reimbursement, pricing and insurance regimes;
- workforce uncertainty in countries where labor unrest is common;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

Risks Related to Our Business Operations and Industry

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.

Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to:

- the timing and cost of, and level of investment in, research, development, marketing approval and commercialization activities relating to our product candidates, which may change from time to time;

- coverage and reimbursement policies with respect to our product candidates, if approved, and potential future drugs that compete with our products;
- the cost of manufacturing our product candidates, which may vary depending on the quantity of production and the terms of our agreements with third-party manufacturers;
- expenditures that we may incur to acquire, develop or commercialize additional product candidates and technologies;
- the level of demand for any approved products, which may vary significantly;
- future accounting pronouncements or changes in our accounting policies; and
- the timing and success or failure of preclinical studies or clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide.

We are dependent on the services of our management and other clinical and scientific personnel, and if we are not able to retain these individuals or recruit additional management or clinical and scientific personnel, our business will suffer.

Our success depends in part on our continued ability to attract, retain, manage and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon our senior management, as well as our senior scientists and other members of our management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, initiation or completion of our preclinical studies and clinical trials or the commercialization of our product candidates. Although we have executed employment agreements or offer letters with each member of our senior management team, these agreements are terminable at will with or without notice and, therefore, we may not be able to retain their services as expected. We do not currently maintain “key person” life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

We will need to expand and effectively manage our managerial, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts. We may not be successful in maintaining our unique company culture and continuing to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biopharmaceutical, biotechnology and other businesses, particularly in the San Diego County area. Our industry has experienced a high rate of turnover of management personnel in recent years. If we are not able to attract, integrate, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

We will need to continue to grow the size and capabilities of our organization, and we may experience difficulties in managing this growth.

As of March 25, 2025, we had 60 full-time employees , including 44 employees engaged in research and development. In order to successfully implement our development and commercialization plans and strategies, we expect to need to continue to add significant additional managerial, operational, sales, marketing, financial and other personnel. Future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining, retaining and motivating our current and additional employees;
- managing our internal development efforts effectively, including the preclinical, clinical, the FDA or comparable foreign regulatory authorities' review process for product candidates, while complying with any contractual obligations to contractors and other third parties;
- managing increasing operational and managerial complexity; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to successfully develop and, if approved, commercialize product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

If we are not able to effectively expand our organization by hiring new employees and/or engaging additional third-party service providers, we may not be able to successfully implement the tasks necessary to further develop and, if approved, commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

We are subject to various federal, state and foreign healthcare laws and regulations, which could increase compliance costs, and our failure to comply with these laws and regulations could harm our results of operations and financial condition.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors and customers expose us to broadly applicable foreign, federal and state fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute any products for which we obtain marketing approval. Such laws include, without limitation:

- the federal Anti-Kickback Statute, which is a criminal law that prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, in return for, either the referral of an individual or the purchase, lease, or order, or arranging for or recommending the purchase, lease, or order of any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti- Kickback Statute or specific intent to violate it in order to have committed a violation;
- the federal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making or causing to be made a false statement to avoid,

decrease or conceal an obligation to pay money to the federal government. In addition, 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 civil False Claims Act;

- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services (CMS) information related to payments and other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants and certified nurse-midwives) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; some state laws require biopharmaceutical and biotechnology companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; some state laws that require biopharmaceutical and biotechnology companies to report information on the pricing of certain drug products; and some state and local laws require the registration or pharmaceutical sales representatives.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve ongoing substantial costs. It is possible that governmental authorities will conclude that our business practices, including certain arrangements with physicians who receive stock or stock options as compensation for services provided to us, may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, results of operations, and financial condition.

We, our future collaborators and our service providers may be subject to a variety of privacy and data security laws and contractual obligations, which could increase compliance costs and our failure to comply with them could subject us to potentially significant fines or penalties and otherwise harm our business. We are subject to laws and regulations governing the privacy and security of sensitive information, including confidential business and health-related information. The global data protection landscape is rapidly evolving, and we may be affected by or subject to new, amended or existing laws and regulations in the future, including as our operations continue to expand or if we operate in foreign jurisdictions. These laws and regulations may be subject to differing interpretations, which adds to the complexity of processing personal information. Guidance on implementation and compliance practices are often updated or otherwise revised.

In the United States, there are numerous federal and state privacy and data security laws and regulations governing the collection, use, disclosure and protection of personal information, including health information privacy laws, security breach notification laws and consumer protection laws. Each of these laws is subject to varying interpretations and constantly evolving. By way of example, HIPAA imposes privacy and security requirements and breach reporting obligations with respect to individually identifiable health information upon "covered entities" (health plans, health care clearinghouses and certain health care providers), and their respective business associates, individuals or entities that create, received, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity, as well as their covered subcontractors. While we do not believe that we are currently acting as a covered entity or business associate under HIPAA and thus are not directly regulated under HIPAA, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could be subject to significant penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information.

In addition, certain state laws and regulations govern the privacy, processing and security of health-related and other personal information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. By way of example, the California Consumer Privacy Act, as amended by the California Privacy Rights Act (collectively, the CCPA) requires covered businesses that process the personal information of California residents to, among other things: (i) provide certain disclosures to California residents regarding the business's collection, use, and disclosure of their personal information; (ii) receive and respond to requests from California residents to access, delete, and correct their personal information, or to opt out of certain disclosures of their personal information; and (iii) enter into specific contractual provisions with service providers that process California resident personal information on the business's behalf. Additional compliance investment and potential business process changes may be required. Similar laws have passed in other states and are continuing to be proposed at the state and federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA, the CCPA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

Our operations abroad may also be subject to increased scrutiny or attention from data protection authorities. For example, in Europe, the European Union General Data Protection Regulation, (GDPR) went into effect in May 2018 and imposes strict requirements for processing the personal data of individuals within the European Economic Area (EEA). Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential

fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EEA, and the United States remains uncertain. Case law from the Court of Justice of the European Union (CJEU) states that reliance on the standard contractual clauses - a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. On July 10, 2023, the European Commission adopted its Adequacy Decision in relation to the new EU-US Data Privacy Framework (DPF), rendering the DPF effective as a GDPR transfer mechanism to U.S. entities self-certified under the DPF. We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue. In particular, we expect the DPF Adequacy Decision to be challenged and international transfers to the United States and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As a result, we may have to make certain operational changes and we will have to implement revised standard contractual clauses and other relevant documentation for existing data transfers within required time frames. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Further, from January 1, 2021, companies have had to comply with the GDPR and also the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, i.e., fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. On October 12, 2023, the UK Extension to the DPF came into effect (as approved by the UK Government), as a data transfer mechanism from the UK to U.S. entities self-certified under the DPF. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, collaborators, or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, and adversely affect our business and results of operations.

Recently enacted legislation, future legislation and healthcare reform measures may increase the difficulty and cost for us to obtain marketing approval for and commercialize our product candidates and may affect the prices we may set.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell any product candidates for which we obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the ACA, was enacted in the United States. Among the

provisions of the ACA of importance to our potential product candidates, the ACA: established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; expanded eligibility criteria for Medicaid programs; expanded the entities eligible for discounts under the 340B drug pricing program; increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; created a new Medicare Part D coverage gap discount program, which was replaced by a new manufacturer discount program on January 1, 2025 (as discussed below); established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, resulted in reductions to Medicare payments to providers, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect into 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In March 2021, Congress enacted the American Rescue Plan Act of 2021, which, among other things, eliminated the statutory cap on drug manufacturers' Medicaid Drug Rebate Program rebate liability, effective January 1, 2024. Drug manufacturers' Medicaid Drug Rebate Program rebate liability was previously capped at 100% of the average manufacturer price for a covered outpatient drug.

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. On August 16, 2022, the Inflation Reduction Act of 2022 (IRA) was passed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023), and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services to implement many of these provisions through guidance, as opposed to regulation, for the initial years. On August 15, 2024, HHS announced the agreed-upon prices for the first ten drugs that are subject to price negotiations, which take effect in January 2026. HHS will select up to fifteen additional products covered under Part D for negotiation in 2025. Each year thereafter, more Part B and Part D products will become subject to the HHS price negotiation program, although the program is currently subject to legal challenges. For that and other reasons, it is currently unclear how the IRA will be effectuated.

At the state level, legislatures have increasingly passed legislation and implemented 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. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be

included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

We expect that these new laws and other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates, if approved.

We and any of our third-party manufacturers or suppliers may use potent chemical agents and hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time consuming or costly.

We and any of our third-party suppliers and potential future collaborators will use biological materials, potent chemical agents and may use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety of the environment. Our operations and 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 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. 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 marketing approvals could be suspended.

Although we maintain workers' compensation insurance for certain costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for toxic tort claims that may be asserted against us in connection with our storage or disposal of biologic, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations, which have tended to become more stringent over time. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions or liabilities, which could materially adversely affect our business, financial condition, results of operations and prospects.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our products.

We face an inherent risk of product liability as a result of the clinical trials of our product candidates and will face an even greater risk if we commercialize our product candidates. For example, we may be sued if our product candidates allegedly cause injury or are found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product candidate, negligence, strict liability and a breach of warranties. Claims may be brought against us by clinical trial participants, patients or others

using, administering or selling products that may be approved in the future. Claims could also be asserted under state consumer protection acts.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or cease the commercialization of our products. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products, if approved;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of our management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- significant negative financial impact;
- the inability to commercialize our product candidates; and
- a decline in our stock price.

We currently hold $10 million of product liability insurance coverage. We may need to increase our insurance coverage as we initiate additional clinical trials or if we commence commercialization of our product candidates, if ever. Insurance coverage is increasingly expensive. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of our product candidates. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies will also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Our insurance policies are expensive and only protect us from some business risks, which will leave us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter, including product liability insurance. Some of the policies we currently maintain include property, general liability, employment benefits liability, business automobile workers' compensation, directors' and officers', employment practices and fiduciary liability insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations.

We and any of our potential future collaborators will be required to report to regulatory authorities if any of our product candidates or approved products in clinical trials cause or contribute to certain adverse medical events, and any failure to do so would result in sanctions that would materially harm our business.

The FDA or comparable foreign regulatory authorities would require that we and potential future collaborators report certain information about adverse medical events relating to any product that is approved or product candidate in clinical trials. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We and any of our potential future collaborators or CROs may fail to report adverse events within the prescribed timeframe. If we or any of our potential future collaborators or CROs fail to comply with such reporting obligations, the FDA or a comparable foreign regulatory authority could take action, including criminal prosecution, the imposition of civil monetary penalties, seizure of our products or delay in approval or clearance of future products.

Our information technology systems, or those of any of our CROs, other contractors or consultants or potential future collaborators, may fail or suffer security breaches, which could result in a material disruption of our product development programs, harm our reputation, significant fines, penalties and liability and loss of customers or sales.

In the ordinary course of business, we collect, store, transmit and otherwise process large amounts of confidential information including, without limitation, intellectual property, proprietary business information, preclinical and clinical trial data, health-related information and personal information (collectively, Confidential Information). Despite the implementation of security measures, our information technology systems (including infrastructure) and those of our current and any future CROs and other contractors, consultants and collaborators are vulnerable to attack, damage or interruption from computer viruses and malware (e.g. ransomware), malicious code, cybersecurity threats (such as denial-of-service attacks, cyberattacks or cyber-intrusions over the Internet, hacking, phishing and other social engineering attacks), misconfigurations, "bugs" or other vulnerabilities, fraud, sophisticated nation-state and nation-state-supported actors, unauthorized access or use, natural disasters, terrorism, war, and telecommunication and electrical failures. Our systems are also subject to compromise from internal threats, such as theft, misuse, unauthorized access or other improper or accidental actions by employees, vendors and other third parties with otherwise legitimate access to our systems. Third parties may also attempt to fraudulently induce our employees and contractors into disclosing sensitive information such as usernames, passwords or other information, or otherwise compromise the security of our electronic systems, networks, and/ or physical facilities in order to gain access to our data.

Given the unpredictability of the timing, nature and scope of information technology disruptions, there can be no assurance that any security procedures and controls that we or our third-party partners and service providers have implemented will be sufficient to prevent cyberattacks from occurring. The latency of a compromise is often measured in months, but could be years, and we may not be able to detect a compromise in a timely manner. New techniques may not be identified until they are launched against a target, and we may be unable to anticipate these techniques or detect an incident, assess its severity or impact, react or appropriately respond in a timely manner or implement adequate preventative measures, resulting in potential data loss or other damage to our information technology systems.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. While we do not believe that we have experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our or our third party service provider's operations or result in the unauthorized disclosure of or access to Confidential Information (violating certain privacy laws such as GDPR), it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other similar disruptions. Some of the federal, state and foreign government requirements include obligations of companies to notify individuals, governmental authorities, supervisory bodies,

the media and other parties of security breaches involving particular personally identifiable information, which could result from breaches experienced by us or by our vendors, contractors, or organizations with which we have formed strategic relationships. Also, due to the continued hybrid working environment, many of our employees are working remotely. As a result, we may have increased cyber security and data security risks, due to increased use of home wi-fi networks and virtual private networks, as well as increased disbursement of physical machines. While we implement information technology controls to reduce the risk of a cyber security or data security breach, there is no guarantee that these measures will be adequate to safeguard all systems, especially with an increased number of employees working remotely.

Any security breach or other incident, whether real or perceived, could impact our reputation, impact the integrity of our data, cause us to incur significant costs, including legal expenses, harm customer confidence, hurt our expansion into new markets, cause us to incur remediation costs, or cause us to lose existing customers. For example, the loss of clinical trial data from clinical trials could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. We also rely on third parties to manufacture our product candidates, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any real or perceived disruption or security breach affects our systems (or those of our third-party collaborators, service providers, contractors or consultants) or were to result in a loss of or accidental, unlawful or unauthorized access to, use of, release of, or other processing of Confidential Information, or damage to, our data or applications, or inappropriate disclosure of Confidential Information, we could incur liability, the further development and commercialization of our product candidates could be delayed, and we could be subject to significant incident response, system restoration or remediation and future compliance costs, as well as significant fines, penalties or liabilities for any noncompliance to certain privacy and security laws. We maintain cyber liability insurance; however, this insurance may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems.

Our business could be affected by litigation, government investigations and enforcement actions.

We operate in a highly regulated industry and we could be subject to litigation, government investigation and enforcement actions on a variety of matters in the United States or foreign jurisdictions, including, without limitation, intellectual property, regulatory, product liability, environmental, whistleblower, false claims, privacy, anti-kickback, anti-bribery, securities, commercial, employment and other claims and legal proceedings which may arise from conducting our business. Any determination that our operations or activities are not in compliance with existing laws or regulations could result in the imposition of fines, civil and criminal penalties, product seizure, equitable remedies, including disgorgement, injunctive relief and/or other sanctions against us, and remediation of any such findings could have an adverse effect on our business operations.

Legal proceedings, government investigations and enforcement actions can be expensive and time consuming. An adverse outcome resulting from any such proceeding, investigations or enforcement actions could result in significant damages awards, fines, penalties, exclusion from the federal healthcare programs, healthcare or regulatory debarment, injunctive relief, product recalls, reputational damage and modifications of our business practices, which could have a material adverse effect on our business and results of operations.

Our employees and independent contractors, including principal investigators, CROs, consultants and vendors, may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees and independent contractors, including principal investigators, CROs, consultants and vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate: (i) the laws and regulations of the FDA and other similar regulatory requirements, including those

laws that require the recording and reporting of true, complete and accurate information to such authorities, (ii) manufacturing standards, including cGMP requirements or similar foreign requirements, (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad or (iv) laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory consequences or sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such 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 and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of intellectual property, products or technologies. Additional potential transactions that we may consider in the future include a variety of business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any future transactions could increase our near and long-term expenditures, result in potentially dilutive issuances of our equity securities, including our common stock, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in-process research and development expenses, any of which could affect our financial condition, liquidity and results of operations. Future acquisitions may also require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions may never be successful and may require significant time and attention of our management. In addition, the integration of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky and costly endeavor for which we may never realize the full benefits of the acquisition. Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects.

