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 001-39926

Terns Pharmaceuticals, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**98-1448275**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1065 East Hillsdale Blvd., Suite 100 Foster City, California	**94404**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 525-5535

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	**TERN**	**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, a 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 approximate aggregate market value of the registrant's Common Stock held by non-affiliates based upon the last sale price of the Common Stock as reported on the Nasdaq Global Select Market as of June 30, 2024 was $426,783,524. Common Stock held by our executive officers, directors and certain stockholders as of such date has been excluded from this calculation because such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares of registrant's Common Stock outstanding as of March 14, 2025 was 87,297,629.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the information called for by Part III of this Annual Report on Form 10-K is hereby incorporated by reference from the definitive proxy statement for the registrant's 2025 annual meeting of stockholders, which will be filed with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year ended December 31, 2024.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business, operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that are in some cases beyond our control and 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.

In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "predict," "potential," "positioned," "seek," "should," "target," "will," "would," and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- our expectations with regard to the results of our clinical studies, preclinical studies and research and development programs, including the timing and availability of data from such studies;
- the location, timing of commencement and data reporting of future nonclinical studies and clinical trials and research and development programs;
- our clinical and regulatory development plans;
- our expectations regarding the product profile, relative benefits and clinical utility of our product candidates;
- our expectations regarding the potential market size and size of the potential patient populations for our product candidates and any future product candidates if approved for commercial use;
- our ability to acquire, discover, develop and advance our product candidates into, and successfully complete, clinical trials;
- our intentions and our ability to establish collaborations and/or partnerships;
- the timing or likelihood of regulatory filings and approvals for our product candidates;
- our commercialization, marketing and manufacturing capabilities and expectations;
- our intentions with respect to the commercialization of our product candidates;
- the pricing and reimbursement of our product candidates, if approved;
- the implementation of our business model and strategic plans for our business and product candidates, including additional indications which we may pursue or elect not to pursue;
- the scope of protection we are able to establish, maintain, protect and enforce for intellectual property rights covering our product candidates including the projected terms of patent protection;
- estimates of our expenses, future revenue, capital requirements, our needs for additional financing and our ability to obtain additional capital and the timing of the sufficiency of our capital resources;
- our future financial performance; and
- developments and projections relating to our competitors and our industry, including competing products.

Summary of Principal Risks Associated with Our Business

- We are a clinical-stage biopharmaceutical company with a limited operating history and no products approved for commercial sale. We have incurred significant losses since our inception, and we anticipate that we will continue to incur significant losses for the foreseeable future, which, together with our limited operating history, makes it difficult to assess our future viability.
- We will require substantial additional financing 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 product development programs, commercialization efforts or other operations.
- We are early in our development efforts. Our business is heavily dependent on the successful development, regulatory approval and commercialization of our current and future product candidates.
- Clinical drug development involves a lengthy and expensive process with uncertain timelines and outcomes, and results of earlier studies and trials may not be predictive of future trial results. If development of our product candidates is unsuccessful or delayed, we may be unable to obtain required regulatory approvals and we may be unable to commercialize our product candidates on a timely basis, if at all.
- We face significant competition for our drug discovery and development efforts in an environment of rapid technological and scientific change, and our product candidates, if approved, will face significant competition, which may prevent us from achieving significant market penetration. Many of our competitors have significantly greater resources than we do, and we may not be able to successfully compete.
- Our development programs are focused on product candidates for the treatment of chronic myeloid leukemia, or CML, and obesity. For one or more of these programs, we may not be able to gain agreement with regulatory authorities regarding an acceptable development plan, the outcome of our clinical trials may not be favorable and, even if favorable, regulatory authorities may not find the results of our clinical trials to be sufficient for marketing approval. This makes it difficult to predict the timing and costs of the clinical development of our product candidates.
- We rely completely on third parties to manufacture our clinical drug supplies and we intend to rely on third parties to produce commercial supplies of any approved product candidate, and our commercialization of any of our product candidates could be stopped, delayed or made less profitable if those third parties fail to obtain approval of the United States Federal Drug Administration, or FDA, or comparable regulatory authorities, fail to provide us with sufficient quantities of drug product or fail to do so at acceptable quality levels or prices.
- We rely on third parties to conduct, supervise and monitor our preclinical and clinical trials. If these third parties do not successfully carry out their contractual duties, meet rigorously enforced regulatory standards or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize any of our product candidates on a timely basis or at all.
- The successful commercialization of our product candidates will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement levels and pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those drugs and decrease our ability to generate revenue.
- Even if our current or future product candidates obtain regulatory approval, they may fail to achieve the broad degree of physician and patient adoption and use necessary for commercial success.
- Our current and any future product candidates could be alleged to infringe patent rights and other intellectual property rights of third parties, which may require costly litigation and, if we are not successful, could cause us to pay substantial damages and/or limit our ability to commercialize our drugs and combination therapy candidates.

- If we are unable to obtain, maintain and enforce intellectual property protection directed to our current and any future technologies that we develop, others may be able to make, use or sell products substantially the same as ours, which could adversely affect our ability to compete in the market.
- If we fail to attract and retain senior management and key scientific personnel or if we lose our personnel for health or other reasons, our business may be materially and adversely affected.
- Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, financial condition, results of operations and prospects.
- Changes in U.S. and international trade policies, particularly with respect to China, may adversely impact our business and operating results.
- China's economic, political and social conditions, as well as government policies, could affect our ability to operate our business.
- 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.

PART I

Item 1. Business.

Company Overview

We are a clinical-stage biopharmaceutical company developing a portfolio of small-molecule product candidates to address serious diseases, including oncology and obesity. Our programs are based on mechanisms of action that have achieved proof-of-concept in clinical trials in indications with significant unmet medical needs. We are advancing multiple drug candidates we believe have the potential to deliver improved clinical outcomes in the target indication as either single-agent or combination therapies. The most advanced product candidates in our pipeline – TERN-701, TERN-601 and TERN-501 – were internally discovered. Additionally, we have an ongoing discovery effort for the TERN-800 series of small-molecule glucose-dependent insulinotropic polypeptide receptor (GIPR) modulators for obesity, which have the potential to be combined with glucagon-like peptide-1 (GLP-1) receptor agonists, such as TERN-601.

Our Development Pipeline

The following table highlights our current development pipeline:

PROGRAM	MECHANISM	INDICATION	PRECLINICAL	EARLY-STAGE CLINICAL DEVELOPMENT	LATE-STAGE CLINICAL DEVELOPMENT	STATUS / NEXT ANTICIPATED MILESTONE
Oncology						
TERN-701	Allosteric BCR-ABL Inhibitor	CML	Phase 1 CARDINAL		*Anticipated registrational trial following Ph 1 trial*	**Ph1 CARDINAL ongoing** Positive early data in Dec '24; dose expansion to start in 2Q25; additional efficacy data in 4Q25
Metabolic						
TERN-601	Oral GLP-1R Agonist	Obesity	Phase 2			**Positive top-line Ph1 data (28-day PoC) Sept '24** Phase 2 underway, initial 12-week data in 4Q25
TERN-501 Combination	THR-β Agonist + Metabolic Agent	Obesity	Phase 2 Ready			**Positive Ph2a NASH data** Preclinical data in combo with GLP-1 (enhanced and higher quality weight)
TERN-800 Series	GIPR Modulators	Obesity	GIPR Antagonist Lead Opt.			**GIPR antagonist lead optimization underway**

Pipeline Candidate in Oncology:

TERN-701 is our proprietary, oral, potent, allosteric BCR-ABL tyrosine kinase inhibitor (TKI) specifically targeting the ABL myristoyl pocket for CML, a form of cancer that begins in the bone marrow and leads to the growth of leukemic cells and is classified as an orphan indication. Terns previously announced positive early data from the Phase 1 CARDINAL trial of TERN-701, demonstrating compelling molecular responses and an encouraging safety profile with no dose limiting toxicities (DLTs), adverse event (AE)-related treatment discontinuations or dose reductions across all dose escalation cohorts. Additional safety and efficacy data from CARDINAL are expected in the fourth quarter of 2025.

Pipeline Candidates for Metabolic Diseases:

TERN-601 is our small-molecule GLP-1 receptor agonist that is intended to be orally administered once-daily for obesity. Obesity is a chronic disease that is increasing in prevalence in adults, adolescents and children and is often defined by having an elevated body mass index (BMI) of 30 or greater. Terns previously announced positive results from the Phase 1 trial of TERN-601, demonstrating weight loss over 28 days up to 5.5% and favorable safety and tolerability despite rapid dose titration every three days. The Phase 2 FALCON trial of TERN-601 initiated with the first patient enrolled in March 2025, and 12-week data are expected in the fourth quarter of 2025.

TERN-501 is our thyroid hormone receptor beta (THR-β) agonist initially developed for metabolic dysfunction-associated steatohepatitis (MASH). Since announcing positive top-line data from the Phase 2a DUET trial in August 2023, we decided to limit spend in the development of TERN-501 for MASH given the current regulatory and clinical development requirements for the indication. We continue to evaluate opportunities for TERN-501 in other metabolic diseases.

TERN-800 series is our ongoing effort to discover small molecule GIPR modulators for obesity, which we believe has the potential for combination with GLP-1 receptor agonists, such as TERN-601. We are prioritizing our discovery efforts towards nominating a GIPR antagonist development candidate based on in-house discoveries and growing specific scientific rationale supporting the potential of GLP-1 receptor agonist and GIPR antagonist combinations for obesity.

Background on Chronic Myeloid Leukemia

CML is classified as an orphan indication and is the second most common adult-onset leukemia in the United States. The prevalence of CML is approximately 90,000 cases in the United States and is expected to reach 180,000 cases in the United States by 2030. In 2025, approximately 9,560 new cases of CML are expected to be diagnosed in the United States, with an expected mortality rate of 1,290 people.

CML is a form of cancer that begins in bone marrow and leads to growth of leukemic cells. Bone marrow is a sponge-like tissue within most bones and is responsible for producing red blood cells, white blood cells and platelets. Leukemia occurs when cancerous blood cells form and overcrowd healthy blood cells within the bone marrow. Leukemias may be defined as acute or chronic, which characterizes how rapidly the disease progresses without treatment. Chronic leukemias progress slowly whereas acute forms tend to progress rapidly. CML develops slowly and involves the myeloid white blood cells of the bone marrow. Over time, the bone marrow produces too many white blood cells, causing excess cells to accumulate in the blood and/or bone marrow. This type of leukemia can be fatal and is caused by an error during the natural cell division process. One type of error is known as translocation, which takes place when one segment of a chromosome separates and attaches to another chromosome. The result of this translocation is known as a fusion gene, an abnormal gene formed when two different genes become fused together. CML is caused by the spontaneous chromosomal translocation of chromosomes 9 and 22. The breakpoint cluster region (BCR) gene on chromosome 22 fuses with the proto-oncogene ABL1 kinase on chromosome 9, creating the BCR-ABL1 fusion oncogene. The result is chromosome 9 being longer than normal and chromosome 22 being shorter than normal. The abnormal chromosome 22 is known as the Philadelphia (Ph) chromosome.

In the chronic phase, leukemic cell proliferation is highly dependent on constitutively active BCR-ABL kinase activity that drives unregulated division of leukemic cells. CML cells crowd out the bone marrow's heathy red blood, white blood and platelet cells and can cause weakness, fatigue, shortness of breath, fever, bone pain and weight loss, amongst other symptoms. Left untreated, CML can progress to become a potentially fatal disease. CML accounts for approximately 15% of newly diagnosed cases of leukemia in adults. The average age of diagnosis is approximately 64 years old, with approximately 50% of CML patients diagnosed at greater than 65 years old. CML is rarely seen in children.

Treatment of CML

CML treatment was transformed by the development and approval of active-site TKIs. The first approved TKI for CML, imatinib, was approved in 2001. Approvals of additional active-site TKIs include dasatinib, nilotinib and bosutinib in 2006, 2007 and 2012, respectively. Each of these active-site TKIs are approved for newly diagnosed or refractory / intolerant patient populations. Ponatinib, which is approved for use in adult patients with the T315I mutation, also gained approval in 2012. Usage of these active-site TKIs have transformed CML from a fatal disease to a chronic condition, where patients may live for decades following diagnosis.

A novel class of TKIs, known as allosteric TKIs, target the myristoyl-binding pocket, locking BCR-ABL1 into the inactive state. Allosteric TKIs are highly selective to the ABL1 myristoyl-binding pocket, and virtually inactive against other cellular kinases, avoiding the off-target effects of the active-site TKIs. Furthermore, mutations in the active-site pocket, such as T315I, may occur frequently, which may ultimately render active-site TKIs ineffective against CML. Allosteric TKIs are largely unaffected by many active-site resistance mutations. The first approved allosteric TKI, asciminib, which validated this mechanism of action, was approved in 2021, and has demonstrated significantly improved clinical efficacy, safety and tolerability compared to an active-site TKI over 96 weeks. We believe TERN-701 is generating emerging data to support a potential best in class profile with improved efficacy, safety and convenience relative to asciminib.

BCR-ABL TKIs for CML

Imatinib represents the first approved active-site TKI, and transformed CML into a disease that can be survived with chronic therapy. Imatinib is approved for newly diagnosed adults and children with Philadelphia chromosome-positive (Ph+) CML in chronic phase and patients in chronic, accelerated or blast phase with Ph+ CML, after failure of interferon-alfa therapy. However, approximately half of patients treated with imatinib develop resistance or intolerance and may progress onto alternative active-site TKIs. Dasatinib, nilotinib and bosutinib are approved for newly diagnosed adults with Ph+ CML in chronic phase and adults in chronic, accelerated or blast phase Ph+ CML with resistance or intolerance to prior therapy. Ponatinib is approved for adult patients with chronic phase, accelerated phase, or blast phase CML for whom no other TKI is indicated and adults with the T315I mutation. These active-site TKIs offer increased potency over imatinib but worse AE profiles and reduced tolerability. Due to resistance or side effect intolerance, approximately 40% of patients treated with active-site TKIs are switched to an alternative TKI therapy. With largely overlapping efficacy and safety profiles, the active-site TKIs (dasatinib, nilotinib and bosutinib) cumulatively generated approximately $4 billion in 2024 sales, despite the availability of generic imatinib.

Allosteric BCR-ABL inhibitors represent a novel class of CML therapy that specifically targets the ABL myristoyl pocket. Asciminib is the first and only approved allosteric inhibitor for CML. In January 2024, Novartis announced top-line data from its Phase 3 study, ASC4FIRST (NCT04971226), of asciminib against investigator-selected TKIs in newly diagnosed (front-line) CML patients. The ASC4FIRST trial met both primary endpoints with clinically meaningful and statistically significant results. Asciminib showed superior major molecular response (MMR) rates at week 48 compared to standard-of-care TKIs including imatinib, nilotinib, dasatinib and bosutinib in newly diagnosed Ph+ CML chronic phase patients. Asciminib also demonstrated a favorable safety and tolerability profile with fewer AEs and treatment discontinuations compared to standard-of-care active-site TKIs, with no new safety signals observed. As of October 2024, asciminib is approved for both newly diagnosed and previously treated CML. Novartis anticipates approximately $3 billion peak sales for asciminib across various lines of therapy.

Clinical validation of BCR-ABL TKIs

CML treatment response is measured through periodic assessments of blood and bone marrow tests. The three types of treatment response are molecular, hematologic and cytogenic response.

Molecular response (MR) is a decrease in the number of cells in the blood with the BCR-ABL gene. A quantitative PCR test is used to measure the number of blood cells containing the BCR-ABL gene and is quantified as a percentage. The initial molecular response to therapy is a significant predictor of outcomes. As a result, MR is the most sensitive method of monitoring BCR-ABL transcripts and is the most relevant in determining further treatment options. Early molecular response (EMR) is achieved when the BCR-ABL1 level is 10% or less at 3 and 6 months after the start of treatment. In EMR, leukemia cells have been reduced by 90% or more. MMR is achieved when the BCR-ABL1 level has decreased to 0.1%, signaling that leukemia cells have been reduced by 99.9% or more. A deep molecular response (DMR) is achieved when the BCR-ABL1 level has decreased to 0.01% or less. When BCR-ABL1 levels can no longer be detected, the patient has achieved Complete Molecular Response.

Hematologic response can be categorized as either partial or complete, depending on the results of a complete blood count test. This assessment measures the number of red blood cells, white blood cells and platelets in the blood. A partial hematologic response is achieved when the number of each blood cell type begins to revert to normal levels. A complete hematologic response is achieved when blood cell counts return to normal and may be observed within one month of treatment initiation. Cytogenic response is assessed by measuring the percentage of cells in the bone marrow containing the Philadelphia chromosome (for example, Ph+ cells). Cytogenic evaluations of bone marrow cells are conducted at three-month intervals to assess a patient's response to treatment. A minor cytogenic response is achieved when the Philadelphia chromosome is present in more than 35% of bone marrow cells. A major cytogenic response is achieved when 35% or fewer cells have the Philadelphia chromosome. When no cells with the Philadelphia chromosome are detected in the bone marrow, a complete cytogenic response is achieved.

In pre-treated third-line patients, asciminib achieved an MMR in 25% of patients by 6 months, which was superior to and approximately two-fold greater bosutinib's MMR rate of 13%, which was adequate to gain accelerated approval in the third-line setting. When asciminib's Phase 3 study progressed to 96 weeks, asciminib achieved MMR in 38% of pretreated third-line patients, more than doubling bosutinib's 16% MMR response rate, resulting in a full approval in the third-line setting. The discontinuation rate after 96 weeks due to the lack of efficacy or AEs in patients on asciminib was nearly half of the rate of patients on bosutinib (31.2% asciminib v. 60.5% bosutinib).

Allosteric BCR-ABL inhibitors have demonstrated clinical benefits as front-line CML treatment in addition to third-line treatment. In the front-line ASC4FIRST Phase 3 study, asciminib showed superior MMR rates at week 48 compared to standard-of-care TKIs (68% v. 49%) in a front-line setting. Asciminib also demonstrated a favorable safety and tolerability profile with fewer AEs and treatment discontinuations compared to standard-of-care TKIs. Overall, asciminib had higher rates of EMRs and DMRs and a markedly favorable safety and tolerability profile at week 48 compared to both imatinib and second generation TKIs. In October 2024, asciminib was granted accelerated approval for newly diagnosed Ph-positive chronic-phase CML.

Limitations of BCR-ABL TKIs

Unmet medical needs in CML remain due to (1) an increasing number of patients becoming refractory or intolerant to the current standard of care, (2) safety concerns for active-site TKIs used in CML patients who are resistant or intolerant to prior TKI therapy, and (3) BCR-ABL mutations that are difficult for active-site TKIs to treat (e.g., T315I).

People with CML can expect to live life-spans nearly as long as healthy adults, and CML treatment is life-long for a high proportion of patients. As a result, treatment is selected and modified throughout the often decades long treatment period to address the course of individual patients' CML disease over time as well as patients' individual needs as they age. A recent publication estimated that approximately 40% of people started on any TKI switch to an alternative TKI. Physicians guide treatment decisions on molecular response to treatment as well as other individual patient needs including drug tolerability, co-morbidity and drug-drug interaction profiles, which may evolve over time. For example, nilotinib-treated patients may be switched to imatinib and bosutinib which are preferred treatment options for patients experiencing cardiovascular or peripheral artery comorbidities, while nilotinib is less preferred. In contrast, nilotinib and dasatinib may be selected as replacement therapies for patients experiencing gastrointestinal or renal comorbidities in whom imatinib and bosutinib are less recommended. Survival rates and treatment durations for people living with CML continue to increase. As a result, physicians are seeking additional novel therapies that are safe, efficacious and well tolerated to address their patients' changing needs over time. In later lines of CML treatment, patients may experience greater challenges with intolerance. For patients who have failed two or more TKIs, up to 55% were intolerant to a previous TKI. Even low-grade, chronic TKI intolerance can impact a patient's compliance with therapy, which in turn can lead to poorer outcomes.

During treatment with agents that inhibit BCR-ABL kinase activity, leukemic cells may also develop resistance mutations, which can block the binding of active-site TKIs and render them ineffective. Approximately 15% to 20% of patients develop BCR-ABL mutations or molecular abnormalities. T315I represents one variation of active-site mutation that renders most active-site TKIs ineffective. Ponatinib is the only active-site TKI approved for the treatment of patients with the T315I mutation but carries black box warning for cardiovascular and other toxicity. Potential resistance in second- and third-line treatment can result in poorer efficacy outcomes and increased risk of discontinuation. Mutations within the BCR-ABL kinase domain may also affect the ability of the majority of active-site TKIs to bind and inhibit BCR-ABL.

Allosteric TKIs, which bind to the myristoyl-binding pocket, represent a novel treatment class for CML and have the potential to address the shortcomings of active-site TKIs, including off-target activity and limited efficacy against active site resistance mutations. Asciminib, the first approved allosteric TKI, is also indicated for the treatment of CML in patients with the T315I mutation although at five times higher than the daily total dose used to treat patients without T315I. High dose asciminib is associated with safety and tolerability issues that may lead to lower adherence in CML patients with T315I. Despite the significant advantages of allosteric TKIs over active-site TKIs, as a class, we believe asciminib leaves opportunities to develop a best in class allosteric TKI with improved efficacy, safety and convenience.

Our solution for BCR-ABL TKIs

TERN-701 aims to address the limitations of active-site TKIs with the goal of achieving improved tumor suppression through a combination of (1) improved efficacy against BCR-ABL, including a broad range of mutations, (2) improved safety and tolerability profiles, and an improved drug-drug interaction profile, and (3) improved convenience with once-a-day dosing for all patients, with or without food. Supporting efficacy data include numerically greater potency than asciminib against multiple BCR-ABL variants, improved pharmacokinetic (PK) and target coverage over asciminib and rescue of clinical response in asciminib failures. TERN-701 has also demonstrated a promising safety profile relative to asciminib, with no DLTs and no AE-related treatment discontinuations or dose reductions in the dose escalation phase of our Phase 1 trial. In healthy volunteer studies, TERN-701 also demonstrated the ability to be dosed once-daily without regard to food, as well as a favorable drug-drug interaction profile, which represents potential key differentiators over asciminib.

Given the emerging clinical profile, we believe TERN-701 has broad opportunities across front- and second-line patient settings. In the front-line, where the allosteric class has demonstrated improvements over active-site TKIs, TERN-701 is building a differentiated profile that has the potential to offer improved efficacy, safety and convenience compared to asciminib. As a result, if TERN-701 successfully completes clinical development and is approved for marketing, we have an opportunity to potentially treat a significant share of newly diagnosed patients. We anticipate that there will be a meaningful share of front-line patients starting on a generic active-site TKI due to cost. Based on historical data, approximately 40% of those who started on an active-site TKI will need to switch therapies due to suboptimal response and/or tolerability and are likely to switch to an allosteric TKI. If approved for marketing, we believe that TERN-701 can be positioned as the allosteric TKI of choice for all patients switching to an allosteric TKI. In the Phase 1 data to date, TERN-701 demonstrated compelling molecular responses in patients who have experienced suboptimal response or intolerance to active-site TKIs and asciminib. Physicians and people with CML continue to seek novel therapies that provide improved efficacy, safety and convenience.

Clinical development of TERN-701

In July 2020, Hansoh (Shanghai) Healthtech Co., Ltd. and Jiangsu Hansoh Pharmaceutical Group Company Ltd. (collectively, Hansoh) in-licensed TERN-701 for development in the greater China region. TERN-701 is referred to by Hansoh as HS-10382. In May 2022, Hansoh initiated an open-label, multicenter, dose-escalation and expansion, first-in-human study in chronic or accelerated phase CML patients, who are resistant or intolerant to prior active-site BCR-ABL TKI treatment. Hansoh is responsible for all development costs in the greater China region, including the ongoing Phase 1 trial in China.

Our Phase 1 trial, CARDINAL, is progressing and includes sites from the United States, Europe and other countries. The FDA granted Orphan Drug Designation for TERN-701 for the treatment of chronic myeloid leukemia in March 2024.

The CARDINAL trial is an ongoing global, multicenter, open-label, two-part Phase 1 clinical trial to evaluate the safety, PK, and efficacy of TERN-701 in patients with previously treated CML. Part 1 is the dose escalation portion of the trial evaluating once-daily TERN-701 monotherapy in up to five dose cohorts in up to 60 adults with chronic phase CML with confirmed BCR-ABL and a history of treatment failure or suboptimal response to at least one second generation TKI (nilotinib, dasatinib or bosutinib). Participants who are intolerant to prior TKI treatment (including asciminib) are also allowed. The primary endpoints for Part 1 are the incidence of DLTs during the first treatment cycle, and additional measures of safety and tolerability. Secondary endpoints include TERN-701 PK and efficacy assessments, such as hematologic and molecular responses as measured by the change from baseline in BCR-ABL transcript levels. The starting dose is 160 mg once-daily (QD) with dose escalations as high as 500 mg QD and the option to explore a lower dose of 80 mg QD.

Part 2 is the dose expansion portion of the trial that will enroll approximately 40 patients, randomized to once-daily treatment with one of two doses of TERN-701 to be selected based on data from Part 1. The primary endpoint of the dose expansion portion of the trial is efficacy, measured by hematologic and molecular responses. Secondary endpoints include safety, tolerability and PK. The overall objective of the CARDINAL trial is to select the optimal dose(s) of TERN-701 to move forward to a potential pivotal trial in chronic phase CML.

In December 2024, we announced positive early data from the Part 1 dose escalation portion of the CARDINAL trial. As of the cutoff date in October 2024, 15 patients were enrolled across three dose levels of 160 mg (n=7), 320 mg (n=5), and 400 mg (n=3) of TERN-701 dosed once daily, with an overall median treatment duration of 3 months (range 0.79 - 7.5 months). Enrolled patients were heavily pretreated with a median of 4 prior TKIs (range: 1 - 6) and 80% having had 3 or more TKIs. 47% and 40% of patients, respectively, had previously received ponatinib and asciminib. 73% were not in MMR at baseline, with 60% having a baseline BCR-ABL transcript >1% international scale. As of the data cutoff, 14 of 15 patients remain on treatment.

12 patients were efficacy evaluable, defined as having baseline BCR-ABL transcript and at least two post-baseline BCR-ABL transcript levels (centrally assessed). All efficacy evaluable patients were in the 160 mg and 320 mg dose levels.

Key efficacy highlights include:

- 88% (7/8) of patients with baseline transcript > 1% had decreases in BCR-ABL on treatment, with 7 ongoing as of data cutoff;
- Cumulative MMR rate of 50% (5/10) in non-T315i mutation patients with 3 or more months of treatment and/or MMR or better at baseline; and
- 100% (4/4) of patients with MMR or better at baseline have maintained their response and remain on treatment.

Additional notable responses include:

- MR2 within 5 months in a 4L patient at 160 mg QD with baseline transcript > 1% and suboptimal response and intolerance to asciminib; and
- MR4 (DMR) within 3 months in a 5L patient treated at 320 mg with baseline transcript >10% and treatment failure on bosutinib at study entry.

TERN-701 showed a highly encouraging safety profile across the 160 mg to 400 mg dose levels, with 500 mg undergoing evaluation as of data cutoff.

Key safety highlights include:

- No DLTs through the 400 mg dose level;
- No AE-related treatment discontinuations or dose reductions;
- No Grade 3 or higher treatment-related AEs; and
- No treatment-related serious AEs.

The incidence of treatment emergent hematologic AEs was notably low in this heavily pre-treated population, with no Grade 3 or higher treatment-related cytopenias. There were no non-hematologic treatment-related AEs more than Grade 2 in severity. Finally, no clinically meaningful changes in liver and pancreatic enzymes, blood pressure and other vitals, or electrocardiogram were seen.

Steady state PK data, available for the 160 mg and 320 mg dose levels at data cutoff, showed linear PK with dose proportional increases in exposure. Plasma protein binding-corrected Caverage for TERN-701 exceeded the in vitro IC90 for multiple mutated and non-mutated BCR-ABL variants with once daily dosing. Importantly, at 160 mg and 320 mg QD, TERN-701 achieved average free drug concentrations approximately 4-fold and 8-fold higher, respectively, than in vivo exposures where potent inhibition of the BCR-ABL signaling pathway in was seen in CML mouse tumor models, indicating robust pharmacodynamic (PD) effects at these clinical doses.

As of December 2024, the CARDINAL study enrolled 19 patients inclusive of the 500 mg cohort, with all dose escalation cohorts having enrolled at least 3 patients. The backfill dosing of new participants continues in existing cohorts of dose escalation. The study is on track to initiate dose expansion in the second quarter of 2025 with additional safety and efficacy data expected in the fourth quarter of 2025. These data are expected to include a larger cohort of patients with longer durations of treatment and a potential first look at six-month MMR data, which is an approval endpoint for CML.

Background on Obesity

Obesity is a chronic disease that is increasing in prevalence in adults, adolescents and children and is defined as a BMI of 30 or greater (calculated as weight in kilograms divided by height in meters squared). Mechanisms that contribute to obesity include sedentary lifestyles, increased calorie intake and medications such as insulins and antipsychotics. Insulin resistance, a hallmark of metabolic syndrome, also plays a key role in obesity.

Obesity is a major health epidemic that has been declared a disease by the American Medical Association and affects populations worldwide. The Obesity Action Coalition (OAC) estimates that nearly 93 million Americans struggle with obesity, and it is predicted to increase to 120 million Americans within the next five years. In addition, the U.S. Center for Disease Control, or CDC, estimates that 42 percent of adults over 20 years of age are obese.

According to the OAC, there are over 40 medical conditions associated with obesity. The most prevalent obesity-related diseases include heart disease, type 2 diabetes, stroke, gallbladder disease, gastroesophageal reflux disease, some forms of cancer, sleep apnea or respiratory problems and a variety of other conditions. According to the Journal of Managed Care and Specialty Pharmacy, the aggregate medical cost due to obesity among adults in the United States was $260 billion in 2016. A prior study examining the future health care costs attributable to obesity projected these annual expenditures to double every decade to approximately $780 billion by 2030, representing 14% of total United States health care costs. As a result, public and private stakeholders worldwide are taking steps to address obesity. Despite the increased public awareness of the obesity epidemic and the significant pharmacoeconomic costs associated with obesity, we believe there remains an unmet need for safe, tolerable and effective pharmacological interventions.

Treatment for Obesity

Treatments for obesity include lifestyle modification, pharmaceutical therapies, surgery and device implantation. Lifestyle modifications, diet and exercise are currently the preferred initial treatment for obesity. However, demands for sustained lifestyle modification for long periods of time tend to lead to attrition, often resulting in regained weight. When lifestyle modification alone has failed, pharmacotherapies are generally recommended. With the launches of semaglutide in 2021 and tirzepatide in 2023, both approved for chronic weight management, the worldwide obesity market is expected to exceed $100 billion by 2035, with the anticipated launches of additional injectable and oral treatments.

GLP-1 receptor agonists for obesity

GLP-1 receptor agonists are intended to address metabolic processes involved in the pathogenesis of obesity and other metabolic indications. Mechanisms that contribute to increased weight include sedentary lifestyles, increased calorie intake and medications such as insulins and antipsychotics. Insulin resistance, a hallmark of metabolic syndrome, also plays a key role in obesity. The natural endogenous ligand GLP-1 promotes insulin secretion from pancreatic β-cells in a glucose-dependent-manner following food ingestion. GLP-1 has also been shown to reduce glucagon secretion in the liver, slow gastric emptying in the gut, create a sense of satiety in the brain, reduce inflammation and improve cardiac function. As a result, synthetic GLP-1 peptides have been approved for obesity and diabetes and have therapeutic potential in other metabolic diseases.

Clinical validation of GLP-1 receptor agonists

The rapidly evolving development landscape for GLP-1 compounds is varied, including single agonists, multi-agonists, an agonist-antagonist combination and can be generally grouped by route of administration and peptidomimetic versus novel small molecule structure. Peptide analogs of GLP-1R have mainly been administered by injectable route. Orally administered formulations of peptidomimetic GLP-1R are available and are being developed and are generally limited by low levels of intestinal absorption, whereas oral small molecule agonists of GLP-1R are designed to have higher oral absorption.

Proof-of-concept for weight loss with oral, small molecule GLP-1 receptor agonists has been demonstrated in clinical trials, validating this mechanism of action. Oral GLP-1 receptor agonists under development, such as aleniglipron, orforglipron, and danuglipron have demonstrated 5-7% placebo-adjusted weight loss over a 12-week period. Carried out to longer durations of 24 and 36 weeks, orforglipron has demonstrated weight loss between 10-12%.

Limitations of GLP-1 receptor agonists

Approved agents are synthetic peptides and potentially require higher doses administered by subcutaneous injections for the potential treatment of obesity. The injectable route of administration is likely to limit their use in obesity patients, particularly if efficacious oral treatments become available.

Oral, small molecule treatments have demonstrated significant weight loss but remain limited by their high rates of gastrointestinal AE rates. In the Phase 2 or 12-week setting, the leading small molecule GLP-1s, aleniglipron, orforglipron and danuglipron, have yielded nausea rates between ~70%-90%, vomiting rates between ~50-60% and diarrhea rates of up to 60%. Long, complex titration schemes have been adopted in an attempt to acclimate patients slowly and reduce gastrointestinal side effects at target doses. The titration schemes require a high number of titration steps to the top dose (up to 11 steps for danuglipron) and a large fold change between the starting dose to the target dose (24x fold change for aleniglipron). As a result, there remains significant opportunity for a best in class, oral, small molecule with competitive weight loss, simple titration and excellent tolerability as measured by gastrointestinal AEs.

Our solution for GLP-1 receptor agonists

TERN-601 is an oral, small-molecule GLP-1 receptor agonist. Internal discovery of our lead GLP-1 receptor agonist was driven by computational interaction mapping, chemical synthesis and in vitro characterization of many GLP-1 receptor agonist compounds. Through this process, we discovered TERN-601, which is a potent GLP-1 receptor agonist partially biased towards cAMP generation over β-arrestin recruitment.

In September 2024, we announced positive results from the Phase 1 trial demonstrating weight loss over 28 days up to 5.5% and favorable safety and tolerability despite rapid dose titration every three days. Importantly, TERN-601 exhibited no AE-related discontinuations, interruptions or dose reductions. The majority of GI-related AEs were mild, with no severe or serious AEs and no clinically meaningful changes in liver enzymes.

Based on the Phase 1 results, we believe TERN-601 is well positioned to demonstrate a differentiated tolerability profile in a Phase 2, 12-week setting with slower titration compared to Phase 1. The Phase 2 titration will range between two to four weeks at each intermediate dose before achieving the target dose. The titration design features the fewest steps and lowest fold change to target dose amongst leading oral, small-molecule GLP-1R agonists in a 12-week study. Our slower titration aims to achieve competitive 12-week weight loss, best in class tolerability and the simplest titration amongst the oral, small-molecule class.

Clinical development of TERN-601

The Phase 1 trial of TERN-601 was a randomized, double-blind, placebo-controlled single and multiple-ascending dose (SAD and MAD) trial to assess the safety, tolerability, PKs and PDs of TERN-601 in healthy adults with obesity or who are overweight. The trial consisted of two parts.

Part 1 was a SAD study that evaluated five TERN-601 dose levels in healthy participants with a BMI of $\geq$ 25 kg/m^2 and < 40 kg/m^2. The starting TERN-601 dose was 30 mg, with subsequent dose levels based on review of emerging safety and PK data from prior cohorts.

Part 2 was a MAD study in which obese and overweight healthy adults were enrolled in cohorts that included titration of TERN-601 administered for 28 days at doses selected based on data from Part 1. Part 2 included healthy participants with a BMI of $\geq$ 27 kg/m^2 to < 40 kg/m^2.

The primary endpoint of the trial was to evaluate safety and tolerability of TERN-601 administered once-daily for 28 days. Secondary endpoints included PK, efficacy as measured by body weight loss following 28 days of treatment with TERN-601, and other exploratory markers.

The clinical trial results showed TERN-601 was well tolerated and demonstrated dose-dependent, statistically significant placebo-adjusted mean weight loss across all three doses evaluated in the 28-day MAD study, with maximum placebo-adjusted mean weight loss of 4.9% ($p<0.0001$) at the highest dose of 740 mg QD.

Mean Percent Weight Change from Baseline to Day 28

	Placebo (N=9)	TERN-601 240 mg (N=9)	TERN-601 500 mg (N=9)	TERN-601 740 mg (N=9)
% weight change from baseline	-0.6%	-2.5%	-4.4%	-5.5%
% weight change placebo-adjusted (90% CI)	-	-1.9%	-3.8%	-4.9%
Exploratory p-value vs. placebo	-	<0.1	<0.01	<0.0001

TERN-601 was well tolerated with no treatment-related dose interruptions, reductions or discontinuations at any dose, despite fast titration to high doses. The majority (>95%) of treatment emergent AEs were mild. All gastrointestinal events were mild to moderate and consistent with the GLP-1R agonist class. Importantly, there were no clinically meaningful changes in liver enzymes, vital signs or electrocardiograms observed. The absence of treatment-related dose interruptions, reductions, or discontinuations with mostly mild AEs, despite aggressive titration to high doses in this 28-day study, indicates potential for further improved tolerability in subsequent studies with slower titration.

Table 2: Treatment Emergent Adverse Events by Maximum Severity

	Placebo (N=9)	TERN-601 240 mg (N=10)	TERN-601 500 mg (N=9)	TERN-601 740 mg (N=9)
Grade 1 (Mild)	5 (55.6%)	5 (50%)	9 (100%)	3 (33.3%)
Grade 2 (Moderate)	0	1 (10%)	0	6 (66.7%)
Grade ≥3 (Severe)	0	0	0	0
Serious Adverse Events	0	0	0	0

TERN-601 has distinct properties that may be advantageous for an oral GLP-1R agonist. Its low solubility and high gut permeability may result in prolonged absorption allowing for sustained target coverage and a flat PK curve, while high drug levels in the gut wall may lead to robust GLP-1R activation in the gut triggering satiety centers in the brain. Additionally, TERN-601 has a low free fraction in circulation which, combined with the flat PK curve, may be allowing TERN-601 to be well tolerated when administered at high doses.

The Phase 2 FALCON trial of TERN-601 initiated with the first patient enrolled in March 2025. FALCON is a U.S.-based, multicenter, randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of TERN-601 dosed once-daily. The trial will evaluate adults with obesity or who are overweight, without diabetes, with BMI ranges from ≥30 to <50 kg/m^2 or ≥27 to <30 kg/m^2 with at least one weight-related comorbidity. Patients will be randomized to one of four active cohorts (n=30 per cohort): 250 mg, 500 mg, 500 mg slow titration, 750 mg or placebo. The primary endpoint is percent change from baseline in body weight compared to placebo over 12 weeks. Secondary endpoints include safety, tolerability and proportion of patients achieving 5% weight loss or greater. Phase 2 12-week data are expected in the fourth quarter of 2025. We believe TERN-601 has potential to be a differentiated oral, small molecule GLP-1R agonist, with competitive weight loss and superior tolerability profile in the context of a 12-week study.