Unstable market and economic conditions and adverse developments with respect to financial institutions and associated liquidity risk may have serious adverse consequences on our business, financial condition and stock price.

From time to time, the global credit and financial markets have experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability, including changes related to the U.S. and foreign governments in tariffs and trade policies affecting trade between the United States and other countries. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts may also adversely impact the financial markets and

the global economy, and any economic countermeasures by affected countries and others could exacerbate market and economic instability. In addition, in 2023 the closures of financial institutions and their placement into receivership with the FDIC created bank-specific and broader financial institution liquidity risk and concerns. Future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market-wide liquidity shortages, impair the ability of companies to access near-term working capital needs, and create additional market and economic uncertainty. There can be no assurance that future credit and financial market instability and a deterioration in confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, liquidity shortages, volatile business environment, changes in tariffs and trade policies or continued unpredictable and unstable market conditions. If the equity and credit markets deteriorate, or if adverse developments are experienced by financial institutions, it may cause short-term liquidity risk and also make any necessary debt or equity financing more difficult, more costly, more onerous with respect to financial and operating covenants and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, financial institutions, manufacturers and other partners may be adversely affected by the foregoing risks, which could directly affect our ability to attain our operating goals on schedule and on budget.

Changes in tax law may materially adversely affect our financial condition, results of operations and cash flows.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, or interpreted, changed, modified or applied adversely to us, any of which could adversely affect our business operations and financial performance. The likelihood of specific changes in tax law being enacted or implemented is unclear. We are currently unable to predict whether such changes will occur. If such changes are enacted or implemented, we are currently unable to predict the ultimate impact on our business. We urge our investors to consult with their legal and tax advisors with respect to any changes in tax law and the potential tax consequences of investing in our common stock.

Our ability to use net operating loss carryforwards and other tax attributes may be limited.

We have incurred substantial losses during our history, do not expect to become profitable in the near future and may never achieve profitability. To the extent that we continue to generate net operating losses (NOLs), such NOLs will carry forward and, subject to limitations, offset future taxable income, if any, until such unused NOL carryforwards expire (if subject to expiration). At December 31, 2024, we had U.S. federal and state NOL carryforwards of approximately $80.5 million and $52.2 million, respectively.

U.S. federal NOLs generated in periods after December 31, 2017 may be carried forward indefinitely but may only be used to offset 80% of our taxable income in years beginning after December 31, 2020.

Our NOL carryforwards and other tax attributes are subject to review and possible adjustment by the U.S. Internal Revenue Service and state tax authorities. Under Section 382 of the U.S. Internal Revenue Code of 1986, as amended (the Code), our U.S. federal NOL carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership of our company. An “ownership change” pursuant to Section 382 of the Code generally occurs if one or more stockholders or groups of stockholders who own at least 5% of a company’s stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Our ability to utilize our NOL carryforwards and other tax attributes to offset future taxable income or tax liabilities may be limited as a result of ownership changes, including potential changes in connection with our initial public offering (IPO) or any other offerings. Similar rules may apply under state tax laws. We have not yet determined the amount of the cumulative change in our ownership resulting from our IPO or other transactions, or any resulting limitations on our ability to utilize our NOL carryforwards and other tax

attributes. If we earn taxable income, such limitations could result in increased future income tax liability to us and our future cash flows could be adversely affected. We have recorded a full valuation allowance related to our NOL carryforwards and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our product candidates and other proprietary technologies we develop, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our product candidates and other proprietary technologies we may develop may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates and other proprietary technologies we may develop as well as our ability to operate without infringing upon the proprietary rights of others. We seek to protect our proprietary position, in part, by filing patent applications in the United States and abroad relating to our product candidates and other proprietary technologies we may develop. If we are unable to obtain or maintain patent protection with respect to our product candidates and other proprietary technologies we may develop, our business, financial condition, results of operations and prospects could be materially harmed.

Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our protection. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any of our issued patents will provide sufficient protection against competitors or other third parties.

The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, CROs, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in any of our pending patent applications, or that we were the first to file for patent protection of such inventions.

The patent position of biopharmaceutical and biotechnology companies generally is highly uncertain, involves complex legal and factual questions and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our patent applications may not result in patents being issued which protect our product candidates and other proprietary technologies we may develop or which effectively prevent others from commercializing competitive technologies and products.

Moreover, the claim coverage in a patent application can be significantly reduced before the patent is granted. Even if they issue, our pending patent applications may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage, and patents issuing from our patent applications may be challenged, narrowed, circumvented or invalidated by third parties. Consequently, we do not know whether our product candidates and other proprietary technology will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our existing patent or patents issuing from our patent applications by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects. In addition, given the amount of time required for the development, testing and regulatory review of our product candidates, patents protecting the product candidates might expire before or shortly after such product candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability and our patents may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third-party pre-issuance submission of prior art to the United States Patent and Trademark Office (USPTO) or become involved in opposition, derivation, revocation, reexamination, post- grant and inter partes review, or other similar proceedings challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our product candidates and other proprietary technologies we may develop and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us.

Substantive examination is just beginning on our pending patent applications, which makes it difficult to forecast the extent of any future patent right.

We cannot be certain that the claims in our U.S. pending patent applications or corresponding international patent applications, or patent applications in certain foreign territories, will be considered patentable by the USPTO. Patent claims are subject to revision during prosecution and pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the third party's technology. There can be no assurance that our patent applications will result in patents being issued or that issued patents will afford sufficient protection against competitors with similar technology. For example, examiners at a patent office may uncover prior art of which we were not previously aware, and if this cited prior art encompasses our claimed inventions, it may restrict patentability or prevent allowance of any pending patent claims. Furthermore, the patent prosecution process is expensive, time-consuming, and often a multi-year process. We and any future licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. Therefore, we cannot be certain that we will own any issued patents or develop a patent portfolio, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

Filing, prosecuting and defending patents on our product candidates and other proprietary technologies we may develop in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions.

Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the United States. These products may compete with our product candidates, 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, trade secrets and other intellectual property protection, particularly those relating to biotechnology and pharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. In India, unlike the United States, there is no link between regulatory approval for a drug and its patent status. In addition, some jurisdictions, such as Europe, Japan and China, may have a higher standard for patentability than in the United States, including, for example, the requirement of claims having literal support in the original patent filing and the limitation on using supporting data that is not in the original patent filing. Under those heightened patentability requirements, we may not be able to obtain sufficient patent protection in certain jurisdictions even though the same or similar patent protection can be secured in U.S. and other jurisdictions.

In addition, geo-political actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of future issued patents or those of any future licensors. For example, the United States and foreign government actions related to Russia's war with Ukraine may limit or prevent filing, prosecution, and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees from the United States without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our 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, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Finally, a Unitary Patent and Unified Patent Court (UPC) system was implemented in Europe on June 1, 2023. This new regime may present uncertainties for our ability to protect and enforce our patent rights against competitors in Europe. Under the UPC, all European patents, including those issued prior to ratification of the European Patent Package, will automatically fall under the jurisdiction of the UPC. The UPC provides our competitors with a new forum to centrally revoke our European patents, and allows for the possibility of a

competitor to obtain pan-European injunctions. It will be several years before we will understand the scope of patent rights that will be recognized and the strength of patent remedies that will be provided by the UPC. Under the EU Patent Package, we will have the right to opt our patents out of the UPC over the first seven years of the court's existence, but doing so may preclude us from realizing the benefits of the new unified court.

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

Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our patents and applications. The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Since March 2013, under the Leahy-Smith America Invents Act (the America Invents Act) enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates and other proprietary technologies we may develop or (ii) invent any of the inventions claimed in our patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of patents issuing from those patent applications, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. For example, the scope of patentable subject matter under 35 U.S.C. § 101 has evolved significantly over the past several years as the Court of Appeals for the Federal Circuit and the Supreme Court issued various opinions, and the USPTO modified its guidance for practitioners on multiple occasions. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our ability to protect and enforce our intellectual property in the future.

Issued patents relating to our product candidates and other proprietary technologies we may develop could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.

If we initiated legal proceedings against a third party to enforce a patent relating to our product candidates and other proprietary technologies we may develop, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may raise claims challenging the validity or enforceability of a patent before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter partes review, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of or amendment to our patents in such a way that they no longer cover our product candidates and other proprietary technologies we may develop. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we or our licensing partners and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates and other proprietary technologies we may develop. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations and prospects.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited, and once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we do not obtain patent term extension for our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidate we may develop, one or more of our patents or patents issuing from our U.S. patent applications may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of

1984 (the Hatch-Waxman Amendments). The Hatch-Waxman Amendments permit a patent extension term (PTE) of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. Similar patent term restoration provisions to compensate for commercialization delay caused by regulatory review are also available in certain foreign jurisdictions, such as in Europe under Supplemental Protection Certificate (SPC). If we encounter delays in our development efforts, including any clinical trials, the period of time during which we could market any future product candidates under patent protection would be reduced. Additionally, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents, or otherwise fail to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patent rights, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates and other proprietary technologies we may develop. Litigation may be necessary to defend against these and other claims challenging inventorship or our patent rights, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates and other proprietary technologies we may develop. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent protection for our product candidates and other proprietary technologies we may develop, we also rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology, and other proprietary information and to maintain our competitive position. With respect to our development programs, we consider trade secrets and know-how to be one of our important sources of intellectual property, including our extensive knowledge of crystallography structure-based drug design. Trade secrets and know-how can be difficult to protect. In particular, the trade secrets and know-how in connection with our development programs and other proprietary technology we may develop may over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology and the movement of personnel with scientific positions in academic and industry.

We seek to protect these trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, CROs, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a

claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed.

We may be subject to claims that third parties have an ownership interest in our trade secrets. For example, we may have disputes arise from conflicting obligations of our employees, consultants or others who are involved in developing our product candidate. Litigation may be necessary to defend against these and other claims challenging ownership of our trade secrets. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable trade secret rights, such as exclusive ownership of, or right to use, trade secrets that are important to our product candidates and other proprietary technologies we may develop. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees. We may need to share our proprietary information, including trade secrets, with our current and future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may not be successful in obtaining necessary rights to any product candidate we may develop through acquisitions and in-licenses.

We currently solely own intellectual property covering our product candidates. Other pharmaceutical companies and academic institutions may also have filed or are planning to file patent applications potentially relevant to our business. In order to avoid infringing these third-party patents, we may find it necessary or prudent to obtain licenses to such patents from such third-party intellectual property holders. However, we may be unable to secure such licenses or otherwise acquire or in-license any compositions, methods of use, processes or other intellectual property rights from third parties that we identify as necessary for our product candidates and other proprietary technologies we may develop. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be subject to claims that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Some of our employees, consultants and advisors are currently or were previously employed at universities or other biopharmaceutical or biotechnology companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any

such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations and prospects.

Third-party claims of intellectual property infringement, misappropriation or other violations against us or our collaborators may prevent or delay the development and commercialization of our product candidates and other proprietary technologies we may develop.

Our commercial success depends in part on our ability to avoid infringing, misappropriating and otherwise violating the patents and other intellectual property rights of third parties. There is a substantial amount of complex litigation involving patents and other intellectual property rights in the biopharmaceutical and biotechnology industries, as well as administrative proceedings for challenging patents, including derivation and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. As discussed above, as a result of the America Invests Act, procedures including inter partes review and post-grant review have been implemented. The America Invents Act adds uncertainty to the possibility of challenge to our patents in the future.

Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are commercializing or plan to commercialize our product candidates and in which we are developing other proprietary technologies. As the biopharmaceutical and biotechnology industries expand and more patents are issued, the risk increases that our product candidates and commercializing activities may give rise to claims of infringement of the patent rights of others. We cannot assure you that our product candidates and other proprietary technologies we may develop will not infringe existing or future patents owned by third parties. We may not be aware of patents that have already been issued and that a third party, for example, a competitor in the fields in which we are developing our product candidates, might assert as infringed by us. It is also possible that patents owned by third parties of which we are aware, but which we do not believe we infringe or that we believe we have valid defenses to any claims of patent infringement, could be found to be infringed by us. It is not unusual that corresponding patents issued in different countries have different scopes of coverage, such that in one country a third-party patent does not pose a material risk, but in another country, the corresponding third-party patent may pose a material risk to our planned products. As such, we monitor third-party patents in the relevant pharmaceutical markets. In addition, because patent applications can take many years to issue and may be confidential for 18 months or more after filing, there may be currently pending patent applications that may later result in issued patents that we may infringe.

In the event that any third party claims that we infringe their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, even if we believe such claims are without merit, a court of competent jurisdiction could hold that such patents are valid, enforceable and infringed by us. In this case, the holders of such patents may be able to block our ability to commercialize the infringing products or technologies unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be held invalid or unenforceable. Such a license may not be available on commercially reasonable terms or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license

fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we may be unable to commercialize the infringing products or technologies or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business.

If we collaborate with third parties in the development of technology in the future, our collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to litigation or potential liability. Further, collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability. In the future, we may agree to indemnify our commercial collaborators against certain intellectual property infringement claims brought by third parties.

Defense of infringement claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. In the event of a successful claim of infringement against us, we may be enjoined from further developing or commercializing the infringing products or technologies. In addition, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties and/or redesign our infringing products or technologies, which may be impossible or require substantial time and monetary expenditure. In that event, we would be unable to further develop and commercialize our product candidate or technologies, which could harm our business significantly. Further, we cannot predict whether any required license would be available at all or whether it would be available on commercially reasonable terms. In the event that we could not obtain a license, we may be unable to further develop our product candidate and commercialize our future product, if approved, which could harm our business significantly. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms.

Engaging in litigation defending against third parties alleging infringement of patent and other intellectual property rights is very expensive, particularly for a company of our size, and time-consuming. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

We may in the future pursue invalidity proceedings with respect to third-party patents. The outcome following legal assertions of invalidity is unpredictable. Even if resolved in our favor, these legal proceedings may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such proceedings adequately. Some of these third parties may be able to sustain the costs of such proceedings more effectively than we can because of their greater financial resources. If we do not prevail in the patent proceedings the third parties may assert a claim of patent infringement directed at our product candidates.

We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time consuming and unsuccessful.

Third parties, such as a competitor, may infringe, misappropriate, or otherwise violate our current or future issued patents and other intellectual property rights. In a patent infringement proceeding, a court may decide that a patent owned by us is invalid or unenforceable or may refuse to stop the other party from using the invention at issue on the grounds that the patent does not cover the technology in question or that the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. § 271(e)(1). In addition, our patent rights may become involved in inventorship, priority or validity disputes. To counter or defend against such claims can be expensive and time consuming. An adverse result in any litigation proceeding could put our patent rights at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Our ability to enforce our patent rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components or methods that are used in connection with their products and services. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product or service. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue any clinical trials, continue our internal research programs, in-license needed technology or other product candidates, or enter into development partnerships that would help us bring our product candidates to market. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we are given an

opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, which may not survive such proceedings. Moreover, any name we have proposed to use with our product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA or an equivalent administrative body in a foreign jurisdiction objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark.

We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, domain name or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to our product candidate or utilize similar technology but that are not covered by the claims of the patents that we may license or may own;
- we might not have been the first to make the inventions covered by our current or future patents;
- we might not have been the first to file patent applications covering our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our current or future patent applications will not lead to issued patents;
- any patents issuing from our current or future patent applications may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and

- we may choose not to file for patent protection in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.

The growth of our business may depend in part on our ability to acquire, in-license or use third-party proprietary component and process rights. For example, our product candidates may require specific formulations to work effectively and efficiently, we may develop product candidates containing our compounds and pre-existing pharmaceutical compounds, or we may be required by the FDA or comparable foreign regulatory authorities to obtain marketing authorization of companion diagnostic test or tests for use with our product candidates, any of which could require us to obtain rights to use intellectual property held by third parties. For example, we are working with diagnostic companies to develop and utilize liquid biopsy companion diagnostic tests to aid in identifying appropriate patients in our SURF301 Phase 1/2 clinical trial, and we will need to engage additional diagnostic partners across all our oncology programs to identify appropriate patients for study inclusion. In addition, with respect to any patents we may co-own with third parties, we may require licenses to such co-owners interest to such patents. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. In addition, we may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. Were that to happen, we may need to cease use of the compositions or methods covered by those third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on those intellectual property rights, which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, which means that our competitors may also receive access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

Additionally, we might sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Even if we hold such an option, we may be unable to negotiate a license from the institution within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies that may be more established or have greater resources than we do may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. There can be no assurance that we will be able to successfully complete these types of negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to develop or market. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of certain programs and our business financial condition, results of operations and prospects could suffer.

Risks Related to Our Common Stock

The trading price of the shares of our common stock could be highly volatile, and purchasers of our common stock could incur substantial losses.

Our stock price is likely to be volatile. The stock market in general and the market for stock of biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price at which they paid. The market price for our common stock may be influenced by those factors discussed in this "Risk Factors" section and many others, including:

- results of our preclinical studies and clinical trials, and the results of trials of our competitors or those of other companies in our market sector;
- our ability to enroll patients in our future clinical trials;
- marketing approval of our product candidates, or limitations to specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- regulatory developments in the United States and foreign countries;
- changes in the structure of healthcare payment systems;
- the success or failure of our efforts to develop, acquire or license additional product candidates;
- innovations, clinical trial results, product approvals and other developments regarding our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- manufacturing, supply or distribution delays or shortages;
- any changes to our relationship with any manufacturers, suppliers, collaborators or other strategic partners;
- achievement of expected product sales and profitability;
- variations in our financial results or those of companies that are perceived to be similar to us;
- market conditions in the biopharmaceutical sector and issuance of securities analysts' reports or recommendations;
- trading volume of our common stock;
- an inability to obtain additional funding;
- sales of our stock by insiders and stockholders;
- the impact of any natural disasters or public health emergencies;
- general economic, industry, geopolitical and market conditions, events or factors, many of which are beyond our control, such as the wars between Russia and Ukraine and Israel and Hamas, inflation and interest rate changes and financial institution instability;
- expiration of market stand-off or lock-up agreements;

- additions or departures of key personnel; and
- intellectual property, product liability or other litigation against us.

In addition, in the past, stockholders have initiated class action lawsuits against biopharmaceutical companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert our management's attention and resources, which could have a material adverse effect on our business, financial condition and results of operations.

An active, liquid and orderly market for our common stock may not be maintained.

We can provide no assurance that we will be able to maintain an active trading market for our common stock. If an active market for our common stock is not sustained, it may be difficult for you to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses or technologies using our shares as consideration, which, in turn, could materially adversely affect our business.

Our executive officers, directors and principal stockholders, if they choose to act together, have the ability to significantly control or influence all matters submitted to stockholders for approval.

Our executive officers, directors and greater than 5% stockholders, in the aggregate, own a majority of our outstanding common stock. Furthermore, many of our current directors were appointed by our principal stockholders. As a result, such persons or their appointees to our board of directors, acting together, have the ability to control or significantly influence all matters submitted to our board of directors or stockholders for approval, including the appointment of our management, the election and removal of directors and approval of any significant transaction, as well as our management and business affairs. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders.

We do not currently intend to pay dividends on our common stock, and, consequently, your ability to achieve a return on your investment will depend on appreciation, if any, in the price of our common stock.

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock by our executive officers, directors and principal stockholders in the public market or the perception that these sales might occur could significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity securities.

In addition, certain of our existing stockholders are entitled to rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined

in Rule 144 under the Securities Act. Also, in connection with the private placement of our common stock in February 2024, we filed a registration statement for the resale by certain holders of our common stock and pre-funded warrants. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

We are an emerging growth company and a smaller reporting company, and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act, and may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of the completion of our IPO. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenues exceed $1.235 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five- year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, unless the SEC determines the new rules are necessary for protecting the public;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We cannot predict whether investors will find our common stock less attractive if we rely 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 reduced or more volatile. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, we will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We are also a smaller reporting company as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

General Risk Factors

We incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses. We are subject to the reporting requirements of the Exchange Act, which requires, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of Sarbanes-Oxley, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC has adopted additional rules and regulations in these areas, such as mandatory "say on pay" voting requirements and "pay versus performance" disclosure requirements that will apply to us when we cease to be an emerging growth company. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

The rules and regulations applicable to public companies have substantially increased our legal and financial compliance costs and made some activities more time consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We could face criminal liability and other serious consequences for violations, which could harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls and anti-corruption and anti-money laundering laws and regulations, including the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, CROs, contractors and other collaborators and partners from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, CROs, contractors and other collaborators and partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in

substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

Furthermore, U.S. export control laws and economic sanctions prohibit the provision of certain products and services to countries, governments, and persons targeted by U.S. sanctions. U.S. sanctions that have been or may be imposed as a result of military conflicts in other countries may impact our ability to continue activities at future clinical trial sites within regions covered by such sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. These export and import controls and economic sanctions could also adversely affect our supply chain.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. We rely on third-party manufacturers to produce our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers were affected by a man-made or natural disaster or other business interruption. In addition, our corporate headquarters is located in Carlsbad, California near major earthquake faults and fire zones, and the ultimate impact on us of being located near major earthquake faults and fire zones and being consolidated in a certain geographical area is unknown. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

Our business is subject to risks arising from pandemic and epidemic diseases.

Future pandemics or other public health epidemics have the potential to present substantial public health and economic challenges and affect our employees, patients, physicians and other healthcare providers, communities and business operations, as well as the U.S. and global economies and financial markets. A pandemic or epidemic poses the risk that we or our employees, contractors, including our CROs, suppliers, collaborators and other partners may be prevented from conducting business activities for an indefinite period of time, including due to spread of the disease within these groups or due to shutdowns that may be requested or mandated by governmental authorities. While it is not possible at this time to estimate the impact on our business of pandemic or epidemic disease outbreaks, such outbreaks could: disrupt the supply chain and the manufacture or shipment of drug substances and finished drug products for our product candidates for use in our research, preclinical studies and clinical trials, delay, limit or prevent our employees and CROs from continuing research and development activities; impede our clinical trial initiation and recruitment and the ability of patients to continue in clinical trials, including the risk that participants enrolled in our clinical trials will contract the pandemic or epidemic disease in question, while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events; and impede testing, monitoring, data collection and analysis and other related activities, any of which could delay our preclinical studies and clinical trials and increase our development costs, and have a material adverse effect on our business, financial condition and results of operations. Future pandemics or epidemics could also potentially affect the business of the FDA or comparable foreign regulatory authorities, which could result in delays in meetings related to planned or ongoing clinical trials. Any future pandemic or epidemic disease outbreak may have an adverse impact on global economic conditions which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed. The extent to which any future pandemic or epidemic disease could impact our results will depend on future developments that are highly uncertain and cannot be predicted.

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

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. If one or more of the analysts who covers us downgrades our stock, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.

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

Pursuant to Section 404 of the Sarbanes-Oxley Act, our management is required to report upon the effectiveness of our internal control over financial reporting. When we lose our status as an "emerging growth company" and reach an accelerated filer threshold, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we may need to upgrade our information technology systems; implement additional financial and management controls, reporting systems and procedures; and hire additional accounting and finance staff. If we or, if required, our independent registered public accounting firm are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begins its Section 404 reviews, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could significantly reduce the value of our shares to a potential acquiror or delay or prevent changes in control or changes in our management without the consent of our board of directors. The provisions in our charter documents include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;

- the exclusive right of our board of directors, unless the board of directors grants such right to the stockholders, to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;

- the required approval of at least 66-2/3% of the shares entitled to vote to remove a director for cause, and the prohibition on removal of directors without cause;

- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;

- the ability of our board of directors to alter our amended and restated bylaws without obtaining stockholder approval;

- the required approval of at least 66-2/3% of the shares entitled to vote to adopt, amend or repeal our amended and restated bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;

- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;

- an exclusive forum provision providing that the Court of Chancery of the State of Delaware will be the exclusive forum for certain actions and proceedings;

- the requirement that a special meeting of stockholders may be called only by the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and

- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders and that the federal district courts shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees or the underwriters or any offering giving rise to such claim.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine, our amended and restated certificate of incorporation also provides that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, including all causes of action asserted against any

defendant named in such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees and result in increased costs for investors to bring a claim. By agreeing to this provision, however, stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. If a court were to find the choice of forum provisions in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us, because biopharmaceutical and biotechnology companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of our management's attention and resources, which could harm our business.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Cybersecurity Risk Management and Strategy

We have developed and implemented a cybersecurity risk management program intended to protect the confidentiality, integrity, and availability of our critical systems and information. We implement reasonable administrative, technical and procedural safeguards to manage cybersecurity risks, including enforcing single sign-on or multi-factor authentication where supported or appropriate. We engage third-party cybersecurity experts to assess the security of our network. In addition, we engage a third-party to perform internal audits of our IT General Controls (ITGCs).

We design and assess our program based on the National Institute of Standards and Technology Cybersecurity Framework (NIST CSF). This does not imply that we meet any particular technical standards,

specifications, or requirements, only that we use the NIST CSF as a guide to help us identify, assess, and manage cybersecurity risks relevant to our business.

Our cybersecurity risk management program is designed to be integrated into our overall risk management program, and shares common methodologies, reporting channels and governance processes that apply across the risk management program to other legal, compliance, strategic, operational, and financial risk areas.

Key elements of our cybersecurity risk management program include but are not limited to the following:

- risk assessments designed to help identify material risks from cybersecurity threats to our critical systems and information;
- a security team principally responsible for managing (i) our cybersecurity risk assessment processes, (ii) our security controls, and (iii) our response to cybersecurity incidents;
- the use of external service providers, where appropriate, to assess, test or otherwise assist with aspects of our security processes;
- cybersecurity awareness training of our employees, including incident response personnel and senior management;
- a cybersecurity incident response plan that includes procedures for responding to cybersecurity incidents; and
- a third-party risk management process for key service providers, based on our assessment of their criticality to our operations and respective risk profile, suppliers, and vendors that have access to our critical systems and information.

We have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected us, including our operations, business strategy, results of operations, or financial condition. We face risks from cybersecurity threats that, if realized, are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition.

Cybersecurity Governance

Our board of directors considers cybersecurity risk as part of its risk oversight function and has delegated to the audit committee (the Committee) oversight of cybersecurity risks, including oversight of management’s implementation of our cybersecurity risk management program.

The Committee receives quarterly reports from management on our cybersecurity risks. In addition, management updates the Committee where it deems appropriate, regarding any cybersecurity incidents it considers to be significant or potentially significant.

The Committee reports to the full board of directors regarding its activities, including those related to cybersecurity. The full board of directors may also receive briefings from management on our cyber risk management program. Board members may receive presentations on cybersecurity topics from our Chief Financial Officer (CFO), internal security staff or external experts as part of the board of director's continuing education on topics that impact public companies. Our IT Senior Director, is primarily responsible for assessing and managing our material risks from cybersecurity threats. Our IT Senior Director has primary responsibility for our overall cybersecurity risk management program, and our IT Senior Director supervises our retained external cybersecurity consultants. Our IT Senior Director has over 25 years of IT and cybersecurity experience.

Our IT Senior Director takes steps to stay informed about and monitor efforts to prevent, detect, mitigate, and remediate cybersecurity risks and incidents through various means, which may include briefings from internal security personnel; threat intelligence and other information obtained from governmental, public or private sources, including external consultants engaged by us; and alerts and reports produced by security tools deployed in the information technology environment.

Item 2. Properties.

Our corporate headquarters are located in Carlsbad, California, where we lease approximately 13,065 square feet of laboratory and office space. Our headquarters consist of approximately 4,734 square feet of original space (the Original Space) and 8,331 square feet of space in an adjacent building (the Expansion Space). The lease for the Expansion Space commenced in November 2023. The lease for the Original Space and Expansion Space will end 120 months after the commencement date (November 2023) of the Expansion Space lease, subject to certain renewal options granted to us. We believe that our existing and planned expansion facilities are adequate for our current needs and that suitable additional or alternative space will be available in the future on commercially reasonable terms, if required.

For additional information, see Note 10, Leases, to the financial statements included in this Annual Report.

Item 3. Legal Proceedings.

We are not currently subject to any material legal proceedings. From time to time, we may be involved in legal proceedings or subject to claims incident to the ordinary course of business. Regardless of the outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

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.

Market Information

Our common stock trades on the Nasdaq Global Select Market under the symbol "TYRA".

Holders of Common Stock

As of March 25, 2025, there were approximately 33 holders of record of our common stock. This number was derived from our shareholder records and does not include beneficial owners of our common stock whose shares are held in the name of various dealers, clearing agencies, banks, brokers and other fiduciaries.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We intend to retain future earnings, if any, to finance the operation of our business and do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our board of directors after considering our financial condition, results of operations, capital requirements, business prospects and other factors the board of directors deems relevant, and subject to the restrictions contained in any future financing instruments.

Securities Authorized for Issuance Under Equity Compensation Plans

See Item 12 of Part III of this Annual Report for information about our equity compensation plans which is incorporated by reference herein.

Performance Graph

Not applicable.

Unregistered Sales of Equity Securities

None.

Use of Proceeds

On September 14, 2021, our registration statement on Form S-1 (File No. 333-258970) was declared effective by the SEC for our IPO. At the closing of the offering on September 17, 2021, we sold 12,420,000 shares of common stock, which included the exercise in full by the underwriters of their option to purchase 1,620,000 additional shares, at an initial public offering price of $16.00 per share and received gross proceeds of $198.7 million, which resulted in net proceeds to us of approximately $181.2 million, after deducting underwriting discounts and commissions of approximately $13.9 million and offering-related transaction costs of approximately $3.6 million.

As of December 31, 2024, we estimate that we have used all of the net proceeds from our IPO to fund the preclinical and clinical development of our product candidates, the hiring of additional personnel, the costs of operating as a public company, and other general corporate purposes. There were no material changes in the planned use of proceeds from that described in the final prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on September 15, 2021.

Issuer Repurchases of Equity Securities and Affiliated Purchasers

None.

Item 6. [Reserved].

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 included elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements that involve risks and uncertainties, including those described in the section entitled "Forward Looking Statements and Market Data." Our actual results and the timing of selected events could differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those set forth under the section entitled "Risk Factors" or in other parts of this Annual Report.

Overview

We are a clinical-stage biotechnology company focused on developing next-generation precision medicines for large opportunities in targeted oncology and genetically defined conditions, with an initial focus on Fibroblast Growth Factor Receptor (FGFR) biology.

Our in-house precision medicine platform, SNÅP, enables rapid and precise drug design through iterative molecular SNÅPshots that help us design and predict which product candidates may demonstrate the highest potency, selectivity and tolerability in the clinic. We have initially leveraged our SNÅP approach to develop TYRA-300, TYRA-200 and TYRA-430: three clinical-stage, novel small molecules designed to overcome the toxicity and resistance liabilities of first generation pan-FGFR inhibitors.

Our FGFR3 Programs - TYRA-300 for Bladder Cancer and Skeletal Conditions

Mutations in the protein receptor FGFR3 are a key driver in two indications with large market opportunities: bladder cancer and skeletal conditions. In bladder cancer, uncontrolled activation of FGFR3 on the cell surface stimulates cellular proliferation. In skeletal conditions, increased activity of FGFR3 expressed in growth plate chondrocytes (cartilage cells) results in excessive limitation of long bone growth.

Our lead program, TYRA-300, was designed to be more selective for FGFR3 over FGFR1, FGFR2, and FGFR4 to minimize off-target side effects, providing potential clinical advantages over less selective first-generation compounds and potentially addressing key unmet needs across both bladder cancer and skeletal conditions.