TERN-501 – A Selective THR-β Agonist With Enhanced Metabolic Stability and Liver Distribution

THR-β Overview

TERN-501 is a selective THR-β agonist with enhanced metabolic stability and liver distribution, characteristics that are intended to improve safety and efficacy when compared to other THR-β candidates. THR-β is the major form of thyroid hormone receptor in the liver and regulates key aspects of energy metabolism, including fatty acid and lipid synthesis and removal of liver fat through induction of fatty acid oxidation. Agonism of THR-β increases fatty acid metabolism via mitochondrial oxidation and affects cholesterol synthesis and metabolism. As a result, THR-β stimulation has the potential to provide broad metabolic benefits including reducing hepatic steatosis, increasing fat oxidation, and improving fibrosis and serum lipid parameters such as LDL cholesterol and triglycerides. THR-β stimulation has been identified as a target for MASH based on its potential to reduce hepatic steatosis, improve fibrosis and improve serum lipid parameters in MASH patients. For any THR agonist, a key concern is toxicity from excess systemic THR-α stimulation. TERN-501 is 23-fold more selective for THR-β than for THR-α activation, thereby minimizing the risk of cardiotoxicity through THR-α stimulation. TERN-501 also has high metabolic stability and a low projected clinical dose, which we believe makes it an attractive candidate for fixed-dose combination co-formulations.

Clinical development of TERN-501

Since announcing positive top-line data from the Phase 2a DUET trial in August 2023, we decided to limit spend in the development of TERN-501 for MASH given the current regulatory and clinical development requirements for the indication. We continue to evaluate opportunities for TERN-501 in other metabolic diseases.

Non-clinical data suggests that TERN-501 may augment the weight loss effects of a GLP-1 receptor agonist. In 2023, we initiated a study of TERN-501 with a GLP-1 receptor agonist, semaglutide, in a diet induced obese mouse model. In this non-clinical model, mice were fed a high calorie diet to induce overweight and obesity. Study arms included lean mouse, vehicle control, TERN-501 monotherapy, semaglutide monotherapy and semaglutide co-administered with TERN-501. Following 10 weeks of treatment, we observed that while semaglutide alone achieved weight loss greater than 20%, semaglutide in combination with high dose TERN-501 significantly enhanced the body weight loss of semaglutide alone, achieving weight loss greater than 30%.

Based on these non-clinical data, THR-β agonism is a complementary mechanism to GLP-1 receptor antagonism, potentially providing broader metabolic and liver benefits in addition to increased weight loss. These preclinical combination data support the potential for TERN-501 as a combination partner for injectable and oral GLP-1 agonists for use in obesity and other metabolic disorders.

TERN-800 series – Glucose-Dependent Insulinotropic Polypeptide (GIP) Receptor Modulators

GIPR Overview

GIP is secreted in response to nutrient ingestion to enhance meal-stimulated insulin secretion in a glucose-dependent manner by activating its cognate GIPR in pancreatic beta cells and other cells in various tissues. In preclinical studies, GIPR activation appears to reduce food intake and promote weight loss when combined with its incretin partner GLP-1. The overlapping body weight-lowering actions of both GIP and GLP-1 suggests that combining the actions of these two peptide hormones may bolster glucose-lowering and appetite-suppressing effects beyond those observed with individual agents.

Non-Clinical development of the TERN-800 series

As part of our ongoing discovery efforts for the treatment of obesity, we are engaging in discovery for our lead series of GIPR modulators in order to identify a development candidate. We plan to combine oral small molecule GIPR modulators with oral small molecule GLP-1 receptor agonists, such as TERN-601, for the treatment of obesity and metabolic diseases.

We are prioritizing its discovery efforts on nominating a GIPR antagonist development candidate based on in-house discoveries and growing scientific rationale supporting the potential of GLP-1 agonist/GIPR antagonist combinations as treatments for obesity.

Manufacturing and Supply

We do not own or operate manufacturing facilities for the production of any of our drug candidates, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently rely, and expect to continue to rely, on third-party contract manufacturers to manufacture all our drug candidates for preclinical research and clinical trials. We do not have long-term agreements with any of these third parties.

If any of our drug candidates are approved by any regulatory agency, we intend to enter into agreements with a third-party contract manufacturer and one or more back-up manufacturers for the commercial production of those drugs. Development and commercial quantities of any drugs that we develop will need to be manufactured in facilities, and by processes, that comply with the requirements of the FDA and the regulatory agencies of other jurisdictions in which we are seeking approval.

Sales and Marketing

We intend to establish a targeted commercial infrastructure in key geographies at the appropriate time prior to regulatory approval of our drug therapies. We expect to manage sales, marketing and distribution through internal resources and third-party relationships.

In addition, we will opportunistically explore commercialization partnerships in territories outside the United States. As our drug candidates progress through our pipeline, our commercial plans may change. Clinical data, the size of the development programs, the size of our target markets, the size of a commercial infrastructure and manufacturing needs may all influence our commercialization strategies.

Competition

The biotechnology industry is intensely competitive and subject to rapid and significant technological change. We believe that our pipeline, development experience and scientific knowledge provide us with competitive advantages. However, we face potential worldwide competition from many different sources, including large multinational pharmaceutical companies, established biotechnology companies and smaller or earlier stage biotechnology companies. In addition, academic institutions, government agencies and other public and private organizations conducting research may seek patent protection with respect to potentially competitive products or technologies.

We are aware of both pharmaceutical and biotechnology companies with development programs in CML. Companies that have recently participated in or are participating in the development of CML treatments include, but are not limited to, Ascentage Pharma Group, BristolMyers Squibb Company, Enliven Therapeutics Inc., Jiangsu Hansoh Pharmaceutical Group Company Ltd., Novartis Pharmaceuticals Corp., Pfizer Inc., Shenzhen TargetRx, Inc., Sun Pharma Industries Ltd., and Takeda Pharmaceutical Co., Ltd.

We are aware of both pharmaceutical and biotechnology companies with development programs in obesity. Companies that are participating in the development of obesity treatments include, but are not limited to, Abbvie Inc., Altimmune, Inc., Amgen, Inc., Ascletis Pharma, Inc., AstraZeneca PLC, Boehringer Ingelheim GmbH, Eli Lilly and Co., Gilead Sciences, Inc., Hanmi Pharmaceutical Co., Jiangsu Hansoh Pharmaceutical Group Company Ltd., Jiangsu Hengrui Pharmaceuticals Co. Ltd., Kailera Therapeutics, Merck & Co., Metsera Inc., LG Chem, Ltd., Novo Nordisk A/S, Pfizer Inc., Regor Therapeutics Group, Rhythm Pharmaceuticals, Inc., Rivus Pharmaceuticals, Inc., Roche Holding AG, Shionogi & Co. Ltd, Sciwind Biosciences Co., Ltd., Structure Therapeutics Inc., Viking Therapeutics, Inc, and Zealand Pharma A/S.

Many of our competitors have substantially greater financial, technical, human and other resources than we do and may be better equipped to develop, manufacture and market technologically superior products. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products. There are generic products currently on the market for certain of the indications that we are pursuing, and additional products are expected to become available on a generic basis over the coming years. If our product candidates are approved, we expect that they will be priced at a significant premium over competitive generic products. In addition, many of these competitors have significantly greater experience than we have in undertaking preclinical studies and human clinical trials of new pharmaceutical products and in obtaining regulatory approvals of human therapeutic products. Accordingly, our competitors may succeed in obtaining FDA approval for superior products. Many of our competitors have established distribution channels for the commercialization of their products, whereas we have no such channel or capabilities. In addition, many competitors have greater name recognition and more extensive collaborative relationships. Smaller and earlier-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Although we believe our product candidate programs possess appealing attributes, we cannot guarantee that our products will achieve regulatory or market success. Our competitors may obtain regulatory approval of their products more rapidly than we do or obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our drug candidate or any future drug candidates. Our competitors may also develop drugs that are more effective, more convenient, more widely used and less costly, or have a better tolerability profile than our drugs. These competitors may also be more successful than we are in manufacturing and marketing their products. Should we not be able to compete with the aforementioned companies or others, it may hinder our ability to bring our product to market as planned.

Intellectual Property

The proprietary nature of, and protection for, our drug candidates and our discovery programs, processes and know-how are important to our business. For our patent portfolio for pipeline drug candidates, we seek to pursue patent protection covering compositions of matter and methods of use and manufacture. Our policy is to pursue, maintain, defend and enforce patent rights in strategic areas, whether developed internally or licensed from third parties, and to protect the technology, inventions and improvements that are commercially important to the development of our business. We also rely on trade secrets, confidential information and other proprietary know-how that may be important to the development of our business. As of February 16, 2025, our owned and exclusively licensed patent portfolio includes:

- For TERN-701, our small-molecule allosteric inhibitor of the BCR-ABL myristoyl pocket, we own one patent family directed to composition-of-matter coverage of TERN-701, methods of synthesis of TERN-701, and its methods of use in the treatment of leukemia and other diseases and conditions. The patent family includes two issued U.S. patents, issued ex-US patents in Australia, China, India, Chile, Colombia, Japan, Mexico, Singapore, South Africa, and Russia, and 23 allowed or pending patent applications in foreign jurisdictions, including Australia, Brazil, Canada, China, the EPO, India, Japan and Korea. Any patents that may issue from applications in the patent family are generally projected to expire in 2039, not including any patent term adjustments and any patent term extensions that may be available. This patent family is subject to an exclusive option and license agreement for the greater China region with Hansoh. For more information regarding this exclusive option and license agreement with Hansoh, please see "—Licensing and Other Intellectual Property-Related Agreements." We also own three patent families which are collectively directed to methods of use of TERN-701 (including combination therapy) in the treatment of leukemia and other diseases and conditions. Any patents resulting from these patent families are projected to expire between 2044 and 2045, not including any patent term adjustments and any patent term extensions that may be available.

- For TERN-501, our THR-β agonist, we own six patent families which collectively are directed to composition-of-matter coverage of TERN-501 and its methods of use (including combination therapy) in the treatment of obesity and certain liver, metabolic and other diseases and conditions. The composition-of-matter patent family includes two issued U.S. patents, issued ex-US patents in China, Chile, Colombia, Israel, India, Japan, Macau, Mexico, Hong Kong, Taiwan, and Russia, three pending U.S. applications, and over 25 pending applications (including allowed applications) in foreign jurisdictions, including Australia, Brazil, Canada, China, the EPO, India, Japan and Korea. Any patents that may issue from applications in the composition-of-matter patent family are generally projected to expire in 2039 except patents which may issue from the pending Chinese priority application are projected to expire in 2038, not including any patent term adjustments and any patent term extensions that may be available.

- We own twelve patent families covering a number of GLP-1R agonists, including TERN-601. These patent families collectively are directed to composition of matter coverage for TERN-601 and other small molecule GLP-1R agonists, as well as formulations and method of use thereof (including combination therapy) in the treatment of obesity and certain metabolic diseases. Any patents that may issue from applications in these patent families are generally projected to expire between 2041 and 2045, not including any patent term adjustments and any patent term extensions that may be available.

- We own a patent family directed to small molecule GIPR modulators. Any patents that may issue from this patent family are projected to expire in 2045, not including any patent term adjustments and any patent term extensions that may be available.

Our commercial success will depend in part on obtaining and maintaining patent protection of our current and future drug candidates, as well as successfully defending these patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell or importing our drugs depends in large part on the extent to which we have rights under valid and enforceable patents that cover these activities. We cannot be sure that patents will be granted with respect to any of our owned or licensed pending patent applications or with respect to any patent applications filed or licensed by us in the future, nor can we be sure that any patents that may be granted to, or licensed by, us in the future will be commercially useful in protecting our drug candidates, discovery programs and processes. Moreover, we cannot be sure that any of our owned or licensed patents will not be challenged, invalidated or circumvented or that such patents will be commercially useful in protecting our technology.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, including the United States, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, the patent term of a patent that covers an FDA-approved drug, in certain cases, may also be eligible for patent term extension, which permits patent term extension as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984 permits such patent term extension of up to five years beyond the expiration of the patent, but 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 among those eligible for an extension may be extended and the amount of available extension to any extension-eligible patent which claims a product, a method of using a product or a method of manufacturing a product, depends on a variety of factors, including the date on which the patent issues and certain dates related to the regulatory review period. Provisions are available in Europe and some other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our drugs receive FDA or analogous foreign approval, we expect to apply for patent term extensions on patents covering those drugs from the applicable authorities where patent term extension is available, including the United States Patent and Trademark Office, or USPTO. There is no guarantee that the applicable authorities, including the USPTO, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions.

In addition to patent protection, we also rely on trademark registration, trade secrets, know-how, other proprietary information and continuing technological innovation to develop and maintain our competitive position. We seek to protect and maintain the confidentiality of proprietary information of our business that is not amenable to, or that we do not consider appropriate for, patent protection. We take steps to protect our proprietary information, including trade secrets and unpatented know-how, by entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors. However, 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, including our trade secrets and unpatented know-how, 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.

Moreover, third parties may still obtain this proprietary information or may come upon this or similar information independently, and we would have no right to prevent them from using that information to compete with us. If any of these events occurs or if we otherwise lose protection for our trade secrets and know how the value of this information may be greatly reduced, our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

The patent positions of biotechnology companies like ours are generally uncertain and involve complex legal, scientific and factual questions. Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent or other intellectual property or other proprietary right would require us to alter our development or commercial strategies, or any of our drug candidates or processes, obtain licenses or cease certain activities. Our breach of any license agreements or our failure to obtain a license to proprietary rights required to develop or commercialize our future drugs may have a material adverse impact on us. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference or derivation proceedings in the USPTO to determine priority of invention. For more information regarding the risks related to intellectual property, please see Item 1A. “Risk Factors—Risks Related to Intellectual Property.”

Licensing and Other Intellectual Property-Related Agreements

TERN-701 Exclusive Option and License Agreement with Hansoh

In July 2020, we entered into an exclusive option and license agreement with Hansoh pursuant to which we granted an exclusive option to Hansoh to obtain an exclusive, sub-licensable and royalty-bearing license under certain patent and other intellectual property rights owned or controlled by us, including patents claiming the composition of TERN-701, our small-molecule allosteric inhibitor of the BCR-ABL fusion gene and methods of using the same, to research, develop, manufacture, use, distribute, sell and otherwise exploit therapeutic products containing TERN-701, or Hansoh Products, for all prophylactic, palliative, therapeutic and/or diagnostic uses in human diseases and disorders in the field of oncology in mainland China, Taiwan, Hong Kong and Macau, or the Hansoh Territory. In November 2021, Hansoh exercised its option to in-license TERN-701 in accordance with the terms of the exclusive option and license agreement. We retain co-exclusive rights under certain know-how licensed to Hansoh and all rights under the patent rights outside of the field of oncology and Hansoh Territory. Pursuant to the terms of the option and license agreement, Hansoh must use commercially reasonable efforts to develop and commercialize a Hansoh Product in the Hansoh Territory and Hansoh may not exploit any other product in the Hansoh Territory with the same primary mechanism of action as the Hansoh Products.

As consideration for the exclusive option, we received an upfront, refundable payment of $0.8 million, which became non-refundable upon Hansoh's exercise of its option in November 2021. Under the license, Hansoh has agreed to pay us up to an aggregate of $67.0 million upon the achievement of pre-specified clinical, regulatory and sales milestones with respect to the Hansoh Products. No such milestones have been achieved to date under this option and license agreement. Hansoh must also pay us royalties of a mid-single digit percentage on net sales of all Hansoh Products. The royalty rate is subject to customary reductions, including reductions based on generic competition to the Hansoh Products and royalties paid to any third party under a license to such third party's rights necessary to commercialize a Hansoh Product. The royalty term will terminate on a Hansoh Product-by-Hansoh Product and country-by-country basis on the later of (i) the expiration date of the last valid claim within the licensed patent rights covering such Hansoh Product in such country, (ii) the loss of regulatory exclusivity for such Hansoh Product in such country and (iii) the tenth anniversary of the first commercial sale of such Hansoh Product in such country.

Intellectual property developed out of the activities under this option and license agreement, and that is necessary or useful to exploit TERN-701 or Hansoh Products, solely developed by one party shall be owned by that party, and jointly developed intellectual property shall be jointly-owned. Hansoh will have the first right to prosecute, maintain, defend and enforce the licensed patent rights in the Hansoh Territory.

The option and license agreement shall expire upon the expiration of the last-to-expire royalty term for the Hansoh Products in the Hansoh Territory. Upon expiration of the option and license agreement, the license under our know-how granted to Hansoh shall be considered fully paid-up, perpetual and co-exclusive. Either we or Hansoh may terminate the option and license agreement if the other party commits a material breach of the agreement and fails to cure that breach within 90 days after written notice is provided, or in the event of insolvency of the other party. Hansoh may terminate the option and license agreement upon 180 days' prior written notice. Hansoh may also terminate the option and license agreement upon 60 days' prior written notice if we undergo certain change of control events. If Hansoh terminates the option and license agreement upon such change of control events, we must negotiate with Hansoh the terms of an assignment of our entire right, title and interest in and to TERN-701 and the Hansoh Products, including all intellectual property rights therein, in the Hansoh Territory and Hansoh shall provide us the fair market value of such assignment.

THR-β Agonist Assignment Agreement with Vintagence Biotechnology Ltd.

In June 2019, we entered into an assignment agreement with Vintagence Biotechnology Ltd., or Vintagence, pursuant to which Vintagence assigned to us certain worldwide intellectual property rights and know-how directed to THR-β agonists. In particular, we have been assigned all rights, title and interest in and to a Chinese patent application and any patents or patent applications resulting or derived therefrom in any country, know-how and potentially certain other patents or patent applications relating to our THR-β program. We are also entitled to license the rights granted to us under the assignment agreement to our affiliates, licensees or contractors. We will be responsible for all regulatory activities, including the obtaining of regulatory approvals for a product.

We must use commercially reasonable efforts to develop and commercialize a product based on the assigned intellectual property in each of several major market territories.

During the term of the assignment agreement, Vintagence and its affiliates may not develop, manufacture, commercialize or otherwise exploit any compound covered by any of the assigned patent rights. In the event Vintagence develops a THR-β agonist not covered by the assigned patent rights, we will have the first right (but no obligation) to negotiate an assignment or license to exclusively develop, manufacture, commercialize or otherwise exploit such agonist worldwide. As initial consideration for the assignment, we paid Vintagence an upfront payment of CNY 5 million ($0.7 million). As additional consideration, we are required to pay Vintagence up to an aggregate of CNY 205 million (approximately $28.1 million) upon the achievement of specified developmental, clinical and regulatory milestone events with respect to products covered by the agreement. As of December 31, 2024, we have paid $4.4 million to Vintagence which includes a milestone payment of $1.5 million in connection with our IND filing for TERN-501 and a milestone payment of $2.2 million in connection with the initiation of dosing in the Phase 2a DUET trial.

We have the sole responsibility and decision-making authority to prosecute the assigned patents. However, if we decline to pay the prosecution costs for any assigned patent, Vintagence shall have the right to prosecute such assigned patent. If Vintagence takes over prosecution of such assigned patent, we must assign such assigned patent back to Vintagence. We also have the first right (but no obligation) to enforce the assigned patents and know-how. If we do not take any steps to enforce any of the assigned patents or know-how against any infringing third party, Vintagence has the right to take any actions necessary to abate such infringement.

The assignment agreement will continue on a country-by-country basis until we have paid all milestone payments. We may terminate the assignment agreement in its entirety or on a covered product-by-covered product and country-by-country basis without cause with 60 days' prior written notice. Either party may terminate the assignment agreement for the other party's material breach that remains uncured for 90 days or for the other party's bankruptcy, insolvency or similar arrangement for the benefit of creditors. If we terminate the assignment agreement without cause or if Vintagence terminates the assignment agreement for our uncured material breach, we must transfer the assigned intellectual property back to Vintagence.

Government Regulation and Product Approval

Among others, the FDA, the European Commission, U.S. Department of Health and Human Services Office of Inspector General, the Centers for Medicare and Medicaid Services, or CMS, and comparable regulatory authorities in state and local jurisdictions and in other countries impose substantial and burdensome requirements on companies involved in the clinical development, manufacture, marketing and distribution of drugs such as those we are developing. These agencies and other federal, state and local entities regulate, among other things, the research and development, testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion, distribution, post-approval monitoring and reporting, sampling and export and import of our product candidates. Any drug candidates that we develop must be approved by the FDA before they may be legally marketed in the United States and by the appropriate foreign regulatory agency before they may be legally marketed in those foreign countries. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States, although there can be important differences. Additionally, some significant aspects of regulation in the European Union, or EU, are addressed in a centralized way, but country-specific regulation remains essential in many respects.

U.S. Drug Development Process

In the United States, the FDA regulates drugs under the federal Food, Drug, and Cosmetic Act, or the FDCA, and its implementing regulations.

A company, institution, or organization which takes responsibility for the initiation and management of a clinical development program for such products is referred to as a sponsor. A sponsor seeking approval to market and distribute a new drug product in the United States must typically secure the following:

- completion of preclinical laboratory tests, animal studies (where necessary) and formulation studies in accordance with FDA's good laboratory practice requirements and other applicable regulations;
- design of a clinical protocol and submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or 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 practice, or GCP, requirements to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of a new drug application, or NDA, after completion of all pivotal trials;
- a determination by the FDA within 60 days of its receipt of an NDA to file the NDA 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 cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity and of selected clinical investigation sites to assess compliance with GCPs;
- potential FDA audit of the preclinical and/or clinical trial sites that generated the data in support of the NDA;
- payment of substantial application and program fees pursuant to the Prescription Drug User Fee Act, or PDUFA;
- FDA review and approval of the NDA to permit commercial marketing of the product for particular indications for use in the United States; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS, and any post-approval studies or other post-marketing commitments required by the FDA.

Prior to beginning the first clinical trial with a product candidate in the United States, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. Some preclinical testing may continue even after the IND is submitted. The IND also includes results of animal and in vitro studies assessing the toxicology, PKs, 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. These studies are generally referred to as IND-enabling studies. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include 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.

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. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data monitoring committee, or DMC, 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.

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. In the case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- 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, dose tolerance and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3: The 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 approval. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of an NDA.

Post-approval trials, sometimes referred to as Phase 4 studies, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, such as with accelerated approval drugs, FDA may mandate the performance of Phase 4 trials. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

In December 2022, with the passage of Food and Drug Omnibus Reform Act, or FDORA, Congress required sponsors to develop and submit a diversity action plan (DAP) for each phase 3 clinical trial or any other "pivotal study" of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products. Specifically, action plans must include the sponsor's goals for enrollment, the underlying rationale for those goals, and an explanation of how the sponsor intends to meet them. In addition to these requirements, the legislation directs the FDA to issue new guidance on DAPs. In June 2024, as mandated by FDORA, the FDA issued draft guidance outlining the general requirements for DAPs. Unlike most guidance documents issued by the FDA, the DAP guidance when finalized will have the force of law because FDORA specifically dictates that the form and manner for submission of DAPs are specified in FDA guidance. On January 27, 2025, in response to an Executive Order issued by President Trump on Diversity, Equity and Inclusion programs, the FDA removed this draft guidance from its website.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the meetings at the end of the Phase 2 trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the new drug.

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 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.

While the IND is active, progress reports (including an annual development safety and update report, or DSUR) 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 AEs, 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.

In connection with our clinical development program, we may conduct trials at sites outside the United States. When a foreign clinical study is conducted under an IND application, all IND requirements must be met unless waived. When a foreign clinical study is not conducted under an IND application, the sponsor must ensure that the study complies with certain regulatory requirements of the FDA in order to use the study as support for an IND application or application for marketing approval. Specifically, the studies must be conducted in accordance with GCP, including undergoing review and receiving approval by an independent ethics committee, or IEC, and seeking and receiving informed consent from subjects. GCP requirements encompass both ethical and data integrity standards for clinical studies. The FDA's regulations are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical studies, as well as the quality and integrity of the resulting data. They further help ensure that non-IND foreign studies are conducted in a manner comparable to that required for IND studies.

Sponsors of clinical trials are required to register and disclose certain clinical trial information on a public registry (clinicaltrials.gov) maintained by the U.S. National Institutes of Health, or NIH. In particular, information related to the product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Although the FDA has historically not enforced these reporting requirements due to the long delay by the Department of Health and Human Services, or HHS, in issuing final implementing regulations. As of December 19, 2024, the FDA had issued six notices of non-compliance, thereby signaling the government's willingness to begin enforcing these requirements against non-compliant clinical trial sponsors. While these notices of non-compliance did not result in civil monetary penalties, the failure to submit clinical trial information to clinicaltrials.gov is a prohibited act under the FDCA with violations subject to potential civil monetary penalties of up to $10,000 for each day the violation continues. Violations may also result in injunctions and/or criminal prosecution or disqualification from federal grants.

Pediatric Studies

Under the Pediatric Research Equity Act, or PREA, of 2003, an NDA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the drug product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. With enactment of the FDASIA in 2012, sponsors must also submit pediatric study plans (if required under PREA), before the date on which the sponsor submits the required assessments or investigation and no later than either 60 calendar days after the date of the end-of-phase 2 meeting or such other time as agreed upon between FDA and the sponsor. Those plans must contain an outline of the proposed pediatric study or studies the sponsor plans to conduct, including study objectives and design, any deferral or waiver requests, and other information required by regulation. The sponsor, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other, and agree upon a final plan. The FDA or the sponsor may request an amendment to the plan at any time.

The FDA may, on its own initiative or at the request of the sponsor, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. A deferral may be granted for several reasons, including a finding that the product or therapeutic candidate is ready for approval for use in adults before pediatric trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric trials begin. Pursuant to the Food and Drug Administration Safety and Innovation Act of 2012, or FDASIA, the FDA must send a PREA Non-Compliance letter to sponsors who have failed to submit their pediatric assessments required under PREA, have failed to seek or obtain a deferral or deferral extension or have failed to request approval for a required pediatric formulation. FDASIA further requires the FDA to publicly post the PREA Non-Compliance letter and sponsor's response.

PREA does not apply to any investigational product for an indication for which orphan designation has been granted, although the FDA has taken steps to limit what it considers abuse of this statutory exemption in PREA by announcing that is does not intend to grant any additional orphan drug designations for rare pediatric subpopulations of what is otherwise a common disease. In May 2023, the FDA issued new draft guidance that further describes the pediatric study requirements under PREA. The FDA also maintains a list of diseases that are exempt from PREA requirements due to low prevalence of disease in the pediatric population.

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, 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 may come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational drug product to the satisfaction of the FDA. The submission of an NDA is subject to the payment of substantial user application and program 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 all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA's regulations state that an application "shall not be considered as filed until all pertinent information and data have been received." In the event that FDA determines that an application does not satisfy this standard, it will issue a Refuse to File, or RTF, determination to the applicant. The FDA may also 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.

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, or PDUFA, guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a "filing" decision after it the application is submitted. The actual review time may be significantly longer, depending on the complexity of the review, FDA requests for additional information and the sponsor's submission of additional information.

The FDA seeks to meet these timelines for review of an application but its ability to do so may be affected by a variety of factors, including government budget and funding levels, the ability to hire and retain key personnel and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. For example, during the past decade, the U.S. government has shut down several times and certain regulatory agencies, including the FDA, have had to furlough critical employees and stop critical activities, including potentially the review of INDs and NDAs.

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.

Moreover, the FDA will review a sponsor's financial relationship with the principal investigators who conducted the clinical trials in support of the NDA. Depending on the level of that compensation and any other financial interest a principal investigator may have in a sponsor, the sponsor may be required to report these relationships to the FDA. The FDA will then evaluate that financial relationship and determine whether it creates a conflict of interest or otherwise affects the interpretation of the trial or the integrity of the data generated at the principal investigator's clinical trial site. If so, the FDA may exclude data from the clinical trial site in connection with its determination of safety and efficacy of the investigational product.

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. With passage of FDORA, Congress clarified FDA's authority to conduct inspections by expressly permitting inspection of facilities involved in the preparation, conduct, or analysis of clinical and non-clinical studies submitted to FDA as well as other persons holding study records or involved in the study process.

After the FDA evaluates an NDA, it will issue an approval letter or a Complete Response Letter, or CRL. An approval letter authorizes commercial marketing of the drug with 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 the specific deficiencies in the NDA identified by the FDA 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. 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 contain 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, or 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. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may also require one or more Phase 4 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, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could impact the timeline for regulatory approval or otherwise impact ongoing development programs.

Expedited Development and Review Programs

The FDA has a number of programs intended to expedite the development or review of products that meet certain criteria. For example, new drugs are eligible for Fast Track designation if they 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 review team during product development, and 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.

The FDA may also designate a product candidate as a "Breakthrough Therapy" if the product candidate is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product 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 product candidate submitted to the FDA for approval, including a product with a Fast Track designation or Breakthrough Therapy designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. An NDA for a product candidate is eligible for priority review if the product candidate has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application designated for priority review in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for review of new molecular entity NDAs under its current PDUFA review goals.

In addition, a product candidate may be eligible for accelerated approval. Drug products intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product candidate 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 approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoints, and to begin such a study prior to accelerated approval, and the drug may be subject to accelerated withdrawal procedures if the sponsor fails to conduct the required post-marketing studies or if such studies fail to verify the predicted clinical benefit. In addition, the FDA currently requires pre-approval of promotional materials as a condition for accelerated approval, which could adversely impact the timing of the commercial launch of the product.

Further, with passage of the FDORA in December 2022, Congress modified certain provisions governing accelerated approval of drug and biologic products. Specifically, the new legislation authorized the FDA to require a sponsor to have its confirmatory clinical trial underway before accelerated approval is awarded and to submit progress reports on its post-approval studies to FDA every six months until the study is completed. Moreover, FDORA established expedited procedures authorizing FDA to withdraw an accelerated approval if certain conditions are met, including where a required confirmatory study fails to verify and describe the predicted clinical benefit or where evidence demonstrates the product is not shown to be safe or effective under the conditions of use. The FDA may also use such procedures to withdraw an accelerated approval if a sponsor fails to conduct any required post-approval study of the product with due diligence, including with respect to "conditions specified by the Secretary."

In March 2023, the FDA issued draft guidance that outlines its current thinking and approach to accelerated approval. Although single-arm trials have been commonly used to support accelerated approval, a randomized controlled trial is the preferred approach as it provides a more robust assessment and allows for direct comparisons to an available therapy. Subsequently, in December 2024 and January 2025, the FDA issued additional draft guidances relating to accelerated approval. These guidances describe FDA's views on what it means to conduct a confirmatory trial with due diligence and how the agency plans to interpret whether such a study needs to be underway at the time of approval. While these guidances are currently only in draft form and will ultimately not be legally binding even when finalized, sponsors typically observe the FDA's guidance closely to ensure that their investigational products qualify for accelerated approval.

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 candidate no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Post-approval Requirements

Any products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to 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 us and our third-party manufacturers. The PREVENT Pandemics Act, which was enacted in December 2022, clarifies that foreign drug manufacturing establishments are subject to registration and listing requirements even if a drug or biologic undergoes further manufacture, preparation, propagation, compounding, or processing at a separate establishment outside the United States prior to being imported or offered for import into the United States.

Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use.

Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including AEs of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical 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 license 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 doctor" 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 also may require post-marketing testing, known as Phase 4 testing, and surveillance to monitor the effects of an approved product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures.

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.

It may be permissible, under very specific, narrow conditions, for a manufacturer to engage in nonpromotional, non-misleading communication regarding off-label information, such as distributing scientific or medical journal information. Moreover, with passage of the Pre-Approval Information Exchange Act, or PIE Act, in December 2022, sponsors of products that have not been approved may proactively communicate to payors certain information about products in development to help expedite patient access upon product approval. Previously, such communications were permitted under FDA guidance but the new legislation explicitly provides protection to sponsors who convey certain information about products in development to payors, including unapproved uses of approved products.

In addition, in January 2025, the FDA published final guidance outlining its policies governing the distribution of scientific information to healthcare providers about unapproved uses of approved products. The final guidance calls for such communications to be truthful, non-misleading and scientifically sound and to include all information necessary for healthcare providers to interpret the strengths and weaknesses and validity and utility of the information about the unapproved use of the approved product. If a company engages in such communications consistent with the guidance's recommendations, the FDA indicated that it will not treat such communications as evidence of unlawful promotion of a new intended use for the approved product.

If a company is found to have promoted off-label uses, it may become subject to adverse public relations and administrative and judicial enforcement by the FDA, the Department of Justice, or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined companies from engaging in off-label promotion. The FDA and other regulatory agencies have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labeling.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Regulatory Exclusivity

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 regulatory 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, or ANDA, or an NDA submitted under Section 505(b)(2), or 505(b)(2) NDA, submitted by another company for another drug based on 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 regulatory 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.

In the United States, the Orphan Drug Act of 1983, as amended, provides incentives for the development of drugs for rare diseases or conditions that affect fewer than 200,000 people in the United States (or for which there is no reasonable expectation that the cost of developing and making available the drug in the United States for such disease or condition will be recovered from sales of the drug in the United States). Certain of the incentives turn on the drug first being designated as an orphan drug. To be eligible for designation as an orphan drug (Orphan Drug Designation), the drug must have the potential to treat such rare disease or condition as described above. In addition, the FDA must not have previously approved a drug considered the "same drug," as defined in the FDA's orphan drug regulations, for the same orphan-designated indication or the sponsor of the subsequent drug must provide a plausible hypothesis of clinical superiority over the previously approved same drug. Upon receipt of Orphan Drug Designation, the sponsor is eligible for tax credits of up to 25% for qualified clinical trial expenses and waiver of the Prescription Drug User Fee Act application fee. In addition, upon marketing approval, an orphan-designated drug could be eligible for seven years of market exclusivity if no drug considered the same drug was previously approved for the same orphan condition (or if the subsequent drug is demonstrated to be clinically superior to any such previously approved same drug). Such orphan drug exclusivity, if awarded, would only block the approval of any drug considered the same drug for the same orphan indication. Moreover, a subsequent same drug could break an approved drug's orphan exclusivity through a demonstration of clinical superiority over the previously approved drug.

In September 2021, the Court of Appeals for the 11th Circuit, in *Catalyst Pharms, Inc. v. Becerra*, or *Catalyst*, held that, for the purpose of determining the scope of orphan drug exclusivity, the term "same disease or condition" in the statute means the designated "rare disease or condition" and could not be interpreted by the FDA to mean the "indication or use." Thus, the court concluded, orphan drug exclusivity applies to the entire designated disease or condition rather than the approved "indication or use." Although there have been legislative proposals to overrule this decision, they have not been enacted into law. On January 23, 2023, the FDA announced that, in matters beyond the scope of the *Catalyst* court order, the FDA will continue to apply its existing regulations tying orphan-drug exclusivity to the uses or indications for which the orphan drug is approved. More recently however, on February 14, 2025, a federal district court in Washington, DC fully embraced the reasoning of the *Catalyst* decision in another decision challenging the scope of orphan drug exclusivity. The implications of this decision, and its impact on the FDA's implementation of the Orphan Drug Act, are unclear at this point.

Pediatric exclusivity is another type of non-patent exclusivity in the United States and, if granted, provides for the attachment of an additional six months of regulatory exclusivity to the term of any existing unexpired patent or regulatory exclusivity, including orphan drug exclusivity. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data about the active moiety in the product. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

Foreign Government Regulation

Our product candidates will be subject to similar laws and regulations imposed by jurisdictions outside of the United States, and, in particular, the EU which may include, for instance, applicable clinical trial, marketing authorization and post-marketing requirements, including safety surveillance, anti-fraud and abuse laws and implementation of corporate compliance programs and reporting of payments or other transfers of value to healthcare professionals. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable foreign regulatory authorities before we can commence clinical trials or marketing of the product in foreign jurisdictions. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Regulations Governing Marketing Authorization of Medicinal Products in the EU

Non-clinical studies and clinical trials

Similar to the United States, the various phases of non-clinical and clinical research in the EU are subject to significant regulatory controls.

Non-clinical studies are performed to demonstrate the health or environmental safety of new biological substances. Non-clinical studies must be conducted in compliance with the principles of good laboratory practice, or GLP, as set forth in EU Directive 2004/10/EC. 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 Organisation 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 Conference on Harmonisation, or ICH, guidelines on Good Clinical Practice, or GCP, as set out in EU Commission Implementing Regulation (EU) 2017/556, EU Regulation (EU) 2016/679, or GDPR, 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, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, or CTD, 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 Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state, 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 to all member states concerned. 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 foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. For clinical trials whose CTA was made under the Clinical Trials Directive before January 31, 2022, the Clinical Trials Directive will continue to apply on a transitional basis for three years. Additionally, sponsors were able to choose to submit a CTA under either the Clinical Trials Directive or the CTR until January 31, 2023 and, if authorized, those will be governed by the Clinical Trials Directive until January 31, 2025. Thereafter, all ongoing trials will become subject to the provisions of the CTR.

Parties conducting certain clinical trials must, as in the United States, post clinical trial information in the EU at the EudraCT website: https://eudract.ema.europa.eu.

Medicines used in clinical trials must be manufactured in accordance with good manufacturing practice, or GMP, as set out in EU Commission Delegated Regulation (EU) 2017/1569. Other national and EU-wide regulatory requirements may also apply.

Marketing Authorization

In order to market our future 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 marketing authorization, or MA. To obtain regulatory approval of a product candidate in the EU, we must submit a marketing authorization application, or 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," which are issued by the European Commission through the centralized procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, and are valid throughout the EU. The centralized procedure is mandatory for certain types of product candidates, such as (i) medicinal products derived from biotechnological processes, (ii) designated orphan medicinal products, (iii) advanced therapy medicinal products, or ATMPs, such as gene therapy, somatic cell-therapy or tissue-engineered medicinal products and (iv) medicinal products indicated for the treatment of HIV/AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune or other immune dysfunctions and viral diseases. The centralized procedure is optional for any 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 for which the granting of a MA would be in the interest of public health in the EU; and
- "national MAs," which are issued by the competent authorities of the EU member states, only cover their respective territory, and are available for products 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 above described procedures, before granting 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 for an unlimited period on the basis of a reevaluation of the risk-benefit balance.

Adaptive pathways

The EMA has adaptive pathways programs which allow for early and progressive patient access to a medicine. The adaptive pathways concept is an approach to medicines approval that aims to improve patients' access to medicines which have potential to address unmet medical needs. To achieve this goal, several approaches are envisaged: identifying small populations with severe disease where a medicine's benefit-risk balance could be favorable; making more use of real-world data where appropriate to support clinical trial data; and involving health technology assessment bodies early in development to increase the chance that medicines will be recommended for payment and ultimately covered by national healthcare systems. The adaptive pathways concept applies primarily to treatments in areas of high medical need where it is difficult to collect data via traditional routes and where large clinical trials would unnecessarily expose patients who are unlikely to benefit from the medicine. The approach builds on regulatory processes already in place within the existing EU legal framework. These include: scientific advice; compassionate use; the conditional approval mechanism (for medicines addressing seriously debilitating or life-threatening diseases or rare diseases); patient registries and other pharmacovigilance tools that allow collection of real-life data and development of a risk-management plan for each medicine.

The adaptive pathways program does not change the standards for the evaluation of benefits and risks or the requirement to demonstrate a positive benefit-risk balance to obtain MA.

PRIME scheme

In July 2016, the EMA launched the PRIME scheme. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicines that target unmet medical needs. It is based on increased interaction and early dialogue with companies developing promising medicines, to optimize their product development plans and speed up their evaluation to help them reach patients earlier. Product developers that benefit from PRIME designation can expect to be eligible for accelerated assessment but this is however not guaranteed. The benefits of a PRIME designation include the appointment of a rapporteur from the Committee for Medicinal Product candidates for Human Use before submission of an MAA, early dialogue and scientific advice at key development milestones, and the potential to qualify product candidates for accelerated review earlier in the application process.

Data and marketing exclusivity

The EU also provides opportunities for market exclusivity. Upon receiving MA, or reference medicinal products qualify for eight years of data exclusivity and an additional two years of market exclusivity. If granted, the data exclusivity period prevents generic or 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 10 years have elapsed from the initial authorization of the reference product in the EU. The overall 10-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those 10 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 entity, and products may not qualify for data exclusivity.

The EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's proposal for revision of several legislative instruments related to medicinal products (potentially reducing the duration of regulatory data protection and exclusivity periods for orphan drugs, revising the eligibility for expedited pathways, etc.) was published in April 2023. In April 2024, the European Parliament adopted a position on the proposal requesting several amendments to the package. The proposed revisions remain to be agreed and adopted by the European Parliament and European Council and the proposals may therefore be substantially revised before adoption, which is not anticipated before early 2026.

Post-approval requirements

Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the member states. The holder of a MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

All new MAA must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

The advertising and promotion of medicinal products is also subject to laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the EU. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each member state and can differ from one country to another.

Failure to comply with the aforementioned EU and member state laws may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, suspension of the conduct of clinical trials, rejection of clinical trial data, or refusal to grant MA, product withdrawals and recalls, product seizures, suspension, withdrawal, revocation 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.

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

Brexit and the Regulatory Framework in the United Kingdom

The UK's withdrawal from the EU, commonly referred to as Brexit, took place on January 31, 2020. The EU and the UK reached an agreement on their new partnership in the Trade and Cooperation Agreement, which entered into force on May 1, 2021. As of January 1, 2021, the Medicines and Healthcare Products Regulatory Agency (the MHRA) became responsible for supervising medicines and medical devices in Great Britain, comprising England, Scotland and Wales under domestic law, whereas Northern Ireland continues to be subject to EU rules under the Northern Ireland Protocol, as amended by the so called Windsor Framework agreed in February 2023. As of January 1, 2025, the changes introduced by the Windsor Framework resulted in the MHRA being responsible for approving all medicinal products destined for the United Kingdom market (Great Britain and Northern Ireland), and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland. The MHRA relies on the Human Medicines Regulations 2012 (SI 2012/1916) (as amended) (the HMR) as the basis for regulating medicines. The HMR has incorporated into the domestic law the body of EU law instruments governing medicinal products that pre-existed prior to the UK's withdrawal from the EU.

As of January 1, 2024 on, a new international recognition procedure (IRP) applies which intends to facilitate approval of pharmaceutical products in the UK. The IRP is open to applicants that have already received an authorization for the same product from one of the MHRA's specified Reference Regulators (RRs). The RRs notably include EMA and regulators in the EEA member states for approvals in the EU centralized procedure and mutual recognition procedure as well as the FDA (for product approvals granted in the U.S.).The RR assessment must have undergone a full and standalone review. RR assessments based on reliance or recognition cannot be used to support an IRP application. A CHMP positive opinion or an MRDC positive end of procedure outcome is an RR authorization for the purposes of IRP.

Other U.S. Healthcare Laws

Pharmaceutical companies 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 laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims and transparency laws and regulations with respect to drug pricing and payments or other transfers of value made to physicians and other healthcare professionals. If their operations are found to be in violation of any of such laws or any other governmental regulations that apply, they may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, integrity oversight and reporting obligations, the curtailment or restructuring of operations, exclusion from participation in federal and state healthcare programs and individual imprisonment.

Coverage and Reimbursement

Sales of any product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state and foreign government healthcare programs, commercial insurance and managed healthcare organizations and the level of reimbursement for such product by third-party payors. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. These third-party payors are increasingly reducing reimbursements for medical products, drugs and services. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls, inflationary rebates and measures, could further limit sales of any product. 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 and also have a material adverse effect on sales.

Outside of the United States, the pricing of pharmaceutical products is subject to governmental control in many countries. In the EU, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost effectiveness of a particular therapy to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. Other countries may allow companies to fix their own prices for products, but monitor and control product volumes and issue guidance to physicians to limit prescriptions. Efforts to control prices and utilization of pharmaceutical products and medical devices will likely continue as countries attempt to manage healthcare expenditures. Historically, products launched in the EU do not follow price structures of the United States and generally prices tend to be significantly lower.

Government Drug Price Reporting

The Medicaid Drug Rebate Program, the 340B drug pricing program, the U.S. Department of Veterans Affairs Federal Supply Schedule program, and other governmental drug pricing programs require participating manufacturers to report certain product and pricing data to the government. Pricing calculations vary among products and programs, are complex, and are often subject to interpretation by manufacturers, governmental or regulatory agencies and the courts, which can change and evolve over time. Manufacturers may be held liable for errors associated with submission of data under these programs, including potential civil monetary penalties per item of falsely reported or misrepresented drug pricing information. Such failure also could be grounds for other sanctions, such as termination from the Medicaid Drug Rebate Program. Further, a growing number of states have enacted drug price transparency laws requiring pharmaceutical manufacturers to report information to certain state agencies and other parties. Many of these laws provide for civil monetary penalties and other enforcement mechanisms if manufacturers are found to have violated requirements.

Healthcare Reform

In the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States. By way of example, 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; 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; creates 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 Innovation at 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, executive and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, the ACA has been challenged at the U.S. Supreme Court multiple times since its enactment. While in 2021, the U.S. Supreme Court dismissed a judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA.

During the first Trump Administration, the Congress and administration sought to overturn the ACA and related measures. Shortly after taking office in January 2025, President Trump revoked numerous executive orders issued by President Biden, including at least two executive orders (EO 14009, Strengthening Medicaid and the Affordable Care Act, and EO 14070, Continuing to Strengthen Americans' Access to Affordable, Quality Health Coverage) which were designed to further implement the ACA. We anticipate similar efforts to undermine the ACA, and the accompanying uncertainty, for the foreseeable future.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers of 2% per fiscal year, which will remain in effect through 2032 absent additional congressional action. Additionally, under the Statutory Pay-As-You-Go Act of 2010 (Statutory PAYGO), the Administration is required to issue a sequestration order (capped at 4% for Medicare payments) if the PAYGO scorecard shows a net cost at the end of a Congressional session. Although Statutory PAYGO was expected to be triggered at the end of the 2021 Congressional session, subsequent legislation has delayed a Statutory PAYGO sequestration order until after 2024. Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed, among other things, to bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for pharmaceutical products.

For example, in August 2022, the Inflation Reduction Act, or IRA, was enacted. The new legislation has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B to give them the option of paying a monthly premium for outpatient prescription drug coverage. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; 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 (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years.

Specifically, with respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B and Part D. CMS may negotiate prices for ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. This provision applies to drug products that have been approved for at least 9 years and biologics that have been licensed for 13 years, but it does not apply to drugs and biologics that have been approved for a single rare disease or condition. Further, the legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law or for taking price increases that exceed inflation.

The first cycle of negotiations for the Medicare Drug Price Negotiation Program commenced in the summer of 2023. In August 2024, the HHS published the results of the first Medicare drug price negotiations for ten selected drugs that treat a range of conditions, including diabetes, chronic kidney disease, and rheumatoid arthritis. The prices of these ten drugs will become effective January 1, 2026. On January 17, 2025, CMS announced its selection of 15 additional drugs covered by Part D for the second cycle of negotiations. Thereafter, following the change in administrations, CMS issued a public statement on January 29, 2025, declaring that lowering the cost of prescription drugs is a top priority of the new administration and CMS is committed to considering opportunities to bring greater transparency in the negotiation program. The second cycle of negotiations with participating drug companies will occur during 2025, and any negotiated prices for this second set of drugs will be effective starting January 1, 2027.

In addition to the drug price negotiation program, the IRA established inflation rebate programs under Medicare Part B and Part D. These programs require manufacturers to pay rebates to Medicare if they raise their prices for certain Part B and Part D drugs faster than the rate of inflation. In December 2024, with issuance of its 2025 Physician Fee Schedule final regulation, CMS finalized its rules governing the IRA inflation rebate programs. The new law also capped Medicare out-of-pocket drug costs at an estimated $4,000 a year in 2024 and, thereafter beginning in 2025, at 2,000 a year.

In June 2023, Merck filed a lawsuit against HHS and CMS asserting that, among other things, the IRA's Drug Price Negotiation Program for Medicare constitutes an uncompensated taking in violation of the Fifth Amendment of the Constitution. Subsequently, a number of other parties, including the U.S. Chamber of Commerce, or Chamber, Bristol Myers Squibb Company, the Pharmaceutical Research and Manufacturers of America, Astellas, Novo Nordisk, Janssen Pharmaceuticals, Novartis, AstraZeneca and Boehringer Ingelheim, also filed lawsuits in various courts with similar constitutional claims against HHS and CMS. HHS has generally won the substantive disputes in these cases, and various federal district court judges have expressed skepticism regarding the merits of the legal arguments being pursued by the pharmaceutical industry. Certain of these cases are now on appeal and, on October 30, 2024, the Court of Appeals for the Third Circuit heard oral argument in three of these cases. Litigation involving these and other provisions of the IRA will continue with unpredictable and uncertain results.

In addition, 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, marketing cost disclosure and other transparency measures and, in some cases, mechanisms to encourage importation from other countries and bulk purchasing. Furthermore, there has been increased interest by third party payors and governmental authorities in reference pricing systems and publication of discounts and list prices. This may be increasingly true with respect to products approved pursuant to the accelerated approval pathway. State Medicaid programs and other payers are developing strategies and implementing significant coverage barriers, or refusing to cover these products outright, arguing that accelerated approval drugs have insufficient or limited evidence despite meeting the FDA's standards for accelerated approval.

Data Privacy and Security Laws

Numerous state, federal and foreign laws govern the collection, dissemination, use, access to, confidentiality and security of health-related information. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy laws and federal and state consumer protection laws and regulations (e.g., Section 5 of the Federal Trade Commission Act, or FTC Act), govern the collection, use, disclosure and protection of health-related and other personal information, and could apply to our operations or the operations of our partners. The FTC has been particularly focused on the unpermitted processing of health data through its recent enforcement actions and is expanding the types of privacy violations that it interprets to be "unfair" under Section 5 of the FTC Act, The agency is also in the process of developing rules related to commercial surveillance and data security. We will need to account for the FTC's evolving rules and guidance for proper privacy and data security practices in order to mitigate risk for a potential enforcement action, which may be costly. The FTC's enforcement priorities (as well as those of other federal regulators) may be impacted by the change in administration and new leadership. These shifts in enforcement priorities may also impact our business.

There are also increased restrictions at the federal level relating to transferring sensitive data outside of the United States to certain foreign countries. For example, in 2024, Congress passed H.B. 815, which included the Protecting Americans' Data from Foreign Adversaries Act of 2024. This law creates certain restrictions for entities that disclose sensitive data (including potential health data) to countries such as China. Failure to comply with these rules can lead to a potential FTC enforcement action. Additionally, the Department of Justice recently finalized a rule implementing Executive Order 14117, which creates similar restrictions related to the transfer of sensitive US data to countries such as China. These data transfer restrictions (and others that may pass in the future) may create operational challenges and legal risks for our business.

At the state level, 19 states to date have enacted omnibus consumer privacy laws, each of which provides special provisions regarding the privacy of health-related information, and each of which provides for civil enforcement, including the levying of fines for violations. Moreover, the California Privacy Rights Act (CPRA) imposes consumer privacy obligations on businesses with respect to their California-based employees and business contacts. Additionally, California's Confidentiality of Medical Information Act (H. R. 8152)—which provides for both civil enforcement and a private right of action—imposes specific obligations on pharmaceutical companies with respect to the privacy of medical information. The state of Washington also passed the My Health My Data Act in 2023, which specifically regulates health information and includes a private right action (and has inspired copycat legislation by other states). Each of these state laws could apply to our operations or the operations of our partners. We note, too, that Congress may also consider federal privacy legislation, which may meaningfully impact our compliance obligations.

In addition, certain foreign laws govern the privacy and security of personal data, including health-related data. For example, the GDPR imposes strict requirements for processing the personal data of individuals within the 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. 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. 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. The GDPR prohibits the transfer of personal data from the European Economic Area, or EEA, to countries outside of the EEA unless made to a country deemed to have adequate data privacy laws by the European Commission or a data transfer mechanism has been put in place. The EU-US Privacy Shield was such a transfer mechanism put in place by the EU and the United States, but the Privacy Shield was invalidated for international transfers of personal data in July 2020 by the Court of Justice of the EU, or CJEU. In October 2022, President Biden signed an executive order to implement the EU-U.S. Data Privacy Framework (DPF), which is intended to be a replacement for the EU-US Privacy Shield. The European Commission adopted an adequacy decision to permit data transfers from the EEA to the United States going forward. This development permits data transfers at this point under this framework and more broadly has made international data transfers more straightforward, but these provisions are being challenged in court. The recent election in the United States and the new administration may also impact whether the DPF remains an adequate data transfer framework. The continuing uncertainty around this issue may further impact our business operations in the EEA.

There is also uncertainty about other data transfer mechanisms. In June 2021, the European Commission adopted new standard contractual clauses (SCCs) that are designed to be a mechanism by which entities can transfer personal information out of the EEA to jurisdictions that the European Commission has not found to provide an adequate level of protection. The SCCs require parties that rely upon that legal mechanism to comply with additional obligations, such as conducting transfer impact assessments to determine whether additional security measures are necessary to protect the transferred personal information. The competent authorities and courts in a number of EU Member States increasingly scrutinize and question the GDPR compliance of processing of personal data by US-based entities or entities with links to US-based entities, independently of whether personal data is actually transferred outside the EEA. In June 2021, the CJEU issued a ruling that expanded the scope of the "one stop shop" under the GDPR. According to the ruling, the competent authorities of EU Member States may, under certain strict conditions, bring claims to their national courts against a company for breaches of the GDPR, including unlawful cross-border processing activities, even such company does not have an establishment in the EU member state in question and the competent authority bringing the claim is not the lead supervisory authority.

Employees and Human Capital Management

As of December 31, 2024, we had 59 employees, all of whom were full-time, all of whom are engaged in research and development activities, operations, finance, or administration. 13 of our employees hold doctorate degrees (Ph.D., M.D. or Pharm.D.). None of our employees are subject to a collective bargaining agreement. We consider our relationship with our employees to be good.

Our key human capital management objectives include, among others: (i) attracting, developing and retaining a diverse and talented workforce; (ii) providing opportunities for learning, development, career growth and movement within our company; (iii) evaluating compensation and benefits and rewarding performance; (iv) investing in physical, emotional and financial health of team members; (v) obtaining team member feedback; (vi) maintaining and enhancing our culture and mission; and (vii) communicating with our board of directors on a routine basis on key topics. We have implemented and continue to develop many programs designed to achieve these priorities.

Corporate Information

We were incorporated under the laws of the Cayman Islands on December 9, 2016. On December 29, 2020, we effected a de-registration under the Cayman Islands Companies Law (2020 Revision) and a domestication under Section 388 of the Delaware General Corporation Law, pursuant to which our jurisdiction of incorporation was changed from the Cayman Islands to the State of Delaware. Our principal executive offices are located at 1065 East Hillsdale Boulevard, Suite 100, Foster City, California 94404, and our telephone number is (650) 525-5535.

Our website address is www.ternspharma.com. We make available on or through our website certain reports and amendments to those reports that we file with or furnish to the Securities and Exchange Commission (SEC) in accordance with the Securities Exchange Act of 1934, as amended, or the Exchange Act. These include our annual reports on Form 10-K, our quarterly reports on Form 10-Q, and our current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act. We make this information available on or through our website free of charge as soon as reasonably practicable after we electronically file the information with, or furnish it to, the SEC. References to our website address do not constitute incorporation by reference of the information contained on the website, and the information contained on the website is not part of this document or any other document that we file with or furnish to the SEC. The SEC maintains a site on the worldwide web that contains reports, proxy and information statements and other information regarding our filings at www.sec.gov.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes and Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could materially and adversely affect our business, financial condition, results of operations and prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations and the market value of our common stock. You should consider all of the risk factors described when evaluating our business.

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

We are a clinical-stage biopharmaceutical company with a limited operating history and no products approved for commercial sale. We have incurred significant losses since our inception, and we anticipate that we will continue to incur significant losses for the foreseeable future, which, together with our limited operating history, makes it difficult to assess our future viability.

We are a clinical-stage biopharmaceutical company, and we have only a limited operating history upon which you can evaluate our business and prospects. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We have no products approved for commercial sale and have not generated any revenue from sales of our product candidates and have incurred losses in each year since our inception in December 2016. We have only a limited operating history upon which you can evaluate our business and prospects. 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 pharmaceutical, biopharmaceutical and biotechnology industry. We expect that it will be a number of years, if ever, before we have a product candidate ready for commercialization.

We have had significant operating losses since our inception. Our net loss attributable to common stockholders for the years ended December 31, 2024 and 2023 was approximately $88.9 million and $90.2 million, respectively. As of December 31, 2024, we had an accumulated deficit of $421.5 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. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase as we continue to develop our product candidates, conduct clinical trials and pursue research and development activities. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

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

Since our inception, we have invested a significant portion of our efforts and financial resources in research and development activities. Our product candidates will require additional clinical development, and we intend to conduct additional research and development activities to discover and develop new product candidates, including conducting preclinical studies and clinical trials, all of which will require substantial additional funds. We will continue to expend significant resources for the foreseeable future in connection with these activities. These expenditures will include costs associated with conducting preclinical studies and clinical trials, obtaining regulatory approvals and manufacturing and supply, as well as marketing and selling any drugs approved for sale. In addition, other unanticipated costs may arise. 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 or any future product candidates.

As of December 31, 2024, we had capital resources consisting of cash, cash equivalents and marketable securities of approximately $358.2 million. We expect our existing capital resources will fund our planned operating expenses into 2028. However, our operating plans 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 offerings or debt financings or other sources, such as strategic collaborations. Such financing may result in dilution to our stockholders, and may also result in imposition of burdensome debt covenants and repayment obligations, or other restrictions that may affect our business. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Our future capital requirements depend on many factors, including:

- the scope, progress and costs of researching and developing our current product candidates or any other future product candidates we choose to pursue;
- the success or failure of our ongoing clinical trials of our current product candidates;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates or any future product candidates;
- the number and characteristics of any additional product candidates we develop or acquire;
- the timing and amount of any milestone, royalty and/or other payments we are required to make pursuant to our current or any future license or collaboration agreements;
- the cost of manufacturing our product candidates or any future product candidates and any products we successfully commercialize;
- the cost of pre-commercial activities and, if approved, commercialization activities related to our product candidates, including marketing, sales and distribution costs;
- the cost of building or contracting a sales force in anticipation of commercialization;
- our ability to establish strategic collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- expenses associated with the potential in-licensing or acquisition of new technologies or therapy candidates;
- any product liability or other lawsuits related to our product candidates, if approved;
- the expenses needed to attract, hire and retain skilled personnel;
- the costs associated with being a public company;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing our intellectual property portfolio; and
- the timing, receipt and amount of sales of any future approved drugs.

Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to:

- delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for our product candidates or any future product candidate;
- delay, limit, reduce or terminate our research and development activities; or
- delay, limit, reduce or terminate our efforts to establish manufacturing and sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates or any future product candidate, or reduce our flexibility in developing or maintaining our sales and marketing strategy.

We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies or product candidates that we would otherwise pursue on our own. We do not expect to realize revenue from sales of products or royalties from licensed products in the foreseeable future, if at all, and unless and until our product candidates are clinically tested, approved for commercialization and successfully marketed. To date, we have primarily financed our operations through the sale of equity and debt securities. We may be required to seek additional funding in the future and currently intend to do so through public or private equity offerings or debt financings, credit or loan facilities, collaborations or a combination of one or more of these funding sources. Our ability to raise additional funds will depend on financial, economic and other factors, many of which are beyond our control. Additional funds may not be available to us on acceptable terms or at all. If we raise additional funds by issuing equity securities, our stockholders will suffer dilution and the terms of any financing may adversely affect the rights of our stockholders. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders or the holders of any future security we may issue. Debt financing, if available, is likely to involve restrictive covenants limiting our flexibility in conducting future business activities, and, in the event of insolvency, debt holders would be repaid before holders of our equity securities received any distribution of our corporate assets.

Due to the significant resources required for the development of our product candidates, we must prioritize development of certain product candidates and/or certain disease indications, with our current clinical-stage drug candidates focused on CML and obesity. We may expend our limited resources on candidates or indications that do not yield a successful product and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Our programs are focused on developing a portfolio of small-molecule product candidates for the treatment of chronic myeloid leukemia, or CML, and obesity. We seek to maintain a process of prioritization and resource allocation among our programs to maintain a balance between progressing our current clinical programs, TERN-701 for CML and TERN-601 for obesity, as well as advancing our earlier stage preclinical programs, including the TERN-800 series for obesity, and developing future product candidates. We may also consider whether to conduct combination trials of our single-agent drug candidates. However, due to the significant resources required for the development of our product candidates, we must focus on specific diseases and disease pathways and decide which product candidates to pursue and the amount of resources to allocate to each product candidate.

Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward product candidates or therapeutic areas may not lead to the development of any viable commercial drug and may divert resources away from better opportunities. We may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain development and commercialization rights.

Similarly, any decision to delay, terminate or collaborate with third parties in respect of certain programs may subsequently also prove to be suboptimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the viability or market potential of any of our programs or product candidates or misinterpret trends in CML, obesity, or other indications or in the pharmaceutical, biopharmaceutical or biotechnology industry, our business, financial condition and results of operations could be materially adversely affected.

Risks Related to the Discovery and Development of Our Product Candidates

We are early in our development efforts. Our business is heavily dependent on the successful development, regulatory approval and commercialization of our current and future product candidates.

We have no drugs approved for sale, and our most advanced development programs are in early stages of clinical development. The success of our business, including our ability to finance our company and generate revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of our product candidates and, in particular, progressing our most advanced development programs. Given our stage of development, it may be many years, if we succeed at all, before we have demonstrated the safety and efficacy of a product candidate sufficient to warrant approval for commercialization. We cannot be certain that our product candidates will receive regulatory approval or be successfully commercialized even if we receive regulatory approval.

We have not previously submitted a new drug application, or NDA, to the U.S. Food and Drug Administration, or FDA, or similar approval filings to a comparable foreign regulatory authority, for any product candidate. An NDA or other relevant regulatory filing must include extensive preclinical and clinical data and supporting information to establish that the product candidate is safe and effective for each desired indication. The NDA or other relevant regulatory filing must also include significant information regarding the chemistry, manufacturing and controls for the product. We cannot be certain that our current or future product candidates will be successful in clinical trials or receive regulatory approval. Further, even if they are successful in clinical trials, our current or future product candidates may not receive regulatory approval. If we do not receive regulatory approvals for current or future product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approval to market a product candidate, our revenue will depend, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights, as well as the availability of competitive products, whether there is sufficient third-party reimbursement and adoption by physicians. We may plan to seek regulatory approval to commercialize our product candidates in the United States and in select foreign countries. While the scope of regulatory approval generally is similar in other countries, in order to obtain separate regulatory approval in other countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy. Other countries also have their own regulations governing, among other things, clinical trials and commercial sales, as well as pricing and distribution of drugs, and we may be required to expend significant resources to obtain regulatory approval and to comply with ongoing regulations in these jurisdictions. In the future, we may also become dependent on other product candidates that we may develop or acquire. The clinical and commercial success of our product candidates and future product candidates will depend on a number of factors, including the following:

- timely completion of our preclinical studies and clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- our ability to raise any additional required capital on acceptable terms, or at all;
- our ability to complete investigational new drug applications, or INDs, IND-enabling studies and successfully submit INDs or comparable applications for our preclinical or future product candidates;
- whether we are required by the FDA or similar foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our product candidates or any future product candidates;
- acceptance of our proposed indications and primary endpoint assessments relating to the proposed indications of our product candidates by the FDA and similar foreign regulatory authorities, including the use of non-invasive or other novel endpoint to initially obtain market authorization for our product candidates;
- our ability to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities the safety, efficacy and acceptable risk to benefit profile of our product candidates or any future product candidates;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates or future approved drugs, if any;
- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
- achieving and maintaining and, where applicable, ensuring that our third-party contractors achieve and maintain compliance with our contractual obligations and with all regulatory requirements applicable to our product candidates or any future product candidates or approved drugs, if any;
- the ability of third parties with whom we contract to manufacture adequate clinical trial and commercial supplies of our product candidates or any future product candidates to remain in good standing with regulatory agencies and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices, or cGMPs or similar foreign requirements;
- our ability to successfully develop a commercial strategy and thereafter commercialize our product candidates or any future product candidates in the United States and internationally, if approved for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others;

- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved drugs;
- the convenience of our treatment or dosing regimen and the degree to which patients are able to comply with the recommended treatment program;
- acceptance by physicians, payors and patients of the benefits, safety and efficacy of our product candidates or any future product candidates, if approved, including relative to alternative and competing treatments;
- the willingness of physicians, operators of clinics and patients to utilize or adopt any of our product candidates or any future product candidates, if approved;
- patients' willingness to enroll or continue to participate in a clinical trial;
- patient demand for our current or future product candidates, if approved, including patients' willingness to pay out-of-pocket for any approved drugs in the absence of coverage and/or adequate reimbursement from third-party payors;
- effectively competing with other therapies;
- the ease, speed and cost at which we execute on our strategy to develop product candidates with desirable profiles;
- our ability to establish and enforce intellectual property rights in and to our product candidates or any future product candidates; and
- our ability to avoid third-party patent interference, intellectual property challenges or intellectual property infringement claims.

These factors, many of which are beyond our control, could cause us to experience significant delays or an inability to obtain regulatory approvals or commercialize our product candidates. Even if regulatory approvals are obtained, we may never be able to successfully commercialize any of our product candidates. Accordingly, we cannot provide assurances that we will be able to generate sufficient revenue through the sale of our product candidates or any future product candidates to continue our business or achieve profitability.

Clinical drug development involves a lengthy and expensive process with uncertain timelines and outcomes, and results of earlier studies and trials may not be predictive of future trial results. If development of our product candidates is unsuccessful or delayed, we may be unable to obtain required regulatory approvals and we may be unable to commercialize our product candidates on a timely basis, if at all.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure or delay can occur at any time during the clinical trial process. Success in nonclinical testing and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in clinical trials, even after promising results in earlier nonclinical or clinical studies. These setbacks have been caused by, among other things, nonclinical findings made while clinical studies were underway and safety or efficacy observations made in clinical studies, including previously unreported AEs. The results of preclinical, nonclinical and early clinical studies of our product candidates may not be predictive of the results of later-stage clinical trials. Likewise, interim or preliminary results from a clinical trial may not be predictive of final results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical and initial clinical trials. Notwithstanding any potential promising results in earlier studies, we cannot be certain that we will not face similar setbacks. Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval for our product candidates.

We may experience delays in initiating our clinical trials and we cannot be certain that the trials or any other future clinical trials for our product candidates will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. Clinical trials can be delayed or terminated for a variety of reasons, including delay or failure related to:

- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- the size of the study population for further analysis of the study's primary endpoints;
- the acceptance by the FDA or comparable foreign regulatory authorities on the use of any of the non-invasive or other novel diagnostics or endpoints we incorporate into our clinical development to obtain initial market authorization;
- obtaining regulatory approval to commence a trial;
- reaching agreement on acceptable terms with prospective contract research organizations, or 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;
- obtaining institutional review board, or IRB, or ethics committee approval at each site;
- recruiting suitable patients to participate in a trial;
- having patients complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;
- addressing patient safety concerns that arise during a trial;
- addressing any conflicts with new or existing laws, regulations or governmental orders;
- adding a sufficient number of clinical trial sites; or
- manufacturing sufficient quantities of our product candidates for use in clinical trials.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions at which such trials are being conducted, by a data monitoring committee, or DMC, for such trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected the interpretation of the trial. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, refusal to accept or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, and may ultimately lead to the denial of marketing approval of our product candidates.

If we experience delays in the completion of any clinical trial of our product candidates or the termination of any such clinical trial, the commercial prospects of our product candidates may be harmed, and our ability to generate drug revenues from any of these product candidates will be delayed or not realized at all. In addition, 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 drug sales and generate revenues. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

In addition, if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted. For example, in December 2022, with the passage of Food and Drug Omnibus Reform Act, or FDORA, Congress required sponsors to develop and submit a Diversity Action Plan, or DAP, for each phase 3 clinical trial or any other "pivotal study" of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products. In June 2024, as mandated by FDORA, the FDA issued draft guidance outlining the general requirements for DAPs. Unlike most guidance documents issued by the FDA, the DAP guidance when finalized will have the force of law because FDORA specifically dictates that the form and manner for submission of DAPs are specified in FDA guidance. On January 27, 2025, in response to an Executive Order issued by President Trump on Diversity, Equity and Inclusion programs, the FDA removed this draft guidance from its website. The implications of this action are not yet known.

The regulatory landscape related to clinical trials in the EU also has recently evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state, 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 to all member states concerned. 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 foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. For clinical trials whose CTA was made under the Clinical Trials Directive before January 31, 2022, the Clinical Trials Directive will continue to apply on a transitional basis for three years. Additionally, sponsors were able to choose to submit a CTA under either the Clinical Trials Directive or the CTR until January 31, 2023 and, if authorized, those will be governed by the Clinical Trials Directive until January 31, 2025. Thereafter, all ongoing trials are subject to the provisions of the CTR.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted.

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

We may not be able to initiate or continue our planned 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 authority. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the clinical trial's primary endpoints;
- the proximity of patients to clinical sites;
- the design of the clinical trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;

- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient informed consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

We face significant competition for our drug discovery and development efforts in an environment of rapid technological and scientific change, and our product candidates, if approved, will face significant competition, which may prevent us from achieving significant market penetration. Many of our competitors have significantly greater resources than we do, and we may not be able to successfully compete.

The pharmaceutical, biopharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on developing proprietary therapeutics. Numerous companies are engaged in the development, patenting, manufacturing and marketing of healthcare products competitive with those that we are developing. We face competition from a number of sources, such as pharmaceutical, biopharmaceutical and biotechnology companies, generic drug companies and academic and research institutions.

We are aware of both pharmaceutical and biotechnology companies with development programs in CML. Companies that have recently participated in or are participating in the development of CML treatments include, but are not limited to, Ascentage Pharma Group, Bristol-Myers Squibb Company, Enliven Therapeutics Inc., Jiangsu Hansoh Pharmaceutical Group Company Ltd., Novartis Pharmaceuticals Corp., Pfizer Inc., Shenzhen TargetRx Inc., Sun Pharma Industries Ltd., and Takeda Pharmaceutical Co., Ltd.

We are aware of both pharmaceutical and biotechnology companies with development programs in obesity. Companies that are participating in the development of obesity treatments include, but are not limited to, Abbvie Inc., Altimmune, Inc., Amgen, Inc., Ascletis Pharma, Inc., AstraZeneca PLC, Boehringer Ingelheim GmbH, Eli Lilly and Co., Gilead Sciences, Inc., Hanmi Pharmaceutical Co., Jiangsu Hansoh Pharmaceutical Group Company Ltd., Jiangsu Hengrui Pharmaceuticals Co. Ltd., Kailera Therapeutics, Merck & Co., Metsera Inc., LG Chem, Ltd., Novo Nordisk A/S, Pfizer Inc., Regor Therapeutics Group, Rhythm Pharmaceuticals, Inc., Rivus Pharmaceuticals, Inc., Roche Holding AG, Shionogi & Co. Ltd, Sciwind Biosciences Co., Ltd., Structure Therapeutics Inc., Viking Therapeutics, Inc, and Zealand Pharma A/S.

For TERN-800, our GIPR discovery series, companies conducting or planning to conduct clinical trials targeting GIPR or combinations with GIPR in the context of obesity include 9 Meters Biopharma, Inc., Amgen, Inc., Biomed Industries Inc., D&D Pharmatech, Eli Lilly and Co., Jiangsu Hansoh Pharmaceutical Group Company Ltd., Kailera Therapeutics, MBX Biosciences, Inc., Pfizer, Inc., Roche Holding AG, Sciwind Biosciences Co., Viking Therapeutics, Inc. Zealand Pharma A/S and Zhejiang Doer Biosciences Co., Ltd.

Furthermore, pharmaceutical and biotechnology companies who have recently engaged in the development of or are developing clinical-stage drugs to treat CML or obesity using mechanisms not mentioned above include 89Bio, Inc., Aardvark Therapeutics, Inc., Akero Therapeutics, Inc., Arrowhead Pharmaceuticals, Inc., Axcella Health, Inc., Carmot Therapeutics, Inc., Cirius Therapeutics, Inc., CohBar, Inc., Coherus Biosciences Inc., Corcept Therapeutics, Inc., Currax Pharmaceuticals LLC, CymaBay Therapeutics, Inc., CytoDyne Inc., Diasome Pharmaceuticals, Esperion Therapeutics, Inc., Fusion Pharma, LLC, Galectin Therapeutics Inc., Galmed Pharmaceuticals Ltd., Gila Therapeutics, Inc., Hanmi Pharmaceutical Co., Ltd., IL-YANG Pharm. Co. Ltd., Inhibikase Therapeutics, Inc., Inventiva Pharma SA, Ionis Pharmaceuticals, Inc., MediciNova, Inc., NGM Biopharmaceuticals, Inc., Norgine B.V., NorthSea Therapeutics, Inc., Pliant Therapeutics, Inc., Poxel SA, Saniona AB, Sagimet Biosciences, Inc., T3D Therapeutics, Inc., Vivus, Inc., and Zydus Cadila Healthcare.

It is also probable that the number of companies seeking to develop drugs and therapies for the treatment of serious diseases we pursue, such as obesity, will increase.

Many of our competitors have greater financial resources, marketing capabilities, sales forces, manufacturing capabilities, research and development capabilities, clinical trial expertise, intellectual property portfolios, experience in obtaining patents and regulatory approvals for drug candidates and other resources than we do. Some of the companies also have a broad range of other product offerings, large direct sales forces and long-term customer relationships with our target physicians, which could inhibit our market penetration efforts. Mergers and acquisitions in the pharmaceutical, biopharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Certain alternative treatments that may be approved and offered by competitors in the future may be available at lower prices and may offer greater efficacy or better safety profiles. Furthermore, currently approved products could be discovered to have application for the intended indication of our product candidates, which could give such products significant regulatory and market timing advantages over any of our product candidates. Our competitors also may obtain FDA or other foreign regulatory approval for their products more rapidly than we may obtain approval for ours and may obtain orphan product exclusivity from the FDA for indications our product candidates are targeting, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products. There are generic products currently on the market for certain of the indications that we are pursuing, and additional products are expected to become available on a generic basis over the coming years. If our product candidates are approved, we expect that they will be priced at a significant premium over competitive generic products.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, cause us to suspend or discontinue clinical trials, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

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 regulatory approval by the FDA or comparable foreign regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. While our clinical stage single-agent product candidates have been generally well-tolerated, we have observed AEs and laboratory abnormalities in the clinical trials for each of our single-agent candidates.

If unacceptable side effects arise in the development of our product candidates, we, the IRBs at the institutions in which our studies are conducted or the DMC could recommend suspension or termination of our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. Furthermore, we may be required to expend time and incur costs to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

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

- we may be forced to suspend marketing of that product candidate, or decide to remove the product candidate from the marketplace;
- regulatory authorities may withdraw or change their approvals of that product candidate;
- regulatory authorities may require additional warnings on the label or limit access of that product candidate to selective specialized centers with additional safety reporting and with requirements that patients be geographically close to these centers for all or part of their treatment;
- we may be required to send "dear doctor" letters to treatment providers or create a medication guide outlining the risks of the product candidate for patients, or to conduct post-marketing studies;
- we may be required to change the way the product candidate is administered;
- we could be subject to fines, injunctions, or the imposition of criminal or civil penalties, or be sued and held liable for harm caused to subjects or patients; and
- the product candidate may become less competitive, and our reputation may suffer.

Any of the foregoing events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and result in the loss of significant revenues to us, which would materially and adversely affect our results of operations and business.

Interim, top-line and preliminary data from our clinical trials that we 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 interim, top-line or preliminary data from our clinical trials, which is 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. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, top-line or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Interim, top-line and preliminary 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, such data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical trials. Interim, top-line or preliminary 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 differences between interim, top-line or preliminary data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine 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, top-line or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

The regulatory approval process is lengthy, expensive and uncertain, and we may be unable to obtain regulatory approval for our product candidates under applicable regulatory requirements. The denial or delay of any such approval would delay commercialization of our product candidates and adversely impact our ability to generate revenue, our business and our results of operations.

The development, research, testing, manufacturing, labeling, approval, selling, import, export, marketing, promotion and distribution of drug products are subject to extensive and evolving regulation by federal, state and local governmental authorities in the United States, principally the FDA and by foreign regulatory authorities, which regulations differ from country to country. Neither we nor any future collaborator is permitted to market any of our product candidates in the United States until we receive regulatory approval of an NDA from the FDA.

Obtaining regulatory approval of an NDA or similar applications required in foreign jurisdictions can be a lengthy, expensive and uncertain process. 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 well-controlled clinical trials, and to the satisfaction of the FDA or other foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. The number of nonclinical studies and clinical trials that will be required for regulatory approval varies depending on the product candidate, the disease or condition that the product candidate is designed to address, and the regulations applicable to any particular product candidate.

Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. Administering product candidates to humans may produce undesirable side effects, which could interrupt, delay or halt clinical trials and result in the FDA or other regulatory authorities denying approval of a product candidate for any or all indications. The FDA or other regulatory authorities may also require us to conduct additional studies or trials for our product candidates either prior to or post-approval, such as additional clinical pharmacology studies or safety or efficacy studies or trials, or it may object to elements of our clinical development program such as the primary endpoints or the number of subjects in our clinical trials.

The FDA or any foreign regulatory authorities can delay, limit or deny approval of our product candidates or require us to conduct additional nonclinical or clinical testing or abandon a program for many reasons, including:

- the FDA or the applicable foreign regulatory authority's disagreement with the design or implementation of our clinical trials;
- negative or ambiguous results from our clinical trials or results that may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- serious and unexpected drug-related side effects experienced by participants in our clinical trials or by individuals using drugs or combination therapies similar to our product candidates;
- our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory authority that our product candidates are safe and effective for the proposed indication;
- the FDA's or the applicable foreign regulatory authority's disagreement with the interpretation of data from nonclinical studies or clinical trials;
- our inability to demonstrate the clinical and other benefits of our product candidates outweigh any safety or other perceived risks;

- the FDA's or the applicable foreign regulatory authority's requirement for additional nonclinical studies or clinical trials;
- the FDA's or the applicable foreign regulatory authority's disagreement regarding the formulation, labeling and/or the specifications of our product candidates;
- the FDA's or the applicable foreign regulatory authority's failure to approve the manufacturing processes or facilities of third-party manufacturers with which we contract;
- the potential for approval policies or regulations of the FDA or the applicable foreign regulatory authorities to significantly change in a manner rendering our clinical data insufficient for approval; or
- the FDA or the applicable foreign regulatory authority's disagreement with the sufficiency of the clinical, non-clinical and/or quality data in the NDA or comparable marketing authorization application.

Of the large number of drugs in development, only a small percentage successfully complete the FDA or other regulatory approval processes and are commercialized. The lengthy development and approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, financial condition, results of operations and prospects.

Moreover, principal investigators for our future clinical trials may serve as scientific advisors or consultants to us and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or a comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

Further, under the Pediatric Research Equity Act, or PREA, an NDA or supplement to an NDA for certain biological products must contain data to assess the safety and effectiveness of the biological product in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective, unless the sponsor receives a deferral or waiver from the FDA. A deferral may be granted for several reasons, including a finding that the product or therapeutic candidate is ready for approval for use in adults before pediatric trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric trials begin. The applicable legislation in the EU also requires sponsors to either conduct clinical trials in a pediatric population in accordance with a Pediatric Investigation Plan approved by the Pediatric Committee of the European Medicines Agency, or EMA, or to obtain a waiver or deferral from the conduct of these studies by this Committee. For any of our product candidates for which we are seeking regulatory approval in the United States or the EU, we cannot guarantee that we will be able to obtain a waiver or alternatively complete any required studies and other requirements in a timely manner, or at all, which could result in associated reputational harm and subject us to enforcement action.

Further, the FDA may determine that we must provide additional evidence and data before approving an NDA for our candidate products. For example, the FDA reviews an application to determine whether there is "substantial evidence" to support a finding of effectiveness for the proposed product for its intended use(s), The FDA has interpreted this evidentiary standard to generally require at least two adequate and well-controlled clinical trials to establish effectiveness of a new product. Under certain circumstances, however, the FDA has indicated that a single trial with certain characteristics and additional confirmatory evidence may satisfy this standard. The FDA issued draft guidance in September 2023 that outlines considerations for relying on confirmatory evidence in lieu of a second clinical trial to demonstrate effectiveness. In the event that we submit an NDA on the basis of one clinical trial and confirmatory evidence, the FDA could determine that such information is not sufficient to support approval of the application and the agency could require us to conduct an additional trial in support of the NDA.

Even if we eventually complete clinical testing and receive approval of an NDA or foreign marketing application for our product candidates, the FDA or the applicable foreign regulatory authority may grant approval contingent on the performance of costly additional clinical trials, including Phase 4 clinical trials, and/or in the case of the FDA, the implementation of a Risk Evaluation and Mitigation Strategy, or REMS, which may be required to ensure safe use of the drug after approval. The FDA or the applicable foreign regulatory authority also may approve a product candidate for a more limited indication or a narrower patient population than we originally requested, and the FDA or applicable foreign regulatory authority may not approve the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval, or the failure to receive marketing authorization with a label that allows us to market the product candidate as we desire, would delay, prevent or otherwise limit commercialization of that product candidate and would materially adversely impact our business and prospects.

We are conducting clinical trials at sites outside the United States. The FDA may not accept data from trials conducted in such locations, and the conduct of trials outside the United States could subject us to additional delays and expense.

We are conducting one or more clinical trials with one or more trial sites that are located outside the United States. For example, our phase 1 clinical trial design of TERN-701 for the treatment of CML includes sites from the United States, Europe and other countries. The acceptance by the FDA or other regulatory authorities of study data from clinical trials conducted outside their jurisdiction may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means.

In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

Conducting clinical trials outside the United States also exposes us to additional risks, including risks associated with:

- additional foreign regulatory requirements;
- foreign exchange fluctuations;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research;
- diminished protection of intellectual property in some countries; and
- interruptions or delays in our trials resulting from geopolitical events, such as war or terrorism.

We may seek Fast Track designation for some or all of our other product candidates, including combination therapy candidates. We may not receive such designation, and even for those product candidates for which we do, it may not lead to a faster development or regulatory review or approval process, and will not increase the likelihood that product candidates will receive marketing approval.

We may seek Fast Track designation for some of our other product candidates, including combination therapy candidates. If a drug is intended for the treatment of a serious or life-threatening condition or disease, and nonclinical or clinical data demonstrate the potential to address an unmet medical need, the drug may qualify for FDA Fast Track designation, for which sponsors must apply. 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 product candidate may be eligible for priority review. 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. The FDA has broad discretion whether or not to grant this designation. Thus, even if we believe a particular product candidate is eligible for this designation, the FDA may decide not to grant it. Moreover, even if we do receive Fast Track designation, we or our collaborators may not experience a faster development process, review or approval compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program.

A Breakthrough Therapy designation by the FDA, even if granted for any of our product candidates, 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 a Breakthrough Therapy designation for one or more of our product candidates if the clinical data support such a designation for one or more product candidates. A Breakthrough Therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drug candidates 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. Breakthrough Therapy designation also provides the sponsor with the same benefits as Fast Track designation, including potential for rolling review of an NDA submission.

Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or approval compared to drug 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 as Breakthrough Therapies, the FDA may later decide that the single-agent or combination therapy no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

We may seek PRIME Designation in the European Union, but we might not receive such designations, and even if we do, such designation may not lead to a faster development or regulatory review or approval process.

In the EU, we may seek PRIME designation for some of our product candidates in the future. PRIME is a voluntary program aimed at enhancing the EMA's role to reinforce scientific and regulatory support in order to optimize development and enable accelerated assessment of new medicines that are of major public health interest with the potential to address unmet medical needs. The program focuses on medicines that target conditions for which there exists no satisfactory method of treatment in the EU or even if such a method exists, it may offer a major therapeutic advantage over existing treatments. PRIME is limited to medicines under development and not authorized in the EU and the applicant intends to apply for an initial marketing authorization application through the centralized procedure. To be accepted for PRIME, a product candidate must meet the eligibility criteria in respect of its major public health interest and therapeutic innovation based on information that is capable of substantiating the claims. The benefits of a PRIME designation include the appointment of a Committee for Medicinal Products for Human Use rapporteur to provide continued support and help to build knowledge ahead of a marketing authorization application, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review, meaning reduction in the review time for an opinion on approvability to be issued earlier in the application process. PRIME enables an applicant to request parallel EMA scientific advice and health technology assessment advice to facilitate timely market access. Even if we receive PRIME designation for any of our product candidates, the designation may not result in a materially faster development process, review or approval compared to conventional EMA procedures. Further, obtaining PRIME designation does not assure or increase the likelihood of EMA's grant of a marketing authorization.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions.

Moreover, in many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our drugs is also subject to approval.

Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our drugs in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Additionally, we could face heightened risks with respect to obtaining marketing authorization in the UK as a result of the withdrawal of the UK from the EU, commonly referred to as Brexit. The UK is no longer part of the European Single Market and EU Customs Union. As of January 1, 2025, the Medicines and Healthcare Products Regulatory Agency, or MHRA, is responsible for approving all medicinal products destined for the United Kingdom market (i.e., Great Britain and Northern Ireland). At the same time, a new international recognition procedure (IRP) will apply, which intends to facilitate approval of pharmaceutical products in the UK. The IRP is open to applicants that have already received an authorization for the same product from one of the MHRA's specified Reference Regulators (RRs). The RRs notably include EMA and regulators in the EU/European Economic Area (EEA) member states for approvals in the EU centralized procedure and mutual recognition procedure as well as the FDA (for product approvals granted in the U.S.). However, the concrete functioning of the IRP is currently unclear. Any delay in obtaining, or an inability to obtain, any marketing approvals may force us or our collaborators to restrict or delay efforts to seek regulatory approval in the UK for our product candidates, which could significantly and materially harm our business.

In addition, foreign regulatory authorities may change their approval policies and new regulations may be enacted. For instance, the EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's proposal for revision of several legislative instruments related to medicinal products (potentially reducing the duration of regulatory data protection and exclusivity periods for orphan drugs, revising the eligibility for expedited pathways, etc.) was published in April 2023. In April 2024, the European Parliament adopted a position on the proposal requesting several amendments to the package. The proposed revisions remain to be agreed and adopted by the European Parliament and European Council and the proposals may therefore be substantially revised before adoption, which is not anticipated before early 2026. The revisions may, however, have a significant impact on the pharmaceutical industry and our business in the long term.

We expect that we will be subject to additional risks in commercializing any of our product candidates that receive marketing approval outside the United States, including tariffs, trade barriers and regulatory requirements; economic weakness, including inflation, or political instability 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 revenue, and other obligations incident to doing business in another country; and workforce uncertainty in countries where labor unrest is more common than in the United States.

Even if we receive regulatory approval of our product candidates, 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.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the drug may be marketed or the conditions of approval, or contain requirements for potentially costly post-market testing and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require us to adopt a REMS, and foreign regulatory authorities may require us to adopt similar risk management measures, to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. We or our collaborators may also be required to adopt a REMS or engage in similar actions, such as patient education, certification of health care professionals or specific monitoring, if we or others later identify undesirable side effects caused by any drug that we develop alone or with collaborators.

In addition, if the FDA or a comparable foreign regulatory authority approves a product candidate, the manufacturing, quality control, labeling, packaging, distribution, AE reporting, storage, advertising, promotion, import, export and recordkeeping for the approved drug will be subject to extensive and ongoing regulatory requirements. The FDA and foreign regulatory authorities also require submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and similar foreign requirements and good clinical practice, or GCPs, for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with a product candidate, including AEs 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:

- issue warning letters or untitled letters;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners, or require other restrictions on the labeling or marketing of such drugs;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend, withdraw or modify regulatory approval;
- suspend or modify any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;

- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain drugs, refuse to permit the import or export of drugs or require us to initiate a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our drugs. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. For example, the policies advanced by the Trump Administration and the FDA Commissioner may impact our business and industry and the regulation of our products. 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.

In addition, we could be adversely affected by several significant administrative law cases decided by the U.S. Supreme Court in 2024. In *Loper Bright Enterprises v. Raimondo*, for example, the court overruled *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc*., which for 40 years required federal courts to defer to permissible agency interpretations of statutes that are silent or ambiguous on a particular topic. The U.S. Supreme Court stripped federal agencies of this presumptive deference and held that courts must exercise their independent judgment when deciding whether an agency such as the FDA acted within its statutory authority under the Administrative Procedure Act, or the APA. Additionally, in *Corner Post, Inc. v. Board of Governors of the Federal Reserve System*, the court held that actions to challenge a federal regulation under the APA can be initiated within six years of the date of injury to the plaintiff, rather than the date the rule is finalized. The decision appears to give prospective plaintiffs a personal statute of limitations to challenge longstanding agency regulations. Another decision, *Securities and Exchange Commission v. Jarkesy*, overturned regulatory agencies' ability to impose civil penalties in administrative proceedings. These decisions could introduce additional uncertainty into the regulatory process and may result in additional legal challenges to actions taken by federal regulatory agencies, including the FDA and CMS, that we rely on. In addition to potential changes to regulations as a result of legal challenges, these decisions may result in increased regulatory uncertainty and delays and other impacts, any of which could adversely impact our business and operations.

Further, our ability to develop and market new drug products may be impacted by litigation challenging the FDA's approval of another company's drug product. In April 2023, the U.S. District Court for the Northern District of Texas invalidated the approval by the FDA of mifepristone, a drug product which was originally approved in 2000 and whose distribution is governed by various measures adopted under a REMS. The Court of Appeals for the Fifth Circuit declined to order the removal of mifepristone from the market but did hold that plaintiffs were likely to prevail in their claim that changes allowing for expanded access of mifepristone, which the FDA authorized in 2016 and 2021, were arbitrary and capricious. In June 2024, the Supreme Court reversed that decision after unanimously finding that the plaintiffs (anti-abortion doctors and organizations) did not have standing to bring this legal action against the FDA. On October 11, 2024, the Attorneys General of three states (Missouri, Idaho and Kansas) filed an amended complaint in the district court in Texas challenging FDA's actions. On January 16, 2025, the district court agreed to allow these states to file an amended complaint and continue to pursue this challenge. Depending on the outcome of this litigation, our ability to develop new drug product candidates and to maintain approval of existing drug products could be delayed, undermined or subject to protracted litigation.

Any regulatory approval to market our products will be limited by indication. If we fail to comply or are found to be in violation of FDA regulations restricting the promotion of our products for unapproved uses, we could be subject to criminal penalties, substantial fines or other sanctions and damage awards.

The regulations relating to the promotion of products for unapproved uses are complex and subject to substantial interpretation by the FDA, EMA, MHRA and other government agencies. In September 2021, the FDA published final regulations which describe the types of evidence that the agency will consider in determining the intended use of a drug product. Physicians may nevertheless prescribe our products off-label to their patients in a manner that is inconsistent with the approved label. We intend to implement compliance and training programs designed to ensure that our sales and marketing practices comply with applicable regulations. Notwithstanding these programs, the FDA or other government agencies may allege or find that our practices constitute prohibited promotion of our products for unapproved uses. We also cannot be sure that our employees will comply with company policies and applicable regulations regarding the promotion of products for unapproved uses.

Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional scientific communications concerning their products in certain circumstances. For example, in January 2025, the FDA published final guidance outlining its policies governing the distribution of scientific information to healthcare providers about unapproved uses of approved products. The final guidance calls for such communications to be truthful, non-misleading and scientifically sound and to include all information necessary for healthcare providers to interpret the strengths and weaknesses and validity and utility of the information about the unapproved use of the approved product. If a company engages in such communications consistent with the guidance's recommendations, the FDA indicated that it will not treat such communications as evidence of unlawful promotion of a new intended use for the approved product.

In addition, under some relatively recent guidance from the FDA and the Pre-Approval Information Exchange Act, or PIE Act, signed into law as part of the Consolidated Appropriations Act of 2023, companies may also promote information that is consistent with the prescribing information and proactively speak to formulary committee members of payors regarding data for an unapproved drug or unapproved uses of an approved drug. We may engage in these discussions and communicate with healthcare providers, payors and other constituencies in compliance with all applicable laws, regulatory guidance and industry best practices. We will need to carefully navigate the FDA's various regulations, guidance and policies, along with recently enacted legislation, to ensure compliance with restrictions governing promotion of our products.

In recent years, a significant number of pharmaceutical and biotechnology companies have been the target of inquiries and investigations by various federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for unapproved uses and other sales practices, including the Department of Justice and various U.S. Attorneys' Offices, the Office of Inspector General of the Department of Health and Human Services, the FDA, the Federal Trade Commission, or the FTC, and various state Attorneys General offices. These investigations have alleged violations of various federal and state laws and regulations, including claims asserting antitrust violations, violations of the FDCA, the False Claims Act, the Prescription Drug Marketing Act and anti-kickback laws and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement. Many of these investigations originate as "*qui tam*" actions under the False Claims Act. Under the False Claims Act, any individual can bring a claim on behalf of the government alleging that a person or entity has presented a false claim or caused a false claim to be submitted to the government for payment. The person bringing a *qui tam* suit is entitled to a share of any recovery or settlement. *Qui tam* suits, also commonly referred to as "whistleblower suits," are often brought by current or former employees. In a *qui tam* suit, the government must decide whether to intervene and prosecute the case. If it declines, the individual may pursue the case alone.

If the FDA or any other governmental agency initiates an enforcement action against us or if we are the subject of a *qui tam* suit and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions would have an adverse effect on our revenue, business, financial prospects and reputation.

Our development programs may target indications that do not have a clearly defined regulatory pathway. For such indications, there is a heightened risk that we will not be able to gain agreement with regulatory authorities regarding an acceptable development plan, that the outcome of our clinical trials will not be favorable or that, even if favorable, regulatory authorities may not find the results of our clinical trials to be sufficient for marketing approval. This may make it difficult to predict the timing and costs of the clinical development of our product candidates.

We may evaluate our product candidates for, and may develop new drug candidates for, indications that do not have a clearly defined regulatory pathway, including potentially indications which have limited or no approved therapies. The regulatory approval process for novel drug candidates can be more expensive and take longer than for other, better known or extensively studied drug candidates. We expect that the path for regulatory approval for these therapies to continue to evolve as companies refine their regulatory approval strategies and interact with regulatory authorities. Such evolution may impact our future clinical trial designs, including trial size and approval endpoints, in ways that we cannot predict today.

In the United States, the FDA generally requires two adequate and well-controlled pivotal clinical trials to approve an NDA. Furthermore, for full approval of an NDA, the FDA requires a demonstration of efficacy based on a clinical benefit endpoint. The FDA may grant accelerated approval based on a surrogate endpoint reasonably likely to predict clinical benefit. Even though our pivotal clinical trials for a specific indication may achieve their primary endpoints and are reasonably believed by us to be likely to predict clinical benefit, the FDA may not accept the results of such trials or approve our product candidates on an accelerated basis, or at all. It is also possible that the FDA may refuse to accept for filing and review any regulatory application we submit for regulatory approval in the United States. Even if our regulatory application is accepted for review, there may be delays in the FDA's review process and the FDA may determine that such regulatory application does not contain adequate clinical or other data or support the approval of the product candidate. In such a case, the FDA may issue a complete response letter that may require that we conduct and/or complete additional clinical trials and preclinical studies or provide additional information or data before it will reconsider an application for approval. Any such requirements may be substantial, expensive and time-consuming, and there is no guarantee that we will continue to pursue such application or that the FDA will ultimately decide that any such application supports the approval of the product candidate. Furthermore, the FDA may also refer any regulatory application to an advisory committee for review and recommendation as to whether, and under what conditions, the application should be approved. While the FDA is not bound by the recommendation of an advisory committee, it considers such recommendations carefully when making decisions. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient revenue to maintain our business. Similar risks may apply in foreign jurisdictions.

Even if we receive accelerated approval for any of our product candidates, we anticipate we may be required to conduct or complete a post-approval clinical outcomes trial to confirm the clinical benefit of such product candidates by demonstrating the correlation of the surrogate endpoint therapeutic response in patients with a significant reduction in adverse clinical outcomes over time. There can be no assurance that the clinical outcomes trial will confirm that the surrogate endpoint used as the basis of the regulatory submissions we make will eventually show an adequate correlation with clinical outcomes.

Further, to the extent that we seek accelerated approval, we will need to comply with new provisions governing that route to approval. For example, with the passage of the Food and Drug Omnibus Reform Act, or FDORA, in December 2022, Congress modified certain provisions governing accelerated approval of drug and biologic products. Specifically, the new legislation authorized the FDA to: require a sponsor to have its confirmatory clinical trial underway before accelerated approval is awarded, require a sponsor of a product granted accelerated approval to submit progress reports on its post-approval studies to FDA every six months (until the study is completed); and use expedited procedures to withdraw accelerated approval of an NDA after the confirmatory trial fails to verify the product's clinical benefit. Further, FDORA requires the agency to publish on its website "the rationale for why a post-approval study is not appropriate or necessary" whenever it decides not to require such a study upon granting accelerated approval.

In March 2023, the FDA issued draft guidance that outlines its current thinking and approach to accelerated approval. The agency indicated that the accelerated approval pathway is commonly used for approval of oncology drugs due to the serious and life-threatening nature of cancer. Although single-arm trials have been commonly used to support accelerated approval, a randomized controlled trial is the preferred approach as it provides a more robust efficacy and safety assessment and allows for direct comparisons to an available therapy. To that end, the FDA outlined considerations for designing, conducting, and analyzing data for trials intended to support accelerated approvals of oncology therapeutics. Subsequently, in December 2024 and January 2025, the FDA issued additional draft guidances relating to accelerated approval. These guidances describe FDA's latest thinking on what it means to conduct a confirmatory trial with due diligence and how the agency plans to interpret whether such a study needs to be underway at the time of approval. While these guidances are currently only in draft form and will ultimately not be legally binding even when finalized, sponsors typically observe the FDA's guidance closely to ensure that their investigational products qualify for accelerated approval.

Our anticipated development costs would likely increase if development of any current or future product candidate is delayed because we are required by the FDA or similar foreign regulatory authorities to perform studies or trials in addition to, or different from, those that we currently conduct or anticipate. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to predict the timing or amount of any increase in our anticipated development costs.

We also may evaluate our product candidates in combination with one or more therapies that have not yet been approved for marketing by the FDA or similar foreign regulatory authorities. We may not be able to market and sell any product candidate we develop in combination with an unapproved therapy if that unapproved therapy does not ultimately obtain marketing approval. In addition, unapproved therapies face the same risks described with respect to our product candidates currently in development, including the potential for serious adverse effects, delay in their clinical trials and lack of FDA or European Commission approval. If the FDA, the European Commission or similar foreign regulatory authorities do not approve these other therapies or revoke their approval of, or if safety, efficacy, manufacturing, or supply issues arise with, the therapies we choose to evaluate in combination with our product candidates, we may be unable to obtain approval of or market any such product candidate.

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

The ability of the FDA and foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees and statutory, regulatory and policy changes. Average review times at the FDA and foreign regulatory authorities 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, EMA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities.

In addition, disruptions may result due to events similar to the COVID-19 pandemic. During the COVID-19 pandemic, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. In the event of a similar public health emergency in the future, the FDA may not be able to continue its current pace and review timelines could be extended. Regulatory authorities outside the United States facing similar circumstances may adopt similar restrictions or other policy measures in response to a similar public health emergency and may also experience delays in their regulatory activities.

Further, there is substantial uncertainty as to how measures being implemented by the new Trump Administration across the government will impact the FDA, CMS and other federal agencies with jurisdiction over our activities. For example, since taking office, President Trump has issued a number of executive orders, which could have a significant impact on the manner in which the FDA conducts its operations and engages in regulatory and oversight activities. These include E.O. 14192, "Unleashing Prosperity Through Deregulation," January 31, 2025; E.O. 14212, "Establishing the President's Make America Healthy Again Commission," February 13, 2025; and E.O. 14219, Ensuring Lawful Governance and Implementing the President's 'Department of Government Efficiency" Deregulatory Initiative," February 21, 2025. If these or other orders or executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. In addition, the loss of FDA personnel could lead to further disruptions and delays in FDA review and oversight of our product candidates. Similarly, efforts by the new administration to substantially reduce or delay research funding by the National Institutes of Health of medical research could have substantial direct or indirect impacts on our research activities.

If a prolonged government shutdown occurs, or if global health concerns continue to 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 other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Risks Related to Our Reliance on Third Parties

We rely completely on third parties to manufacture our clinical drug supplies and we intend to rely on third parties to produce commercial supplies of any approved product candidate, and our commercialization of any of our product candidates could be stopped, delayed or made less profitable if those third parties fail to obtain approval of the FDA or comparable regulatory authorities, fail to provide us with sufficient quantities of drug product or fail to do so at acceptable quality levels or prices.

We do not currently have nor do we plan to acquire the infrastructure or capability internally to manufacture our clinical drug supplies for use in the conduct of our clinical trials, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA or comparable foreign regulatory authorities pursuant to inspections that will be conducted after we submit our NDA to the FDA or comparable applications to those foreign authorities. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs or similar foreign requirements for manufacture of both active drug substances and finished drug products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority 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 regulatory approval for or market our product candidates, if approved.

We may be unable to obtain raw materials or drug components for an indeterminate period of time if any of our third-party suppliers and manufacturers were to cease or interrupt production or otherwise fail to supply these materials or components to us for any reason, including due to regulatory requirements or actions (including recalls), adverse financial developments at or affecting the supplier or manufacturer, failure by the supplier or manufacturer to comply with current good manufacturing practices, or cGMPs, contaminations, business interruptions, or labor shortages or disputes, or if we were to terminate our relationship with any of our third-party suppliers or manufacturers for any reason. For example, proposed legislation has been introduced in Congress that could prohibit, among other things, U.S. government agencies from entering into contracts with companies that use certain equipment or services provided by certain Chinese companies, which could cause us to reevaluate our relationship with our Chinese contract manufacturer.

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 technology required to manufacture our product candidates may be unique to the original manufacturer and we may have difficulty transferring such skills or technology to another third party. The process of changing manufacturers is extensive and time-consuming and could cause delays or interruptions in our drug development. Further, if we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical trials. There are a limited number of suppliers for raw materials that we use to manufacture our drugs and there may be a need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our clinical trials, and if approved, ultimately for commercial sale. We do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials. Although we generally do not begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the clinical trial, any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

We, or our manufacturing partners, may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If we or our manufacturing partners are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or become infeasible, and marketing approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business.

We expect to continue to depend on third-party contract manufacturers for the foreseeable future. We have not entered into long-term agreements with our current contract manufacturers or with any alternate fill/finish suppliers, and though we intend to do so prior to commercial launch in order to ensure that we maintain adequate supplies of finished drug product, we may be unable to enter into such an agreement or do so on commercially reasonable terms, which could have a material adverse impact upon our business. We currently obtain our supplies of finished drug product through individual purchase orders.

We rely on third parties to conduct, supervise and monitor our preclinical and clinical trials. If these third parties do not successfully carry out their contractual duties, meet rigorously enforced regulatory standards or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize any of our product candidates on a timely basis or at all.

We currently do not have the ability to independently conduct preclinical studies that comply with the regulatory requirements known as good laboratory practice, or GLP, requirements. The FDA and regulatory authorities in other jurisdictions require us to comply with GCP requirements for conducting, monitoring, recording and reporting the results of clinical trials, in order to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. We rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct GLP-compliant nonclinical studies and GCP-compliant clinical trials on our product candidates properly and on time. While we will have agreements governing their activities, we control only certain aspects of their activities and have limited influence over their actual performance. The third parties with whom we contract for execution of our GLP nonclinical studies and our GCP clinical trials play a significant role in the conduct of these studies and trials and the subsequent collection and analysis of data. These third parties are not our employees and, except for restrictions imposed by our contracts with such third parties, we have limited ability to control the amount or timing of resources that they devote to our programs. Although we rely on these third parties to conduct GLP-compliant preclinical and nonclinical studies and GCP-compliant clinical trials for our product candidates, we remain responsible for ensuring that each of our GLP preclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

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 drug development activities that could harm our competitive position. If the third parties conducting our GLP preclinical or nonclinical studies or our clinical trials do not perform their contractual duties or obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical trial protocols or to GCPs, or for any other reason, we may need to enter into new arrangements with alternative third parties. This could be difficult, costly or impossible, and our preclinical studies or clinical trials may need to be extended, delayed, terminated or repeated. As a result we may not be able to obtain regulatory approval in a timely fashion, or at all, for the applicable product candidate, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

We depend on collaborations with third parties for the development of certain of our drug candidates, and we may depend on additional collaborations in the future for the development and commercialization of these or other potential candidates. If our collaborations are not successful, our ability to develop and commercialize our product candidates could be adversely affected.

We are currently collaborating with third parties to develop certain of our potential drug candidates. For example, we are collaborating with Hansoh (Shanghai) Healthtech Co., Ltd. and Jiangsu Hansoh Pharmaceutical Group Company Ltd. with respect to certain aspects of TERN-701, our small-molecule allosteric inhibitor of the BCR-ABL fusion gene. In the future, we may seek collaboration arrangements for the commercialization, or potentially for the development, of certain of our other product candidates depending on the merits of retaining commercialization rights for ourselves as compared to entering into collaboration arrangements. For example, certain of the disease areas that we believe our product candidates address require large, costly and later-stage clinical trials, which a collaboration partner may be better positioned to finance and/or conduct. In addition, a component of our strategy is to maximize the commercial value of our current and future product candidates, which may also strategically align with partnering commercial rights with partners that have large and established sales organizations. To the extent that we decide to enter into collaboration agreements, we may face significant competition for appropriate collaborators. Moreover, collaboration arrangements are complex and time-consuming to negotiate, document, implement and maintain and challenging to manage. We may not be successful in our efforts to enter into collaboration agreements. The terms of collaborations or other arrangements that we may establish may not be favorable to us.

The success of our current and future collaboration arrangements will depend heavily on the efforts and activities of our collaborators.

Collaborations are subject to numerous risks, which may include risks that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to their acquisition of competitive products or their internal development of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, drugs that compete directly or indirectly with our product candidates;
- collaborators with marketing, manufacturing and distribution rights to one or more drugs may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and collaborators that cause the delay or termination of the research, development or commercialization of our current or future product candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, and, if terminated, this may result in a need for additional capital to pursue further development or commercialization of the applicable current or future product candidates;
- collaborators may own or co-own intellectual property covering drugs and other research that result from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property and may not be able to commercialize such intellectual property without their consent;
- disputes may arise with respect to the ownership of any intellectual property developed pursuant to our collaborations; and
- collaborators' sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

If our collaborations on research and development candidates do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future milestone or royalty payments under the collaboration.

If conflicts arise between us and our collaborators or strategic partners, these parties may act in a manner adverse to us and could limit our ability to implement our strategies.

If conflicts arise between our collaborators or strategic partners and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Current or future collaborators or strategic partners may develop, either alone or with others, products in related fields that are competitive with the products or potential products that are the subject of these collaborations.

Our current or future collaborators or strategic partners may preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, terminate their agreements with us prematurely or fail to devote sufficient resources to the development and commercialization of products. Furthermore, competing products, either developed by our current or future collaborators or strategic partners or to which our collaborators or strategic partners may have rights, may result in the withdrawal of partner support for our product candidates. Any of these developments could harm our product development efforts.

Risks Related to Commercialization of Our Product Candidates

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

The availability and adequacy of coverage and 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, assuming FDA approval. Our ability to achieve acceptable levels of coverage and reimbursement for products by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize our product candidates. Assuming we obtain coverage for our product candidates by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the European Economic Area, or EEA, or elsewhere will be available for our product candidates or any product that we may develop, and any reimbursement that may become available may be decreased or eliminated.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs or biologics when an equivalent generic drug, biosimilar or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates as substitutable and only offer to reimburse patients for the less expensive drug. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing third-party therapeutics may limit the amount we will be able to charge for our product candidates. 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 our product candidates. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be even more challenging given third-party payor price sensitivity to high-cost therapeutics (including oncology and other specialty medicines). 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. 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 our product candidates.

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 product candidates 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 on short notice, and such changes also may significantly impact the coverage and reimbursement levels for our products.

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 have and will continue to put pressure on the pricing and usage of our product candidates. 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, and instead 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 product candidates. Accordingly, in markets outside the United States, the reimbursement for our product candidates 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 product candidates. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and surgical procedures and other treatments, has become and remains intense. As a result, increasingly high barriers are being erected to the entry of new products.

Even if our current or future product candidates obtain regulatory approval, they may fail to achieve the broad degree of physician and patient adoption and use necessary for commercial success.

Even if one or more of our product candidates receive FDA or other regulatory approvals, 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. Given the number of drugs commercially available or in development for the treatment of CML, obesity, and other indications we pursue or may pursue, if we are unsuccessful in achieving a differentiated profile with our product candidates based on efficacy, safety and tolerability, dosing and administration, market acceptance may be limited. Our product candidates may not be commercially successful for a variety of reasons, including, among other things, competitive factors, pricing or physician preference, reimbursement by insurers, the degree and rate of physician and patient adoption of our current or future product candidates. If approved, the commercial success of our product candidates will depend on a number of factors, including:

- the clinical indications for which the product candidate is approved and patient demand for approved drugs that treat those indications;
- the safety and efficacy of our product candidates as compared to other available therapies;
- the availability of coverage and adequate reimbursement from managed care plans, insurers and other healthcare payors for any of our product candidates that may be approved;
- acceptance by physicians, operators of clinics and patients of the product candidate as a safe and effective treatment;
- physician and patient willingness to adopt a new therapy over other available therapies to treat approved indications;
- overcoming any biases physicians or patients may have toward particular therapies for the treatment of approved indications;
- proper training and administration of our product candidates by physicians and medical staff;
- public misperception regarding the use of our therapies, if approved for commercial sale;
- patient satisfaction with the results and administration of our product candidates and overall treatment experience, including, for example, the convenience of any dosing regimen;
- the cost of treatment with our product candidates in relation to alternative treatments and reimbursement levels, if any, and willingness to pay for the drug, if approved, on the part of insurance companies and other third-party payors, physicians and patients;
- the revenue and profitability that our product candidates may offer a physician as compared to alternative therapies;
- the prevalence and severity of side effects;
- limitations or warnings contained in the approved labeling for our drugs;
- the willingness of physicians, operators of clinics and patients to utilize or adopt our products as a solution;
- any FDA requirement to undertake a REMS or similar foreign regulatory requirement;
- the effectiveness of our sales, marketing and distribution efforts;
- adverse publicity about our product candidates or favorable publicity about competitive drugs; and

- potential product liability claims.

We cannot assure you that our current or future product candidates, if approved, will achieve broad market acceptance among physicians and patients. Any failure by our product candidates that obtain regulatory approval to achieve market acceptance or commercial success would adversely affect our results of operations.

We currently have no sales organization. If we are unable to establish sales capabilities on our own or through third parties, we may not be able to market and sell our product candidates, if approved, effectively in the United States and foreign jurisdictions or generate drug revenue.

We currently do not have a sales organization. In order to commercialize our product candidates in the United States and foreign jurisdictions, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If any of our product candidates receive regulatory approval, we expect to establish a sales organization with technical expertise and supporting distribution capabilities to commercialize each such product candidate, which will be expensive and time consuming. We have no prior experience in the marketing, sale and distribution of pharmaceutical, biopharmaceutical and biotechnology 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 choose to 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. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our product candidates. If we are not successful in commercializing our product candidates or any future product candidates, either on our own or through arrangements with one or more third parties, we may not be able to generate any future drug revenue and we would incur significant additional losses.

Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, CROs, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA and non-U.S. regulators, provide accurate information to the FDA and non-U.S. regulators, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, 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 comply with these laws or regulations. If any such actions are instituted against us those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations.

In addition, our contractors, consultants, employees, officers and members of our board of directors are regularly exposed to non-public information about corporate developments which could impact our stock price. Although we have procedures in place that are intended to prevent them from seeking to take advantage of that non-public information, it is possible that those individuals could attempt to profit from non-public information obtained from us, causing us reputational harm and exposing us to potential liability.

Our business operations and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we will conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. Such laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. 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 U.S. federal false claims and civil monetary penalties laws, including the civil False Claims Act, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. 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 a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or 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 U.S. 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 U.S. federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the government information related to certain payments and other transfers of value 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 the physicians described above and their immediate family members;

- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our future business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and
- similar healthcare laws and regulations in the EEA and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance 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 the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations.

If we successfully commercialize any of our product candidates, we may participate in the Medicaid Drug Rebate Program or other governmental pricing programs, and may become subject to state drug price transparency requirements. Our failure to comply with the related reporting and payment obligations could result in additional reimbursement requirements, penalties, sanctions and fines that could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

The Medicaid Drug Rebate Program, the 340B drug pricing program, the U.S. Department of Veterans Affairs Federal Supply Schedule program and other governmental pricing programs require participating manufacturers to report certain product and pricing data to the government. Pricing calculations vary among products and programs, are complex, and are often subject to interpretation by manufacturers, governmental or regulatory agencies and the courts, which can change and evolve over time. If we successfully commercialize any of our product candidates and participate in such governmental pricing programs, we may be held liable for errors associated with our submission of data. That liability could be significant, including potential civil monetary penalties per item of falsely reported or misrepresented drug pricing information. Such failure also could be grounds for other sanctions, such as termination from the Medicaid Drug Rebate Program. We cannot provide assurance that any of our submissions, if we participate in government price reporting programs, will not be found by a governmental agency to be incomplete, incorrect, or otherwise non-compliant. Further, a growing number of states have enacted drug price transparency laws requiring pharmaceutical manufacturers to report information to certain state agencies and other parties. Many of these laws provide for civil monetary penalties and other enforcement mechanisms if manufacturers are found to have violated requirements.

Enacted and future healthcare legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and may affect the prices we may set.

In the United States, the EEA and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. 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, or collectively the ACA, was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA, those of greatest importance to the pharmaceutical and biotechnology industries include the following:

- an annual, non-deductible fee payable by any entity that manufactures or imports certain branded prescription drugs and biologic agents (other than those designated as orphan drugs), which is apportioned among these entities according to their market share in certain government healthcare programs;

- a new Medicare Part D coverage gap discount program, in which manufacturers must agree 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;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- 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;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; and
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability.

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 a judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form. During the first Trump Administration, the Congress and administration sought to overturn the ACA and related measures. Shortly after taking office in January 2025, President Trump revoked numerous executive orders issued by President Biden, including at least two executive orders (EO 14009, Strengthening Medicaid and the Affordable Care Act, and EO 14070, Continuing to Strengthen Americans' Access to Affordable, Quality Health Coverage) which were designed to further implement the ACA. We anticipate similar efforts to undermine the ACA, and the accompanying uncertainty, for the foreseeable future.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, the Budget Control Act of 2011 resulted in aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2031, unless additional action is taken by Congress. Additionally, under Statutory PAYGO, the Administration is required to issue a sequestration order (capped at 4% for Medicare payments) if the PAYGO scorecard shows a net cost at the end of a Congressional session. Although Statutory PAYGO was expected to be triggered at the end of the 2021 Congressional session, subsequent legislation has delayed a Statutory PAYGO sequestration order until after 2024. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws or any other similar laws introduced in the future may result in additional reductions in Medicare and other health care funding, which could negatively affect our future customers and accordingly, our financial operations. Indeed, under current legislation, the actual reductions in Medicare payments may vary up to 4%.

The prices of prescription pharmaceuticals in the United States and foreign jurisdictions are subject to scrutiny and considerable legislative and executive actions that could impact the prices we obtain for our drug products, if and when approved.

The prices of prescription pharmaceuticals have been the subject of considerable discussion in the United States. There have been Congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to pharmaceutical pricing, review the relationship between pricing and manufacturer patient programs and reduce the costs of pharmaceuticals under Medicare and Medicaid.

In addition, in October 2020, HHS and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program, or SIP, to import certain prescription drugs from Canada into the United States. That regulation was challenged in a lawsuit by the Pharmaceutical Research and Manufacturers of America (PhRMA) but the case was dismissed by a federal district court in February 2023 after the court found that PhRMA did not have standing to sue HHS. Seven states (Colorado, Florida, Maine, New Hampshire, New Mexico, Texas and Vermont) have passed laws allowing for the importation of drugs from Canada. North Dakota and Virginia have passed legislation establishing workgroups to examine the impact of a state importation program. As of May 2024, five states (Colorado, Florida, Maine, New Hampshire and New Mexico) had submitted Section 804 Importation Program proposals to the FDA and, on January 5, 2024, the FDA approved Florida's plan for Canadian drug importation. That state now has authority to import certain drugs from Canada for a period of two years once certain conditions are met. Florida will first need to submit a pre-import request for each drug selected for importation, which must be approved by the FDA. The state will also need to relabel the drugs and perform quality testing of the products to meet FDA standards.

Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Pursuant to court order, the removal and addition of the aforementioned safe harbors were delayed and recent legislation imposed a moratorium on implementation of the rule until January 1, 2026. The Inflation Reduction Act of 2022 (IRA) further delayed implementation of this rule to January 1, 2032.

On August 16, 2022, the IRA was signed into law by President Biden. The new legislation has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B to give them the option of paying a monthly premium for outpatient prescription drug coverage. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; 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 HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years.

Specifically, with respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B and Part D. CMS may negotiate prices for ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028 and 20 Part B or Part D drugs in 2029 and beyond. This provision applies to drug products that have been approved for at least 9 years and biologics that have been licensed for 13 years, but it does not apply to drugs and biologics that have been approved for a single rare disease or condition. Nonetheless, since CMS may establish a maximum price for these products in price negotiations, we would be fully at risk of government action if our products are the subject of Medicare price negotiations. Moreover, given the risk that could be the case, these provisions of the IRA may also further heighten the risk that we would not be able to achieve the expected return on our drug products or full value of our patents protecting our products if prices are set after such products have been on the market for nine years.

The first cycle of negotiations for the Medicare Drug Price Negotiation Program commenced in the summer of 2023. In August 2024, the HHS published the results of the first Medicare drug price negotiations for ten selected drugs that treat a range of conditions, including diabetes, chronic kidney disease, and rheumatoid arthritis. The prices of these ten drugs will become effective January 1, 2026. On January 17, 2025, CMS announced its selection of 15 additional drugs covered by Part D for the second cycle of negotiations. Thereafter, following the change in administrations, CMS issued a public statement on January 29, 2025, declaring that lowering the cost of prescription drugs is a top priority of the new administration and CMS is committed to considering opportunities to bring greater transparency in the negotiation program. The second cycle of negotiations with participating drug companies will occur during 2025, and any negotiated prices for this second set of drugs will be effective starting January 1, 2027.