TYRA-300 is to be evaluated in three Phase 2 studies: SURF301, for the treatment of metastatic urothelial carcinoma (mUC); SURF302, for the treatment of non-muscle invasive bladder cancer (NMIBC); and BEACH301, for the treatment of pediatric achondroplasia (ACH).

SURF301 for mUC: This ongoing study is an international, multi-center, open label Phase 1/2 clinical trial that was designed to determine the optimal and maximum tolerated doses (MTD), and the recommended Phase 2 dose (RP2D) of TYRA-300, as well as to evaluate the preliminary antitumor activity of TYRA-300. In late October 2024, we reported interim data that in patients with FGFR3+ mUC who received doses ≥ 90 mg once daily (QD), 6 out of 11 (54.5%) patients achieved a confirmed partial response. Preliminary data, as of the August 15, 2024 data cutoff, suggested TYRA-300 was generally well-tolerated, with infrequent FGFR2- and FGFR1-associated toxicities. Dose optimization is ongoing in this study.

SURF302 for NMIBC: This study is an open-label Phase 2 clinical trial evaluating the efficacy and safety of TYRA-300 at lower doses (50 and 60mg QD) in participants with FGFR3-altered low-grade, intermediate risk (IR) NMIBC. We expect to dose the first patient in this study in the second quarter of 2025.

BEACH301 for ACH: This study is an open-label, Phase 2 dose-escalation/dose-expansion trial evaluating TYRA-300 at lower doses (0.125, 0.25, 0.375, 0.50 mg/kg) in children ages 3 to 10 with ACH with open growth plates. Prior to initiation of the first two cohorts, the study will enroll a safety sentinel cohort of up to 3 treatment-naïve participants per dose level in children ages 5 to 10. We expect to dose the first child in this study in the second quarter of 2025.

Our FGFR2 Program - TYRA-200 for Intrahepatic Cholangiocarcinoma

FGFR2 is a protein receptor present on the cell surface that promotes cellular proliferation and transformation upon binding of fibroblast growth factor. Activating gene alterations of FGFR2 have been implicated in the tumorigenesis of multiple solid tumor types, with pan-FGFR inhibitors approved for intrahepatic cholangiocarcinoma (ICC).

TYRA-200 is an FGFR1/2/3 inhibitor designed to be active against nearly all of the clinically identified acquired resistant mutations that arise during treatment with pan-FGFR inhibitors, which we believe is necessary to address the problem of disease progression due to polyclonal resistance. TYRA-200 is currently being evaluated in a multi-center, open label Phase 1 clinical study, SURF201 that is designed to evaluate the safety, tolerability, and pharmacokinetics (PK) of TYRA-200, determine the optimal dose for further development and the MTD and RP2D, and evaluate preliminary antitumor activity, with a focus on achieving proof-of-concept in a cohort of FGFR2-driven ICC resistant to previous FGFR inhibitors.

Our FGF19+ Program - TYRA-430 for Hepatocellular Carcinoma

FGF19 is a post-prandial enterohepatic hormone that signals through FGFR4 and its associated co-receptor Klotho Beta (KLB) to exert its normal cellular functions. In certain cancers, FGF19 is aberrantly expressed due to focal chromosomal amplifications or epigenetic mechanisms, promoting tumor cells to become dependent on the FGFR4/KLB/FGF19 oncogenic axis. Recent insights into FGF/FGFR signaling in HCC have indicated an important bypass mechanism in FGFR3, which shares the Klotho Beta coreceptor.

TYRA-430 was designed to be biased for FGFR4 and FGFR3 over the FGFR1 and FGFR2 isoforms specifically to address the FGF19 signaling pathway, while also potentially limiting side effects due to inhibition of FGFR1 and FGFR2, as well as to address acquired resistance mutations that have limited the efficacy of previous FGFR4-specific inhibitors. TYRA-430 will be initially studied in SURF431, a global Phase 1 multicenter, open-label, study in advanced HCC and other solid tumors with activating FGF/FGFR pathway aberrations (SURF431). We expect to dose the first patient in this study in the second quarter of 2025.

Financial Overview

Since the commencement of our operations in 2018, we have devoted substantially all of our resources to organizing and staffing the company, business planning, raising capital, developing our proprietary SNÅP platform, undertaking research and development activities for our development programs, establishing our intellectual property portfolio, and providing general and administrative support for our operations. We have not generated any revenue to date and have funded our operations primarily from our initial public offering (IPO), private placements of our convertible preferred stock, the issuance of Simple Agreements for Future Equity and the issuance of common stock and pre-funded common stock warrants through a private placement. Our net losses for the years ended December 31, 2024 and 2023 were $86.5 million and $69.1 million, respectively. As of December 31, 2024, we had an accumulated deficit of $251.3 million. As of December 31, 2024, we had cash, cash equivalents, and marketable securities of $341.4 million.

We have incurred significant operating losses since inception. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical development activities, other research and development activities and capital expenditures. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future particularly if and as we conduct preclinical studies and clinical trials, continue our research and development activities, utilize third parties to manufacture our product candidates and related raw materials, hire additional personnel, expand and protect our intellectual property, and incur additional costs associated with being a public company.

Based on our current operating plan, we believe that our cash, cash equivalents and marketable securities as of December 31, 2024 will be sufficient to fund our operating expenses and capital expenditures through at least 2027. We have never generated any revenue and do not expect to generate any revenue from product sales unless and until we successfully complete the development of and obtain regulatory approval for our product candidates,

which will not be for several years, if ever. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, until we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. However, we may not be able to raise additional funds or enter into such other arrangements when needed or on favorable terms, or at all. If we are unable to raise additional capital or enter into such arrangements when needed, we could be forced to delay, limit, reduce or terminate our research and development programs or future commercialization efforts, or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves.

Components of Results of Operations

Operating Expenses

Research and Development Expenses

To date, our research and development expenses consist primarily of external and internal costs related to the development of our SNÅP platform and our product candidates and development programs. Our research and development expenses primarily include:

- external costs, including:
    - expenses incurred in connection with conducting clinical trials, including investigator grants and site payments for time and pass-through expenses and expenses incurred under agreements with contract research organizations (CROs), central laboratories and other vendors and service providers engaged to conduct our trials;
    - expenses incurred in connection with the discovery and preclinical development of our product candidates, including under agreements with third parties, such as consultants and CROs;
    - costs associated with consultants for chemistry, manufacturing and controls (CMC) development, and other services;
    - the cost of manufacturing compounds for use in our preclinical studies, including under agreements with third parties, such as consultants and third-party manufacturers; and
    - costs related to compliance with drug development regulatory requirements; and
- internal costs, including:
    - employee-related expenses, including salaries, related benefits, travel and share-based compensation expenses for employees engaged in research and development functions;
    - the costs of laboratory supplies and acquiring, developing and manufacturing preclinical study materials; and
    - facilities, depreciation and other indirect expenses, which include allocated expenses for rent and maintenance of facilities and supplies.

We expense research and development expenses in the periods in which they are incurred. External expenses are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers or our estimate of the level of service that has been performed at each reporting date. We track external expenses on a development program and other program-specific basis. However, we do not track internal costs on a program-specific basis because these costs primarily relate to compensation, early research and consumable costs, which are deployed across multiple programs under development.

Research and development activities are central to our business model. There are numerous factors associated with the successful development of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. In addition, future regulatory factors beyond our control may impact our clinical development programs. Product candidates in later stages of development generally have higher development costs than those in earlier stages of development. As a result, we expect that our research and development expenses will increase substantially over the next several years as we advance our product candidates through preclinical studies into and through clinical trials, continue to discover and develop additional product candidates and expand our pipeline, maintain, expand, protect and enforce our intellectual property portfolio, and hire additional personnel.

Our future research and development expenses may vary significantly based on a wide variety of factors, such as:

- the number and scope, rate of progress, expense and results of our discovery and preclinical development activities and clinical trials;
- the number of trials required for approval;
- the number of sites included in each of our trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the ability to identify appropriate patients eligible for our clinical trials;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the phase of development of the product candidate;
- the efficacy and safety profile of the product candidate;
- the timing, receipt, and terms of any approvals from applicable regulatory authorities including the FDA and non-U.S. regulators;
- maintaining a continued acceptable safety profile of our product candidates following approval, if any;
- the cost and timing of manufacturing our product candidates;
- significant and changing government regulation and regulatory guidance;
- the ability to attract and retain personnel;
- the impact of any business interruptions to our operations or to those of the third parties with whom we work;
- geopolitical instability, such as the war and other conflicts in Ukraine and the Middle East;

- adverse effects on the financial markets, the global economy, the supply chain and our expenses due to pandemic or epidemic diseases, geopolitical instability, inflation, interest rates and other factors; and

- the extent to which we establish additional strategic collaborations or other arrangements.

A change in the outcome of any of these variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate.

The process of conducting the necessary preclinical and clinical research to obtain regulatory approval is costly and time-consuming. The actual probability of success for our product candidates or any future candidates may be affected by a variety of factors. We may never succeed in achieving regulatory approval for any of our product candidates or any future candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related expenses, including employee salaries, bonuses, benefits, and stock-based compensation charges for personnel in executive, finance and other administrative functions. Other significant general and administrative expenses include legal fees relating to intellectual property and corporate matters, allocated facility-related costs, professional fees for accounting, tax, business development and consulting services and insurance costs. We expect our general and administrative expenses will increase for the foreseeable future to support our increased research and development activities, manufacturing activities, and the increased costs associated with operating as a public company. These increased costs will likely include increased expenses related to hiring additional personnel, audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and the Securities and Exchange Commission (SEC) requirements, director and officer insurance costs, and investor and public relations costs.

Other Income

Other income consist primarily of interest income from cash, cash equivalents and marketable securities and accretion income from marketable securities.

Results of Operations for the Years Ended December 31, 2024 and 2023

The following table summarizes our results of operations for the periods indicated (in thousands):

	Year Ended December 31,		
	2024	2023	Change
Operating expenses:			
Research and development	$ 80,077	$ 62,518	$ 17,559
General and administrative	24,100	17,427	6,673
Total operating expenses	104,177	79,945	24,232
Loss from operations	(104,177)	(79,945)	(24,232)
Other income:			
Interest and other income, net	17,696	10,811	6,885
Total other income	17,696	10,811	6,885
Net loss	$ (86,481)	$ (69,134)	$ (17,347)

Research and Development Expenses

We track most external development costs by development program. We do not allocate internal costs, such as personnel-related expenses, stock-based compensation expense, facility, supplies and certain external consultant costs, to individual development programs.

The following table summarizes our research and development expenses by development program for the periods indicated (in thousands):

	Year Ended December 31,		
	2024	2023	Change
External research and development expenses by program			
TYRA-300^{ACH}	$ 7,718	$ 5,268	$ 2,450
TYRA-300^{mUC}	14,319	15,613	(1,294)
TYRA-430	5,677	4,987	690
TYRA-200	4,969	4,418	551
FGFR discovery	8,321	5,492	2,829
Other development programs	2,537	2,448	89
Unallocated research and development expenses			
Personnel costs	30,423	20,039	10,384
Facilities and other costs	6,113	4,253	1,860
Total research and development expenses	$ 80,077	$ 62,518	$ 17,559

Research and development expenses were $80.1 million and $62.5 million for the years ended December 31, 2024 and 2023, respectively. The overall increase of $17.6 million was driven by:

- $7.3 million increase in clinical costs driven by progression of SURF301 and SURF201 clinical trials and start-up activities related to BEACH301, SURF302 and SURF431 study launches;
- $1.7 million decrease in preclinical costs due to a decrease in early drug discovery and toxicology costs as various programs moved into clinical development;
- $0.3 million decrease in CMC costs for most programs in the clinical stage, except for TYRA-300^{ACH} and certain preclinical programs;
- $10.4 million increase in compensation and other personnel expenses, including an increase in stock-based compensation costs of $6.0 million, driven by headcount growth; and
- $1.9 million increase in facilities and other operating costs due to our continuing expansion efforts.

General and Administrative Expenses

General and administrative expenses were $24.1 million and $17.4 million for the years ended December 31, 2024 and 2023, respectively. The increase of $6.7 million was driven by:

- $4.9 million increase in compensation and other personnel expenses, including an increase in stock-based compensation costs of $3.3 million, driven by headcount growth;
- $1.4 million increase in professional services, legal and other public company costs; and
- $0.4 million increase in facilities and other operating costs to support growing operations.

Other Income

Other income was $17.7 million and $10.8 million for the years ended December 31, 2024 and 2023, respectively. The increase of $6.9 million was primarily related to an increase in our cash, cash equivalents and marketable securities balances due to proceeds received from our private placement completed in February 2024.

Liquidity and Capital Resources

Sources of Liquidity

On September 17, 2021, we completed our IPO and issued 12,420,000 shares of common stock for net proceeds of approximately $181.2 million. Prior to our IPO, we funded our operations primarily through private

placements of our convertible preferred stock with net proceeds of $157.2 million, excluding issuance costs of $0.4 million.

On February 6, 2024, we completed a private placement and issued 9,286,023 shares of our common stock and pre-funded warrants to purchase an aggregate of 6,087,230 shares of our common stock (the 2024 Private Placement) for net proceeds of approximately $199.6 million, excluding issuance costs of $0.4 million.

On October 3, 2022, we entered into an ATM Sales Agreement (the Sales Agreement) with Virtu Americas LLC (the Agent), under which we may, from time to time, sell shares of our common stock having an aggregate offering price of up to $150.0 million in "at the market" offerings through the Agent. Sales of the shares of common stock, if any, will be made at prevailing market prices at the time of sale or as otherwise agreed with the Agent. The Agent will receive a commission from us of up to 3.0% of the gross proceeds of any shares of common stock sold under the Sales Agreement. As of December 31, 2024, we have not sold any shares under the Sales Agreement.

Cash Flows

The following table sets forth a summary of our cash flows for the periods indicated (in thousands):

	Year Ended December 31,	
	2024	2023
Net cash used in operating activities	$ (69,774)	$ (50,139)
Net cash used in investing activities	(98,403)	(144,605)
Net cash provided by financing activities	202,137	1,537
Net cash increase (decrease) for the period	$ 33,960	$ (193,207)

Operating Activities

Net cash used in operating activities for the year ended December 31, 2024 was $69.8 million, consisting primarily of our net loss of $86.5 million, adjusted for $17.4 million of non-cash charges primarily related to stock-based compensation expense and accretion on marketable securities, partially offset by $0.7 million for net changes in operating assets and liabilities.

Net cash used in operating activities for the year ended December 31, 2023 was $50.1 million, consisting primarily of our net loss of $69.1 million, adjusted for $12.6 million of non-cash charges primarily related to stock-based compensation expense and accretion on marketable securities and $6.4 million for net changes in operating assets and liabilities.

Investing Activities

Net cash used in investing activities for the year ended December 31, 2024 was $98.4 million, consisting of $263.6 million for purchases of marketable securities available-for-sale and $0.7 million for purchases of property and equipment, offset by $165.9 for maturities of marketable securities available-for-sale.

Net cash used in investing activities for the year ended December 31, 2023 was $144.6 million, consisting of $143.8 million for purchases of marketable securities available-for-sale and $0.8 million for purchases of property and equipment.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2024 was $202.1 million, consisting primarily of proceeds from the issuance of common stock and pre-funded warrants from the 2024 Private Placement of $200 million, offset by issuance costs of $0.4 million, and proceeds from the issuance of common stock under benefit plans of $2.5 million.

Net cash provided by financing activities for the year ended December 31, 2023 was $1.5 million, related to proceeds from the issuance of common stock under benefit plans.

Material Cash Requirements

Our material cash requirements consist of expected operating expenses to conduct our clinical trials and other research and development activities, facility and operating lease obligations.

Our primary uses of cash to date have been to fund our research and development activities, including with respect to TYRA-300, TYRA-300 ACH, TYRA-430 and TYRA-200 and other research programs, business planning, establishing and maintaining our intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these operations.