Further, the legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law or for taking price increases that exceed inflation. In addition to the drug price negotiation program, the IRA established inflation rebate programs under Medicare Part B and Part D. These programs require manufacturers to pay rebates to Medicare if they raise their prices for certain Part B and Part D drugs faster than the rate of inflation. On December 9, 2024, with issuance of its 2025 Physician Fee Schedule final regulation, CMS finalized its rules governing the IRA inflation rebate programs. The new law also capped Medicare out-of-pocket drug costs at an estimated $4,000 a year in 2024 and, thereafter beginning in 2025, at $2,000 a year. In addition, the IRA potentially raises legal risks with respect to individuals participating in a Medicare Part D prescription drug plan who may experience a gap in coverage if they required coverage above their initial annual coverage limit before they reached the higher threshold, or "catastrophic period" of the plan. Individuals requiring services exceeding the initial annual coverage limit and below the catastrophic period, must pay 100% of the cost of their prescriptions until they reach the catastrophic period. Among other things, the IRA contains many provisions aimed at reducing this financial burden on individuals by reducing the co-insurance and co-payment costs, expanding eligibility for lower income subsidy plans and price caps on annual out-of-pocket expenses, each of which could have potential pricing and reporting implications.

On June 6, 2023, Merck & Co. filed a lawsuit against the HHS and CMS asserting that, among other things, the IRA's Drug Price Negotiation Program for Medicare constitutes an uncompensated taking in violation of the Fifth Amendment of the Constitution. Subsequently, a number of other parties, including the U.S. Chamber of Commerce, Bristol Myers Squibb Company, the PhRMA, Astellas, Novo Nordisk, Janssen Pharmaceuticals, Novartis, AstraZeneca and Boehringer Ingelheim, also filed lawsuits in various courts with similar constitutional claims against the HHS and CMS. HHS has generally won the substantive disputes in these cases, and various federal district court judges have expressed skepticism regarding the merits of the legal arguments being pursued by the pharmaceutical industry. Certain of these cases are now on appeal and, on October 30, 2024, the Court of Appeals for the Third Circuit heard oral argument in three of these cases. We expect that litigation involving these and other provisions of the IRA will continue, with unpredictable and uncertain results.

Accordingly, while it is currently unclear how the IRA will be effectuated, we cannot predict with certainty what impact any federal or state health reforms will have on us, but such changes could impose new or more stringent regulatory requirements on our activities or result in reduced reimbursement for our products, any of which could adversely affect our business, results of operations and financial condition.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, designed to encourage importation from other countries and bulk purchasing. 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 or put pressure on our product pricing. This may be increasingly true with respect to products approved pursuant to the accelerated approval pathway. State Medicaid programs and other payers are developing strategies and implementing significant coverage barriers, or refusing to cover these products outright, arguing that accelerated approval drugs have insufficient or limited evidence despite meeting the FDA's standards for accelerated approval.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

If the market opportunities for any product candidate that we or our strategic collaborators develop are smaller than we believe they are, our revenue may be adversely affected and our business may suffer.

We intend to initially focus our product candidate development on therapies for the treatment of serious diseases such as CML and obesity. Our projections of addressable patient populations that have the potential to benefit from treatment with our product candidates are based on 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 studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may not ultimately be amenable to treatment with our product candidates. Our market opportunity may also be limited by future competitor treatments that enter the market. If any of our estimates are inaccurate, the market opportunities for any of our product candidates could be significantly diminished and have an adverse material impact on our business.

Risks Related to Intellectual Property

Our current and any future product candidates could be alleged to infringe patent rights and other intellectual property rights of third parties, which may require costly litigation and, if we are not successful, could cause us to pay substantial damages and/or limit our ability to commercialize our drugs and combination therapy candidates.

Our commercial success depends on our ability to develop, manufacture and market our current and any future product candidates that may be approved for sale and to use our proprietary technology without infringing the patents and other intellectual property rights of third parties. If any third-party patents or other intellectual property rights are found to cover our product candidates or their compositions, methods of use or manufacturing, we may be required to pay damages, which could be substantial, and we would not be free to manufacture or market our product candidates or to do so without obtaining a license, which may not be available on commercially reasonable terms, or at all. Regardless of merits, intellectual property disputes can be costly to defend, time-consuming and may cause our business, operating results and financial condition to suffer.

We operate in an industry with extensive intellectual property litigation. As the pharmaceutical, biopharmaceutical and biotechnology industries expand and more patents are issued, the risks increase that there may be patents issued to third parties that relate to our products and technology of which we are not aware or that we may need to challenge to continue our operations as currently contemplated. These risks may also increase because of the highly competitive therapeutic areas in which we are developing product candidates, in particular oncology and obesity, and the number of other companies pursuing new and innovative treatments for serious diseases in these areas, potentially resulting in various overlapping patent claims held by a number of different companies.

From time to time, we may be subject to legal proceedings and claims with respect to intellectual property relating to our product candidates and technologies we use in our business. The risks of being involved in such legal proceedings may increase as our product candidates advance in clinical development and near potential commercialization. We may face allegations that we have infringed the trademarks, copyrights, patents and other intellectual property rights of third parties, including patents held by our competitors or by non-practicing entities. For example, we are aware of patents and patent applications owned by third parties, some with broad claims, that such parties may assert cover our compounds currently in research and development. Litigation may make it necessary to defend ourselves by determining the scope, enforceability and validity of third-party proprietary rights, or to establish our proprietary rights. Interference or derivation proceedings provoked by third parties or brought by us or declared by the United States Patent and Trademark Office, or USPTO, may be necessary to determine the priority of inventions or establish proprietary rights with respect to our patents or patent applications or those of our licensors. Regardless of whether claims that we are infringing patents or other intellectual property rights have merit, the claims can be time consuming, divert management attention and financial resources and are costly to evaluate and defend. The legal threshold for initiating litigation or contested proceedings is low, so that even lawsuits or proceedings with a modest probability of success might be initiated against us. Results of any such litigation are difficult to predict and may prevent us from further developing, manufacturing, or commercializing the infringing product candidate or treating certain conditions, may require us to obtain licenses or modify our drugs or combination therapies and features while we develop non-infringing substitutes, or may result in significant settlement costs. For example, litigation can involve substantial damages for infringement, and if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees. We may also be prohibited from selling or licensing our product candidates unless the third party licenses rights to us, which it may not be required to do at a commercially reasonable price or at all. If a license is available from a third party, we may have to pay substantial

royalties or upfront fees or grant cross-licenses to intellectual property rights for our product candidates. Even if we were able to obtain a license, it could be non-exclusive, thereby giving competitors access to the same intellectual property or technologies licensed to us.

Although we have reviewed certain third-party patents and patent applications that we believe may be relevant to certain of our product candidates, we have not conducted a freedom-to-operate search or analysis for all of our product candidates. As such, we may not be aware of patents or pending or future patent applications that, if issued, would block us from commercializing our product candidates. We cannot guarantee that our product candidates, or our commercialization thereof, do not and will not infringe any third party's intellectual property.

In addition, patent applications in the United States and many international jurisdictions are typically not published until 18 months after the filing of certain priority documents (or, in some cases, are not published until they issue as patents) and publications in the scientific literature often lag behind actual discoveries. Claims in patent applications can also be revised before issuance. Therefore, we cannot be certain that others have not filed patent applications or made public disclosures relating to our technology or our contemplated technology. A third party may have filed, and may in the future file, patent applications covering our product candidates or technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, depending on whether the timing of the filing date falls under certain patent laws, we may have to participate in a priority contest (such as an interference proceeding) declared by the USPTO to determine priority of invention in the United States. The costs of patent litigation and other proceedings could be substantial, and it is possible that such efforts would be unsuccessful if it is determined that the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such invention.

The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our product candidates either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be successful in doing so. Proving invalidity or unenforceability is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, or enforceability.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively or dedicate substantially greater resources to prosecuting legal actions than we can. 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 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 material adverse effect on the price of our common stock. Any uncertainties resulting from the actual or potential initiation and continuation of any litigation, regardless of merit, could have a material adverse effect on our ability to finance our continuing operations or to support our research and development activities for a particular product candidate, whether through public or private equity offerings, debt financings or other sources, such as license transactions or strategic collaborations.

There can be no assurance with respect to the outcome of any future litigation brought by or against us, and the outcome of any such litigation could have a material adverse impact on our business, operating results and financial condition. Litigation is inherently unpredictable, and outcomes are uncertain. Further, as the costs and outcome of these types of claims and proceedings can vary significantly, it is difficult to estimate potential losses that may occur. Such claims and 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. Accordingly, we are unable at this time to estimate the effects of these potential future lawsuits on our financial condition, operations or cash flows.

We may be subject to claims by employees, consultants and contractors claiming ownership of what we regard as our own intellectual property.

While it is our policy to require our employees, consultants 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, which may result in claims by or against us related to the ownership of such intellectual property. In addition, such agreements may not be self-executing such that the intellectual property subject to such agreements may not be assigned to us without additional assignments being executed, and we may fail to obtain such assignments. In addition, such agreements may be breached. Accordingly, 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. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to obtain, maintain and enforce intellectual property protection directed to our current and any future technologies that we develop, others may be able to make, use or sell products substantially the same as ours, which could adversely affect our ability to compete in the market.

The market for pharmaceuticals and biopharmaceuticals is highly competitive and subject to rapid technological change. Our success depends, in part, upon our ability to maintain a competitive position in the development and protection of technologies and any future product candidates for use in these fields and upon our ability to obtain, maintain and enforce our intellectual property rights. We seek to obtain and maintain patents and other intellectual property rights to restrict the ability of others to market products that misappropriate our technology and/or infringe our intellectual property to unfairly and illegally compete with any of our product candidates. If we are unable to protect our intellectual property and proprietary rights, our competitive position and our business could be harmed, as third parties may be able to make, use or sell products that are substantially the same as any product candidates we may sell without incurring the sizeable development and, in some cases, licensing costs that we have incurred, which would adversely affect our ability to compete in the market. We use a combination of patents, trademarks, know-how, confidentiality procedures and contractual provisions to protect our proprietary technology and that of our licensors. However, these protections may not be adequate and may not provide us with any competitive advantage. For example, patents may not issue from any of our or our licensors' currently pending or any future patent applications, and our or our licensors' issued patents and any future patents that may issue may not survive legal challenges to their scope, validity or enforceability or provide significant protection for us.

To protect our proprietary position, we generally file patent applications in the United States and in certain foreign countries related to our product candidates that we consider important to our business. The patent application and approval process is expensive, time-consuming and complex. We may not be able to file, prosecute and maintain all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, depending on the terms of any future license or collaboration agreements to which we may become a party, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology licensed from third parties. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

Furthermore, the patent position of biotechnology and pharmaceutical companies generally is highly uncertain. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. The standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. In addition, the determination of patent rights with respect to biological and pharmaceutical products commonly involves complex legal and factual questions, which have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Thus, we cannot offer any assurances about which, if any, patents will issue, the breadth of any such patents, whether any issued patents will be found invalid and unenforceable or will be threatened by third parties or whether any issued patents will effectively prevent others from commercializing competing technologies and product candidates.

The USPTO, international patent offices or judicial bodies may deny or significantly narrow claims made under our patent applications, and our issued patents may be successfully challenged, may be designed around or may otherwise be of insufficient scope to provide us with protection for our drugs or combination therapies. Further, the USPTO, international trademark offices or judicial bodies may deny our trademark applications and, even if published or registered, these trademarks may not effectively protect our brand and goodwill. Like patents, trademarks also may be successfully opposed or challenged.

We cannot be certain that the steps we have taken will prevent unauthorized use or unauthorized reverse engineering of our technology. Moreover, third parties may independently develop technologies that are competitive with ours and such competitive technologies may or may not infringe our intellectual property. The enforcement of our intellectual property rights also depends on the success of any legal actions we may take against these infringers in the respective country or forum, but these actions may not be successful. As with all granted intellectual property, such intellectual property may be challenged, invalidated or circumvented, may not provide protection and/or may not prove to be enforceable in actions against specific alleged infringers.

Even if our patents are determined by a court to be valid and enforceable, they may not be interpreted sufficiently broadly to prevent others from marketing products similar to ours or designing around our patents. For example, third parties may be able to make products that are similar to ours but that are not covered by the claims of our patents. Third parties may assert that we or our licensors were not the first to make the inventions covered by our issued patents or pending patent applications. The claims of our or our licensors' issued patents or patent applications when issued may not cover our product candidates or any future products that we develop. We may not have freedom to commercialize unimpeded by the patent rights of others. Third parties may have patents that dominate, block or are otherwise relevant to our technology. There may be prior public disclosures or other art that could be deemed to invalidate one or more of our patent claims. Further, we may not develop additional proprietary technologies in the future, and, if we do, they may not be patentable.

We may not be able to correctly estimate or control our future operating expenses in relation to obtaining intellectual property, enforcing intellectual property and/or defending intellectual property, which could affect operating expenses. Our operating expenses may fluctuate significantly in the future as a result of a variety of factors, including the costs of preparing, filing, prosecuting, defending and enforcing patent and trademark claims and other intellectual property-related costs, including adverse proceedings and litigation costs.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful. Further, our issued patents could be found invalid or unenforceable if challenged in court.

Competitors may infringe our intellectual property rights or those of our licensors. To prevent infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in a patent infringement proceeding, a court may decide that one or more patent of ours or any of our current licensors or future licensors is not valid or is unenforceable, in whole or in part, or may refuse to stop the other party from using the technology at issue on the grounds that our or our licensors' patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our or our licensors' patents at risk of being invalidated or interpreted narrowly, which may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products, and could put our or our licensors' patent applications at risk of not issuing. If we or any of our potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at our products, the defendant could counterclaim that our or our licensors' patent is invalid and/or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could also include 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 also raise similar validity claims before the USPTO in post-grant proceedings such as *ex parte* reexaminations, inter partes review or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation.

If a defendant were to prevail on a legal assertion of invalidity or unenforceability of our or our licensors' patents covering one of our product candidates, we could lose a part, and perhaps all, of the patent protection covering such candidate. Competing products may also be sold in other countries in which our patent coverage might not exist or be as strong. If we lose a foreign patent lawsuit, alleging our infringement of a competitor's patents, we could be prevented from marketing our products in one or more foreign countries. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition.

The outcome following legal assertions of invalidity and unenforceability is unpredictable, and prior art could render our patents or those of our licensors invalid. Similar mechanisms for challenging the validity and enforceability of a patent exist in ex-U.S. patent offices and may result in the revocation, cancellation, or amendment of any ex-U.S. patents we hold in the future. For the patents and patent applications that we may license in the future, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on such product candidate. Such a loss of patent protection would have a material adverse impact on our business.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. 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. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

We may not be able to prevent, alone or with our potential licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Our defense of litigation or interference or other intellectual property proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring our products to market.

We license or otherwise have access to patent rights from third-party owners. Such licenses or other arrangements may be subject to early termination if we fail to comply with our obligations in our agreements with third parties, which could result in the loss of rights or technology that are material to our business.

We are a party to licenses and other agreements that give us rights to third-party intellectual property that are necessary or useful for our business, and we may enter into additional licenses or other agreements in the future. For example, we are party to an assignment agreement with Vintagence Biotechnology Ltd. with respect to our THR-β program. Under these agreements, we are obligated to pay the counterparties fees, which may include annual license fees, milestone payments, royalties, a percentage of revenues associated with the applicable technology and a percentage of sublicensing revenue. In addition, under certain of such agreements, we are required to diligently pursue the development of products using the applicable technology. If we fail to comply with these obligations and fail to cure our breach within a specified period of time, the counterparty may have the right to terminate the applicable agreement, in which event we could lose valuable rights and technology that are material to our business.

We may rely on third parties from whom we license proprietary technology to file and prosecute patent applications and maintain patents and otherwise protect the intellectual property we license from them. We may have limited control over these activities or any other intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that such activities by these licensors will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We may have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that may be licensed to us. It is possible that the licensors' infringement proceeding or defense activities may be less vigorous than if we conduct them ourselves.

Our intellectual property agreements with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations to our licensors.

Certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology, or affect financial or other obligations under the relevant agreement, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may jointly own certain patent rights with third parties. Our ability to out-license these patent rights, or to prevent the third party from out-licensing these patent rights, may be limited in certain countries.

We may jointly own patents and patent applications with third parties in the future. Unless we enter into an agreement with the joint owner, we will be subject to certain default rules pertaining to joint ownership. Certain countries require the consent of all joint owners to license jointly owned patents, and if we are unable to obtain such consent from the joint owner, we may not be able to license our rights under these patents and patent applications. In certain other countries, including the United States, the joint owner could license its rights under these patents and patent applications to another party without our consent and without any duty of accounting to us.

We may in the future be dependent on intellectual property licensed or sublicensed to us from, or for which development was funded or otherwise assisted by, government agencies, such as the National Institutes of Health, for development of our technology and product candidates. Failure to meet our own obligations to our licensors or upstream licensors, including such government agencies, may result in the loss of our rights to such intellectual property, which could harm our business.

In the future, government agencies may provide funding, facilities, personnel or other assistance in connection with the development of the intellectual property rights owned by or licensed to us. Such government agencies may retain rights in such intellectual property, including the right to grant or require us to grant mandatory licenses or sublicenses to such intellectual property to third parties under certain specified circumstances, including if it is necessary to meet health and safety needs that we are not reasonably satisfying or if it is necessary to meet requirements for public use specified by federal regulations, or to manufacture products in the United States. Any exercise of such rights, including with respect to any such required sublicense of these licenses could result in the loss of significant rights and could harm our ability to commercialize licensed products.

We may be subject to claims challenging the inventorship or ownership 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 patents or other intellectual property as an inventor or co-inventor or owner. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship and/or ownership. 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, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We or our licensors may in the future rely on third-party consultants or collaborators or on funds from third parties, such as the U.S. government, such that we or our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights or other rights to our patents, including in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is common in the pharmaceutical and biotechnology industries, in addition to our employees, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, universities or other pharmaceutical or biotechnology companies including our competitors or potential competitors. These employees and consultants may have executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such other current or previous employment. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us and seek assurances that they will not, we may become subject to claims that we, our employees or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. Litigation may be necessary to defend against these claims. If we fail in successfully defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, which could adversely affect our business. Such intellectual property could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or drugs and combination therapies. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team. Any of the foregoing would 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 rights throughout the world.

We have a number of patents and patent applications in foreign countries, and expect to continue to pursue patent protection in many of the significant markets in which we intend to do business. However, filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. The requirements for patentability may differ in certain countries, particularly in developing countries. In addition, any future intellectual property license agreements may not always include worldwide rights. Consequently, we have not pursued or maintained, and may not pursue or maintain in the future, patent protection for our product candidates in every country or territory in which we may sell our drugs and combination therapies and 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 or maintained patent protection to develop their own products, and may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the United States and where our ability to enforce our patents to stop infringing activities may be inadequate. These products may compete with any current or future product candidates we may sell, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

Moreover, our ability to protect and enforce our intellectual property and proprietary rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, the laws of some countries outside of the United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States and Europe. Many companies have encountered significant problems in protecting and defending intellectual property and proprietary rights in certain foreign jurisdictions. The legal systems of some countries, including, for example, India, the PRC, and other developing countries, do not favor the enforcement of patents and other intellectual property or proprietary rights, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement, misappropriation or other violation of our patents or other intellectual property or proprietary rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the United States and Europe. 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.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and 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 rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our single-agent and combination therapies.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents or patent applications, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending patent application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending patent application may be incorrect, which may negatively impact our ability to market our product candidates. We may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third-party's pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents or patent applications may negatively impact our ability to develop and market our product candidates.

One aspect of the determination of patentability of our inventions depends on the scope and content of the "prior art," information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim. Further, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates or their intended uses, and as a result the impact of such third-party intellectual property rights upon the patentability of our own patents and patent applications, as well as the impact of such third-party intellectual property upon our freedom to operate, is highly uncertain. Because patent applications in the United States and most other countries are confidential for typically a period of 18 months after filing, or may not be published at all, we cannot be certain that we were the first to file any patent application related to our product candidates. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Furthermore, for U.S. applications in which all claims are entitled to a priority date before March 2013, an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. For U.S. patents and patent applications containing a claim not entitled to priority before March 2013, there is a greater level of uncertainty in the patent law in view of the passage of the Leahy-Smith America Invents Act, or the AIA, which brought into effect significant changes to the U.S. patent laws, including new procedures for challenging pending patent applications and issued patents.

Patent terms may be inadequate to establish 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 effective non-provisional filing date. Patent terms may be shortened or lengthened by, for example, terminal disclaimers, patent term adjustments, supplemental protection certificates and patent term extensions, but the life of a patent, and the protection it affords, is limited. Non-payment or delay in payment of patent fees, maintenance fees or annuities, delay in patent filings or delay in extension filings (including any patent term extension or adjustment filings), whether intentional or unintentional, may result in the loss of patent rights important to our business. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from competitive medications, including generic versions. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents directed towards such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours for a meaningful amount of time, or at all.

Depending upon the timing, duration and conditions of any FDA marketing approval of our product candidates, one or more of our owned or licensed U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or Hatch-Waxman Act and similar legislation in the EU and certain other jurisdictions. The Hatch-Waxman Act permits, in certain cases, a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval, and the amount of available extension to any extension-eligible patent which claims a product, a method of using a product or a method of manufacturing a product, depends on a variety of factors, including the date on which the patent issues and certain dates related to the regulatory review period. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product candidate will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and nonclinical data and launch their product earlier than might otherwise be the case, and our competitive position, business, financial condition, results of operations and prospects could be materially harmed.

Further, there are detailed rules and requirements regarding the patents that may be submitted to the FDA for listing in the Orange Book. We may be unable to obtain patents covering our product candidates that contain one or more claims that satisfy the requirements for listing in the Orange Book. Even if we submit a patent for listing in the Orange Book, the FDA may decline to list the patent, or a manufacturer of generic drugs may challenge the listing. If one of our product candidates is approved and a patent covering that product candidate is not listed in the Orange Book, a manufacturer of generic drugs would not have to provide advance notice to us of any abbreviated new drug application filed with the FDA to obtain permission to sell a generic version of such product candidate. Any of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects.

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or patent applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or patent applications. We employ reputable professionals and rely on such third parties to help us comply with these requirements and effect payment of these fees with respect to the patents and patent applications that we own, and we may have to rely upon our licensors to comply with these requirements and effect payment of these fees with respect to any patents and patent applications that we license. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

Changes in patent law in the United States or in other countries could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Our patent rights may be affected by developments or uncertainty in U.S. or ex-U.S. patent statutes, patent case laws in USPTO rules and regulations or in the rules and regulations of ex-U.S. patent offices. There are a number of changes to the U.S. patent laws that may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, in September 2011, the AIA, was signed into law. The AIA includes provisions that affect the way patent applications are prosecuted and affect patent litigation. In particular, under the AIA, the United States transitioned in March 2013 to a "first to file" system in which the first inventor to file a patent application is entitled to the patent. Third parties are allowed to submit prior art before the issuance of a patent by the USPTO, and may become involved in post-grant proceedings including opposition, derivation, reexamination, inter partes review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position. This could have a negative impact on some of our intellectual property and could increase uncertainties surrounding obtaining and enforcement or defense of our issued patents.

In addition, Congress may pass patent reform legislation that is unfavorable to us. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on decisions by Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents we might obtain in the future. Similarly, statutory or judicial changes to the patent laws of other countries may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U.S. and international legislative bodies. Those changes may materially affect the patents and patent applications of our licensors, our existing or future patents and patent applications and our ability to obtain additional patents in the future.

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

We rely on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information. We have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors. 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, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Even though we use commonly accepted security measures, the criteria for protection of trade secrets can vary among different jurisdictions. Additionally, such security measures may not provide adequate protection for our proprietary information, for example, in the case of misappropriation of a trade secret by an employee, consultant, customer or third party with authorized access. Recourse we take against such misconduct may not provide an adequate remedy to fully protect our interests. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our product candidates that we consider proprietary.

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. Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. Trade secrets will over time be disseminated within the industry through independent development, the publication of journal articles and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. Though our agreements with third parties typically restrict the ability of our advisors, employees, collaborators, licensors, suppliers, third-party contractors and consultants to publish data potentially relating to our trade secrets, our agreements may contain certain limited publication rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Because from time to time we expect to rely on third parties in the development, manufacture and distribution of our product candidates, we must, at times, share trade secrets with them. Despite employing the contractual and other security precautions described above, the need to share trade secrets increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

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 current or future trademarks or trade names may be challenged, infringed, circumvented or declared generic or descriptive determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we would be 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, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

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 single-agent or combination therapy names, it 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. 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. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

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 product candidates that are similar to ours but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of 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 owned or licensed pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors 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;
- we cannot predict the scope of protection of any patent issuing based on our owned or licensed patent applications, including whether the patent applications that we own or in-license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries;
- the claims of any patent issuing based on our owned or licensed patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties;
- if enforced, a court may not hold that our owned or licensed patents are valid, enforceable and infringed;
- we may need to participate in litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- we may be required to coordinate with licensors on enforcement of our patents;
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application and secure an issued patent covering such intellectual property;
- we may fail to adequately protect and police our trademarks and trade secrets; and
- the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patents and patent applications.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

Other Risks Related to Our Business

If we fail to attract and retain senior management and key scientific personnel or if we lose our personnel for health or other reasons, our business may be materially and adversely affected.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management and clinical and scientific personnel. We are highly dependent upon members of our senior management team and our senior scientists. The loss of services of any of these individuals could delay or prevent the successful development of our pipeline, initiation or completion of our planned clinical trials or the commercialization of our current or future product candidates.

Competition for qualified personnel in the pharmaceutical, biopharmaceutical and biotechnology field is intense due to the limited number of individuals who possess the knowledge, skills and experience required by our industry. We will need to hire additional personnel as we expand our clinical development and, if we initiate commercial activities, establish newly created roles at the leadership and operational levels. We may not be able to attract and retain quality personnel on acceptable terms, or at all. In addition, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output.

We will need to increase the size of our organization, and we may experience difficulties in managing growth.

As of December 31, 2024, we had 59 full-time employees. We will need to continue to expand our managerial, operational, finance and other resources to manage our operations and clinical trials, continue our development activities and, if approved, commercialize our preclinical and clinical-stage product candidates or any future product candidates. Our management and personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our growth strategy requires that we:

- manage our preclinical studies and clinical trials effectively;
- identify, recruit, retain, incentivize, train and integrate additional employees, including additional clinical development and sales personnel;
- manage our internal development and operational efforts effectively while carrying out our contractual obligations to third parties; and
- continue to improve our operational, financial and management controls, reports systems and procedures.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- we will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful;
- we may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law;
- we are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification;

- we will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification;
- the rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons; and
- we may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

While we maintain a directors' and officers' insurance policy, such insurance may not be adequate to cover all liabilities that we may incur, which may reduce our available funds to satisfy third-party claims and may adversely impact our cash position.

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

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any single-agent or combination therapies. For example, we may be sued if any drug we develop allegedly causes injury or is found to be otherwise unsuitable during clinical 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, negligence, strict liability and breach of warranty. 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 commercialization of our product candidates. 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 current or future product candidates;
- injury to our reputation;
- delay or termination of clinical trials;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue; and
- the inability to commercialize our current or any future product candidates, if approved.

If we are unable to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims, the commercialization of our current or any future product candidates we develop could be inhibited or prevented. We currently carry product liability insurance covering our clinical trials. 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 also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will 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 funds to pay such amounts.

Moreover, insurance laws vary significantly from country to country, and many countries require insurance to be approved by regulators of the respective country. As such, our existing insurance policies might not meet the requirements of a global trial, which could cause significant delays in our clinical trials and related business objectives. Additionally, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. If and when we obtain approval for marketing any of our product candidates, we intend to expand our insurance coverage to include the sale of such product candidate; however, we may be unable to obtain this liability insurance on commercially reasonable terms or at all.

As a company with some operations and vendors located outside of the United States, our business is subject to economic, political, regulatory and other risks associated with international operations.

As a company with some operations and vendors outside of the United States, including our outsourced manufacturing vendors, our business is subject to risks associated with conducting business outside the United States. Accordingly, our future results could be harmed by a variety of factors, including:

- economic weakness, including inflation, or political instability in particular non-U.S. economies and markets;
- differing jurisdictions could present different issues for securing, maintaining or obtaining freedom to operate in such jurisdictions;
- potentially reduced protection for intellectual property rights;
- difficulties in compliance with different, complex and changing laws, regulations and court systems of multiple jurisdictions and compliance with a wide variety of foreign laws, treaties and regulations;
- changes in non-U.S. regulations and customs, tariffs and trade barriers;
- changes in non-U.S. currency exchange rates of the Renminbi, or RMB, U.S. dollar, euro and currency controls;
- changes in a specific country's or region's political or economic environment, particularly China;
- trade protection measures, import or export licensing requirements or other restrictive actions by governments;
- negative consequences from changes in tax laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad, including, for example, the variable tax treatment in different jurisdictions of options granted or to be granted under our equity plans;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- litigation or administrative actions resulting from claims against us by current or former employees or consultants individually or as part of class actions, including claims of wrongful terminations, discrimination, misclassification or other violations of labor law or other alleged conduct;
- difficulties associated with staffing and managing international operations, including differing labor relations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, state and non-state sponsored cyber intrusions and attacks, health epidemics, or natural disasters including earthquakes, typhoons, floods and fires.

See "—Risks Related to Doing Business in China" for additional risks related to our operations in China.

Our business involves the use of hazardous materials, and we and our suppliers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our research and development activities and our third-party suppliers' activities involve the controlled storage, use and disposal of hazardous materials owned by us, including the components of our product candidates and other hazardous compounds. We and any third-party manufacturers and suppliers are subject to numerous federal, state and local environmental, health and safety laws, regulations and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air and water; and employee health and safety. Our operations and those of our third-party manufacturers and CROs involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations and those of our third-party manufacturers and CROs also produce hazardous waste. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' and CROs' facilities pending their use and disposal. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations and environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products.

We cannot guarantee that the safety procedures utilized by our third-party manufacturers and CROs for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, nor can we eliminate the risk of accidental contamination or injury from these materials. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources, and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance.

Compliance with applicable environmental laws and regulations change regularly and may be expensive and difficult to execute effectively, and current or future environmental laws and regulations may impair our research and product development efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from hazardous materials or wastes. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could have a material adverse effect on our business, results of operations and financial condition.

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

The global data protection landscape is rapidly evolving, and we and our partners and vendors are or may become subject to various federal, state and foreign laws, regulations and requirements governing the collection, use, disclosure, retention and security of personal information, such as information that we may collect in connection with clinical trials. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulations, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our operations, financial performance and business.

In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy laws and federal and state consumer protection laws and regulations that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our partners. For example, most healthcare providers, including research institutions from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009. Under HIPAA, we could potentially face substantial criminal or civil 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, or otherwise violate applicable HIPAA requirements related to the protection of such information.

Even when HIPAA does not apply, failing to take appropriate steps to keep consumers' personal information secure may constitute a violation of the FTC Act. The FTC has been particularly focused on the unpermitted processing of health data through its recent enforcement actions and is expanding the types of privacy violations that it interprets to be "unfair" under Section 5 of the FTC Act, The agency is also in the process of developing rules related to commercial surveillance and data security. We will need to account for the FTC's evolving rules and guidance for proper privacy and data security practices in order to mitigate risk for a potential enforcement action, which may be costly. The FTC's enforcement priorities (as well as those of other federal regulators) may be impacted by the change in administration and new leadership. These shifts in enforcement priorities may also impact our business.

There are also increased restrictions at the federal level relating to transferring sensitive data outside of the United States to certain foreign countries. For example, in 2024, Congress passed H.B. 815, which included the Protecting Americans' Data from Foreign Adversaries Act of 2024. This law creates certain restrictions for entities that disclose sensitive data (including potential health data) to countries such as China. Failure to comply with these rules can lead to a potential FTC enforcement action. Additionally, the Department of Justice recently finalized a rule implementing Executive Order 14117, which creates similar restrictions related to the transfer of sensitive US data to countries such as China. These data transfer restrictions (and others that may pass in the future) may create operational challenges and legal risks for our business.

In addition, we may maintain sensitive personally identifiable information, including health information, that we receive throughout the clinical trial process, in the course of our research collaborations and directly from individuals (or their healthcare providers) who enroll in our patient assistance programs. As such, we may be subject to state laws requiring notification of affected individuals and state regulators in the event of a breach of personal information. In 2018 California passed into law the California Consumer Privacy Act, or CCPA, which took effect on January 1, 2020, and imposed many requirements on businesses that process the personal information of California residents. Many of the CCPA's requirements are similar to those found in the General Data Protection Regulation, or the GDPR, including requiring businesses to provide notice to data subjects regarding the information collected about them and how such information is used and shared, and providing data subjects the right to request access to such personal information and, in certain cases, request the erasure of such personal information. The CCPA also affords California residents the right to opt-out of "sales" of their personal information. The CCPA contains significant penalties for companies that violate its requirements. In November 2020 California voters passed a ballot initiative for the California Privacy Rights Act, or the CPRA, which went into effect on January 1, 2023, and significantly expanded the CCPA to incorporate additional GDPR-like provisions including requiring that the use, retention, and sharing of personal information of California residents be reasonably necessary and proportionate to the purposes of collection or processing, granting additional protections for sensitive personal information, and requiring greater disclosures related to notice to residents regarding retention of information. The CPRA also created a new enforcement agency – the California Privacy Protection Agency – whose sole responsibility is to enforce the CPRA and other California privacy laws, which will further increase compliance risk. The provisions in the CPRA may apply to some of our business activities.

In addition to California, at least 18 other states have passed comprehensive privacy laws similar to the CCPA and CPRA. These laws are either in effect or will go into effect sometime before the end of 2026. Like the CCPA and CPRA, these laws create obligations related to the processing of personal information, as well as special obligations for the processing of "sensitive" data (which includes health data in some cases). Some of the provisions of these laws may apply to our business activities. There are also states that are considering or have already passed comprehensive privacy laws during the 2023 legislative sessions that will go into effect in 2024 and beyond. There are also states that are specifically regulating health information that may affect our business. For example, Washington state recently passed a health privacy law that will regulate the collection and sharing of health information, and the law also has a private right of action, which further increases the relevant compliance risk. These laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

Plaintiffs' lawyers are also increasingly using privacy-related statutes at both the state and federal level to bring lawsuits against companies for their data-related practices. In particular, there have been a significant number of cases filed against companies for their use of pixels and other web trackers. These cases often allege violations of the California Invasion of Privacy Act and other state laws regulating wiretapping, as well as the federal Video Privacy Protection Act. The rise in these types of lawsuits creates potential risk for our business.

Our Phase 1 trial for TERN-701, the CARDINAL trial, includes sites from the United States, Europe and other countries. Any clinical trial programs and research collaborations, among other activities, that we engage in outside the United States may implicate international data protection laws, including, in the EEA, the GDPR, which became effective in 2018. The GDPR imposes stringent operational requirements for processors and controllers of personal data. Among other things, the GDPR requires covered companies to provide detailed notices and to abide by consent requirements for clinical trial subjects and other data subjects, to follow procedures regarding the security of personal data and notification of data processing obligations or security incidents to appropriate data protection authorities or data subjects, and to honor and provide certain privacy rights to individuals within the EEA, including the right to access, correct and delete their personal data. If our privacy or data security measures fail to comply with the requirements of the GDPR or other applicable laws or regulations, we may be subject to litigation, regulatory investigations, enforcement notices and/or enforcement actions requiring us to change the way we use personal data and/or fines. In addition to statutory enforcement, a personal data breach can lead to negative publicity and a potential loss of business. 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. Further, from January 1, 2021, we have had to comply with the GDPR and the United Kingdom GDPR, or 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. The relationship between the United Kingdom and the EU in relation to certain aspects of data protection law remains unclear, and it is unclear how United Kingdom data protection laws and regulations will develop in the medium to longer term. The European Commission has adopted an adequacy decision in

favor of the United Kingdom, enabling data transfers from EU member states to the United Kingdom without additional safeguards. However, the UK adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews or extends that decision.

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; in July 2020, the Court of Justice of the European Union, or CJEU, invalidated the EU-US Privacy Shield Framework, or Privacy Shield for purposes of international transfers. The EU-US Privacy Shield has now been replaced with the EU-US Data Privacy Framework (DPF), which is intended to address the issues cited by the CJEU in its 2020 court decision. The European Commission issued an adequacy decision for the DPF on July 10, 2023, and it is now a valid mechanism to transfer data from the EU to the US for entities that have registered as part of the DPF. However, it is possible that the validity of the DPF will be challenged in court, which could further create instability related to international data transfers. Additionally, the recent election in the United States and the new administration may also impact whether the DPF remains an adequate data transfer framework. The continuing uncertainty around this issue may further impact our business operations in the EEA.

The CJEU's decision in 2020 also imposed further restrictions on the use of SCCs. The European Commission issued revised SCCs on June 4, 2021 to account for the decision of the CJEU and recommendations made by the European Data Protection Board. The revised SCCs must be used for relevant new data transfers from September 27, 2021. There is also some uncertainty around whether the revised clauses can be used for all types of data transfers, particularly whether they can be relied on for data transfers to non-EEA entities subject to the GDPR. 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.

The new SCCs apply only to the transfer of personal data outside of the EEA and not the United Kingdom. The United Kingdom has its own guidance for data transfers to other jurisdictions that are not covered by an "adequacy" decision (which includes the United States) and has adopted the International Data Transfer Agreement, which can serve as a basis for companies to lawfully transfer outside of the United Kingdom. The United Kingdom also has its own data privacy framework that allows registered companies to transfer data from the UK to the US in accordance with the UK GDPR. It is unclear whether this data transfer mechanism will also be challenged in the future.

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. We will likely be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. Claims that we have violated individuals' privacy rights, failed to comply with applicable laws or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend, and could result in adverse publicity that could harm our business. Moreover, even if we take all necessary action to comply with regulatory requirements, we could be subject to a hack or data breach, which could subject us to fines and penalties, as well as reputational damage.

If we or our partners or vendors fail to comply with applicable federal, state, or local regulatory requirements, we could be subject to a range of regulatory actions that could affect our or any collaborators' ability to seek to commercialize our clinical candidates. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business. Any of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects.

We or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our corporate headquarters and other facilities are located in the San Francisco Bay Area, which has experienced both severe earthquakes and the effects of wildfires. We do not carry earthquake insurance. Earthquakes, wildfires or other natural disasters could severely disrupt our operations, and could materially and adversely affect our business, financial condition, results of operations and prospects.

If a natural disaster, power outage or other event occurred that damaged critical infrastructure or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

Furthermore, integral parties in our supply chain are similarly vulnerable to natural disasters or other sudden, unforeseen and severe AEs.

If such an event were to affect our supply chain, it could have a material adverse effect on our business.

Significant disruptions of information technology systems, breaches of data security and other incidents could materially adversely affect our business, results of operations and financial condition.

We collect and maintain information in digital and other forms that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the privacy, security, confidentiality and integrity of such confidential information. We have established physical, electronic and organizational measures designed to safeguard and secure our systems to prevent a data compromise, and rely on commercially available systems, software, tools and monitoring to provide security for our information technology systems and the processing, transmission and storage of digital information. We have also outsourced elements of our information technology infrastructure, and as a result, our third-party vendors may have access to our confidential information. Our internal information technology systems and infrastructure, and those of any future collaborators and our contractors, consultants, vendors and other third parties on which we rely, are vulnerable to damage or unauthorized access or use resulting from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, denial or degradation of service attacks, ransomware, hacking, phishing and other social engineering attacks, attachments to emails, persons inside our organization or persons with access to systems inside our organization.