Based on our current operating plan, we believe that our existing cash, cash equivalents and marketable securities as of December 31, 2024 will be sufficient to meet our anticipated operating expenses and capital expenditures through at least 2027. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect. Additionally, the process of conducting preclinical studies and testing product candidates in clinical trials is costly, and the timing of progress and expenses in these studies and trials is uncertain.

Our future capital requirements will depend on many factors, including:

- the initiation, type, number, scope, results, costs and timing of our ongoing and planned preclinical studies and clinical trials of existing product candidates or clinical trials of other potential product candidates we may choose to pursue in the future, including based on feedback received from regulatory authorities;
- the costs and timing of manufacturing for current or future product candidates, including commercial scale manufacturing if any product candidate is approved;
- the costs, timing and outcome of regulatory review of current or future product candidates;
- the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal controls over financial reporting;
- the costs associated with hiring additional personnel and consultants as our business grows, including additional executive officers and clinical development personnel, as well as retaining personnel;
- the costs and timing of establishing or securing sales and marketing capabilities if any current or future product candidate is approved;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;
- costs associated with any products or technologies that we may in-license or acquire; and
- delays or issues with any of the above, including that the risk of each may be exacerbated by any future pandemics or epidemic diseases, potential geopolitical instability and war, inflation or rising interest rates.

Until such time, if ever, as we can generate substantial product revenues to support our cost structure, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including

potential collaborations, licenses and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations or other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves.

We lease our corporate office and laboratory space in Carlsbad, California. As of December 31, 2024, total future aggregate operating lease commitments were $8.7 million, with approximately $0.9 million due in 2025, and the remaining due in periods from 2026 through 2033. These obligations are further described in Note 10 to our audited financial statements.

In addition, we enter into agreements and purchase orders in the normal course of business with vendors for the provision of goods and services. These agreements may include certain provisions for termination, with notice, which typically consist of payments for services provided or expenses incurred through the date of cancellation. We believe that our non-cancelable obligations under these agreements are not material.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States (GAAP). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events, and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 1 to our financial statements included elsewhere in this filing, we believe the following accounting policies and estimates to be most critical to the preparation of our financial statements.

Accrued Research and Development Expenses

Research and development expenses consist of external and internal costs associated with the Company's research and development activities, including its discovery and research efforts and the preclinical and clinical development of its product candidates. Research and development costs are expensed in the period incurred.

The Company has entered into various research and development contracts with clinical research organizations, clinical manufacturing organizations, clinical sites and other vendors and consultants. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and payments made in advance of or after the performance are reflected in the accompanying balance sheets as prepaid expenses or accrued liabilities, respectively. The Company records accruals for estimated costs incurred for ongoing research and development activities. When evaluating the adequacy of the accrued liabilities, the Company analyzes the progress of the services, including the phase or completion of events, invoices received and contracted costs. The Company holds discussions with applicable personnel and outside service providers as to the progress of clinical trials, or the services completed. Significant judgments and estimates may be made in determining the prepaid or accrued balances at the end of any reporting period. Actual results could differ from the

Company's estimates. Nonrefundable advance payments for goods and services, including fees for process development, are deferred and recognized as expenses in the period that the related goods are consumed or services are performed.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 1 to our financial statements appearing elsewhere in this Annual Report on Form 10-K.

Emerging Growth Company and Smaller Reporting Company Status

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended (JOBS Act). We will remain an emerging growth company until the earliest to occur of: (i) the last day of the fiscal year in which we have more than $1.235 billion in annual revenue; (ii) the date we qualify as a "large accelerated filer," with at least $700 million of equity securities held by non-affiliates; (iii) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period; and (iv) December 31, 2026. As a result of this status, we have taken advantage of reduced reporting requirements in this Annual Report on Form 10-K and may elect to take advantage of other reduced reporting requirements in our future filings with the SEC. In particular, in this Annual Report on Form 10-K, we have provided only two years of audited financial statements and have not included all of the executive compensation-related information that would be required if we were not an emerging growth company.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards, delaying the adoption of these accounting standards until they would apply to private companies. We have elected to use the extended transition period to enable us to comply with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date on which we (i) are no longer an emerging growth company and (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We are also a "smaller reporting company" as defined in the Exchange Act. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250 million measured on the last business day of our second fiscal quarter or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million measured on the last business day of our second fiscal quarter. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation and other matters.

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

Interest Rate Risk

We are exposed to market risk based on changes in interest rates. Our cash, cash equivalents and marketable securities were $341.4 million as of December 31, 2024 and consisted of cash, money market funds and securities issued by the U.S. government and its agencies. Due to the short-term nature of these instruments, we believe that we do not have any material exposure to changes in the fair value of our portfolio. However, declines in interest rates would reduce future interest income and cash flow. A hypothetical 10% relative change in interest rates during the periods presented would not have had a material impact on our financial statements.

Foreign Currency Exchange Risk

Our expenses are generally denominated in U.S. dollars. However, we have entered into a limited number of contracts with vendors for research and development services that are denominated in foreign currencies. We are subject to foreign currency transaction gains or losses on our contracts denominated in foreign currencies. As of December 31, 2024, foreign currency transaction gains and losses have not been material to our financial statements, and we have not had a formal hedging program with respect to foreign currency. A hypothetical 10% increase or decrease in exchange rates during any of the periods presented would not have had a material impact on our financial results.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our financial results during the periods presented.

Item 8. Financial Statements and Supplementary Data.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Tyra Biosciences, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Tyra Biosciences, Inc. (the Company) as of December 31, 2024 and 2023, the related statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2024, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, 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.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2021.

San Diego, California
March 27, 2025

Tyra Biosciences, Inc.
Balance Sheets
(in thousands, except share and per share data)

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 91,966	$ 58,006
Marketable securities	249,475	145,463
Prepaid expenses and other current assets	6,022	8,202
Total current assets	347,463	211,671
Restricted cash	1,000	1,000
Property and equipment, net	1,651	1,628
Right-of-use assets	6,068	6,526
Other long-term assets	7,376	5,032
Total assets	$ 363,558	$ 225,857
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 590	$ 4,662
Lease liabilities, current	412	280
Accrued expenses and other current liabilities	13,592	10,391
Total current liabilities	14,594	15,333
Lease liabilities, noncurrent	5,810	6,216
Other long-term liabilities	3	46
Total liabilities	20,407	21,595
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 50,000,000 shares authorized at December 31, 2024 and December 31, 2023; no shares issued and outstanding at December 31, 2024 and December 31, 2023.	—	—
Common stock, $0.0001 par value; 500,000,000 shares authorized at December 31, 2024 and December 31, 2023; 50,754,262 and 43,099,055 shares issued at December 31, 2024 and December 31, 2023, respectively, and 50,749,945 and 43,024,634 shares outstanding at December 31, 2024 and December 31, 2023, respectively.	5	4
Additional paid-in capital	593,687	368,707
Accumulated other comprehensive income	770	381
Accumulated deficit	(251,311)	(164,830)
Total stockholders' equity	343,151	204,262
Total liabilities and stockholders' equity	$ 363,558	$ 225,857

See accompanying notes to financial statements.

Tyra Biosciences, Inc.
Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	Year Ended December 31,	
	2024	2023
Operating expenses:		
Research and development	$ 80,077	$ 62,518
General and administrative	24,100	17,427
Total operating expenses	104,177	79,945
Loss from operations	(104,177)	(79,945)
Other income:		
Interest and other income, net	17,696	10,811
Total other income	17,696	10,811
Net loss	(86,481)	(69,134)
Unrealized gain on marketable securities available-for-sale, net	389	381
Comprehensive loss	$ (86,092)	$ (68,753)
Net loss per share, basic and diluted	$ (1.51)	$ (1.62)
Weighted-average shares used to compute net loss per share, basic and diluted	57,217,746	42,704,876

See accompanying notes to financial statements.

Tyra Biosciences, Inc.
Statements of Stockholders' Equity
(in thousands, except share amounts)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2022	42,353,550	$ 4	$ 353,521	$ —	$ (95,696)	$ 257,829
Issuance of common stock under benefit plans	464,596	—	1,537	—	—	1,537
Vesting of shares of common stock subject to repurchase	206,488	—	124	—	—	124
Stock-based compensation	—	—	13,525	—	—	13,525
Unrealized gain on marketable securities available-for-sale, net	—	—	—	381	—	381
Net loss	—	—	—	—	(69,134)	(69,134)
Balance at December 31, 2023	43,024,634	$ 4	$ 368,707	$ 381	$ (164,830)	$ 204,262
Issuance of common stock under Private Placement, net of issuance costs of $0.2 million	9,286,023	1	120,557	—	—	120,558
Issuance of pre-funded warrants, under Private Placement, net of issuance costs of $0.2 million	—	—	79,022	—	—	79,022
Issuance of common stock pursuant to pre-funded warrant exercise	705,000	—	—	—	—	—
Exchange of common stock for pre-funded warrants	(3,000,000)	—	—	—	—	—
Issuance of common stock under benefit plans	664,184	—	2,557	—	—	2,557
Vesting of shares of common stock subject to repurchase	70,104	—	43	—	—	43
Stock-based compensation	—	—	22,801	—	—	22,801
Unrealized gain on marketable securities available-for-sale, net	—	—	—	389	—	389
Net loss	—	—	—	—	(86,481)	(86,481)
Balance at December 31, 2024	50,749,945	$ 5	$ 593,687	$ 770	$ (251,311)	$ 343,151

See accompanying notes to financial statements.

Tyra Biosciences, Inc.
Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2024	2023
Cash flows from operating activities:		
Net loss	$ (86,481)	$ (69,134)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	519	357
Stock-based compensation	22,801	13,525
Accretion on marketable securities, net	(5,884)	(1,247)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(169)	(2,823)
Accounts payable, accrued expenses and other liabilities	(744)	9,369
Right-of-use assets and lease liabilities, net	184	(186)
Net cash used in operating activities	(69,774)	(50,139)
Cash flows from investing activities:		
Purchases of marketable securities	(263,624)	(143,835)
Maturities of marketable securities	165,885	—
Purchases of property and equipment	(664)	(770)
Net cash used in investing activities	(98,403)	(144,605)
Cash flows from financing activities:		
Proceeds from issuances of common stock under benefit plans	2,557	1,537
Proceeds from issuance of common stock and pre-funded warrants from Private Placement	200,000	—
Payments of issuance costs for common stock and pre-funded warrants from Private Placement	(420)	—
Net cash provided by financing activities	202,137	1,537
Net cash increase (decrease) for the period	33,960	(193,207)
Cash, cash equivalents and restricted cash at beginning of the period	59,006	252,213
Cash, cash equivalents and restricted cash at end of the period	$ 92,966	$ 59,006
Reconciliation of cash, cash equivalents and restricted cash to the balance sheet		
Cash and cash equivalents	$ 91,966	$ 58,006
Restricted cash	1,000	1,000
Total cash, cash equivalents and restricted cash	$ 92,966	$ 59,006
Supplemental disclosure of cash flow information:		
Right-of-use assets obtained in exchange for lease liabilities	$ —	$ 4,405
Non-cash investing and financing activities:		
Purchases of property and equipment included in accounts payable and accrued expenses and other current liabilities	$ —	$ 125
Vesting of options early exercised subject to repurchase	$ 43	$ 124

See accompanying notes to financial statements.

Tyra Biosciences, Inc.
Notes to the Financial Statements

1. Organization and Summary of Significant Accounting Policies

Organization

Tyra Biosciences, Inc. (the Company) was incorporated in the state of Delaware on August 2, 2018. The Company is a clinical-stage biotechnology company focused on developing next-generation precision medicines that target large opportunities in Fibroblast Growth Factor Receptor (FGFR) biology. The Company's in-house precision medicine platform, SNÅP, enables rapid and precise drug design through iterative molecular SNÅPshots that help predict genetic alterations most likely to cause acquired resistance to existing therapies. The Company's initial focus is on applying its accelerated small molecule drug discovery engine to develop therapies in targeted oncology and genetically defined conditions.

Since its inception, the Company has devoted substantially all of its resources to research and development activities, business planning, establishing and maintaining its intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these operations. It has incurred losses and negative cash flows from operations since commencement of its operations. The Company had an accumulated deficit of $251.3 million and cash, cash equivalents and marketable securities of $341.4 million as of December 31, 2024. From its inception through December 31, 2024, the Company has financed its operations primarily through the sale of common stock, private placements of its convertible preferred stock, and the issuance of common stock and pre-funded common stock warrants through a private placement.

As the Company continues its expansion, it may seek additional financing and/or strategic investments. However, there can be no assurance that any additional financing or strategic investments will be available to the Company on acceptable terms, if at all. If events or circumstances occur such that the Company does not obtain additional funding, it will most likely be required to reduce its plans and/or certain discretionary spending, which could have a material adverse effect on the Company's ability to achieve its intended business objectives. Management believes that it has sufficient working capital on hand to fund operations through at least the next twelve months from the date of issuance of these financial statements.

Basis of Presentation

The accompanying financial statements have been prepared in accordance with generally accepted accounting principles in the United States (GAAP). Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification (ASC) and Accounting Standards Updates (ASU) promulgated by the Financial Accounting Standards Board (FASB).

Summary of Significant Accounting Policies

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 and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Estimates and assumptions made in the accompanying financial statements include, but are not limited to, the valuation of share-based awards, the valuation of deferred tax assets and income tax uncertainties, accruals for research and development activities, and incremental borrowing rate (IBR) for right-of-use (ROU) assets. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable. Actual results may differ from those estimates or assumptions.

Concentration of Credit Risk

Financial instruments which potentially subject the Company to a significant concentration of credit risk consist of cash, cash equivalents and marketable securities. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts, and management believes that the Company is not exposed to significant credit risk due to the nature of the instruments held in the depository institutions.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash equivalents. Cash equivalents primarily represent funds invested in readily available money market accounts. As of December 31, 2024, the Company had cash and cash equivalents balances deposited at major financial institutions.

Marketable Securities

Marketable securities consist of debt securities of government-sponsored entities. These securities are classified as available-for sale, as the sale of such securities may be required prior to their maturity. Available-for-sale securities are recorded at fair value, with the related unrealized gains and losses included in accumulated other comprehensive income or loss and included as a separate component of stockholders' equity. The amortized cost of available-for-sale securities reflects amortization of premiums and accretion of discounts to maturity. Premiums and discounts on debt securities are amortized or accreted into interest and other income, net. The Company classifies investments in marketable debt securities as current assets, regardless of the stated maturity date, which may be beyond one year from the current balance sheet date. Short-term classification reflects management's view that the entire portfolio is available, and the Company may use the proceeds from sales of these investments to fund current operations, as necessary.

Allowance for Credit Losses

The Company regularly reviews its portfolio for declines in fair value. For investments in an unrealized loss position, the Company assesses whether the decline is based on credit losses or other factor. As part of this assessment, the Company considers the cause of the impairment, the creditworthiness of the security issuers, current market conditions, the number of securities in an unrealized loss position, the severity of the losses, whether it will be required or will intend to sell the investment before recovery of its amortized cost basis. If fair value decline is determined to be due to a credit-related factor, the amortized cost basis is written down to fair value through net loss. If fair value decline is not due to credit-related factors, a loss is recorded in other comprehensive income or loss. The Company recognizes an allowance for credit losses up to the amount of the unrealized loss when appropriate.

We do not measure an allowance for credit losses for accrued interest receivables. For the purposes of identifying and measuring an impairment, accrued interest is excluded from both the fair value and amortized costs basis of the investment. Uncollectible accrued interest receivables associated with an impaired marketable security are reversed against interest income in a timely manner upon identification of the impairment.

Fair Value Measurements

The Company measures cash equivalents and available-for-sale debt securities at fair value. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. Therefore, fair value is a market-based measurement that is determined based on assumptions that market participants would use in pricing an asset or liability. Fair value is affected by a number of factors, including the type of asset or liability, the characteristics specific to the asset or liability and the state of the marketplace, including the existence and transparency of transactions between market participants. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1—Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.