The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, non-state foreign actors and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. The prevalent use of mobile devices that access confidential information also increases the risk of lost or stolen devices, security incidents and data security breaches, which could lead to the loss of confidential information or other intellectual property. A number of our employees work remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. Although we do not believe that we have experienced any material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations or those of our third-party CROs, vendors and other contractors and consultants, it could result in a material disruption of our development programs and our business operations. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or those of our third-party CROs, vendors and other contractors and consultants, or inappropriate disclosure of confidential or proprietary information or patient information, we could incur liability and the further development and commercialization of our product candidates could be delayed. For example, the loss or misuse of

clinical trial or patient data from completed or future clinical trials could result in material delays in and interruptions to our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on our third-party research institution collaborators for research and development of our product candidates and other third parties for the manufacture of our product candidates and to conduct clinical trials and similar events relating to their computer systems could also have a material adverse effect on our business. We cannot assure you that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages, breaches in our systems, or those of our third-party CROs, vendors and other contractors and consultants, or other cyber incidents that could have a material adverse effect upon our reputation, business, operations or financial condition. Any security incident or disruption event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our clinical trial subjects or employees, could harm our reputation, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business. The costs related to significant security breaches or disruptions could also be material and exceed the limits of any applicable insurance we may maintain against such risks. If the information technology systems of our third-party CROs, vendors and other contractors and consultants become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring.

In addition, we have and will enter into collaboration, license, contract research and/or manufacturing relationships with contract organizations that operate in certain countries that are at heightened risk of theft of technology, data and intellectual property through direct intrusion by private parties or foreign actors, including those affiliated with or controlled by state actors. Accordingly, our efforts to protect and enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license, and we may be at heightened risk of losing our proprietary intellectual property rights around the world, including outside of such countries, to the extent such theft or intrusion destroy the proprietary nature of our intellectual property.

Any failure of our technology or systems to perform satisfactorily could result in an adverse impact on our business.

We rely on software, hardware, network systems and similar technology, including cloud-based technology, that is either developed by us or licensed from or maintained by third parties to operate our website, our internal systems and processes, and to store and track certain data, and to support our business operations. As much of this technology is complex, there may be future errors, defects or performance problems, including when we update our technology or integrate new technology to expand and enhance our capabilities. Our technology may malfunction or suffer from defects that become apparent only after extended use. The integrity of our technology may also be compromised as a result of third-party cyber-attacks, such as hacking, spear phishing campaigns and denial of service attacks, which are negatively impacting companies. In addition, our operations depend on our ability to protect our information technology systems against damage from third-party cyber-attacks, fire, power loss, water, earthquakes, telecommunications failures and similar unexpected AEs. Disruptions in our website, internal systems and clinical research or network systems could result from a number of factors, including unknown technical defects, insufficient capacity, the failure of our third-party providers to provide continuous and uninterrupted service and unusual volume in traffic for our internal systems. Such disruptions would be most impactful if they occurred in connection with our data storage and clinical research data and may impact accessibility to our clinical research and operations. While we maintain disaster recovery capabilities to return to normal operation in a timely manner, and we deploy multiple parallel instances of our applications across multiple computer resources, we do not have a fully redundant system that includes an instantaneous recovery capability. In the event we experience significant disruptions, we may be unable to repair our systems in an efficient and timely manner, which could have an adverse impact on our business.

As a result of such possible defects, failures, interruptions or other problems, our data and clinical research could be rendered inoperable, which could result in harm to our reputation and our ability to develop our product candidates. Any failure of our technology or systems could result in an adverse impact on our business.

We are subject to United States and foreign anti-corruption and anti-money laundering laws with respect to our operations and non-compliance with such laws can subject us to criminal and/or civil liability and harm our business.

We are subject to the FCPA, the United States domestic bribery statute contained in 18 U.S.C. § 201, the United States Travel Act, the USA PATRIOT Act and other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, third-party intermediaries, joint venture partners and collaborators from authorizing, promising, offering or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We may have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. In addition, we may engage third party intermediaries to promote our clinical research activities abroad and/or to obtain necessary permits, licenses and other regulatory approvals. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, partners and agents, even if we do not explicitly authorize or have actual knowledge of such activities.

Noncompliance with anti-corruption and anti-money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension and/or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage and other collateral consequences. If any subpoenas, investigations or other enforcement actions are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense and compliance costs and other professional fees. In certain cases, enforcement authorities may even cause us to appoint an independent compliance monitor which can result in added costs and administrative burdens.

We will also need to carefully navigate the new administration's implementation of the FCPA. On February 10, 2025, President Trump issued an Executive Order directing the Attorney General to review the guidelines and policies governing FCPA investigations and enforcement actions. Per the Executive Order, this review will result in new DOJ FCPA guidelines intended to enhance American economic competitiveness and to safeguard national security interests. During the 180-day review period, any new FCPA investigations and enforcement actions are to be suspended absent authorization from the Attorney General, and all existing FCPA investigations and enforcement actions will be reviewed. Additionally, after the Attorney General issues revised guidelines, the Executive Order directs her to assess whether "remedial measures" related to past FCPA actions are warranted.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. Further, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order, or use of medicinal products is prohibited in the EU. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of EU Member States and the United Kingdom Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes, or professional codes of conduct applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines, or imprisonment.

Risks Related to Doing Business in China

Changes in U.S. and international trade policies, particularly with respect to China, may adversely impact our business and operating results.

The U.S. government has recently made statements and taken certain actions that may lead to potential changes to U.S. and international trade policies, including imposing several rounds of tariffs and export control restrictions affecting certain products manufactured in China, and most recently, proposing legislation that, if enacted would restrict trade with certain Chinese companies that provide biopharmaceutical research, development, and manufacturing services. Recently both China and the United States have each imposed tariffs indicating the potential for further trade barriers, including the U.S. Commerce Department adding numerous Chinese entities to its "unverified list," which requires U.S. exporters to go through more procedures before exporting goods to such entities. It is unknown whether and to what extent new tariffs, export controls, or other new laws or regulations will be adopted, or the effect that any such actions would have on us or our industry. Sustained uncertainty about, or the further escalation of, trade and political tensions between the United States and China could result in a disadvantageous research and manufacturing environment in China, particularly for U.S. based companies, including retaliatory restrictions that hinder or potentially inhibit our ability to rely on CDMOs and other service providers that operate in China. For example, proposed legislation has been introduced in Congress that could prohibit, among other things, the use of U.S. government executive agency contract, grant, or loan funding to procure or obtain, or enter into, extend or renew contracts involving the use of certain equipment or services produced or provided by certain Chinese companies, including our current CDMO, WuXi Biologics, which could cause us to reevaluate our relationship with our current CDMO.

Further, some of our manufacturers and suppliers are located in China. Trade tensions and conflicts between the United States and China have been escalating in recent years and, as such, we are exposed to the possibility of product supply disruption and increased costs and expenses in the event of changes to the laws, rules, regulations and policies of the governments of the United States or China, or due to geopolitical unrest and unstable economic conditions. Certain Chinese biotechnology companies may become subject to trade restrictions, sanctions, other regulatory requirements or proposed legislation by the U.S. government, which could restrict or even prohibit our ability to work with such entities, thereby potentially disrupting their supply of material to us. For example, in February 2024, U.S. lawmakers called for investigations into and the imposition of possible trade sanctions against certain Chinese biotechnology companies, including WuXi AppTec and WuXi Biologics, or collectively WuXi, over alleged ties to the Chinese military. Escalating tensions between the United States and China may prevent or hinder the export of materials or technical information between us and our CDMO and third parties, such as pharmaceutical partners. These third parties may voluntarily require compliance or supply chain requirements that go above and beyond potential legislation to address perceived risk of "pass through," which would make it difficult for us to operate our business.

In addition, in September 2024 during the 118th Congress, the U.S. House of Representatives passed the BIOSECURE Act (H.R. 8333). This bill names the following as biotechnology companies of concern: BGI, MGI, Complete Genomics, WuXi AppTec, and WuXi Biologics. The Senate advanced a substantially similar bill (S. 3558) but it did not pass. The Senate bill named the following as biotechnology companies of concern: BGI, MGI, Complete Genomics, WuXi AppTec, and any subsidiary, parent affiliate, or successor of such entities. If this legislation had been enacted into law, and while both bills had certain grandfather provision, the legislation would have potentially restricted the ability of U.S. biotechnology companies like ours to purchase services or products from, or otherwise collaborate with, specifically named Chinese biotechnology companies, including WuXi, and it would have authorized the U.S. government to impose such restrictions on entities' transactions with additional Chinese biotechnology companies as a condition of U.S. government contract, grant and loan funding. We anticipate these bills will be reintroduced during the 119th Congress but, as of February 20, 2025, they have not been introduced in either chamber. If these bills become law, or similar laws are passed, they would have the potential to severely restrict the ability of companies like ours to contract with certain Chinese biotechnology companies of concern without losing the ability to contract with, or otherwise received funding from, the U.S. government. Such disruptions could have adverse effects on the development of our product candidates and our business operations.

Any unfavorable government policies on international trade, such as export controls, capital controls or tariffs, may increase the cost of manufacturing our product candidates and platform materials, affect the demand for our drug products (if and once approved), the competitive position of our product candidates, and import or export of raw materials and finished product candidate used in our and our collaborators' preclinical studies and clinical trials, particularly with respect to any product candidates and materials that we import from China, including pursuant to our manufacturing service arrangements with WuXi. If any new tariffs, export controls, legislation and/or regulations are implemented, or if existing trade agreements are renegotiated or, in particular, if either the U.S. or Chinese government takes retaliatory trade actions due to the recent trade tension, such changes could have an adverse effect on our business, financial condition and results of operations.

China's economic, political and social conditions, as well as governmental policies, could affect our ability to operate our business.

A significant portion of our manufacturing operations is currently conducted in China. Accordingly, our business, results of operations, financial condition and prospects may be influenced to a significant degree by economic, political, legal and social conditions in China as well as China's economic, political, legal and social conditions in relation to the rest of the world. China's economy differs from the economies of developed countries in many respects, including with respect to the amount of government involvement, level of development, growth rate, control of foreign exchange and allocation of resources. While China's economy has experienced significant growth in the past, growth has slowed down and has been uneven across different regions and among various economic sectors of China. China's government has implemented various measures to encourage economic development and guide the allocation of resources. Some of these measures may have a negative effect on us. For example, our financial condition and results of operations may be adversely affected by government control over capital investments or changes in tax regulations that are currently applicable to us. In addition, in the past, China's government implemented certain measures, including interest rate increases, to control the pace of economic growth. These measures may cause decreased economic activity in China, which may adversely affect our business and results of operation. More generally, if the business environment in China deteriorates from the perspective of domestic or international investment, our business in China may also be adversely affected.

The pharmaceutical industry in China is highly regulated and such regulations are subject to change which may affect approval and commercialization of our product candidates.

Some of our research and development operations and manufacturing facilities are in China. The pharmaceutical industry in China is subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new drugs. In recent years, the regulatory framework in China regarding the pharmaceutical industry has undergone significant changes, and we expect that it will continue to undergo significant changes. Any such changes or amendments may result in increased compliance costs on our business or cause delays in or prevent the successful development of our product candidates in China and reduce the current benefits we believe are available to us from developing and manufacturing drugs in China. PRC authorities have become increasingly vigilant in enforcing laws in the pharmaceutical industry and any failure by us or our partners to maintain compliance with applicable laws and regulations or obtain and maintain required licenses and permits may result in the suspension or termination of our business activities in China. We believe our strategy and approach are aligned with the PRC government's regulatory policies, but we cannot ensure that our strategy and approach will continue to be aligned.

If we fail to comply with environmental, health and safety laws and regulations of China, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our manufacturing operations primarily occur in China and involve the use of hazardous materials, including chemical materials. Our operations also produce hazardous waste products. We are therefore subject to PRC laws and regulations concerning the discharge of waste water, gaseous waste and solid waste during our processes of research and development of our product candidates. We engage competent third-party contractors for the transfer and disposal of these materials and wastes. Despite our intention to do so, we may not comply fully with environmental regulations at all times. Any violation of these regulations may result in substantial fines, criminal sanctions, revocations of operating permits, shutdown of our facilities and obligations to take corrective measures. We cannot completely eliminate the risk of contamination or injury from these materials and wastes. In the event of contamination or injury resulting from the use or discharge of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil, administrative or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover costs and expenses incurred due to on-the-job injuries to our employees and third-party liability insurance for injuries caused by unexpected seepage, pollution or contamination, such insurance may not provide adequate coverage against potential liabilities. Furthermore, China may take steps towards the adoption of more stringent environmental regulations. Due to the possibility of unanticipated regulatory or other developments, the amount and timing of future environmental expenditures may vary substantially from those currently anticipated. If there is any unanticipated change in the environmental regulations, we may need to incur substantial capital expenditures to install, replace, upgrade or supplement our manufacturing facility and equipment or make operational changes to limit any adverse impact or potential adverse impact on the environment in order to comply with new environmental protection laws and regulations. If such costs become prohibitively expensive, we may be forced to cease certain aspects of our business operations.

Failure to comply with PRC regulations regarding the registration requirements for employee stock ownership plans or equity incentive plans may subject the PRC plan participants or us to fines and other legal or administrative sanctions.

Under the applicable regulations and State Administration of Foreign Exchange of the People's Republic of China, or SAFE, rules, PRC citizens who participate in an employee stock ownership plan or a stock option plan in an overseas publicly listed company are required to register with SAFE and complete certain other procedures. In February 2012, SAFE promulgated the Notices on Issues concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Publicly Listed Companies, or the Stock Option Rules, which replaced the Application Procedures of Foreign Exchange Administration for Domestic Individuals Participating in Employee Stock Ownership Plan or Stock Option Plans of Overseas Publicly Listed Companies issued by SAFE in March 2007. Pursuant to the Stock Option Rules, if a PRC resident participates in any stock incentive plan of an overseas publicly listed company, a qualified PRC domestic agent must, among other things, file on behalf of such participant an application with SAFE to conduct the SAFE registration with respect to such stock incentive plan and obtain approval for an annual allowance with respect to the purchase of foreign exchange in connection with the exercise or sale of stock options or stock such participant holds. Such participating PRC residents' foreign exchange income received from the sale of stock and dividends distributed by the overseas publicly listed company must be fully remitted into a PRC collective foreign currency account opened and managed by the PRC agent before distribution to such participants. We and our PRC resident employees who have been granted stock options or other stock-based incentives of ours are subject to the Stock Option Rules. If we or our PRC resident participants fail to comply with these regulations, we and/or our PRC resident participants may be subject to fines and legal sanctions.

Risks Related to Our Common Stock

Our stock price may be volatile and you may not be able to resell shares of our common stock at or above the price you paid.

The trading price of our common stock could be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. In particular, the trading prices for pharmaceutical, biopharmaceutical and biotechnology companies have been highly volatile. These factors include those discussed in this Item 1A. "Risk Factors" section of this Annual Report on Form 10-K and others such as:

- results from, and any delays in, our clinical trials for our clinical-stage drug candidates or any other future clinical development programs;
- announcements of regulatory approval or disapproval of our current or any future product candidates;
- the failure or discontinuation of any of our research and development programs;
- the termination of any of our existing license agreements;
- announcements relating to any future licensing, collaboration or development agreements;
- delays in the commercialization of our current or any future product candidates;
- public misperception regarding the use of our product candidates;
- acquisitions and sales of new products or product candidates, technologies or businesses;
- manufacturing and supply issues related to our product candidates for clinical trials or future product candidates for commercialization;
- quarterly variations in our results of operations or those of our competitors;
- changes in earnings estimates or recommendations by securities analysts;
- announcements by us or our competitors related to new or existing products or drug candidates, significant contracts, commercial relationships, acquisitions or capital commitments;
- developments with respect to intellectual property rights;
- our commencement of, or involvement in, litigation;
- changes in financial estimates or guidance or publicly communicated corporate plans or strategy;
- any major changes in our board of directors or management;
- new legislation or regulation in the United States or abroad relating to the sale or pricing of pharmaceuticals;
- the FDA or other U.S. or foreign regulatory actions affecting us or our industry or the indications for which we are developing our current or future product candidates;
- product liability claims or other litigation or public concern about the safety of our product candidates;
- market conditions in the pharmaceutical, biopharmaceutical and biotechnology sectors; and
- general economic conditions in the United States and abroad, including as a result of an economic recession or depression and market volatility related to the COVID-19 pandemic and global health concerns.

In addition, the stock markets in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme volatility that may have been unrelated to the operating performance of the issuer. These broad market fluctuations may adversely affect the trading price or liquidity of our common stock.

We have incurred and will continue to incur significant costs as a result of operating as a public company, and our management devotes substantial time to new compliance initiatives. We may fail to comply with the rules that apply to public companies, including Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, which could result in sanctions or other penalties that could materially and adversely affect our business, financial condition, results of operations and prospects.

We have incurred and will continue to incur significant legal, accounting and other expenses as a public company, including costs resulting from public company reporting obligations under the Exchange Act and regulations regarding corporate governance practices. The listing requirements of The Nasdaq Global Select Market and the rules of the SEC require that we satisfy certain corporate governance requirements relating to director independence, filing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel need to devote a substantial amount of time to ensure that we comply with all of these requirements. Moreover, the reporting requirements, rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

We are subject to Section 404 and the related rules of the SEC, which generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Section 404 requires an annual management assessment of the effectiveness of our internal control over financial reporting. However, for so long as we remain an emerging growth company as defined in the JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are available to emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404. Once we are no longer an emerging growth company or, if prior to such date, we opt to no longer take advantage of the applicable exemption, we will be required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting.

During the course of our review and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports. Furthermore, if we identify any material weaknesses, or even if we do not identify a material weakness but one exists, we may not detect those errors on a timely basis and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could materially and adversely affect our business, financial condition, results of operations and prospects, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company we will be required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. In order to report our results of operations and financial statements on an accurate and timely basis, we will depend in part on CROs and other third parties to provide timely and accurate notice of their costs to us. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from the Nasdaq Global Market or other adverse consequences that would materially and adversely affect our business, financial condition, results of operations and prospects.

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.

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 and may be difficult to predict, including but not limited to:

- the timing and cost of, and level of investment in, research, development, pre-commercial and, if approved, commercialization activities relating to our product candidates, which may change from time to time;
- the timing and status of enrollment for our clinical trials;
- the cost of manufacturing our product candidates, as well as building out our supply chain, which may vary depending on the quantity of production and the terms of our agreements with manufacturers;

- expenditures that we may incur to acquire, develop or commercialize additional product candidates and technologies;
- timing and amount of any milestone, royalty or other payments due under any collaboration or license agreement;
- future accounting pronouncements or changes in our accounting policies;
- the timing and success or failure of preclinical studies and 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 timing of receipt of approvals for, and the scope of or limitation on the marketing authorizations received on, our product candidates from regulatory authorities in the United States and internationally;
- coverage and reimbursement policies with respect to our product candidates, if approved, and potential future drugs that compete with our single agent and combination therapies;
- the level of demand for our product candidates, if approved, which may vary significantly over time; and
- the impact from COVID-19, which may have the effect of magnifying many of the factors described above.

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 any 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.

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

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards, or NOLs and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income or taxes may be limited. We have experienced ownership changes in the past and may experience ownership changes as a result of subsequent shifts in our stock ownership (some of which are outside our control). In addition, under current tax law, federal NOLs generated in periods after December 31, 2017 may be carried forward indefinitely but in taxable years beginning after December 31, 2020, may only be used to offset 80% of our taxable income. As a result, our ability to use our pre-change NOLs and tax credits to offset future taxable income, if any, could be subject to limitations. Similar provisions of state tax law may also apply. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and tax credits.

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 delay or prevent changes in control or changes in our management without the consent of our board of directors. These provisions 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 to elect a director to fill a vacancy, however occurring, including by an expansion of the board of directors, which prevents stockholders from being able to fill vacancies on our board of directors;
- 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 voting or other rights or preferences, 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 at an election of directors 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;
- 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 and amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for certain disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware (or, in the event that the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of 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; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. Our amended and restated certificate of incorporation and amended and restated bylaws also provide that the federal district courts of the United States of America are the exclusive forum for the resolution of any complaint asserting a cause of action against us or any of our directors, officers, employees or agents and arising under the Securities Act. Nothing in our amended and restated certificate of incorporation and amended and restated bylaws precludes stockholders that assert claims under the Exchange Act from bringing such claims in state or federal court, subject to applicable law.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims, although our stockholders will not be deemed to have waived our compliance with 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. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. If a court were to find the choice of forum provision that is contained in our amended and restated certificate of incorporation and amended and restated bylaws 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 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 in the price of our common stock.

We do not currently intend to pay any cash dividends on our common stock for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, you are not likely to receive any dividends on your common stock for the foreseeable future. Since we do not intend to pay dividends, your ability to receive a return on your investment will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which our holders have purchased it.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us or our business. We do not have any control over these analysts or what they publish, and we may have limited opportunity to communicate with them during certain times of the year. There can be no assurance that analysts will continue to cover us, cover us accurately, or provide favorable coverage. In the event any of the analysts who cover us issue an adverse or misleading opinion, or fail to correct an error in their reports or statements, about us, our business model, our intellectual property or our stock performance, or if our clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Future sales and issuances of our common stock could and would likely result in additional dilution of the percentage ownership of our stockholders and could cause our share price to fall.

We may from time to time issue additional shares of common stock at a discount from the current trading price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our common stockholders would experience additional dilution and, as a result, our stock price may decline.

We may be subject to securities litigation, which is expensive and could divert our management's attention.

In the past, companies that have experienced volatility in the market price of their securities have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Regardless of the merits or the ultimate results of such litigation, securities litigation brought against us could result in substantial costs and divert our management's attention from other business concerns.

We are an "emerging growth company," and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, our common stock may be less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are available to emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements 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. In addition, as an "emerging growth company," the JOBS Act allows us to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies. We have elected to use this extended transition period under the JOBS Act. As a result, our consolidated financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies, which may make comparison of our financials to those of other public companies more difficult.

We cannot predict if investors will find our common stock less attractive because we will 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 more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year following the fifth anniversary of the consummation of our IPO, (2) the last day of the fiscal year in which we have total annual gross revenue of at least $1.235 billion, (3) the last day of the fiscal year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year, or (4) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

General Risk Factors

Our business has been and could in the future be adversely affected by a global pandemic or other future public health events, including any economic impact due to the recovery therefrom, in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites or other business operations.

While the economic impact brought by, and the duration of, the COVID-19 pandemic was difficult to assess or predict, we know that potential impacts from any potential future global pandemic or similar public health event include impediment to the development of our product candidates, disruption in our supply chains, delays in our clinical trials, reduced productivity of our employees, reduced access to capital or limitations to our business development activities.

In the event of a future pandemic or similar public health events, potential patients in our ongoing or planned clinical trials may choose to not enroll, not participate in follow-up clinical visits or drop out of the trials. Further, some patients may not be able or willing to comply with clinical trial protocols if quarantines impede patient movement or interrupts healthcare services. Similarly, our ability to recruit and retain principal investigators and site staff may be adversely impacted.

In addition, ongoing or planned clinical trials may also be impacted by interruptions or delays in the operations of the FDA and comparable foreign regulatory authorities, in the event of a future pandemic or similar public health events. We may need to make certain adjustments to the operation of our trials in an effort to ensure the monitoring and safety of patients and minimize risks to trial integrity during the pandemic in accordance with the guidance issued by the FDA as a result.

We may also encounter a shortage in supplies of, or in delays in shipping, our study drug or other components of the clinical trial vital for successful conduct of the trial. Further, the successful conduct of our clinical trials depends on retrieving laboratory, imaging and other data from patients. Any failure by the vendors we work with to send us such data could impair the progress of such clinical trials. These events could delay our clinical trials, increase the cost of completing our clinical trials and negatively impact the integrity, reliability or robustness of the data from our clinical trials.

Quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, which could disrupt the supply chain for our product candidates or other goods or services used in our clinical trials. To the extent our suppliers and service providers are unable to comply with their obligations under our agreements with them or they are otherwise unable to deliver or are delayed in delivering goods and services to us due to a future pandemic, our ability to continue meeting clinical supply demand for our product candidates or otherwise advancing development of our product candidates may become impaired.

Unfavorable global economic or political conditions could adversely affect our business, financial condition or results of operations.

Our business is susceptible to general conditions in the global economy and in the global financial markets. A global financial crisis or a global or regional political disruption could cause extreme volatility in the capital and credit markets. A severe or prolonged economic downturn or political disruption could result in a variety of risks to our business, including weakened demand for our current or future product candidates, if approved, and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our potential drugs, if approved. Any of the foregoing could materially and adversely affect our business, financial condition, results of operations and prospects, and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could adversely impact our business.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

The audit committee of our board of directors is responsible for the general oversight around cybersecurity-related matters, while our management is responsible for the day-to-day operations around the assessment and management of any cybersecurity risks we might face. Our board of directors and the audit committee, in consultation with management, established and maintain robust procedures and internal controls around cybersecurity. These mechanisms are designed to help protect our information assets and operations from internal and external cyber threats, protect employee and clinical trial information from unauthorized access or attack, as well as secure our networks and systems.

At each regularly scheduled audit committee meeting, our chief financial officer provides an update on our cybersecurity position, and where necessary, the audit committee then provides an update to the board of directors. Our incident response process also contemplates that the executive team will notify the audit committee of a material cybersecurity incident.

We engage an experienced consultant to oversee the day-to-day functions of cybersecurity management, including proactive reviews of activity logs, regular vulnerability scans, and, where applicable, effective incident response. Our expert consultant has over 30 years of experience in the cybersecurity space, and reports to the chief financial officer. We also engage a highly qualified third-party cybersecurity assessor to conduct annual threat assessments and penetration tests. To date, we have not encountered cybersecurity incidents that have materially impacted our operations or financial standing.

Item 2. Properties.

We lease approximately 9,750 square feet of space for our current headquarters in Foster City, California under an agreement that expires in October 2027. The Company has the option to extend the lease agreement for a period of three years. We believe that our existing facilities are adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms.

Item 3. Legal Proceedings.

From time to time, we may be involved in legal proceedings or subject to claims incident to the ordinary course of business. While the outcome of any such proceedings cannot be predicted with certainty, as of December 31, 2024, we were not a party to any litigation or legal proceedings that, in the opinion of our management, are probable to have a material adverse effect on our 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, reputational harm, and other factors, and there can be no assurances that favorable outcomes will be obtained.

Item 4. Mine Safety Disclosures.

None.

PART II

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

Market Information

Our common stock has been listed on the Nasdaq Global Select Market since February 5, 2021 under the symbol "TERN." Prior to such time, there was no public market for our common stock.

Holders of Record

As of March 14, 2025, there were approximately 4 stockholders of record of our common stock. Certain shares are held in "street" name and thus the actual number of beneficial owners of such shares is not known or included in the foregoing number.

Dividend Policy

We have never declared or paid cash dividends on our capital stock, and we do not currently intend to pay any cash dividends on our capital stock in the foreseeable future. We currently intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business. Any future determination related to dividend policy will be made at the discretion of our board of directors, subject to applicable laws, and will depend upon, among other factors, our results of operations, financial condition, contractual restrictions and capital requirements.

Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Use of Proceeds from Public Offering of Common Stock

In February 2021, we completed our initial public offering, or IPO, and issued an aggregate of 8,625,000 shares of our common stock at a price of $17.00 per share, including the exercise in full of the underwriters' option to purchase additional shares of our common stock. We received net proceeds from the IPO of $133.0 million, after deducting underwriting discounts and commissions of $10.3 million and offering expenses of $3.3 million. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to their associates. J.P. Morgan Securities LLC, Goldman Sachs & Co. LLC and Cowen and Company, LLC acted as book-running managers for the IPO.

Since the completion of our IPO, our common stock is traded on the Nasdaq Global Select Market. The offer and sale of the shares were registered under the Securities Act on a registration statement on Form S-1 (Registration No. 333-252180), which was declared effective on February 4, 2021.

As of December 31, 2024, we have used all of the proceeds from our IPO. The net proceeds from our IPO were used, together with our cash and cash equivalents to fund continued advancement of our product pipeline, working capital and other general corporate purposes. There has been no material change in the planned use of proceeds from our IPO as described in the related prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act. We invested the funds received in cash equivalents and other marketable securities in accordance with our investment policy.

Issuer Purchases of Equity Securities

None.

Item 6. Reserved.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. In addition to historical financial information, this discussion contains forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under "Special Note Regarding Forward-Looking Statements" and "Risk Factors" and elsewhere in this Annual Report on Form 10-K. Our fiscal year ends on December 31 each year.

Overview

We are a clinical-stage biopharmaceutical company developing a portfolio of small-molecule product candidates to address serious diseases, including oncology and obesity. Our programs are based on mechanisms of action that have achieved proof-of-concept in clinical trials in indications with significant unmet medical needs. We are advancing multiple drug candidates we believe have the potential to deliver improved clinical outcomes in the target indication as either single-agent or combination therapies. The most advanced product candidates in our pipeline – TERN-701, TERN-601 and TERN-501 – were internally discovered. Additionally, we have an ongoing discovery effort for the TERN-800 series of small-molecule glucose-dependent insulinotropic polypeptide receptor (GIPR) modulators for obesity, which have the potential to be combined with glucagon-like peptide-1 (GLP-1) receptor agonists.

TERN-701 is our proprietary, oral, potent, allosteric BCR-ABL tyrosine kinase inhibitor (TKI) specifically targeting the ABL myristoyl pocket for chronic myeloid leukemia (CML), a form of cancer that begins in the bone marrow and leads to the growth of leukemic cells and is classified as an orphan indication. Allosteric TKIs, which bind to the myristoyl-binding pocket, represent a novel treatment class for CML that addresses the shortcomings of active-site TKIs, including off-target activity and limited efficacy against active site resistance mutations. TERN-701 aims to address the limitations of active-site TKIs with the goal of achieving improved tumor suppression through a combination of (1) improved efficacy against BCR-ABL, including a broad range of mutations, (2) improved safety and tolerability profiles, and an improved drug-drug interaction profile, and (3) improved convenience with once-a-day dosing for all patients, with or without food. Because of increased survival rates and treatment durations for people living with CML, physicians are seeking additional safe and efficacious therapies for people whose tolerability of their CML therapy, co-morbidity and/or drug-drug interaction profiles change over time, limiting their available treatment options, quality of life and the effectiveness of mainstay therapies. Within the allosteric TKI class, which has one approved agent, asciminib, we have generated emerging data to support a potential best in class profile for TERN-701. Supporting efficacy data include numerically greater potency than asciminib against multiple BCR-ABL variants, improved pharmacokinetic and target coverage over asciminib and rescue of clinical response in asciminib failures. TERN-701 has also demonstrated a promising safety profile relative to asciminib, with no dose limiting toxicities (DLTs) and no adverse event (AE)-related treatment discontinuations or dose reductions in the dose escalation phase of our Phase 1 trial. In healthy volunteer studies, TERN-701 also demonstrated the ability to be dosed once-daily without regard to food, as well as a favorable drug-drug interaction profile, which represents potential key differentiators over asciminib. Our Phase 1 trial, CARDINAL, is progressing and includes sites from the United States, Europe and other countries. In December 2024, we announced positive early data from the CARDINAL trial. As of the cutoff date, 15 patients were enrolled across three dose cohorts of 160 mg, 320 mg and 400 mg, with an overall median treatment duration of 3 months. TERN-701 demonstrated compelling molecular responses starting at the lowest dose level in heavily pre-treated patients with high baseline BCR-ABL transcript levels. TERN-701 also showed an encouraging safety profile with no DLTs, AE-related treatment discontinuations or dose reductions across all dose escalation cohorts. The dose escalation phase is complete and initiation of dose expansion is expected in the second quarter of 2025. The backfill dosing of new participants continues in existing cohorts of dose escalation. Additional safety and efficacy data are expected in the fourth quarter of 2025, which is expected to include a larger cohort of patients with longer durations of treatment and read through to a potential approval endpoint of a six-month major molecular response (MMR). The United States Food and Drug Administration (FDA) granted Orphan Drug Designation for TERN-701 for the treatment of chronic myeloid leukemia in March 2024.

TERN-601 is our small-molecule GLP-1 receptor agonist program that is intended to be orally administered once-daily for obesity. Obesity is a chronic disease that is increasing in prevalence in adults, adolescents and children and is often defined by having an elevated body mass index (BMI) of 30 or greater. Mechanisms that contribute to increased weight include sedentary lifestyles, increased calorie intake and medications such as insulins and antipsychotics. Insulin resistance, a hallmark of metabolic syndrome, also plays a key role in obesity. GLP-1 offers multiple benefits including increased insulin secretion to the pancreas, reduced glucagon secretion in the liver, slowed gastric emptying into the gut, increased sense of satiety in the brain and reduced inflammation. In September 2024, we announced positive top-line results from our Phase 1 trial of TERN-601. The Phase 1 trial was a randomized, double-blind, placebo-controlled single and multiple-ascending dose (SAD and MAD) trial in healthy adults with obesity or who are overweight. TERN-601 was well tolerated and demonstrated dose-dependent, statistically significant placebo-adjusted mean weight loss across 240 mg, 500 mg and 740 mg doses evaluated in the 28-day MAD study, with maximum placebo-adjusted mean weight loss of 4.9% at the highest dose. TERN-601 was well tolerated with no treatment-related dose interruptions, reductions or discontinuations at any dose, despite rapid dose titration every three days. The majority of treatment emergent AEs were mild. All gastrointestinal events were mild to moderate and consistent with the GLP-1R agonist class. There were no clinically meaningful changes in liver enzymes, vital signs or electrocardiograms observed. The absence of treatment-related dose interruptions, reductions, or discontinuations with mostly mild AEs, despite rapid titration, indicates potential for further improved tolerability in subsequent studies with slower titration. The Phase 2 FALCON study for TERN-601 initiated with the first patient enrolled in March 2025. FALCON is a U.S.-based, multicenter, randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of TERN-601 dosed once-daily. The trial will evaluate adults with obesity or who are overweight, without diabetes, with BMI ranges from $\geq$30 to <50 kg/m^2 or $\geq$27 to <30 kg/m^2 with at least one weight-related comorbidity. Patients will be randomized to one of four active cohorts (n=30 per cohort): 250 mg, 500 mg, 500 mg slow titration, 750 mg or placebo. The primary endpoint is percent change from baseline in body weight compared to placebo over 12 weeks. Secondary endpoints include safety, tolerability and proportion of patients achieving 5% weight loss or greater. Phase 2 12-week data are expected in the fourth quarter of 2025. Based on the Phase 1 results, we believe TERN-601 is well positioned to demonstrate a differentiated tolerability profile in a Phase 2, 12-week setting with slower titration compared to Phase 1. Phase 2 titration will range between two to four weeks at each intermediate dose before achieving the target dose. The titration design features the fewest steps and lowest fold change to target dose amongst leading oral, small-molecule GLP-1R agonists in a 12-week study. Our slower titration aims to achieve competitive 12-week weight loss, best in class tolerability and the simplest titration amongst the oral, small-molecule class.

TERN-501 is our thyroid hormone receptor beta (THR-β) agonist initially developed for metabolic dysfunction-associated steatohepatitis (MASH). Agonism of THR-β increases fatty acid metabolism via mitochondrial oxidation and affects cholesterol synthesis and metabolism. As a result, THR-β stimulation has the potential to provide broad metabolic benefits including reducing hepatic steatosis, increasing fat oxidation, and improving fibrosis and serum lipid parameters such as LDL cholesterol and triglycerides. Since announcing positive top-line data from the Phase 2a DUET trial in August 2023, we have decided to limit spend in the development of TERN-501 for MASH given the current regulatory and clinical development requirements for the indication. We continue to evaluate opportunities for TERN-501 in metabolic diseases. Based on non-clinical studies, THR-β agonism is a complementary mechanism to GLP-1 receptor antagonism, potentially providing broader metabolic and liver benefits in addition to increased weight loss. In June 2024, we highlighted preclinical data supporting TERN-501 in combination with a GLP-1R agonist for obesity at the American Diabetes Association 84th Scientific Sessions. TERN-501 significantly improved the efficacy of a GLP-1 receptor agonist in an obese mouse model by normalizing energy expenditure, resulting in greater weight loss, increased fat mass loss and relative preservation of lean mass compared to the GLP-1R agonist alone. These preclinical combination data support the potential for TERN-501 as a combination partner for injectable and oral GLP-1 agonists for use in obesity and other metabolic disorders.

TERN-800 series is our ongoing effort to discover small molecule GIPR modulators for obesity, which we believe has the potential for combination with GLP-1 receptor agonists. In preclinical studies, GIPR activation appears to reduce food intake and promote weight loss when combined with its incretin partner GLP-1. The overlapping body weight-lowering actions of both Glucose-dependent insulinotropic polypeptide (GIP) and GLP-1 suggests that combining the actions of these two peptide hormones may bolster glucose-lowering and appetite-suppressing effects beyond those observed with individual agents. We are prioritizing our discovery efforts towards nominating a GIPR antagonist development candidate based on in-house discoveries and growing scientific rationale supporting the potential of GLP-1 receptor agonist and GIPR antagonist combinations as treatments for obesity.

Since the commencement of our operations, we have devoted substantially all of our resources to research and development activities, organizing and staffing our company, business planning, raising capital, establishing and maintaining our intellectual property portfolio, conducting preclinical studies and clinical trials and providing general and administrative support for these operations.

We do not have any product candidates approved for commercial sale, and we have not generated any revenue from product sales. Our ability to generate product revenue sufficient to achieve profitability, if ever, will depend on the successful development and eventual commercialization of one or more of our product candidates which we expect, if it ever occurs, will take a number of years. We will not generate any revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for one or more of our product candidates. If we obtain regulatory approval for any of our product candidates, we expect to incur significant expenses related to developing our internal commercialization capability to support product sales, marketing and distribution.

In February 2021, we received total net proceeds of $133.0 million through our initial public offering. In August 2022, December 2022, and September 2024, we received total net proceeds of $60.7 million, $80.8 million, and $161.9 million, respectively, through securities offerings. We also have active at-the-market facilities which will allow us to issue up to approximately $156 million in our securities. We believe that our existing cash and cash equivalents will be sufficient to fund our planned operating expenses and capital expenditure requirements into 2028. We will need substantial additional funding to support our operating activities.

Results of operations

The following table summarizes our results of operations for the years ended December 31, 2024 and 2023:

	Year Ended December 31,		
(in thousands)	**2024**	**2023**	**Change**
Results of operations			
Operating expenses:			
Research and development	$ 70,112	$ 63,497	$ 6,615
General and administrative	31,759	39,061	(7,302)
Total operating expenses	101,871	102,558	(687)
Loss from operations	(101,871)	(102,558)	687
Other income:			
Interest income	13,289	12,901	388
Other expense, net	(11)	(314)	303
Total other income, net	13,278	12,587	691
Loss before income taxes	(88,593)	(89,971)	1,378
Income tax expense	(260)	(239)	(21)
Net loss	$ (88,853)	$ (90,210)	$ 1,357

Revenue

To date, we have not generated, and do not expect to generate for the foreseeable future, any revenue from the sale of products. We may generate revenue from pre-specified clinical, regulatory and sales milestones as part of an exclusive option and license agreement for TERN-701 in greater China with Hansoh.

Research and development expenses

Research and development expenses account for a significant portion of our operating expenses and consist primarily of external and internal expenses incurred in connection with the discovery and development of our product candidates. To date, our research and development expenses have related primarily to discovery efforts, preclinical and clinical development of our product candidates. Research and development expenses are recognized as incurred and payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received. Costs for certain activities, such as manufacturing and preclinical studies and clinical trials, are generally recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and collaborators. Technology acquisitions are expensed or capitalized based upon the asset achieving technological feasibility in accordance with management's assessment regarding the ultimate recoverability of the amounts paid and the potential for alternative future use.

External expenses include:

- expenses incurred in connection with the discovery and preclinical and clinical development of our product candidates, including those incurred under agreements with third parties, such as consultants and contract research organizations, or CROs;
- the cost of manufacturing products for use in our preclinical studies and clinical trials, including payments to contract manufacturing organizations, or CMOs, and consultants;
- the costs of funding research performed by third-party vendors for performing preclinical testing on our behalf;
- the costs of purchasing lab supplies and non-capital equipment used in designing, developing and manufacturing preclinical study and clinical trial materials;
- costs associated with consultants for chemistry, manufacturing and controls development, regulatory, statistics and other services;
- expenses related to regulatory activities, including filing fees paid to regulatory agencies; and
- expenses incurred in connection with the acquisition or in-licensing of assets from other parties.

Internal expenses include:

- personnel-related expenses, including salaries, benefits and stock-based compensation expense for personnel engaged in research and development functions. We use internal resources primarily to oversee the research and discovery as well as for managing our preclinical development, process development, manufacturing and clinical development activities; and
- other expenses, including rent, depreciation, maintenance and allocated overhead.

We expect our research and development expenses to increase substantially in absolute dollars for the foreseeable future as we advance our product candidates or any other future product candidates we may develop into and through preclinical studies and clinical trials and pursue regulatory approval of our product candidates. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming. The actual probability of success for our product candidates or any other future product candidate that we may develop may be affected by a variety of factors including: the safety and efficacy of our product candidates, early clinical data, investment in our clinical program, the ability of collaborators to successfully develop our licensed product candidates, competition, manufacturing capability and commercial viability. We may never succeed in achieving regulatory approval for our product candidates. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of our product candidates or any other future product candidates we may develop. The duration, costs and timing of preclinical studies and clinical trials and development of our product candidates will depend on a variety of factors.

The following table summarizes our research and development expenses for the years ended December 31, 2024 and 2023:

(in thousands)	Year Ended December 31, 2024	2023	Change
Research and development expenses			
External expenses by program:			
TERN-701	$ 15,757	$ 6,627	$ 9,130
TERN-601	15,486	7,247	8,239
TERN-501	881	17,819	(16,938)
Other programs	11,004	9,579	1,425
Total external expenses	43,128	41,272	1,856
Unallocated internal expenses:			
Personnel-related expenses	25,732	21,017	4,715
Other expenses	1,252	1,208	44
Total research and development expenses	$ 70,112	$ 63,497	$ 6,615

The increase in research and development expenses for the year ended December 31, 2024, compared to the same period in 2023, was primarily due to a $4.7 million net increase in personnel-related expenses from higher executive leadership transition costs, wages, annual bonuses, and stock-based compensation. Additionally, there was a $1.9 million increase related to clinical and pre-clinical program expenses.

General and administrative expenses

General and administrative expenses consist primarily of personnel-related expenses, including salaries, benefits and stock-based compensation expense, for personnel in executive, finance, accounting, business development, legal, human resources, information technology, and other administrative functions. General and administrative expenses also include corporate facility costs, depreciation and other expenses, which include direct or allocated expenses for rent and maintenance of facilities and insurance, not otherwise included in research and development expenses, as well as professional fees for legal, patent, consulting, investor and public relations, accounting and tax services.

We expect that our general and administrative expenses will increase in the foreseeable future as we increase our headcount to support the continued research and development of our programs and the growth of our business.

The decrease in general and administrative expenses for the year ended December 31, 2024, compared to the same period in 2023, was primarily due to a $7.6 million net decrease in personnel-related expenses as there were higher expenses in 2023 related to executive leadership transitions, partially offset by a $0.3 million increase in other professional services consulting.

Interest income

Interest income primarily consists of interest income on our marketable securities.

Interest income for the year ended December 31, 2024 was $13.3 million compared to $12.9 million for the same period in 2023. The increase in interest income was primarily due to an increase in cash, cash equivalents and marketable securities.

Other expense, net

Other expense, net for the year ended December 31, 2024 was less than $0.1 million compared to $0.3 million for the same period in 2023 which is consistent year over year.

Income tax expense

Income tax expense for the year ended December 31, 2024 was $0.3 million compared to $0.2 million for the same period in 2023 which is consistent year over year.

Liquidity and capital resources

Uses of cash

Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures and general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

We believe that our existing cash and cash equivalents will be sufficient to fund our planned operating expenses and capital expenditure requirements into 2028, including key clinical data readouts from our lead programs in CML and obesity. However, we continue to anticipate that our research and development expenses, general and administrative expenses and capital expenditures will remain significant to support our ongoing and planned activities. We expect to continue to incur net operating losses for at least the next several years.

Sources of liquidity

We have primarily funded our operations through proceeds from the sale of shares of our common stock, convertible preferred stock and convertible promissory notes. We have devoted substantially all of our resources to research and development activities, organizing and staffing our company, raising capital, establishing and maintaining our intellectual property portfolio, conducting preclinical studies and clinical trials and providing general and administrative support for these operations.

Since our inception, we have not generated any revenue from product sales and we have incurred significant operating losses and negative cash flows from our operations. As of December 31, 2024, we had an accumulated deficit of approximately $421.5 million and cash, cash equivalents and marketable securities of $358.2 million. For the year ended December 31, 2024, we had a net loss of approximately $88.9 million and negative cash flows from operations of approximately $70.0 million.

In March 2022, we entered into a Sales Agreement with Cowen and Company, LLC (Cowen), as sales agent, pursuant to which we could offer and sell, from time to time, through Cowen, shares of our common stock having an aggregate offering price of up to $75.0 million in an at-the-market offering. The shares were offered pursuant to our shelf registration statement on Form S-3 filed with the SEC, which became effective in March 2022. This registration statement has now expired, the related Sales Agreement is terminated and we will not sell any additional shares under this at-the-market offering. There were 9,781,673 shares of our common stock sold for aggregate net proceeds of $66.6 million after deducting commissions and offering expenses pursuant to this agreement through December 31, 2024.

In May 2023, we entered into a Sales Agreement with Cowen, as sales agent, pursuant to which we have the ability to offer and sell, from time to time, through Cowen, shares of our common stock having an aggregate offering price of up to $150.0 million in an at-the-market offering. The shares are offered pursuant to our shelf registration statement on Form S-3 filed with the SEC, which became effective in February 2023. This Sales Agreement remains in effect. There were no sales of our common stock pursuant to this agreement through December 31, 2024.

In September 2024, we issued 14,064,048 shares of our common stock at a public offering price of $10.50 per share and, to certain investors in lieu of common stock, pre-funded warrants to purchase 2,380,952 shares of common stock at a public offering price of $10.4999 per pre-funded warrant in an underwritten public offering. The purchase price per share of each pre-funded warrant represents the per share public offering price for the common stock, minus the $0.0001 per share exercise price of such pre-funded warrant. Aggregate net proceeds were $161.9 million after deducting underwriting discounts and commissions and offering expenses.

Future funding requirements

We expect to incur significant expenses and operating losses for the foreseeable future as we advance the preclinical and clinical development of our product candidates. We expect that our research and development and general and administrative costs will remain significant for the foreseeable future in connection with conducting additional preclinical studies and clinical trials for our current and future research programs and product candidates, contracting with CROs and CMOs to support preclinical studies and clinical trials, expanding our intellectual property portfolio, and providing general and administrative support for our operations. As a result, we will need additional capital to fund our operations, which we may obtain from additional equity or debt financings, collaborations, licensing arrangements or other sources.

Our primary uses of cash are to fund our research and development activities, business planning, establishing and maintaining our intellectual property portfolio, hiring personnel, raising capital and providing general and administrative support for these operations.

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, continue or initiate clinical trials of, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for our product candidates, we expect to incur significant commercialization expenses related to any approved products, marketing, manufacturing and distribution to the extent that such sales, marketing and distribution are not the responsibility of potential collaborators. 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 would be forced to delay, reduce, or eliminate our research and development programs or future commercialization efforts.

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

- the scope, progress, results and costs of product discovery, preclinical studies and clinical trials;
- the scope, prioritization and number of our research and development programs;
- the costs, timing and outcome of regulatory review of our product candidates;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments under any collaboration agreements we enter into;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under collaboration agreements, if any;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other product candidates and technologies;
- the costs of securing manufacturing arrangements for commercial production; and
- the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory approvals to market our product candidates.

Until such time, if ever, as we can generate substantial revenues from product sales, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt 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, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us.

Cash flows

Operating activities

Net cash used in operating activities for the year ended December 31, 2024 was $70.0 million and consisted primarily of our net loss of $88.9 million. This was partially offset by a $4.4 million increase from changes in operating assets and liabilities primarily attributable to the timing of expenses incurred and payments issued, and non-cash adjustments of $15.6 million of stock-based compensation, $2.1 million of net accretion on marketable securities, $0.6 million in amortization of operating lease assets and $0.3 million of depreciation.

Net cash used in operating activities for the year ended December 31, 2023 was $67.4 million and consisted primarily of our net loss of $90.2 million. This was partially offset by a $1.5 million increase from changes in operating assets and liabilities primarily attributable to the timing of expenses incurred and payments issued, and non-cash adjustments of $25.5 million of stock-based compensation, $0.3 million of depreciation, $5.2 million of net accretion on marketable securities, $0.1 million from changes in deferred tax and uncertain tax positions and $0.6 million in amortization of operating lease assets.

Investing activities

Net cash used in investing activities for the year ended December 31, 2024 was $12.4 million and consisted primarily of $169.9 million in purchases of investments. This was partially offset by proceeds from the sale and maturity of investments of $157.6 million.

Net cash used in investing activities for the year ended December 31, 2023 was $38.0 million and consisted primarily of $275.8 million in purchases of investments. This was partially offset by proceeds from the sale and maturity of investments of $237.8 million.

Financing activities

Net cash provided by financing activities for the year ended December 31, 2024 was $164.0 million and consisted of $162.3 million in proceeds from the issuance of common stock and pre-funded warrants in connection with the September 2024 Financing, $1.4 million in proceeds from stock option exercises, and $0.6 million of proceeds from the issuance of common stock under our employee stock purchase plan. This was partially offset by $0.4 million in payments of deferred offering costs.

Net cash provided by financing activities for the year ended December 31, 2023 was $42.0 million and consisted of $41.6 million in proceeds from the issuance of common stock in an at-the-market offering, $0.4 million of proceeds from the issuance of common stock under our employee stock purchase plan and $0.3 million in proceeds from stock option exercises. This was partially offset by $0.3 million in payments of deferred offering costs.

Off-balance sheet arrangements

We do not have any off-balance sheet arrangements (as defined by applicable regulations of the SEC) that are reasonably likely to have a current or future material effect on our financial condition, results of operations, liquidity, capital expenditures or capital resources.

Critical accounting policies and significant estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, expenses and the disclosure of our contingent liabilities in our consolidated 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. We evaluate our estimates and assumptions on an ongoing basis. 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, Nature of the Business, Basis of Presentation and Summary of Significant Accounting Policies, to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our audited consolidated financial statements.

Accrued research and development expenses

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred to discover, research and develop drug candidates, including personnel expenses, stock-based compensation expense, allocated facility-related and depreciation expenses, third-party license fees and external costs, including fees paid to consultants and CROs in connection with nonclinical studies and clinical trials and other related clinical trial fees, such as for investigator grants, patient screening, laboratory work, clinical trial database management, clinical trial material management and statistical compilation and analysis. Non-refundable prepayments for goods or services that will be used or rendered for future research and development activities are recorded as prepaid expenses. Such amounts are recognized as an expense as the goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered, or the services rendered. Costs incurred in obtaining technology licenses are charged immediately to research and development expense if the technology licensed has not reached technological feasibility and has no alternative future uses.

From time to time, we have entered into various research and development and other agreements with commercial firms, researchers, universities and others for provisions of goods and services. These agreements are generally cancelable, and the related costs are recorded as research and development expenses as incurred. We record accruals for estimated ongoing research and development costs. When evaluating the adequacy of the accrued liabilities, we analyze progress of the studies or clinical trials, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ materially from our estimates. Since inception, our historical accrual estimates have not been materially different from the actual costs.

Emerging growth company status

The Jumpstart Our Business Startups Act of 2012, or the JOBS Act, permits an "emerging growth company" to take advantage of an extended transition to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition provided in the JOBS Act. As a result, we will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies and our consolidated financial statements may not be comparable to other public companies that comply with new or revised accounting pronouncements as of public company effective dates. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies. The JOBS Act also exempts us from having to provide an auditor attestation of internal control over financial reporting under Sarbanes-Oxley Act Section 404(b).

We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year following the fifth anniversary of the consummation of our initial public offering, (ii) the last day of the fiscal year in which we have total annual gross revenue of at least $1.235 billion, (iii) the last day of the fiscal year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year or (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

Further, even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company" which would allow us to take advantage of many of the same exceptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our shares of common stock less attractive because we may rely on these exemptions. If some investors find our shares of common stock less attractive as a result, there may be a less active trading market for shares of our common stock and our share price may be more volatile.

Recently issued accounting pronouncements

See Note 1, Nature of the Business, Basis of Presentation and Summary of Significant Accounting Policies to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K for a description of recent accounting pronouncements applicable to our consolidated financial statements.

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

We are exposed to market risks in the ordinary course of our business, including the effects of foreign currency fluctuations and interest rate changes. Information relating to quantitative and qualitative disclosures about these market risks is set forth below.

Interest rate risk

Cash, cash equivalents and marketable securities are held primarily in bank and time deposits. The fair value of our cash and marketable securities would not be significantly affected by either an increase or decrease in interest rates due mainly to the short-term nature of these instruments.

Foreign currency exchange risk

Foreign currency risk arises from future commercial transactions and recognized assets and liabilities. A portion of our expense-related transactions are denominated in Chinese Yuan which is the functional currency of Terns Suzhou and Terns China.

Item 8. Financial Statements and Supplementary Data.

The financial statements of Terns Pharmaceuticals, Inc. listed below are set forth in Item 8 of this Annual Report for the year ended December 31, 2024:

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Terns Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Terns Pharmaceuticals, Inc. (the Company) as of December 31, 2024 and 2023, the related consolidated 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 "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 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 2020.

San Mateo, California

March 20, 2025

TERNS PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
(Amounts in thousands, except share and per share data)

	December 31,	
	2024	2023
Assets		
Current assets:		
Cash and cash equivalents	$ 161,439	$ 79,926
Marketable securities	196,725	183,514
Prepaid expenses and other current assets	3,945	3,992
Total current assets	362,109	267,432
Property and equipment, net	222	506
Operating lease assets	1,248	523
Other assets	350	56
Total assets	$ 363,929	$ 268,517
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,148	$ 2,515
Accrued expenses and other current liabilities	13,074	8,826
Current portion of operating lease liabilities	428	603
Total current liabilities	15,650	11,944
Taxes payable, non-current	1,490	1,206
Operating lease liabilities, non-current	919	—
Total liabilities	18,059	13,150
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.0001 par value, 150,000,000 shares authorized at December 31, 2024 and 2023; 87,126,583 and 64,576,719 shares issued and outstanding at December 31, 2024 and 2023, respectively	9	6
Additional paid-in capital	767,621	588,008
Accumulated other comprehensive loss	(279)	(19)
Accumulated deficit	(421,481)	(332,628)
Total stockholders' equity	345,870	255,367
Total liabilities and stockholders' equity	$ 363,929	$ 268,517

The accompanying notes are an integral part of these financial statements.

TERNS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Amounts in thousands, except share and per share data)

	Year Ended December 31,	
	2024	2023
Operating expenses:		
Research and development	$ 70,112	$ 63,497
General and administrative	31,759	39,061
Total operating expenses	101,871	102,558
Loss from operations	(101,871)	(102,558)
Other income:		
Interest income	13,289	12,901
Other expense, net	(11)	(314)
Total other income, net	13,278	12,587
Loss before income taxes	(88,593)	(89,971)
Income tax expense	(260)	(239)
Net loss	$ (88,853)	$ (90,210)
Net loss per share, basic and diluted	$ (1.12)	$ (1.27)
Weighted average common stock outstanding, basic and diluted	79,507,474	71,259,239
Other comprehensive loss:		
Net loss	$ (88,853)	$ (90,210)
Unrealized (loss) gain on available-for-sale securities, net of tax	(235)	671
Foreign exchange translation adjustment, net of tax	(25)	132
Comprehensive loss	$ (89,113)	$ (89,407)

The accompanying notes are an integral part of these financial statements.

TERNS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(Amounts in thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2022	53,723,171	$ 5	$ 520,178	$ (822)	$ (242,418)	$ 276,943
Issuance of common stock in at-the-market offering	5,659,045	1	41,610	—	—	41,611
Issuance of common stock in connection with exercise of pre-funded warrants	4,878,446	—	—	—	—	—
Exercise of stock options	106,176	—	274	—	—	274
Vesting of restricted stock units with service conditions	50,401	—	—	—	—	—
Issuance of common stock under employee stock purchase plan	159,480	—	410	—	—	410
Stock-based compensation expense	—	—	25,536	—	—	25,536
Unrealized gain on available-for-sale securities	—	—	—	671	—	671
Foreign exchange translation adjustment	—	—	—	132	—	132
Net loss	—	—	—	—	(90,210)	(90,210)
Balances at December 31, 2023	64,576,719	$ 6	$ 588,008	$ (19)	$ (332,628)	$ 255,367
Issuance of common stock and pre-funded warrants, net of issuance costs of $394	14,064,048	2	161,916	—	—	161,918
Issuance of common stock in connection with exercise of pre-funded warrants	7,941,366	1	(1)	—	—	—
Exercise of stock options	244,913	—	1,448	—	—	1,448
Vesting of restricted stock units with service conditions	160,936	—	—	—	—	—
Issuance of common stock under employee stock purchase plan	138,601	—	623	—	—	623
Stock-based compensation expense	—	—	15,627	—	—	15,627
Unrealized loss on available-for-sale securities	—	—	—	(235)	—	(235)
Foreign exchange translation adjustment	—	—	—	(25)	—	(25)
Net loss	—	—	—	—	(88,853)	(88,853)
Balances at December 31, 2024	87,126,583	$ 9	$ 767,621	$ (279)	$ (421,481)	$ 345,870

The accompanying notes are an integral part of these financial statements.

TERNS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Amounts in thousands)

	Year Ended December 31,	
	2024	2023
Cash flows from operating activities:		
Net loss	$ (88,853)	$ (90,210)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	15,627	25,536
Depreciation expense	319	292
Net accretion on marketable securities	(2,090)	(5,213)
Change in deferred taxes and uncertain tax positions	23	141
Amortization of right-of-use assets	577	589
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	47	(1,921)
Accrued interest, net of interest received	1,012	184
Accounts payable	(367)	1,149
Accrued expenses and other current liabilities	4,244	2,729
Operating lease liabilities	(555)	(666)
Net cash used in operating activities	(70,016)	(67,390)
Cash flows from investing activities:		
Purchase of property and equipment	(42)	(52)
Purchase of marketable securities	(169,942)	(275,781)
Proceeds from maturities of marketable securities	157,574	237,846
Net cash used in investing activities	(12,410)	(37,987)
Cash flows from financing activities:		
Net proceeds from the issuance of common stock and pre-funded warrants	162,312	—
Net proceeds from issuance of common stock in at-the-market offering	—	41,611
Payment of deferred offering costs	(388)	(344)
Proceeds from the issuance of common stock under employee stock purchase plan	623	410
Proceeds from stock option exercises	1,448	274
Net cash provided by financing activities	163,995	41,951
Effect of exchange rate changes on cash and cash equivalents	(56)	117
Net increase (decrease) in cash and cash equivalents	81,513	(63,309)
Cash and cash equivalents at beginning of period	79,926	143,235
Cash and cash equivalents at end of period	$ 161,439	$ 79,926
Supplemental disclosure of cash flow information:		
Cash paid for amounts included in the measurement of lease liabilities	$ 626	$ 721
Cash paid for taxes	$ 60	$ 28
Supplemental disclosure of noncash investing and financing activities:		
Right-of-use assets obtained in exchange for lease liabilities	$ 1,302	$ 65
Deferred offering costs included in accrued expense	$ 6	$ —

The accompanying notes are an integral part of these financial statements.

1. Nature of the Business, Basis of Presentation and Summary of Significant Accounting Policies

Nature of the Business

Terns Pharmaceuticals, Inc. (Terns or the Company) is a clinical-stage biopharmaceutical company developing a portfolio of small-molecule product candidates to address serious diseases including oncology and obesity.

Terns was incorporated as an exempted company in the Cayman Islands in December 2016. In December 2020, the Company effected a de-registration of the Company in the Cayman Islands and a domestication in the State of Delaware, pursuant to which it became a Delaware corporation. Terns owns all of the share capital of Terns Pharmaceutical HongKong Limited (Terns Hong Kong) and Terns, Inc., a Delaware corporation (Terns U.S. Opco). Terns Hong Kong holds all of the share capital of Terns China Biotechnology Co., Ltd. (organized in Shanghai, People's Republic of China (PRC)) (Terns China) and Terns (Suzhou) Biotechnology Co., Ltd. (organized in Suzhou, PRC) (Terns Suzhou).

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions.

Basis of Presentation

The accompanying consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP) and include the accounts of Terns and its wholly owned subsidiaries Terns U.S. Opco and Terns Hong Kong and its wholly owned subsidiaries Terns China and Terns Suzhou. The Company's consolidated financial statements have been prepared in conformity with U.S. GAAP. All intercompany balances and transactions have been eliminated in consolidation.

Reclassifications

Certain reclassifications have been made to prior period balances in the accompanying Consolidated Financial Statements and Notes thereto to conform to the current year presentation. The reclassifications had no effect on previously reported results of operations, accumulated deficit, subtotals of operating, investing or financing cash flows or consolidated balance sheet totals.

At-the-Market Offering

In March 2022, the Company entered into a Sales Agreement with Cowen and Company, LLC (Cowen) as sales agent, pursuant to which the Company could offer and sell, from time to time, through Cowen, shares of its common stock having an aggregate offering price of up to $75.0 million in an at-the-market offering. The shares were offered pursuant to the Company's shelf registration statement on Form S-3 filed with the SEC which became effective in March 2022. This registration statement has now expired, the related Sales Agreement is terminated and the Company will not sell any additional shares under this at-the-market offering. As of December 31, 2024, there were 9,781,673 shares of our common stock sold for aggregate net proceeds of $66.6 million after deducting commissions and offering expenses pursuant to this agreement. There were no sales of the Company's common stock pursuant to this agreement during the year ended December 31, 2024.

In May 2023, the Company entered into a Sales Agreement with Cowen as sales agent, pursuant to which the Company has the ability to offer and sell, from time to time, through Cowen, shares of its common stock having an aggregate offering price of up to $150.0 million in an at-the-market offering. This Sales Agreement remains in effect. The shares are offered pursuant to the Company's shelf registration statement on Form S-3 filed with the SEC, which became effective in February 2023. There were no sales of the Company's common stock pursuant to this agreement through December 31, 2024.

September 2024 Financing

In September 2024, the Company issued 14,064,048 shares of its common stock at a public offering price of $10.50 per share and, to certain investors in lieu of common stock, pre-funded warrants to purchase 2,380,952 shares of common stock at a public offering price of $10.4999 per pre-funded warrant in an underwritten public offering. The purchase price per share of each pre-funded warrant represents the per share public offering price for the common stock, minus the $0.0001 per share exercise price of each such pre-funded warrant. Aggregate net proceeds were $161.9 million after deducting underwriting discounts and commissions and offering expenses.

The pre-funded warrants were classified as a component of permanent stockholders' equity within additional paid-in capital and were recorded at the issuance date using a relative fair value allocation method. The pre-funded warrants are equity classified because they (i) are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, (ii) are immediately exercisable, (iii) do not embody an obligation for the Company to repurchase its shares, (iv) permit the holders to receive a fixed number of shares of common stock upon exercise, (v) are indexed to the Company's common stock and (vi) meet the equity classification criteria. In addition, such pre-funded warrants do not provide any guarantee of value or return. The Company valued the pre-funded warrants at issuance, concluding that their sales price approximated their fair value, and allocated net proceeds from the sale proportionately to the common stock and pre-funded warrants, of which $23.4 million was allocated to the pre-funded warrants and recorded as a component of additional paid-in capital. No pre-funded warrants have been exercised as of December 31, 2024.

Summary of Significant Accounting Policies

Revenue Recognition

To determine revenue recognition for arrangements, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that it will collect the consideration it is entitled to in exchange for the goods and services it transfers to the customer. At contract inception, the Company assesses the goods or services promised within each contract, determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The Company enters into corporate collaborations under which it may obtain upfront license fees, research and development funding, and development, regulatory and commercial milestone payments and royalty payments. The Company's performance obligations under these arrangements may include licenses of intellectual property, distribution rights, research and development services, delivery of manufactured product and/or participation on joint steering committees.

Licenses of intellectual property

If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from upfront license fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgement to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring proportional performance for purposes of recognizing revenue from non-refundable, upfront fees. The Company evaluates the measure of proportional performance each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone payments

At the inception of each arrangement that includes development, regulatory or commercial milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price. The Company considers two alternatives to use when estimating the amount of variable consideration: the expected value method and the most likely amount method. Under the expected value method, an entity considers the sum of probability-weighted amounts in a range of possible consideration amounts. Under the most likely amount method, an entity considers the single most likely amount in a range of possible consideration amounts. Whichever method is used, it should be consistently applied throughout the life of the contract; however, it is not necessary for the Company to use the same approach for all contracts. The Company expects to use the most likely amount method for development and regulatory milestone payments. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis. The Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability or achievement of each such milestone and any related constraint, and if necessary, adjusts its estimates of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

Commercial milestones and royalties

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and in which the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue when the related sales occur. To date, the Company has not recognized any royalty revenue resulting from its collaboration arrangements.

Upfront payments and fees are recorded as deferred revenue upon receipt or when due and may require deferral of revenue recognition to a future period until the Company performs its obligations under these arrangements. Amounts payable to the Company are recorded as accounts receivable when the Company's right to consideration is unconditional.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and reported amounts of expenses during the reporting period. Estimates and assumptions made in the accompanying consolidated financial statements include, but are not limited to, the estimates for accruals of research and development expenses, accrual of research contract costs, unrecognized tax benefits, fair value of common stock and stock option valuations. On an ongoing basis, the Company evaluates its estimates and judgments, using historical and anticipated results and trends and on various other assumptions that management believes to be reasonable under the circumstances. Actual results could materially differ from those estimates.

Cash, Cash Equivalents and Marketable Securities

Cash and cash equivalents consist of standard checking accounts and money market funds. The Company considers all highly liquid investments with an original maturity of 90 days or less at the date of purchase to be cash equivalents.

The Company classifies as available-for-sale marketable securities with a remaining maturity when purchased of greater than three months. The Company's marketable securities are maintained by investment managers and consist of U.S. government securities. Debt securities are carried at fair value with the unrealized gains and losses included in other comprehensive loss as a component of stockholders' equity until realized. Any premium arising at purchase is amortized to the earliest call date and any discount arising at purchase is accreted to maturity. Amortization and accretion of premiums and discounts are recorded in interest income and/or expense. Gains and losses on securities sold are recorded based on the specific identification method and are included in interest income, net in the consolidated statements of operations and comprehensive loss. The Company has not incurred any material realized gains or losses from sales of securities to date.

The Company assesses its available-for-sale debt securities for impairment as of each reporting date in order to determine if a portion of any decline in fair value below carrying value is the result of a credit loss. The Company records credit losses in the consolidated statements of operations and comprehensive loss as credit loss expense within other expense, net, which is limited to the difference between the fair value and the amortized cost of the security. To date, the Company has not recorded any credit losses on its available-for-sale debt securities.

Interest receivable related to the Company's available-for-sale debt securities is presented as marketable securities on the Company's consolidated balance sheets. The Company writes off interest receivable once it has determined that the asset is not realizable. To date, the Company has not written off any interest receivables associated with its marketable securities.

Operating Leases and Rent Expense

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, upon lease commencement, the Company records a lease liability which represents the Company's obligation to make lease payments arising from the lease, and a corresponding right-of-use (ROU) asset which represents the Company's right to use an underlying asset during the lease term.

Operating lease ROU assets and liabilities are recognized on the balance sheet at the lease commencement date based on the present value of the future minimum lease payments over the lease term. In determining the net present value of the lease payments, the Company uses its incremental borrowing rate applicable to the underlying asset unless the implicit rate is readily determinable. Any lease incentives received are deferred and recorded as a reduction of the ROU asset and amortized over the term of the lease. The Company does not separate lease and non-lease components and instead treats them as a single component. Rent expense is recognized on a straight-line basis over the lease term. The Company determines the lease term as the noncancellable period of the lease and may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise such options.

The Company elected to not apply the recognition requirements of the new leasing standard to short term leases with terms of 12 months or less which do not include an option to purchase the underlying asset that the Company is reasonably certain to exercise. For short-term leases, lease payments are recognized as operating expenses on a straight-line basis over the lease term. As a result, leases with a term of 12 months or less are not recognized on the balance sheet.

Research and Development Expenses

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred to discover, research and develop drug candidates, including personnel expenses, stock-based compensation expense, allocated facility-related and depreciation expenses, third-party license fees and external costs, including fees paid to consultants and contract research organizations, or CROs, in connection with nonclinical studies and clinical trials and other related clinical trial fees, such as for investigator grants, patient screening, laboratory work, clinical trial database management, clinical trial material management and statistical compilation and analysis. Non-refundable prepayments for goods or services that will be used or rendered for future research and development activities are recorded as prepaid expenses. Such amounts are recognized as an expense as the goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered, or the services rendered. Costs incurred in obtaining technology licenses are charged immediately to research and development expense if the technology licensed has not reached technological feasibility and has no alternative future uses.

The Company has from time to time entered into various research and development and other agreements with commercial firms, researchers, universities and others for provisions of goods and services. These agreements are generally cancelable, and the related costs are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research and development costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies or clinical trials, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ materially from the Company's estimates. Since inception, the Company's historical accrual estimates have not been materially different from the actual costs.

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities included the following:

	December 31,	
(in thousands)	**2024**	**2023**
Research and development costs	$ 3,388	$ 2,010
Compensation and benefit costs	7,912	5,683
Accrued professional fees	1,319	855
Other	455	278
Total accrued expenses and other current liabilities	$ 13,074	$ 8,826

Executive Leadership Transition

In August 2023, Bryan Yoon, former chief operating officer and general counsel, and Mark Vignola, Ph.D., former chief financial officer, received retention awards payable in cash in the aggregate amount of $0.5 million for Mr. Yoon and $0.7 million for Dr. Vignola. Each retention award was payable in two installments of 33% of the award on February 1, 2024 and 67% of the award on August 1, 2024, subject to the applicable officer's continued employment with the Company through such date. Expense was recognized on a straight-line basis over the requisite service period. During the year ended December 31, 2024, the Company recognized an expense of $0.7 million related to the retention awards. The retention awards were fully paid as of December 31, 2024. The expenses were recognized as operating expenses within the Consolidated Statements of Operations and Comprehensive Loss under General and administrative.

In July 2024, Mr. Yoon entered into a separation agreement with the Company. The separation agreement provided for Mr. Yoon's continued service as chief operating officer and special counsel for a transition period until September 3, 2024. Pursuant to the separation agreement, Mr. Yoon is entitled to receive severance in the amount of $0.5 million, equivalent to 12 months of his annual base salary, the remaining unpaid portion of his retention award of $0.3 million and a pro rata portion of his target annual bonus for 2024 of $0.1 million. During the year ended December 31, 2024, the Company recorded an accrued liability and recognized expense of $0.6 million related to the departure of the former chief operating officer. As of December 31, 2024, the ending accrued liability was $0.5 million and is presented within the Consolidated Balance Sheets under Accrued expenses and other current liabilities. Additionally, the separation agreement provides that the time for Mr. Yoon to exercise any outstanding equity award that is vested as of the separation date shall continue to April 30, 2025. As a result of the change in terms for these option grants to Mr. Yoon, the Company recognized an additional $0.6 million in stock-based compensation expense during the year ended December 31, 2024. The expenses were recognized as operating expenses within the Consolidated Statements of Operations and Comprehensive Loss under General and administrative.

In July 2024, Dr. Vignola entered into a transition agreement with the Company. The transition agreement provided for Dr. Vignola's continued service as chief financial officer for a transition period until the date of his separation from employment, February 1, 2025. Pursuant to the transition agreement, Dr. Vignola is entitled to receive severance in the amount of $0.5 million, equivalent to 12 months of his annual base salary, the remaining unpaid portion of his retention award of $0.5 million, his target annual bonus for 2024 of $0.2 million and a pro rata portion of his target annual bonus for 2025. In addition, the Company has paid Dr. Vignola an additional retention bonus in the amount of $0.5 million, provided Dr. Vignola remained employed until February 1, 2025, with such additional retention bonus being payable in a pro rata amount under certain conditions per the transition agreement. During the year ended December 31, 2024, the Company recorded an accrued liability and recognized expense of $1.0 million related to the planned transition of the former chief financial officer. As of December 31, 2024, the ending accrued liability was $1.1 million and is presented within the Consolidated Balance Sheets under Accrued expenses and other current liabilities. Additionally, the transition agreement provided that the time for Dr. Vignola to exercise any outstanding equity award that is vested as of the separation date shall continue to the end of the 12th month following the separation date. As a result of the change in terms for these option grants to Dr. Vignola, the Company recognized an additional $0.4 million in stock-based compensation expense during the year ended December 31, 2024. The expenses were recognized as operating expenses within the Consolidated Statements of Operations and Comprehensive Loss under General and administrative.

In November 2023, Erin Quirk, M.D., former president and head of research & development, received a retention award payable in cash in the aggregate amount of $0.6 million and a recognition bonus in the aggregate amount of $0.1 million. The retention award was payable in two installments of 33% of the award on February 1, 2024, and 67% of the award on August 1, 2024, and the recognition bonus was payable on January 1, 2024, subject to Dr. Quirk's continued employment with the Company through such date. Expense was recognized on a straight-line basis over the requisite service period. On May 7, 2024, Dr. Quirk entered into a separation agreement with the Company. Pursuant to the separation agreement, Dr. Quirk was entitled to receive severance in the amount of $0.2 million and the remaining unpaid portion of her recognition bonus of $0.4 million. As of December 31, 2024, there was no ending accrued liability as all balances have been paid. During the year ended December 31, 2024, the vesting of each equity award held by Dr. Quirk was accelerated with respect to the number of shares of common stock that would have become vested had Dr. Quirk remained employed at the Company through August 31, 2024, and the time for Dr. Quirk to exercise any vested stock options continued up to November 30, 2024. As a result of the change in terms for these option grants to Dr. Quirk in May 2024, the Company recognized $0.4 million in stock-based compensation expense during year ended December 31, 2024. The expenses were recognized as operating expenses within the Consolidated Statements of Operations and Comprehensive Loss under Research and development.

In August 2023, the Company and Senthil Sundaram, former chief executive officer, entered into a separation agreement. Pursuant to the separation agreement, Mr. Sundaram was entitled to receive severance in the amount of $0.6 million and 100% of his annual target discretionary bonus for 2023 in the amount of $0.3 million. During the year ended December 31, 2023, the Company recorded an accrued liability and recognized expense of $0.9 million related to the departure of the former chief executive officer. As of December 31, 2024, there was no ending accrued liability as all balances have been paid. The vesting of each equity award held by Mr. Sundaram was fully accelerated as of December 31, 2023. As a result of the change in service period for all outstanding unvested option grants to the Company's former chief executive officer in August 2023, the Company recognized $10.5 million in stock-based compensation expense during year ended December 31, 2023. The expense was recognized as operating expenses within the Consolidated Statements of Operations and Comprehensive Loss under General and administrative.

Income Taxes

The provision for income taxes primarily relates to projected federal, state and foreign income taxes. Income taxes are computed using the asset and liability approach that requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the Company's financial statements. In estimating future tax consequences, the Company considers all expected future events including the enactment of changes in tax laws or rates. A valuation allowance is recorded, if necessary, to reduce net deferred tax assets to their realizable values if management does not believe it is more likely than not that the net deferred tax assets will 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, and ongoing prudent and feasible tax planning strategies in assessing the amount of the valuation allowance. When the Company establishes or reduces the valuation allowance against its deferred tax assets, its provision for income taxes will increase or decrease, respectively, in the period such determination is made.

The Company assesses accounting for uncertainty in income taxes by modeling for the recognition, measurement and disclosure in financial statements any uncertain income tax positions that the Company has taken or expects to take on a tax return. The Company accrues interest and related penalties, if applicable, on all tax exposures for which reserves have been established consistent with jurisdictional tax laws.

Comprehensive Loss

Comprehensive loss is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources.

Stock-Based Compensation

Stock-based compensation expense relates to stock options, restricted stock units (RSUs) with service conditions, and RSUs with market conditions issued under the Company's equity incentive plan and rights to acquire stock granted under the Company's employee stock purchase plan (ESPP). Grants are measured at the grant date based on the fair value of the awards and is recognized as an expense on a straight-line basis over the requisite service period, which is generally the vesting period. Forfeitures are recognized as they occur.

The Black-Scholes option pricing model estimates the fair value of stock options with time-based vesting and rights to acquire stock under the ESPP. The Company lacks sufficient company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The Company estimates risk-free rates using the implied yield currently available on U.S. Treasury zero-coupon issues with a remaining term equal to the expected term and dividend yield using the Company's expectations and historical data. The Company uses the simplified method to calculate the expected term of stock option grants as the Company has limited historical information from which to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for its stock option grants. Under the simplified method, the expected term is estimated to be the mid-point between the vesting

date and the contractual term of the option. The fair value is calculated based upon the Company's common stock valuation on the date of the grant.

The fair value of RSUs with service conditions is based upon the Company's common stock valuation on the date of the grant.

The Monte Carlo simulation model estimates the fair value of the RSUs with market conditions, using inputs for the common stock valuation on the date of the grant, volatility, the risk-free interest rate, and the dividend yield. Compensation expense is recognized on a straight-line basis over the derived service period commencing on the grant date. The derived service period is the median duration of the successful stock price paths to meet the price goal for each tranche as simulated in the Monte Carlo valuation model. If the related market condition is achieved earlier than its estimated derived service period, the stock-based compensation expense is accelerated, and a cumulative catch-up expense is recorded during the period in which the market condition is met.

Pre-funded Warrants

Pre-funded warrants are classified as a component of permanent stockholders' equity within additional paid-in capital and are recorded at the issuance date using a relative fair value allocation method. The pre-funded warrants are equity classified because they (i) are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, (ii) are immediately exercisable, (iii) do not embody an obligation for the Company to repurchase its shares, (iv) permit the holders to receive a fixed number of shares of common stock upon exercise, (v) are indexed to the Company's common stock and (vi) meet the equity classification criteria. In addition, such pre-funded warrants do not provide any guarantee of value or return. The value of the pre-funded warrants is known at issuance, as their sales price approximates their fair value, and net proceeds from the sale are recorded as a component of additional paid-in capital.