Level 2—Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs that are observable, either directly or indirectly, for substantially the full term of the asset or liability.

Level 3—Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e. supported by little or no market activity).

Money market funds are highly liquid investments and are classified as Level 1. The pricing information for these assets is readily available and can be independently validated as of the measurement date. Available-for-sale debt securities, including U.S. Treasury securities and U.S. Agency bonds are classified as Level 2. These securities are valued using fair value from third-party pricing services, which may use observable inputs based on real-time trade data for similar assets, broker/dealer quotes, bids and/or offers and other observable inputs. The Company validates valuations obtained from third-party pricing services by understanding the models used and obtaining market values from independent sources.

Restricted Cash

Restricted cash is comprised of cash that is restricted as to its withdrawal or use under the terms of certain contractual agreements. Restricted cash as of December 31, 2024 and 2023 was $1.0 million, which consisted of collateral for letters of credit related to the Company's operating leases.

Property and Equipment

Property and equipment is stated at cost and depreciated using the straight-line method over the estimated useful lives of the assets (generally three to seven years, or the remaining term of the lease).

Impairment of Long-Lived Assets

The Company accounts for the impairment of long-lived assets by reviewing these assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If circumstances require a long-lived asset or asset group to be tested for possible impairment, the Company first compares undiscounted cash flows expected to be generated by that asset or asset group to its carrying value. If the carrying value of the long-lived asset or asset group is not recoverable on an undiscounted-cash-flow basis, an impairment is recognized to the extent that the carrying value exceeds its fair value. The Company did not recognize impairment losses for the years ended December 31, 2024 and 2023.

Accrued Research and Development Expenses

Research and development expenses consist of external and internal costs associated with the Company's research and development activities, including its discovery and research efforts and the preclinical and clinical development of its product candidates. Research and development costs are expensed in the period incurred.

The Company has entered into various research and development contracts with clinical research organizations, clinical manufacturing organizations, clinical sites and other vendors and consultants. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and payments made in advance of or after the performance are reflected in the accompanying balance sheets as prepaid expenses or accrued liabilities, respectively. The Company records accruals for estimated costs incurred for ongoing research and development activities. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the services, including the phase or completion of events, invoices received and contracted costs. The Company holds discussions with applicable personnel and outside service providers as to the progress of clinical trials, or the services completed. Significant judgments and estimates may be made in determining the prepaid or accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. Nonrefundable advance payments for goods and services, including fees for process

development, are deferred and recognized as expenses in the period that the related goods are consumed or services are performed.

Patent Costs

The Company expenses all costs as incurred in connection with patent applications (including direct application fees, and the legal and consulting expenses related to making such applications) and such costs are included in general and administrative expenses in the statements of operations and comprehensive loss.

Leases

The Company has operating leases for office and lab space. At the inception of a contractual arrangement, the Company determines whether the contract contains a lease by assessing whether there is an identified asset and whether the contract conveys the right to control the use of the identified asset in exchange for consideration over a period of time. If both criteria are met, the Company records the associated lease liability and corresponding ROU asset upon commencement of the lease using the implicit rate or a discount rate based on a credit-adjusted secured borrowing rate commensurate with the term of the lease. The Company evaluates leases at their inception to determine if they are to be accounted for as an operating lease or a finance lease.

Operating lease assets represent a right to use an underlying asset for the lease term and operating lease liabilities represent an obligation to make lease payments arising from the lease. Operating lease liabilities with a term greater than one year and their corresponding ROU assets are recognized on the balance sheet at the commencement date of the lease based on the present value of lease payments over the expected lease term. The Company excludes short-term leases, if any, having initial terms of 12 months or less at lease commencement as an accounting policy election.

Certain adjustments to the ROU assets may be required for items such as payments made at or before the commencement date, initial direct costs paid or lease incentives received. As the Company's leases do not typically provide an implicit rate, the Company utilizes the appropriate IBR, determined as the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term and in a similar economic environment. Lease cost is recognized on a straight-line basis over the lease term and variable lease payments are recognized as operating expenses in the period in which the obligation for those payments is incurred. Variable lease payments primarily include common area maintenance, utilities, real estate taxes, insurance, and other operating costs that are passed on from the lessor in proportion to the space leased by the Company. In measuring the ROU assets and lease liabilities, the Company has elected to combine lease and non-lease components.

Operating ROU assets are reflected in right-of-use assets in the accompanying balance sheets. Operating lease liabilities are reflected in lease liabilities, current and noncurrent in the accompanying balance sheets.

Common Stock Warrants

Common stock warrants are classified as either a liability or equity, based on an assessment of specific terms and applicable authoritative guidance in ASC 480, Distinguishing Liabilities from Equity (ASC 480) and ASC 815, Derivatives and Hedging (ASC 815). The Company considers whether the warrants are freestanding financial instruments, whether they meet the definition of a liability pursuant to ASC 480, and whether they meet all of the requirements for equity classification under ASC 815. This assessment is performed at the time of warrant issuance and re-assessed as of each subsequent quarterly balance sheet date, while the warrants are outstanding.

Stock-Based Compensation

Stock-based compensation expense represents the cost of the grant date fair value of employee, officer, director and non-employee equity awards, estimated in accordance with the applicable accounting guidance, and, for those awards subject only to service conditions, recognized on a straight-line basis over the vesting period. The vesting period generally approximates the expected service period of the awards. The Company recognizes stock-based compensation expense for awards with performance conditions when it is probable that the condition will be

met, and the award will vest. If the achievement of performance conditions is no longer deemed probable, previously recognized compensation cost is reversed. For awards with performance and service conditions, the Company begins recording share-based compensation when achieving the performance criteria is probable and recognizes the costs using the accelerated attribution method. The Company recognizes forfeitures as they occur.

The fair value of stock options is estimated using a Black-Scholes valuation model on the date of grant. This method requires certain assumptions to be used as inputs, such as the fair value of the underlying common stock, expected term of the option before exercise, expected volatility of the Company's common stock, risk-free interest rate and expected dividend. Options granted have a maximum contractual term of ten years. The Company has limited historical stock option activity and therefore estimates the expected term of stock options granted using the simplified method, which represents the arithmetic average of the original contractual term of the stock option and its weighted-average vesting term. The expected volatility of stock options is estimated based on the average historical volatilities of common stock of comparable publicly traded companies and the Company's own volatility. The comparable companies are chosen based on their size and stage in the life cycle. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available. The risk-free interest rates used are based on the U.S. Treasury yield in effect at the time of grant for zero-coupon U.S. treasury notes with maturities approximately equal to the expected term of the stock options. The Company has historically not declared or paid any dividends and does not currently expect to do so in the foreseeable future, and therefore, has estimated the dividend yield to be zero.

Commitments and Contingencies

The Company recognizes a liability with regard to loss contingencies when it believes it is probable a liability has been incurred, and the amount can be reasonably estimated. If some amount within a range of loss appears at the time to be a better estimate than any other amount within the range, the Company accrues that amount. When no amount within the range is a better estimate than any other amount, the Company accrues the minimum amount in the range.

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in the statement of operations in the period that includes the enactment date.

The Company recognizes deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management 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. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

As of December 31, 2024 and 2023, the Company maintained valuation allowances against its deferred tax assets as the Company concluded it had not met the "more likely than not" to be realized threshold. Changes in the valuation allowance when they are recognized in the provision for income taxes may result in a change in the estimated annual effective tax rate.

The Company records uncertain tax positions on the basis of a two-step process whereby (1) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority. The Company recognizes interest and penalties related to

unrecognized tax benefits within income tax expense. Any accrued interest and penalties are included within the related tax liability. As of December 31, 2024, the Company had no accrued interest or penalties.

Comprehensive Loss

Comprehensive loss consists of two components: net loss and other comprehensive income or loss. Other comprehensive income (loss) refers to gains or losses that are recorded as an element of stockholders' equity but are excluded from net loss. The Company's other comprehensive income (loss) consists of unrealized gains and losses on marketable securities.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of shares of common stock and common stock equivalents outstanding for the period. Common stock equivalents are only included when their effect is dilutive. Pre-funded warrants are considered outstanding for the purposes of computing basic and diluted net loss per share because shares may be issued for little or no additional consideration and are fully vested and exercisable after the original issuance date of the pre-funded warrant. The Company's potentially dilutive securities include unvested common stock, unvested common stock upon early exercise of stock options, outstanding stock options under the Company's equity incentive plan, and estimated shares purchasable under the employee stock purchase plan, and have been excluded from the computation of diluted net loss per share as their inclusion would be anti-dilutive. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the Company's net loss position.

Related Parties

Transactions between related parties are considered to be related party transactions even though they may not be given accounting recognition. FASB ASC 850, Related Party Disclosures (ASC 850) requires that transactions with related parties that would make a difference in decision making shall be disclosed so that users of the financial statements can evaluate their significance.

Capitalized Software Implementation Costs

The Company capitalizes certain implementation costs incurred under a cloud computing arrangement that is a service contract. Costs incurred during the application development stage related to the implementation of the hosting arrangement are capitalized and included within prepaid and other current assets, and other long-term assets on the accompanying balance sheets. Amortization of capitalized implementation costs is recognized on a straight-line basis over the term of the associated hosting arrangement when it is ready for its intended use. Costs related to preliminary project activities and post-implementation activities are expensed as incurred.

Recently Adopted Accounting Pronouncements

On August 5, 2020, the FASB issued ASU 2020-06, "Debt - Debt With Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40)", which simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity's own equity. The ASU is part of the FASB's simplification initiative, which aims to reduce unnecessary complexity in GAAP. For smaller reporting companies, this ASU is effective for fiscal years beginning after December 15, 2023. The Company adopted this standard effective January 1, 2024, which did not have a material impact on the Company's financial statements.

In November 2023, the FASB issued ASU 2023-07, "Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures". ASU 2023-07 updates reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. ASU 2023-07 is effective for all entities for fiscal years beginning after December 15, 2023, and for interim periods within fiscal years beginning after December 15,

2024. Public entities with a single reportable segment are required to apply the disclosure requirements in ASU-2023-07, as well as all existing segments disclosures as required by ASC 280. The Company adopted this standard effective January 1, 2024 and retrospectively to all prior periods. The adoption impacted the disclosures and did not impact the financial statements. See Note 13, *Segment Information*, for disclosures related to the adoption of ASU 2023-07.

Issued Accounting Pronouncements Not Yet Adopted

In November 2024, the FASB issued ASU 2024-03, "Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses". ASU 2024-03 requires public entities to disclose specified information about certain costs and expenses on an interim and annual basis and is effective for annual reporting periods beginning after December 15, 2026 and interim periods beginning after December 15, 2027, with early adoption permitted. The new standard is expected to be applied prospectively, but retrospective application is permitted. The Company is currently evaluating the impact of ASU 2024-03 on the financial statements and related disclosures.

In December 2023, the FASB issued ASU 2023-09, “Income Taxes (Topic 740): Improvements to Income Tax Disclosures.” ASU 2023-09 requires disaggregated information about a reporting entity’s effective tax rate reconciliation as well as information on income taxes paid. ASU 2023-09 is effective for public entities with annual periods beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact of ASU 2023-09 on its financial statements and related disclosures.

2. Fair Value Measurements

The following tables show the Company’s cash, cash equivalents, marketable securities, and restricted cash measured at fair value as of December 31, 2024 and 2023 (in thousands):

	December 31, 2024			
	Total	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Cash and cash equivalents:				
Cash and money market funds	$ 91,966	$ 91,966	$ —	$ —
Restricted cash:				
Cash	1,000	1,000	—	—
Marketable securities:				
U.S. Treasury securities	122,980	—	122,980	—
U.S. government agency securities	126,495	—	126,495	—
Total marketable securities	249,475	—	249,475	—
Total	$ 342,441	$ 92,966	$ 249,475	$ —

	December 31, 2023			
	Total	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Cash and cash equivalents:				
Cash and money market funds	$ 58,006	$ 58,006	$ —	$ —
Restricted cash:				
Cash	1,000	1,000	—	—
Marketable securities:				
U.S. Treasury securities	95,599	—	95,599	—
U.S. government agency securities	49,864	—	49,864	—
Total marketable securities	145,463	—	145,463	—
Total	$ 204,469	$ 59,006	$ 145,463	$ —

The carrying amounts of the Company's prepaid and other current assets, accounts payable, and accrued and other current liabilities, approximate fair value due to their short maturities. None of the Company's non-financial assets or liabilities are recorded at fair value on a non-recurring basis. There were no transfers between Levels 1, 2 or 3 for any of the periods presented.

3. Marketable Securities

The following tables summarize the Company's marketable securities (see below and Note 2) accounted for as available-for-sale securities (in thousands, except years):

	December 31, 2024				
	Maturity (in years)	Amortized cost	Unrealized gains	Unrealized losses	Estimated fair value
U.S. Treasury securities	Less than one	$ 77,990	$ 210	$ (3)	$ 78,197
U.S. government agency securities	Less than one	94,153	189	(9)	94,333
U.S. Treasury securities	1-2	44,547	239	(3)	44,783
U.S. government agency securities	1-2	32,015	159	(12)	32,162
Total		$ 248,705	$ 797	$ (27)	$ 249,475

	December 31, 2023				
	Maturity (in years)	Amortized cost	Unrealized gains	Unrealized losses	Estimated fair value
U.S. Treasury securities	Less than one	$ 76,481	$ 153	$ —	$ 76,634
U.S. government agency securities	Less than one	37,376	38	(3)	37,411
U.S. Treasury securities	1-2	18,846	118	—	18,964
U.S. government agency securities	1-2	12,379	75	—	12,454
Total		$ 145,082	$ 384	$ (3)	$ 145,463

The following tables present fair values and gross unrealized losses for those available-for-sale securities that were in an unrealized loss position, aggregated by category and the length of time that the securities have been in a continuous loss position (in thousands):

	December 31, 2024					
	Less than 12 months		12 months or longer		Total	
	Fair value	Unrealized losses	Fair value	Unrealized losses	Fair value	Unrealized losses
U.S. Treasury securities	$ 16,033	$ (6)	$ —	$ —	$ 16,033	$ (6)
U.S. government agency securities	9,891	(21)	—	—	9,891	(21)
Total	$ 25,924	$ (27)	$ —	$ —	$ 25,924	$ (27)

	December 31, 2023					
	Less than 12 months		12 months or longer		Total	
	Fair value	Unrealized losses	Fair value	Unrealized losses	Fair value	Unrealized losses
U.S. government agency securities	$ 9,939	$ (3)	$ —	$ —	$ 9,939	$ (3)
Total	$ 9,939	$ (3)	$ —	$ —	$ 9,939	$ (3)

As of December 31, 2024, there were six available-for-sale securities with an estimated fair value of $25.9 million in gross unrealized loss positions for less than 12 months. As of December 31, 2024, unrealized losses on available-for-sale securities are not attributed to credit risk. The Company believes that an allowance for credit losses is unnecessary because the unrealized loss is due to market factors and interest rate fluctuations. Additionally, the Company does not intend to sell the securities nor is it more likely than not that the Company will be required to sell the securities before recovery of their amortized cost basis.

The amortized cost and fair value of marketable securities excludes $2.0 million and $0.7 million of accrued interest receivable as of December 31, 2024 and 2023, respectively. Accrued interest receivable is included in prepaid expenses and other current assets on the Company's balance sheets. We have not written off any accrued interest receivables for the years ended December 31, 2024 and 2023.

4. Property and Equipment

Property and equipment consisted of the following (in thousands):

	December 31, 2024	December 31, 2023
Equipment	$ 1,875	$ 1,443
Computers and software	205	208
Leasehold improvements	469	402
Furniture and fixtures	383	382
	2,932	2,435
Less: accumulated depreciation	(1,281)	(807)
Total property and equipment, net	$ 1,651	$ 1,628

The Company recognized $0.5 million and $0.4 million in depreciation expense for the years ended December 31, 2024 and 2023, respectively.

5. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	December 31, 2024	December 31, 2023
Accrued payroll and other employee benefits	$ 6,451	$ 5,117
Accrued research and development expenses	6,612	4,848
Accrued legal and professional fees	296	132
Accrued other general and administrative fees	233	294
Total accrued and other current liabilities	$ 13,592	$ 10,391

6. Stockholders' Equity

Common Stock

Common stock reserved for future issuance consisted of the following:

	December 31, 2024	December 31, 2023
Common stock options granted and outstanding	10,462,129	8,276,442
Shares available for future issuance under the 2021 Incentive Award Plan	3,051,588	3,677,313
Shares available for future issuance under the 2021 Employee Stock Purchase Plan	1,491,195	1,129,399
Pre-funded warrants issued and outstanding	8,382,187	—
Total common stock reserved for future issuance	23,387,099	13,083,154

On October 3, 2022, the Company entered into an ATM Sales Agreement (the Sales Agreement) with Virtu Americas LLC (the Agent), under which the Company may, from time to time, sell shares of its common stock having an aggregate offering price of up to $150.0 million in “at the market” offerings through the Agent. Sales of the shares of common stock, if any, will be made at prevailing market prices at the time of sale, or as otherwise agreed with the Agent. The Agent will receive a commission from the Company of up to 3.0% of the gross proceeds of any shares of common stock sold under the Sales Agreement. As of December 31, 2024, no shares of common stock were issued and sold pursuant to the Sales Agreement since inception.

On February 1, 2024, the Company entered into a securities purchase agreement for a private placement of 9,286,023 shares of the Company's common stock at a price of $13.01 per share (the 2024 Private Placement). The 2024 Private Placement also included pre-funded warrants (the 2024 Pre-Funded Warrants) to purchase an aggregate of 6,087,230 shares of common stock at a purchase price of $13.009 per pre-funded warrant. Each pre-funded warrant has an exercise price of $0.001 per share of common stock, is immediately exercisable on the date of issuance and will not expire. The 2024 Private Placement closed on February 6, 2024 and the Company received gross proceeds of approximately $200 million, before deducting offering expenses of $0.4 million. On March 19, 2024, the Company filed a registration statement on Form S-3 with the SEC registering the resale of the shares of common stock issued, or underlying the pre-funded warrants issued, in the 2024 Private Placement. The 2024 Pre-funded Warrants did not meet the characteristics of a liability or a derivative and are classified within stockholders' equity.

RA Capital Healthcare Fund, L.P. (RA Capital) is considered a related party to the Company because Jake Simson, Ph.D. is a member of the Company's board of directors and a partner at RA Capital. In connection with the 2024 Private Placement, the Company issued 3,180,155 shares of common stock and pre-funded warrants to purchase 1,538,457 shares of the Company's common stock to RA Capital, resulting in aggregate gross proceeds of approximately $61.4 million.

Boxer Capital, LLC (Boxer Capital) was considered a related party to the Company because, at the time of the 2024 Private Placement closing, Siddarth Subramony, Ph.D., was a member of the Company's board of directors and a managing director of Boxer Capital. Dr. Subramony subsequently resigned from the Company's board of directors on October 24, 2024. In connection with the 2024 Private Placement, the Company issued 63,412 shares of common stock and pre-funded warrants to purchase 705,280 shares of the Company's common stock to Boxer Capital, resulting in aggregate gross proceeds of approximately $10.0 million. During the year ended December 31, 2024, Boxer Capital exercised 705,043 of 2024 Pre-Funded Warrants in cashless transactions, which resulted in 705,000 shares of common stock being issued to Boxer Capital. There were no other 2024 Pre-Funded Warrant exercises during the period.

Nextech VI Oncology SCSP is considered a related party to the Company because Melissa McCracken, Ph.D., is a member of the Company's board of directors and a principal at Nextech Invest Ltd. (an affiliate of Nextech VI Oncology SCSP). In connection with the 2024 Private Placement, the Company issued 1,537,279 shares of common stock to Nextech VI Oncology SCSP, resulting in aggregate gross proceeds of approximately $20.0 million.

On October 18, 2024, the Company entered into an exchange agreement with Boxer Capital and RA Capital, the Company's stockholders and related parties to the Company at the time of the exchange. Pursuant to the exchange agreement (i) Boxer Capital agreed to exchange 2,000,000 shares of the Company’s common stock for one or more pre-funded warrants to acquire an aggregate of 2,000,000 shares of common stock and (ii) RA Capital agreed to exchange 1,000,000 shares of common stock for one or more pre-funded warrants to acquire an aggregate of 1,000,000 shares of common stock (each of such pre-funded warrants an Exchange Warrant and collectively the Exchange Warrants, and such exchanges of common stock for Exchange Warrants collectively the Exchange). Each Exchange Warrant has an exercise price of $0.001 per share of common stock, is immediately exercisable on the date of issuance and will not expire. No cash was exchanged related to the transaction. The Exchange closed on October 22, 2024. The Exchange Warrants did not meet the characteristics of a liability or a derivative and are classified within stockholders' equity. During the year ended December 31, 2024, there were no exercises of the Exchange Warrants.

As of December 31, 2024, a total of 8,382,187 pre-funded warrants remained available for exercise, including 3,000,000 Exchange Warrants and 5,382,187 2024 Pre-Funded Warrants. In February 2025, Boxer Capital exercised its remaining 2024 Pre-Funded Warrants and Exchange Warrants (see Note 14 - Subsequent Events). Following Boxer Capital's exercises, a total of 6,381,950 pre-funded warrants remained available for exercise, including 1,000,000 Exchange Warrants and 5,381,950 2024 Pre-Funded Warrants.

7. Equity Incentive Plans and Stock-Based Compensation

2021 Incentive Award Plan

In September 2021, the Company's Board of Directors adopted, and its stockholders approved, the 2021 Incentive Award Plan (the 2021 Plan). Upon the adoption of the 2021 Plan, the Company restricted the grant of future equity awards under the 2020 Equity Incentive Plan (the 2020 Plan).

The 2021 Plan provides for the grants of stock options and other equity-based awards to employees, non-employee directors, and consultants of the Company. Shares that expire, terminate or are cancelled under the 2020 Plan are added back to the 2021 Plan share reserve. In addition, the number of shares of the Company’s common stock available for issuance under the 2021 Plan automatically increases on the first day of each fiscal year, beginning with the Company’s 2022 fiscal year, in an amount equal to the lesser of (1) 5% of the outstanding shares of the Company’s common stock on the last day of the immediately preceding fiscal year, or (2) such smaller amount as determined by the Company’s Board of Directors. The Company issues new shares of common stock upon exercise of options. As of December 31, 2024, 3,051,588 shares were available for future grant under the 2021 Plan.

A summary of the Company's stock option activity for the year ended December 31, 2024 was as follows (in thousands, except share and per share data and years):

	Options	Weighted-Average Exercise Price per Share	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2023	8,276,442	$ 10.07	8.3	$ 40,420
Granted	3,070,898	$ 20.60		
Exercised	(594,990)	$ 3.41		
Cancelled	(290,221)	$ 13.93		
Outstanding at December 31, 2024	10,462,129	$ 13.43	7.6	$ 33,798
Exercisable at December 31, 2024	5,042,930	$ 10.26	6.4	$ 26,483
Vested and expected to vest as of December 31, 2024	10,462,129	$ 13.43	7.6	$ 33,798

Employee Stock Purchase Plan

In September 2021, the Company's Board of Directors adopted, and its stockholders approved, the 2021 Employee Stock Purchase Plan (ESPP). The ESPP permits eligible employees who elect to participate in an offering under the ESPP to have up to 15% of their eligible earnings withheld, subject to certain limitations, to purchase shares of common stock pursuant to the ESPP. The price of common stock purchased under the ESPP is equal to 85% of the lower of the fair market value of the common stock at the commencement date of each offering period or the relevant date of purchase. As of December 31, 2024, there were 1,491,195 shares available for future purchase under the ESPP.

The Company recognized compensation expense of $0.3 million and $0.5 million for the years ended December 31, 2024 and 2023, respectively, related to the ESPP. As of December 31, 2024, the remaining unrecognized compensation expense related to the ESPP was $0.4 million, and is expected to be recognized as expense over a weighted-average period of approximately 1.5 years.

Stock-Based Compensation Expense

The Company estimated the fair value of stock options using the Black-Scholes valuation model. The Company accounts for forfeitures of options when they occur. Previously recognized compensation expense for an award is reversed in the period that the award is forfeited. The fair value of stock options was estimated using the following assumptions:

	Year Ended December 31,	
	2024	2023
Risk-free rate of interest	3.5 - 4.6%	3.5 - 4.7%
Expected term (years)	5.3 - 6.1	5.2 - 6.1
Expected stock price volatility	87.8 - 98.7%	86.2 - 92.3 %
Dividend yield	—	—

Stock-based compensation expense recognized for all equity awards has been reported in the statements of operations and comprehensive loss as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Research and development expense	$ 14,291	$ 8,337
General and administrative expense	8,510	5,188
Total	$ 22,801	$ 13,525

The weighted-average grant date fair value of options granted for the years ended December 31, 2024 and 2023 was $15.95 and $9.96 per share, respectively.

During the year ended December 31, 2024, the Company entered into a transition agreement (the Transition Agreement) with its Chief Medical Officer. The Transition Agreement included accelerated vesting of 50% of unvested stock options and modified the original award terms to extend the exercise period of vested options from three months to two years from the separation date. As a result, the Company recognized an additional stock-based compensation expense of $2.0 million recorded within research and development expenses.

For the years ended December 31, 2024 and 2023, forfeitures resulting in the reversal of compensation expenses were immaterial.

As of December 31, 2024, the unrecognized compensation cost related to options was $65.1 million, and is expected to be recognized as expense over a weighted-average period of approximately 2.5 years.

8. Net Loss Per Share

The following table sets forth the computation of the basic and diluted net loss per share (in thousands, except share and per share amounts):

	Year Ended December 31,	
	2024	2023
Numerator:		
Net loss	$ (86,481)	$ (69,134)
Denominator:		
Weighted-average common shares outstanding	57,250,061	42,882,832
Less: weighted-average unvested restricted common stock subject to repurchase	—	(2,393)
Less: weighted-average unvested common stock issued upon early exercise of common stock options	(32,315)	(175,563)
Weighted-average shares used to compute net loss per common share, basic and diluted	57,217,746	42,704,876
Net loss per share, basic and diluted	$ (1.51)	$ (1.62)

Included in the weighted-average shares of common stock outstanding, both basic and diluted for the year ended December 31, 2024 are weighted shares of common stock issuable upon the exercise of the 2024 Pre-Funded Warrants and the Exchange Warrants (described in Note 6). The 2024 Pre-Funded Warrants and the Exchange Warrants are exercisable at any time for nominal consideration, and therefore, these shares are considered outstanding for the purpose of calculating basic and diluted net loss per share.

The following table sets forth the outstanding potentially dilutive securities that have been excluded from the calculation of diluted net loss per share because their inclusion would be anti-dilutive.

	As of December 31,	
	2024	2023
Unvested common stock upon early exercise of stock options	4,317	74,421
Options to purchase common stock	10,462,129	8,276,442
Estimated shares purchasable under the ESPP	14,280	27,035
	10,480,726	8,377,898

9. Income Taxes

The following is a reconciliation between the provision for income taxes and income taxes computed using the U.S. federal statutory corporate tax rate for the years ended December 31, 2024 and 2023 is as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Expected tax benefit at statutory rate	$ (18,161)	$ (14,518)
State income tax, net of federal benefit	(134)	(67)
Officers compensation	977	389
Permanent items and other	(750)	(374)
Research credits	(4,363)	(3,345)
Change in valuation allowance	22,431	17,915
Provision for income taxes	$ —	$ —

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and deferred tax liabilities as of December 31, 2024 and 2023 are as follows (in thousands):

	As of December 31,	
	2024	2023
Deferred tax assets:		
Net operating loss carryforwards	$ 18,938	$ 14,126
Capitalized research and development	27,105	16,906
Tax credits	10,725	6,412
Stock compensation	5,771	2,871
Other, net	2,267	2,248
Total deferred tax assets	64,806	42,563
Valuation allowance	(63,267)	(40,920)
Deferred tax assets, net of valuation allowance	1,539	1,643
Deferred tax liabilities:		
Depreciation	(256)	(266)
Right of use assets	(1,283)	(1,377)
Total deferred tax liabilities	(1,539)	(1,643)
Net deferred tax assets / (liabilities)	$ —	$ —

The Company has established a valuation allowance against its net deferred tax assets due to the uncertainty surrounding the realization of such assets. The Company periodically evaluates the recoverability of the deferred tax assets. At such time as it is determined that it is more likely than not that deferred assets are realizable, the valuation allowance will be reduced. The Company has recorded a full valuation allowance of $63.3 million as of December 31, 2024 as management cannot conclude that it is more likely than not that certain deferred tax assets will be realized primarily due to the history of losses from inception. The Company increased its valuation allowance by approximately $22.3 million during the year ended December 31, 2024.

At December 31, 2024, the Company had federal and state tax loss carry forwards of approximately $80.5 million and $52.2 million, respectively. As a result of the Tax Cuts and Jobs Act of 2017, for U.S. income tax purposes, net operating losses generated after December 31, 2017 can be carried forward indefinitely, but are limited to 80% utilization against future taxable income each year. Of the amount of federal and state net operating loss carryforwards, $80.5 million and $1.9 million, respectively, can be carried forward indefinitely. Unless previously utilized, certain state net operating losses will begin to expire in 2038.

In accordance with the 2017 Tax Cuts and Jobs Act, research and experimental (R&E) expenses under Internal Revenue Code (IRC) Section 174 are required to be capitalized beginning in 2022. R&E expenses are required to be amortized over a period of five years for domestic expenses and 15 years for foreign expenses. The Company has capitalized R&E expenses in its current tax provision pursuant to the IRC Section 174.

At December 31, 2024, the Company has federal and California research and development tax credits of $11.6 million and $3.0 million, respectively. The federal research and development tax credits begin to expire in 2038 unless previously utilized. The California research and development tax credits carry forward indefinitely.

Pursuant to the IRC Sections 382 and 383, annual use of the Company's net operating loss (NOL) and research and development credit carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period. The Company has not completed an ownership change analysis pursuant to IRC Section 382. If ownership changes have occurred or occurs in the future, the amount of remaining tax attribute carryforwards available to offset taxable income and income tax expense in future years may be restricted or eliminated. If eliminated, the related asset would be removed from deferred tax assets with a corresponding reduction in the valuation allowance.

Uncertain tax positions are evaluated based upon the facts and circumstances that exist at each reporting period. Subsequent changes in judgment based upon new information may lead to changes in recognition, derecognition, and measurement. Adjustment may result, for example, upon resolution of an issue with the taxing authorities or expiration of a statute of limitations barring an assessment for an issue.

The Company recognizes a tax benefit from an uncertain tax position when it is more likely than not that the position will be sustained upon examination by tax authorities.

The following table summarizes the changes to the Company's gross unrecognized tax benefits for the years ended December 31, 2024 and 2023, respectively (in thousands):

	Year Ended December 31,	
	2024	2023
Beginning balance at January 1	$ 3,006	$ 1,574
Additions related to current year positions	1,869	605
Additions related to prior year positions	654	827
Ending balance at December 31	$ 5,529	$ 3,006

Due to the existence of the valuation allowance, future recognition of previously unrecognized tax benefits will not impact the Company's effective tax rate. The Company is subject to taxation in the United States and various state jurisdictions. All of the Company's tax years from inception are subject to examination by federal and state tax authorities. The Company's practice is to recognize interest and penalties related to income tax matters in income tax expense.

The Company had no accrued interest or penalties related to income tax matters in the Company's balance sheet as of December 31, 2024 and has not recognized interest or penalties in the Company's statements of operations and comprehensive loss for the years ended December 31, 2024 and 2023. Further, the Company is not currently under examination by any federal, state or local tax authority.

10. Leases

The Company has operating leases for its office and laboratory space, including its corporate headquarters.

In August 2020, the Company entered into a lease agreement for approximately 4,734 square feet of office and lab space at 2656 State Street in Carlsbad, California, for the Company's headquarters (the Original Lease). The Original Lease commenced in May 2021 and had an original term of 60 months, with an option to extend for two additional 36 month periods.

In March 2022, the Company entered into a lease agreement for approximately 8,331 square feet of additional office and laboratory space at 2676 State Street in Carlsbad, California (the Expansion Lease). The Expansion Lease commenced for accounting purposes when the Company gained access to the premises in May 2023. The Company's obligation for payment of base rent began on the date the landlord delivered possession of the Expansion Lease premises in November 2023. The landlord completed improvements on the Expansion Lease premises, and the Company paid $0.5 million of these costs prior to the Expansion Lease commencement. The Company has concluded that the landlord is the accounting owner of these improvements, and therefore this payment was included in the calculation of the right-of-use asset and lease liability. The Company is entitled to certain rent abatement for delays related to the landlord's delivery of the Expansion Lease premises to the Company. The Expansion Lease has a lease term of 120 months, starting on the day the landlord delivered possession of the Expansion Lease premises. The Company has an option to renew the Expansion Lease for two additional 36 month periods. The Original Lease was also amended to have the same lease expiration as the Expansion Lease.

The Company did not include the renewal periods in determining the lease term, as the Company was not reasonably certain to exercise either the amended Original Lease or the Expansion Lease renewal options.

In connection with the Company's lease agreements, the Company paid security deposits of $0.1 million and is required to maintain a letter of credit of $1.0 million. The letter of credit may be reduced to $0.9 million in 2027 and further reduced to $0.5 million in 2028.

Cash paid for amounts included in the measurement of lease liabilities was $0.8 million for each of the years ended December 31, 2024 and 2023.

The components of lease expense include operating, short-term, and variable lease costs. Amortization is recorded within research and development and general and administrative expenses in the statements of operations and comprehensive loss. Components of lease cost for the years ended December 31, 2024 and 2023, respectively, were as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Operating lease cost	$ 957	$ 708
Short-term lease cost	90	61
Variable lease cost	127	79
Total lease cost	$ 1,174	$ 848

Maturities of lease liabilities, weighted-average remaining term and weighted-average discount rate were as follows (in thousands):

	As of December 31,
Year ending December 31,	
2025	$ 874
2026	900
2027	927
2028	955
2029	983
Thereafter	4,048
Total minimum lease payments	8,687
Less: amount representing interest	(2,465)
Present value of lease liabilities	6,222
Less: current portion of lease liabilities	(412)
Lease liabilities, noncurrent	$ 5,810

	December 31, 2024	December 31, 2023
Weighted-average remaining lease term (years) - operating leases	8.9	9.9
Weighted-average incremental borrowing rate - operating leases	8.07%	8.07%

11. Commitments and Contingencies

Other Funding Commitments

As of December 31, 2024, the Company had ongoing clinical and pre-clinical studies for its various programs. The Company enters into contracts in the normal course of business with contract research organizations in preparation for clinical trials, professional consultants for expert advice and other vendors for clinical supply manufacturing or other services. These contracts are generally cancellable, with notice, at the Company's option and do not have significant cancellation penalties.

Litigation

The Company, from time to time, may be party to litigation arising in the ordinary course of business. The Company was not subject to any material legal proceedings as of December 31, 2024, and no material legal proceedings are currently pending or threatened. If the potential loss from any claim, asserted or unasserted, or legal proceeding is considered probable and the amount is reasonably estimable, the Company will accrue a liability for the estimated loss.

12. Employee Benefits

The Company offers a 401(k) plan (401(k) Plan) for all employees who have met certain eligibility requirements. Under the 401(k) Plan, employees may elect to contribute a portion of their eligible compensation, subject to certain limitations. The Company did not make any matching employer contributions to the 401(k) Plan for the years ended December 31, 2024 and 2023.

13. Segment Information

The Company reports segment information based on the management approach, which reflects the way in which the internal reporting is used by the chief operating decision maker (“CODM”) to analyze performance, make decisions and allocate resources. The CODM is the Company’s Chief Executive Officer.

The Company manages its operations as a single reportable segment, which includes all activities related to the research, development, and potential future commercialization of its small molecule drug development candidates. The CODM assesses performance and decides how to allocate resources based on net loss (presented in the Statements of Operations and Comprehensive Loss). The measure of segment assets is reported on the Balance Sheets as total assets. All long-lived assets are located in the United States.

The table below shows a reconciliation of the Company's net loss, including the significant expense categories regularly provided to and reviewed by the CODM, to the Company's total net loss in the Statements of Operations and Comprehensive Loss (in thousands):

	Year ended December 31,	
	2024	2023
Research and development expenses:		
External research and development expenses by program:		
TYRA-300^{ACH}	$ 7,718	$ 5,268
TYRA-300^{mUC}	14,319	15,613
TYRA-430	5,677	4,987
TYRA-200	4,969	4,418
FGFR discovery	8,321	5,492
Other development programs	2,537	2,448
Unallocated research and development expenses:		
Personnel costs[(1)]	30,423	20,039
Facilities and other costs[(2)]	6,113	4,253
Total research and development expenses	80,077	62,518
General and administrative expenses[(3)]	24,100	17,427
Interest and other income, net	(17,696)	(10,811)
Net loss	$ (86,481)	$ (69,134)

[(1)] Personnel costs include $14.3 million and $8.3 million of stock-based compensation for the years ended December 31, 2024 and 2023, respectively.

[(2)] Facilities and other costs consist of research consumables, facility-related costs, depreciation and costs not attributed to a specific program.

[(3)] General and administrative expenses consist of personnel-related expenses, including stock-based compensation, legal fees, facility-related costs, depreciation, professional and consulting fees and insurance costs.

14. Subsequent Events

Subsequent to December 31, 2024, Exchange Warrants (as defined in Note 6) to purchase an aggregate of 2,000,000 shares of common stock and 2024 Pre-Funded Warrants (as defined in Note 6) to purchase 237 shares of common stock were exercised in cashless transactions, which resulted in an aggregate of 2,000,069 shares of common stock being issued.

Effective January 1, 2025, the Company amended its 401(k) Plan to adopt a program to match 100% of employee contributions to the 401(k) Plan up to a maximum of 4% of eligible earnings, subject to statutory limitations.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and our chief financial officer (our principal executive officer and principal financial and accounting officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2024. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission (the SEC)'s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

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. Based on the evaluation of our disclosure controls and procedures as of December 31, 2024, our chief executive officer and our chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management’s Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rules 13a-15(f). Management assessed our internal control over financial reporting as of December 31, 2024, and based its assessment on criteria established in "Internal Control - Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on that assessment, our management concluded that our internal control over financial reporting was effective as of December 31, 2024.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Director and Officer Trading Arrangements:

Rule 10b5-1 Trading Plans

From time to time, our officers (as defined in Rule 16a-1(f) of the Exchange Act) and directors may enter into Rule 10b5-1 or non-Rule 10b5-1 trading arrangements (as each such term is defined in Item 408 of Regulation S-K). During the three months ended December 31, 2024, certain of our officers adopted such trading arrangements as noted below:

			Trading Arrangement			
Name and Title	**Action**	**Date**	**Rule 10b5-1***	**Non-Rule 10b5-1****	**Total Shares Authorized to be Sold*****	**Expiration Date**
Todd Harris President, Chief Executive Officer and Director	Adoption	11/4/2024	X		315,000	12/31/2026
Daniel Bensen Chief Operating Officer	Adoption	11/5/2024	X		350,000	2/26/2027
Alan Fuhrman Chief Financial Officer	Adoption	11/5/2024	X		80,000	7/31/2026

* Intended to satisfy the affirmative defense of Rule 10b5-1(c)
** Not intended to satisfy the affirmative defense of Rule 10b5-1(c)
*** Represents the maximum number of shares that may be sold pursuant to the 10b5-1 arrangement. The number of shares sold is dependent on the satisfaction of certain conditions as set forth in the written plan and the satisfaction of applicable vesting conditions of equity awards.

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information required by this item and not set forth below will be contained in our definitive proxy statement to be filed with the SEC in connection with our 2025 Annual Meeting of Stockholders (the Definitive Proxy Statement), which is expected to be filed not later than 120 days after the end of our fiscal year ended December 31, 2024, and is incorporated herein by reference.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics that applies to our officers, directors and employees, which is available on our website at www.tyra.bio. The Code of Business Conduct and Ethics contains general guidelines for conducting the business of our company consistent with the highest standards of business ethics and is intended to qualify as a "code of ethics" within the meaning of Section 406 of the Sarbanes-Oxley Act of 2002 and Item 406 of Regulation S-K. In addition, we intend to promptly disclose (1) the nature of any amendment to our Code of Business Conduct and Ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions and (2) the nature of any waiver, including an implicit waiver, from a provision of our code of ethics that is granted to one of these

specified officers, the name of such person who is granted the waiver and the date of the waiver on our website in the future.

Insider Trading Policy and Procedures

We have adopted an insider trading policy and procedures governing the purchase, sale, and/or other dispositions of our securities by our directors, officers, employees and other covered persons that are designed to promote compliance with insider trading laws, rules and regulations, and the Nasdaq Stock Market LLC listing rules, as applicable. A copy of our Insider Trading Compliance Policy and Procedures is filed as Exhibit 19.1 to this Annual Report. It is our policy to comply with U.S. insider trading laws and regulations, including with respect to transactions in our own securities.

Item 11. Executive Compensation.

Information required by this item will be contained in our Definitive Proxy Statement and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Information required by this item will be contained in our Definitive Proxy Statement and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Information required by this item will be contained in our Definitive Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

Information required by this item will be contained in our Definitive Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

1. Financial Statements.

The financial statements of Tyra Biosciences, Inc., together with the report thereon of Ernst & Young LLP, an independent registered public accounting firm (PCAOB ID No. 42), are included in this Annual Report contained in Part II, Item 8. Financial Statements and Supplementary Data.

2. Finance Statement Schedules.

All schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

3. Exhibits.

A list of exhibits is set forth on the Exhibit Index immediately preceding the signature page of this Annual Report and is incorporated herein by reference.

Item 16. Form 10-K Summary.

None.

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation	10-K	3/22/23	3.1	
3.2	Amended and Restated Bylaws, effective as of October 26, 2023	8-K	10/26/23	3.1	
4.1	Specimen stock certificate evidencing the shares of common stock	S-1	8/20/21	4.1	
4.2	Amended and Restated Investors' Rights Agreement, dated March 5, 2021, by and among the Registrant and certain of its stockholders	S-1/A	9/9/21	4.2	
4.3	Description of Registered Securities	10-K	3/3/22	4.3	
4.4	Form of Pre-Funded Warrant	8-K	2/5/24	4.1	
10.1#	Tyra Biosciences, Inc. 2020 Equity Incentive Plan and form of stock option agreement thereunder	S-1	8/20/21	10.1	
10.2#	Tyra Biosciences, Inc. 2021 Incentive Award Plan and form of stock option grant notice and stock option agreement thereunder	S-1/A	9/9/21	10.2	
10.3#	Tyra Biosciences, Inc. 2021 Employee Stock Purchase Plan	S-1/A	9/9/21	10.3	
10.4#	Non-Employee Director Compensation Program, amended and restated effective May 1, 2024	10-Q	5/9/2024	10.3	
10.5#	Tyra Biosciences, Inc. Annual Bonus Plan	10-K	3/22/23	10.5	
10.6#	Second Amended and Restated Employment Letter Agreement, dated August 18, 2021, by and between Todd Harris and the Registrant	S-1	8/20/21	10.12	
10.7#	Second Amended and Restated Employment Letter Agreement, dated August 18, 2021, by and between Daniel Bensen and the Registrant	S-1	8/20/21	10.13	
10.8#	Employment Letter Agreement, dated December 31, 2022, by and between Alan Fuhrman and the Registrant	10-K	3/22/23	10.14	
10.9#	Employment Agreement, dated September 9, 2024, between the Registrant and Douglas Warner, M.D.	10-Q	11/7/2024	10.2	
10.10#	Transition Agreement, dated August 3, 2024, between the Registrant and Hiroomi Tada, M.D., Ph.D.	10-Q	11/7/2024	10.1	
10.11#	Form of Indemnification Agreement for Directors and Officers	S-1	8/20/21	10.20	
10.12	Office Lease, between the Registrant and Fabric 2656 State, LLC, a California limited liability company, dated August 5, 2020	S-1	8/20/21	10.19	
10.13	First Amendment to Lease, between the Registrant and Fabric 2656 State, LLC, a California limited liability company, dated March 2, 2022	10-K	3/3/22	10.14	
10.14	Second Amendment to Lease, between the Registrant and Fabric 2656 State, LLC, a California limited liability company, dated December 20, 2022	10-K	3/22/23	10.19	
10.15	Office Lease, between the Registrant and Fabric 2676 State Street, LLC, a California limited liability company, dated March 2, 2022	10-K	3/3/22	10.15	
10.16	First Amendment to Lease, between the Registrant and Fabric 2676 State, LLC, a California limited liability company, dated May 16, 2022	10-K	3/22/23	10.21	

10.17	Second Amendment to Lease, between the Registrant and Fabric 2676 State, LLC, a California limited liability company, dated January 6, 2023	10-K	3/22/23	10.22	
10.18	Third Amendment to Lease, between the Registrant and Fabric 2676 State, LLC, a California limited liability company, dated March 18, 2024	10-K	3/19/2024	10.23	
10.19	ATM Sales Agreement, dated October 3, 2022, by and between Virtu Americas LLC and the Registrant	8-K	10/3/22	1.2	
19.1	Insider Trading Compliance Policy and Procedures				X
23.1	Consent of Independent Registered Public Accounting Firm				X
31.1	Certification of Chief Executive Officer, as required by Rule 13a-14(a) or Rule 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				X
31.2	Certification of Chief Financial Officer, as required by Rule 13a-14(a) or Rule 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				X
32.1*	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				X
32.2*	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				X
97.1	Policy for Recovery of Erroneously Awarded Compensation	10-K	3/19/2024	97.1	
101.INS	Inline XBRL Instance Document - the Instance Document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document				X
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents				X
104	Cover Page Interactive Data File (embedded within the Inline XBRL Document)				X

# Indicates management contract or compensatory plan.
* This certification is deemed not filed for purpose of Section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.
** Certain schedules and annexes have been omitted in accordance with Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule and/or annex will be furnished as a supplement to the U.S. Securities and Exchange Commission upon request.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

TYRA BIOSCIENCES, INC.

/s/ Todd Harris, Ph.D.
Todd Harris, Ph.D.
President, Chief Executive Officer, and Director

Date: March 27, 2025

Pursuant to the requirements of the Securities 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.

Name	Title	Date
/s/ Todd Harris, Ph.D. **Todd Harris, Ph.D.**	President, Chief Executive Officer and Director (principal executive officer)	March 27, 2025
/s/ Alan Fuhrman **Alan Fuhrman**	Chief Financial Officer (principal financial and accounting officer)	March 27, 2025
/s/ Adele M. Gulfo **Adele M. Gulfo**	Director	March 27, 2025
/s/ Gilla Kaplan, Ph.D. **Gilla Kaplan, Ph.D.**	Director	March 27, 2025
/s/ Melissa McCracken, Ph.D. **Melissa McCracken, Ph.D.**	Director	March 27, 2025
/s/ Susan Moran, M.D., M.S.C.E. **Susan Moran, M.D., M.S.C.E.**	Director	March 27, 2025
/s/ Robert More **Robert More**	Director	March 27, 2025
/s/ S. Michael Rothenberg, M.D., Ph.D. **S. Michael Rothenberg, M.D., Ph.D.**	Director	March 27, 2025
/s/ Jake Simson, Ph.D **Jake Simson, Ph.D.**	Director	March 27, 2025
/s/ Rehan Verjee **Rehan Verjee**	Director	March 27, 2025