Net Loss Per Share of Common Stock

Basic net income (loss) per share of common stock is computed by dividing the net income (loss) per share of common stock by the weighted average number of shares of common stock outstanding for the period. The weighted-average shares of common stock outstanding as of December 31, 2024 included pre-funded warrants, as the warrants were issued for minimal consideration and were immediately exercisable.

Diluted net income (loss) per share of common stock is computed by adjusting net income (loss) to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net loss per share of common stock is computed by dividing the diluted net loss by the weighted average number of shares of common stock outstanding for the period, including potential dilutive shares.

The Company reported a net loss for the years ended December 31, 2024 and 2023. In periods in which the Company reported a net loss, diluted net loss per share of common stock was the same as basic net loss per share of common stock, since dilutive shares were not assumed to have been issued if their effect is anti-dilutive. The Company excluded the following potential shares of common stock, presented based on amounts outstanding at each period end, from the computation of diluted net loss attributable to common stockholders per share of common stock for the periods indicated because including them would have had an anti-dilutive effect:

	December 31,	
	2024	2023
Options to purchase common stock	10,610,387	8,349,922
Unvested restricted stock units with service conditions	547,430	365,892
Unvested restricted stock units with market conditions	150,000	—
Shares issuable under employee stock purchase plan	13,983	16,258
Total	11,321,800	8,732,072

Deferred Offering Costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated.

After consummation of the equity financing, these costs are recorded as a reduction to the carrying value of stockholders' equity as a reduction of additional paid-in capital or equity generated as a result of such offering. Should an in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the consolidated statements of operations and comprehensive loss.

Property and Equipment, net

Property and equipment are stated at cost, net of accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives. The general range of useful lives of equipment is 3 to 5 years.

When assets are sold or retired, the cost and related accumulated depreciation are removed from the accounts, with any resulting gain or loss recorded in operating expenses in the consolidated statements of operations and comprehensive loss. Costs of repairs and maintenance are expensed as incurred.

Property and equipment, net consisted of the following:

(in thousands)	Estimated Useful Lives	December 31, 2024	December 31, 2023
Leasehold improvements	Shorter of remaining life of lease or useful life of asset	$ 750	$ 734
Furniture and fixtures	5 years	302	303
Computer equipment	3 years	170	162
Office equipment	5 years	145	146
Lab equipment	3 to 5 years	747	770
Property and equipment, gross		2,114	2,115
Less: Accumulated depreciation		(1,892)	(1,609)
Total property and equipment, net		$ 222	$ 506

The Company recognized depreciation expense related to these assets of $0.3 million during the years ended December 31, 2024 and 2023.

Impairment of Long-Lived Assets

The Company's long-lived assets are evaluated for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset or asset group may not be recoverable. Recoverability of an asset to be held and used is measured by a comparison of the carrying amount of an asset or asset group to the future undiscounted cash flows expected to be generated by the asset or asset group. If such asset is considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds its fair value. There were no impairments of long-lived assets for any of the periods presented.

Functional Currencies and Foreign Currency Translation

The Company's reporting currency is U.S. dollars. The functional currency of Terns U.S. Opco and Terns H.K. is U.S. dollars, while the functional currency of Terns Suzhou and Terns China is the Chinese Yuan (CNY). Transactions denominated in other than the functional currencies are remeasured into the functional currency of the entity at the exchange rates prevailing on the transaction dates. Financial assets and liabilities denominated in other than the functional currency are remeasured at the balance sheet date exchange rate. The resulting exchange rate differences are recorded in the consolidated statements of operations and comprehensive loss as a foreign exchange related gain or loss.

Assets and liabilities of Terns Suzhou and Terns China are translated into U.S. dollars at the balance sheet date exchange rates, while income and expense items are translated at the average exchange rates prevailing during the fiscal year. Translation adjustments arising from these are reported as foreign currency translation adjustments and are shown as accumulated other comprehensive loss on the consolidated balance sheets.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash, cash equivalents and marketable securities. The Company maintains deposits in federally insured depository institutions in excess of federally insured limits. The Company has not experienced any losses on such deposits.

The Company has established guidelines regarding approved investments and maturities of investments, which are designed to maintain safety and liquidity.

Patent Costs

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

Commitments and Contingencies

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business. The Company accrues a liability for such matters when it is probable that future expenditures will be made, and such expenditures can be reasonably estimated. For all periods presented, the Company was not a party to any pending material litigation or other material legal proceedings.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies. The Company is an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012, as amended (JOBS Act). Under the JOBS Act, emerging growth companies have extended transition periods available for complying with new or revised accounting standards. The Company has elected to use this exemption to delay adopting new or revised accounting standards until such time as those standards apply to private companies. Where allowable, the Company has early adopted certain standards as described below.

Recently Adopted Accounting Pronouncements

In November 2023, the FASB issued ASU 2023-07 – Segment Reporting (Topic 280) – Improvements to Reportable Segment Disclosures, which improves segment disclosure requirements, primarily through enhanced disclosure requirements for significant segment expenses. The improved disclosure requirements apply to all public entities that are required to report segment information, including those with only one reportable segment. The amendments in ASU 2023-07 are effective for fiscal years beginning after December 15, 2023, with early adoption permitted. The Company adopted ASU 2023-07 effective for the fiscal year beginning January 1, 2024. There was no impact on the Company's reportable segments. Incremental disclosure requirements have been included in the footnotes.

Recently Issued Accounting Pronouncements Not Yet Adopted

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures (ASU 2023-09), which requires additional income tax disclosures in the annual consolidated financial statements. The amendments in ASU 2023-09 are intended to enhance the transparency and decision usefulness of income tax disclosures. For public entities, ASU 2023-09 is effective for annual periods beginning after December 15, 2024, with early adoption permitted. For non-public entities, ASU 2023-09 is effective for annual reporting periods beginning after December 15, 2025. Under the JOBS Act, emerging growth companies have extended transition periods available for complying with new or revised accounting standards. The Company is currently evaluating the impact of ASU 2023-09 on its financial statements and related disclosures.

2. Cash Equivalents and Marketable Securities

The amortized cost and fair value of cash equivalents and marketable securities by major security type is as follows:

	December 31, 2024			
(in thousands)	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Money market funds	$ 147,566	$ —	$ —	$ 147,566
U.S. government securities	196,803	175	(253)	196,725
Total	$ 344,369	$ 175	$ (253)	$ 344,291
Classified as:				
Cash equivalents				$ 147,566
Marketable securities				196,725
Total				$ 344,291

	December 31, 2023			
(in thousands)	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Money market funds	$ 33,788	$ —	$ —	$ 33,788
U.S. government securities	183,357	219	(62)	183,514
Total	$ 217,145	$ 219	$ (62)	$ 217,302
Classified as:				
Cash equivalents				$ 33,788
Marketable securities				183,514
Total				$ 217,302

The aggregate fair value of the Company's available-for-sale marketable securities that have been in a continuous unrealized loss position for less than twelve months or twelve months or longer is as follows:

	December 31, 2024					
	Less than 12 months		12 months or longer		Total	
(in thousands)	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
U.S. government securities	$ 119,081	$ (252)	$ 2,007	$ (1)	$ 121,088	$ (253)
Total	$ 119,081	$ (252)	$ 2,007	$ (1)	$ 121,088	$ (253)

	December 31, 2023					
	Less than 12 months		12 months or longer		Total	
(in thousands)	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
U.S. government securities	$ 80,461	$ (62)	$ —	$ —	$ 80,461	$ (62)
Total	$ 80,461	$ (62)	$ —	$ —	$ 80,461	$ (62)

At December 31, 2024, the Company had 11 available-for-sale marketable securities in an unrealized loss position without an allowance for credit losses. The Company does not intend to sell these securities and the Company believes it is more likely than not that marketable securities in an unrealized loss position will be held until maturity and that the Company will not be required to sell these securities before recovery of their amortized cost basis. The Company believes that an allowance for credit losses is unnecessary as the securities are of high credit quality and the decline in fair value is due to market conditions and/or changes in interest rates.

3. Fair Value

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The three levels of inputs that may be used to measure fair value are defined below:

- Level 1—Quoted prices in active markets for identical assets or liabilities at the measurement date.
- Level 2—Inputs other than quoted prices included in Level 1 that are observable for the asset or liability, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3—Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The carrying values of the Company's other assets, accounts payable and accrued expenses and other current liabilities approximate their fair values due to the short-term nature of these assets and liabilities.

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis:

	Fair Value at December 31, 2024			
(in thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Cash and cash equivalents				
Cash in bank balances	$ 13,873	$ —	$ —	$ 13,873
Money market funds	147,566	—	—	147,566
Total cash and cash equivalents	$ 161,439	$ —	$ —	$ 161,439
Marketable securities				
U.S. government securities	$ —	$ 196,725	$ —	$ 196,725
Total marketable securities	$ —	$ 196,725	$ —	$ 196,725

	Fair Value at December 31, 2023			
(in thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Cash and cash equivalents				
Cash in bank balances	$ 46,138	$ —	$ —	$ 46,138
Money market funds	33,788	—	—	33,788
Total cash and cash equivalents	$ 79,926	$ —	$ —	$ 79,926
Marketable securities				
U.S. government securities	$ —	$ 183,514	$ —	$ 183,514
Total marketable securities	$ —	$ 183,514	$ —	$ 183,514

The aggregate amortized cost and fair value of marketable securities as of December 31, 2024, by contractual maturity, are as follows:

(in thousands)	Amortized Cost	Fair Value
Due in one year or less	$ 108,559	$ 108,711
Due after one year through two years	88,244	88,014
Total marketable securities	$ 196,803	$ 196,725

During the years ended December 31, 2024 and 2023, there were no transfers between Level 1, Level 2 and Level 3.

4. Leases

In March 2019, the Company entered into a lease agreement for office space in Foster City, California which was set to expire in October 2024. In July 2024, the Company amended the lease agreement to extend for three years commencing as of November 1, 2024, and expiring on October 31, 2027. The Company has the option to extend the amended lease agreement for an additional three years. The other terms of the amendment are substantially the same as the original lease agreement and annual lease payments are approximately $0.5 million. Additionally, the Company leases office space in Shanghai and Suzhou, China.

Components of lease cost are as follows:

	Year Ended December 31,	
(in thousands)	**2024**	**2023**
Operating lease cost	$ 651	$ 648
Short-term cost	15	17
Total lease cost	$ 666	$ 665

	December 31,	
	2024	**2023**
Weighted-average remaining lease term	2.92	0.84
Weighted-average discount rate	10.00%	6.00%

The Company's future minimum lease payments are as follows:

(in thousands)	Operating Leases
2025	$ 544
2026	545
2027	465
2028 and thereafter	—
Total lease payments	1,554
Less: Imputed interest	(207)
Present value of lease liabilities	1,347
Less: Current portion of lease liabilities	(428)
Total lease liabilities, non-current	$ 919

5. Common Stock and Stock-Based Compensation

The Company is authorized to issue 150,000,000 shares of common stock and 10,000,000 shares of preferred stock. All classes of stock have a par value of $0.0001. There were no shares of preferred stock outstanding as of December 31, 2024 and 2023.

As of each balance sheet date, the Company had reserved shares of common stock for issuance in connection with the following:

	December 31,	
	2024	2023
Options outstanding under incentive award plans	10,610,387	8,349,922
Unvested restricted stock units with service conditions	547,430	365,892
Unvested restricted stock units with market conditions	150,000	—
Shares available for future grant under incentive award plans	4,092,569	1,005,587
Shares available for future grant under employee stock purchase plans	1,208,837	701,671
Shares available for future grant under employment inducement award plans	2,685,001	3,291,000
Pre-funded warrants	4,190,952	9,751,500
Total shares reserved	23,485,176	23,465,572

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, if any, as may be declared by the Company's board of directors, subject to the preferential dividend rights of the convertible preferred stock. Through December 31, 2024, no cash dividends have been declared or paid by the Company.

Stock-Based Compensation Plans

The Company has three stock-based compensation plans, the 2017 Incentive Award Plan (the 2017 Plan), the 2021 Incentive Award Plan (the 2021 Plan) and the 2022 Employment Inducement Award Plan (the 2022 Inducement Plan). Although awards made under the 2017 Plan continue to be governed by its terms, the 2017 Plan was terminated at the time of our IPO and no further awards are made under this plan. The 2021 Plan, while effective, authorizes the granting of equity awards to employees and directors of the Company, as well as non-employee consultants. The 2022 Inducement Plan authorizes the granting of equity awards to newly hired employees of the Company.

2021 Incentive Award Plan

In January 2021, the Company's board of directors approved the 2021 Plan which permits the granting of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock awards, RSU awards, performance bonus awards, performance stock unit awards and other stock awards to employees, directors, officers and consultants. In February 2021, 2,400,007 shares were authorized for issuance under the 2021 Plan, which shall be cumulatively increased on the first day of each year beginning in 2022 and ending in 2031 equal to the lesser of (i) the amount equal to 5% of the number of shares issued and outstanding on the last day of the immediately preceding fiscal year or (ii) such lower number of shares as may be determined by the Company's board of directors. The 2021 Plan is the successor to the 2017 Plan and no additional awards may be issued from the 2017 Plan. However, the 2017 Plan will continue to govern the terms and conditions of the outstanding awards granted under this plan. Shares of common stock subject to awards granted under the 2017 Plan that are forfeited or lapse unexercised and which following the effective date of the 2021 Plan are not issued under the 2017 Plan will be available for issuance under the 2021 Plan. As of December 31, 2024, 4,092,569 shares of the Company's common stock were available for future grants under the 2021 Plan. The number of authorized shares reserved for issuance under the 2021 Plan was increased by 4,356,329 shares effective as of January 1, 2025.

2021 Employee Stock Purchase Plan

The 2021 Employee Stock Purchase Plan (the 2021 ESPP) was approved by the Company's board of directors in January 2021. In February 2021, a total of 240,000 shares were initially reserved for issuance under this plan, which shall be cumulatively increased on the first day of each year beginning in 2022 and ending in 2031 equal to the lesser of (i) 1% of the shares outstanding (on an as converted basis) on the last day of the immediately preceding fiscal year and (ii) such number of shares as may be determined by the Company's board of directors. As of December 31, 2024, 1,208,837 shares of the Company's common stock were available for future grants under the 2021 ESPP. The number of authorized shares reserved for issuance under the 2021 ESPP was increased by 871,265 shares effective as of January 1, 2025.

Under the 2021 ESPP, eligible employees may select a rate of payroll deduction up to 15% of their eligible compensation subject to certain maximum purchase limitations. The duration for each offering period is 24 months and is divided into four purchase periods of approximately six months in length. Offerings are concurrent. The purchase price of the shares under the offering is the lesser of 85% of the fair market value of the shares on the offering date or 85% of the fair market value of the shares on the purchase date. A look-back feature in the 2021 ESPP causes the offering period to automatically reset if the fair value of the Company's common stock on the last day of the purchase period is less than that on the original offering date. 2021 ESPP purchases by employees are settled with newly-issued common stock from the 2021 ESPP's previously authorized and available pool of shares.

As of December 31, 2024, there was $0.5 million of unrecognized stock-based compensation expense related to unvested employee stock purchases. The unrecognized stock-based compensation expense is estimated to be recognized over a period of 1.13 years as of December 31, 2024. There were 138,601 shares purchased by employees under the ESPP during the year ended December 31, 2024.

2022 Employment Inducement Award Plan

In September 2022, the Company's compensation committee approved the 2022 Inducement Plan, which authorized 1,400,000 shares of common stock to be issued and permits the granting of nonqualified stock options, stock appreciation rights, restricted stock awards and RSU awards to newly hired employees and officers. In August 2024 and September 2023, the Company approved amendments to the 2022 Inducement Plan which increased the number of authorized shares reserved for issuance by 2,250,000 and 3,113,250 shares, respectively. As of December 31, 2024, 2,685,001 shares of the Company's common stock were available for future grants under the 2022 Inducement Plan.

Pre-Funded Warrants

In September 2024, the Company sold pre-funded warrants to purchase 2,380,952 shares of common stock at a price of $10.4999 per pre-funded warrant. The purchase price per share of each pre-funded warrant represents the per share public offering price for the common stock sold in the same offering, minus the $0.0001 per share exercise price of such pre-funded warrant. As of December 31, 2024, no pre-funded warrants have been exercised.

In August 2022, the Company sold pre-funded warrants to purchase 14,630,000 shares of common stock at a price of $2.4199 per pre-funded warrant. The purchase price per share of each pre-funded warrant represents the per share offering price for the common stock, minus the $0.0001 per share exercise price of such pre-funded warrant. As of December 31, 2024, 12,820,000 pre-funded warrants have been exercised.

Stock Options

Stock options granted to employees and non-employees under the plans generally vest over four years and allow the holder of the option to purchase common stock at a stated exercise price. Options granted under the plans generally expire ten years after the date of grant. The Company recognizes the stock-based compensation expense over the requisite service period of the individual grantees, which generally equals the vesting period.

The following table summarizes the stock option activity for all stock plans during the years ended December 31, 2024 and 2023:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
			(in years)	*(in thousands)*
Outstanding as of December 31, 2022	4,823,928	$ 8.22	8.46	$ 11,721
Granted	4,269,925	9.51		
Exercised	(106,176)	2.58		925
Forfeited	(637,755)	6.99		
Outstanding as of December 31, 2023	8,349,922	$ 9.04	6.82	$ 2,225
Granted	4,948,813	6.69		
Exercised	(244,913)	5.91		723
Forfeited	(2,443,435)	8.81		
Outstanding as of December 31, 2024	10,610,387	$ 8.07	6.66	$ 1,288
Exercisable, December 31, 2024	5,151,571	$ 8.91	4.05	$ 931
Vested and expected to vest, December 31, 2024	10,610,387	$ 8.07	6.66	$ 1,288

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock.

As of December 31, 2024 and 2023, there was $23.4 million and $21.7 million, respectively, of unrecognized stock-based compensation expense related to unvested stock options. The unrecognized stock-based compensation expense is estimated to be recognized over a period of 2.90 years as of December 31, 2024.

The total fair value of options vested during the year ended December 31, 2024 and 2023 was $13.1 million and $20.2 million, respectively.

Restricted Stock Units with Service Conditions

RSUs with service conditions granted to employees under the plans generally vest over four years. The number of shares issued on the date the RSUs vest is net of the minimum statutory tax withholdings, which are paid in cash to the appropriate taxing authorities on behalf of the Company's employees. The Company recognizes the stock-based compensation expense over the requisite service period of the individual grantees, which generally equals the vesting period.

The following table summarizes the RSUs with service conditions activity for all stock plans during the years ended December 31, 2024 and 2023:

	Number of Shares	Weighted Average Grant-Date Fair Value Per Share
Unvested restricted stock units as of December 31, 2022	128,280	$ 4.09
Granted	308,013	9.86
Vested	(50,401)	4.11
Forfeited	(20,000)	7.04
Unvested restricted stock units as of December 31, 2023	365,892	$ 8.79
Granted	635,650	6.16
Vested	(160,936)	8.58
Forfeited	(293,176)	6.39
Unvested restricted stock units as of December 31, 2024	547,430	$ 7.09

As of December 31, 2024 and 2023, there was $3.0 million and $2.5 million, respectively, of unrecognized stock-based compensation expense related to RSUs with service conditions. The unrecognized stock-based compensation expense is estimated to be recognized over a period of 2.59 years as of December 31, 2024.

The total fair value of RSUs with service conditions vested during the years ended December 31, 2024 and 2023 was $1.4 million and $0.2 million, respectively.

Restricted Stock Units with Market Conditions

In March 2024, the Company granted 150,000 RSUs with market conditions, which are subject to the achievement of certain escalating stock price thresholds established by the Company's compensation committee of the board of directors. The RSUs with market conditions vest in equal installments upon the achievement of escalating stock price thresholds of $15.00 and $20.00, respectively, calculated based on the average price per share of the Company’s common stock for a period of 30 consecutive trading days equaling or exceeding the applicable price threshold, with vesting occurring as of the last day of the 30 consecutive trading day period. The escalating stock price thresholds can be met any time after the first anniversary of employment of the recipient but prior to the fourth anniversary from the date of grant.

The Company estimated the fair value of RSUs with market conditions granted using a Monte Carlo simulation model with the following assumptions:

	Year Ended December 31, 2024
Expected volatility	78.45%
Risk-free interest rate	4.27%
Fair value of underlying common stock	$ 7.31
Weighted average grant-date fair value per share	$ 5.39

As of December 31, 2024, none of the escalating stock price thresholds had been met for any of the RSUs with market conditions, resulting in no shares vested.

As of December 31, 2024, there was $0.4 million of unrecognized stock-based compensation expense related to RSUs with market conditions which is estimated to be recognized over a period of 0.81 years.

Stock-Based Compensation Expense

The Company estimated the fair value of options granted and rights to acquire stock granted under the Company's ESPP using a Black-Scholes option pricing model with the following assumptions presented on a weighted average basis:

	Year Ended December 31,	
	2024	2023
Stock Option Plans		
Expected term (years)	6.04	6.05
Expected volatility	76.75%	73.84%
Risk-free interest rate	4.22%	3.62%
Fair value of underlying common stock	$ 6.69	$ 9.51
Weighted average grant-date fair value per share	$ 4.66	$ 6.41
Employee Stock Purchase Plans		
Expected term (years)	1.13	1.33
Expected volatility	77.92%	82.05%
Risk-free interest rate	4.69%	4.84%
Fair value of underlying common stock	$ 6.13	$ 7.48
Weighted average grant-date fair value per share	$ 2.89	$ 3.84

Stock-based compensation expense was classified in the consolidated statements of operations and comprehensive loss as follows:

	Year Ended December 31,	
(in thousands)	2024	2023
Research and development expense	$ 6,709	$ 5,870
General and administrative expense	8,918	19,666
Total stock-based compensation expense	$ 15,627	$ 25,536

6. Income Tax

The following table presents domestic and foreign components of income (loss) before income taxes:

	Year Ended December 31,	
(in thousands)	**2024**	**2023**
U.S.	$ (89,010)	$ (90,017)
Foreign	417	46
Total loss before income tax	$ (88,593)	$ (89,971)

The following table presents the provision for income taxes:

	Year Ended December 31,	
(in thousands)	**2024**	**2023**
Current		
Federal	$ —	$ 5
State	31	14
Foreign	523	239
Total current	$ 554	$ 258
Deferred		
Foreign	$ (294)	$ (19)
Total deferred	$ (294)	$ (19)
Total income tax expense	$ 260	$ 239

The reconciliation of the U.S. federal statutory income tax benefit to the Company's effective income tax rate is as follows:

	Year Ended December 31,	
	2024	**2023**
Tax benefit at U.S. statutory rate	21.00%	21.00%
State income taxes, net of Federal tax benefit	(0.03)	(0.02)
Foreign income taxed at non-U.S. rates	(0.02)	(0.07)
Other permanent items	(0.12)	(0.10)
Deferred tax asset write-off	(3.47)	(5.05)
Stock-based compensation	(2.01)	(0.39)
Research and development credits	2.56	3.99
Unrecognized tax benefit	2.43	(1.21)
162(m) limitation	(0.33)	(0.04)
Global intangible low-taxed income	(0.48)	(0.05)
Increase in valuation allowance	(19.86)	(18.74)
Other	0.04	0.41
	(0.29)%	(0.27)%

The difference between the provision for income taxes and the income tax determined by applying the statutory federal income tax rate of 21% was primarily due to the change in valuation allowance.

Significant components of the Company's deferred tax assets and liabilities are as follows:

(in thousands)	As of December 31, 2024	2023
Deferred tax assets:		
Accruals and reserves	$ 1,821	$ 1,280
Intangibles	9,626	11,288
Stock-based compensation	4,783	3,730
Net operating loss	28,004	19,929
Research and development credits	8,919	6,551
Lease liability	271	114
Capitalized research and development	25,315	16,839
Other	101	72
Valuation allowance	(78,220)	(59,621)
Total deferred tax assets	$ 620	$ 182
Deferred tax liabilities:		
Fixed assets	$ (12)	$ (29)
Operating lease assets	(258)	(97)
Total deferred tax liabilities	$ (270)	$ (126)
Net deferred tax assets	$ 350	$ 56

As of December 31, 2024, the Company recorded a full valuation allowance against its U.S. net deferred tax assets as it believes these deferred tax assets were not realizable on a more likely than not basis. This is based upon the weight of available evidence, including historical operating performance, and that a net loss will be expected to occur in the foreseeable future.

As of December 31, 2024, the Company had federal and state net operating loss carryforwards of approximately $132.8 million and $3.2 million, respectively. The federal net operating loss has an indefinite carryforward while the state net operating loss will begin to expire in 2041. As of December 31, 2023, the Company had federal and state net operating loss carryforwards of approximately $94.8 million and $2.2 million, respectively.

As of December 31, 2024 and 2023, the Company had federal Research & Development (R&D) credit carryforwards of approximately $9.5 million and $7.5 million, respectively, which will begin to expire in 2039. As of December 31, 2024 and 2023, the Company had California R&D credit carryforwards of approximately $4.7 million and $2.9 million, respectively, which do not expire.

Utilization of net operating loss carryforwards and credits may be subject to a substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code of 1986, as amended, and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization. The Company does not expect any previous ownership changes, as defined under Section 382 and 383 of the Internal Revenue Code, to result in a limitation that will materially reduce the total amount of net operating loss carryforwards and credits that can be utilized.

Beginning in 2022, as part of the Tax Cuts and Job Act (TCJA) passed in 2017, the TCJA enacted tax legislation requiring U.S. R&D expenditures to be capitalized and amortized ratably over a five-year period. Expenditures attributed to research conducted outside of the U.S. must be capitalized and amortized over a 15-year period.

As of December 31, 2024, the Company has provided U.S. income taxes on all its foreign earnings. The Company continues to permanently reinvest the cash held offshore to support its working capital needs, as of end of the year. Any withholding taxes from the foreign jurisdictions in the event of a cash distribution would have been immaterial.

As of December 31, 2024 and 2023, the total amount of unrecognized tax benefits was $5.5 million and $7.5 million, respectively, $1.0 million and $4.1 million of which would affect income tax expense, if recognized, before consideration of any valuation allowance. The Company does not expect the unrecognized tax benefits to change significantly over the next 12 months.

A reconciliation of the beginning and ending unrecognized tax benefit are as follows:

	Year Ended December 31,	
(in thousands)	**2024**	**2023**
Unrecognized tax benefit at beginning of year	$ 7,506	$ 6,316
Increases related to prior year tax positions	84	14
Increases related to current year tax positions	1,490	1,339
Decreases related to prior year tax positions	(3,538)	(163)
Unrecognized tax benefit at end of year	$ 5,542	$ 7,506

The Company includes interest and penalties related to unrecognized tax benefits within the provision for income taxes. As of December 31, 2024 and 2023, the total amount of gross interest and penalties accrued was $0.5 million and $0.4 million, respectively.

The Company is subject to income taxes in the U.S. federal, state and various foreign jurisdictions. Tax regulations within each jurisdiction are subject to the interpretation of the related tax laws and regulations and require significant judgment to apply. The Company's tax years remain open for examination by all tax authorities since inception as well as carryover attributes beginning December 31, 2019, remain open to adjustment by the U.S. and foreign authorities.

7. Assignment, License and Collaboration Agreements

Assignment Agreement

In June 2019, the Company entered into an assignment agreement with Vintagence Biotechnology Ltd. (Vintagence) (Vintagence 2019 Assignment Agreement). Under the terms of the Vintagence 2019 Assignment Agreement, Vintagence assigned and agreed to assign to the Company any and all worldwide rights, title and interest in and to the Vintagence technology and gave Terns a sublicensing right that allows the Company to grant sublicenses to any of its affiliates and/or to licensees or contractors to perform any portion of the development, manufacture, and/or commercialization of covered compounds or covered products. The Company will remain directly responsible for all amounts owed to Vintagence under this agreement, regardless of sublicenses. The Company is required to use commercially reasonable efforts to commercialize the covered product in the field in the major markets.

In June 2019, the Company paid Vintagence an upfront payment of $0.7 million. In addition, pursuant to the terms of the Vintagence 2019 Assignment Agreement, the Company agreed to pay Vintagence up to CNY 205.0 million in development milestones for the first covered product. The term of the Vintagence 2019 Assignment Agreement will continue in effect on a country-by-country basis until all milestone payments are made. The Company has the right to terminate the agreement in its entirety or on a covered product-by-covered product and country-by-country basis, in its sole discretion by giving 60 days advance written notice to Vintagence. As of December 31, 2024, the Company has paid $4.4 million to Vintagence which includes a milestone payment of $1.5 million in connection with the Company's investigational new drug filing for TERN-501 in December 2020 and a milestone payment of $2.2 million in connection with the initiation of dosing in the Phase 2a DUET trial in July 2022. The Company has not recognized any research and development expense during the years ended December 31, 2024 and 2023 related to this agreement.

Hansoh Option and License Agreement

In July 2020, the Company entered into an exclusive option and license agreement with Hansoh (Shanghai) Healthtech Co., Ltd. (Hansoh Healthtech) and Jiangsu Hansoh Pharmaceutical Group Company Ltd. (Jiangsu Hansoh) (collectively, Hansoh) (Hansoh 2020 Option and License Agreement). Under the terms of the Hansoh 2020 Option and License Agreement, the Company granted Hansoh an exclusive, non-transferable, non-sublicensable, fully-paid, royalty-free license to conduct preliminary studies on the licensed compound, TERN-701, with an option to exclusively license the same for development and commercialization of licensed products in all prophylactic, palliative, therapeutic and/or diagnostic uses in connection with all human diseases and disorders (including development and research activities on animal models thereof) in the field of oncology, including all types of cancers (Field) in mainland China, Taiwan, Hong Kong and Macau (collectively, the Territory).

In November 2021, Hansoh exercised its option and was granted an exclusive, royalty-bearing license, with the right to sublicense to exploit the licensed compound and licensed products in the Field and in the Territory. In connection with Hansoh’s exercise of its option in November 2021, the Company recognized $1.0 million in license fee revenue within the consolidated statements of operations and comprehensive loss during the year ended December 31, 2021. In addition, Hansoh has agreed to pay the Company up to $67.0 million in pre-specified clinical, regulatory and sales milestones. Hansoh must also pay the Company royalties in the mid-single digits based on net sales of all licensed products. The term of the Hansoh 2020 Option and License Agreement will continue until the end of the last-to-expire royalty term. As of December 31, 2024, no milestones have been met and future payments are all constrained.

8. Segment Reporting

The Company has one reportable segment, the consolidated entity's operations, relating to the research and development of its portfolio of small-molecule product candidates to address serious diseases including oncology and obesity.

The Company's chief operating decision maker (the CODM), its chief executive officer, manages the Company's operations as a single segment for the purposes of assessing performance and making operating decisions. When evaluating the Company's financial position, the CODM reviews, as presented on a consolidated basis, cash, cash equivalents and marketable securities, total assets, cash flows from operating activities, research and development expenses by program, personnel and other, general and administrative expenses and net loss.

Cash, cash equivalents and marketable securities and total assets are presented within Item 8, Financial Statements and Supplementary Data, under Consolidated Balance Sheets. Cash flows from operating activities are presented within Item 8, Financial Statements and Supplementary Data, under Consolidated Statements of Cash Flows.

Consolidated segment loss, including segment expenses reviewed by the CODM, include the following:

(in thousands)	Year Ended December 31, 2024	2023
Research and development expenses		
External expenses by program:		
TERN-701	$ 15,757	$ 6,627
TERN-601	15,486	7,247
TERN-501	881	17,819
Other programs	11,004	9,579
Total external expenses	43,128	41,272
Unallocated internal expenses:		
Personnel-related expenses	25,732	21,017
Other expenses	1,252	1,208
Total research and development expenses	70,112	63,497
General and administrative	31,759	39,061
Total operating expenses	101,871	102,558
Loss from operations	(101,871)	(102,558)
Other income:		
Interest income	13,289	12,901
Other expense, net	(11)	(314)
Total other income, net	13,278	12,587
Loss before income taxes	(88,593)	(89,971)
Income tax expense	(260)	(239)
Net loss	$ (88,853)	$ (90,210)

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

None.

Item 9A. Controls and Procedures.

Conclusions Regarding the Effectiveness of Disclosure Controls and Procedures

As of December 31, 2024, management, with the supervision and participation of our chief executive officer and the chief financial officer, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including the chief executive officer and the chief financial officer, to allow timely decisions regarding required disclosures.

Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our chief executive officer and the chief financial officer concluded that, as of December 31, 2024, the design and operation of our disclosure controls and procedures were effective at a reasonable assurance level.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting for our company. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, the company's principal executive and principal financial officers and effected by the company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of our company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our company's assets that could have a material effect on the financial statements.

Internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements prepared for external purposes in accordance with generally accepted accounting principles. 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 risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management, with the participation of our chief executive officer and the chief financial officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2024. In making this assessment, our management used the criteria set forth in the Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on its assessment, management concluded that our internal control over financial reporting was effective as of December 31, 2024 based on those criteria.

Attestation Report of the Registered Public Accounting Firm

This report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting.

Changes in Internal Control over Financial Reporting

There were no changes during the quarter ended December 31, 2024 to our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Rule 10b5-1 Trading Plans

During the three months ended December 31, 2024, none of our directors or officers, or the Company, has entered into, modified or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c), in each case as defined in Item 408 of Regulation S-K.

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

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item will be contained in our definitive proxy statement to be filed with the SEC in connection with our 2025 annual meeting of stockholders (the 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 in this report by reference.

Item 11. Executive Compensation.

The information required by this item will be set forth in our Proxy Statement and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item will be set forth in our Proxy Statement and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item will be set forth in our Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this item will be set forth in our Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a)(1) Financial Statements.

The response to this portion of Item 15 is set forth under Part II, Item 8 above.

(a)(2) Financial Statement Schedules.

All schedules have been omitted because they are not required or because the required information is given in the Financial Statements or Notes thereto set forth under Item 8 above.

(a)(3) Exhibits

The exhibits listed in the Exhibit Index below are filed or incorporated by reference as part of this Annual Report.

		Incorporated by Reference			
Exhibit Number	Exhibit Description	Form	Date	Number	Filed Herewith
3.1	Amended and Restated Certificate of Incorporation.	8-K	2/9/2021	3.1	
3.2	Amended and Restated Bylaws.	8-K	10/10/2023	3.1	
4.1	Reference is made to Exhibits 3.1 through 3.2.				
4.2	Form of Common Stock Certificate.	S-1/A	2/1/2021	4.2	
4.3	Description of Securities.				X
4.4	Form of Pre-Funded Warrant (August 2022).	8-K	8/16/2022	4.1	
4.5	Form of Pre-Funded Warrant (September 2024).	8-K	9/12/2024	4.1	
4.6	Amended and Restated Investors' Rights Agreement, dated December 29, 2020, by and among the Registrant and the investors listed therein.	S-1	1/15/2021	10.1	
10.1	Lease, dated March 1, 2019, by and between the Registrant and DWF IV Century Plaza, LLC.	S-1	1/15/2021	10.2	
10.2(a)#	2017 Equity Incentive Plan, as amended.	S-1	1/15/2021	10.4(a)	
10.2(b)#	Form of Stock Option Grant Notice and Stock Option Agreement under 2017 Equity Incentive Plan, as amended.	S-1	1/15/2021	10.4(b)	
10.2(c)#	Form of Early Exercise Stock Option Grant Notice and Stock Option Agreement under 2017 Equity Incentive Plan, as amended.	S-1	1/15/2021	10.4(c)	
10.2(d)#	Form of International Stock Option Grant Notice and Stock Option Agreement under 2017 Equity Incentive Plan, as amended.	S-1	1/15/2021	10.4(d)	
10.3(a)#	2021 Incentive Award Plan.	S-8	2/12/2021	99.2(a)	
10.3(b)#	Form of Stock Option Grant Notice and Stock Option Agreement under the 2021 Incentive Award Plan.	S-1/A	2/1/2021	10.5(b)	
10.3(c)#	Form of Restricted Stock Award Grant Notice and Restricted Stock Award Agreement under the 2021 Incentive Award Plan.	S-1/A	2/1/2021	10.5(c)	
10.3(d)#	Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement under the 2021 Incentive Award Plan.	S-1/A	2/1/2021	10.5(d)	
10.4#	2021 Employee Stock Purchase Plan.	S-8	2/12/2021	99.3	

10.5#	Amended and Restated Employment Agreement by and between the Registrant and Erin Quirk, M.D.	10-K	3/14/2024	10.6#	
10.6#	Amended and Restated Employment Agreement by and between the Registrant and Bryan Yoon, Esq.	10-K	3/14/2024	10.8#	
10.7#	Employment Agreement by and between the Registrant and Jill M. Quigley.	10-K	3/14/2024	10.9#	
10.8#	Amended and Restated Employment Agreement by and between the Registrant and Mark Vignola.	10-K	3/14/2024	10.10#	
10.9#	Second Amended and Restated Non-employee Director Compensation Program, as amended.				X
10.10	Form of Indemnification Agreement for directors and officers.	S-1/A	2/1/2021	10.11	
10.11†	Assignment Agreement, dated as of June 24, 2019, by and among Terns Pharmaceuticals, Inc. and Vintagence Biotechnology Ltd.	S-1	1/15/2021	10.15	
10.12†	Exclusive Option and License, dated as of July 27, 2020, by and among Terns Pharmaceuticals, Inc., Terns, Inc., CaspianTern LLC, Hansoh (Shanghai) Healthtech Co., Ltd. and Jiangsu Hansoh Pharmaceutical Group Company Ltd.	S-1	1/15/2021	10.16	
10.13(a)#	2022 Employment Inducement Award Plan.	10-Q	11/9/2022	10.1(a)#	
10.13(b)#	Form of Stock Option Grant Notice and Stock Option Agreement under the 2022 Employment Inducement Award Plan.	10-Q	11/9/2022	10.1(b)#	
10.13(c)#	Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement under the 2022 Employment Inducement Award Plan.	10-Q	11/9/2022	10.1(c)#	
10.13(d)#	Amendment No. 1 to 2022 Employment Inducement Award Plan.	10-Q	11/14/2023	10.2#	
10.14	Sales Agreement, dated May 15, 2023, by and between Terns Pharmaceuticals, Inc. and Cowen and Company, LLC.	8-K	5/15/2023	1.1	
10.15#	Separation Agreement between Terns, Inc. and Bryan Yoon dated July 23, 2024.	10-Q	11/12/2024	10.1#	
10.16#	Transition Agreement between Terns, Inc. and Mark Vignola dated July 23, 2024.	10-Q	11/12/2024	10.2#	
10.17#	Amendment No. 2 to 2022 Employment Inducement Award Plan.	10-Q	11/12/2024	10.3#	
10.18	First Amendment to Office Lease dated July 1, 2024.	8-K	7/3/2024	10.1	
10.19#	Separation Agreement between Terns, Inc. and Erin Quirk dated May 7, 2024.	10-Q	8/5/2024	10.1#	
10.20#	Employment Agreement by and between the Registrant and Amy Burroughs dated February 7, 2024.	10-Q	5/13/2024	10.2#	
10.21#	Reference is made to Exhibit 97.0.				
19.1	Terns Pharmaceuticals, Inc. Insider Trading Policy.				X
21.1	List of subsidiaries.	S-1	1/15/2021	21.1	
23.1	Consent of Ernst & Young LLP, independent registered public accounting firm.				X
24.1	Power of Attorney. Reference is made to the signature page hereto.				X

31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1^	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
32.2^	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
97.0#	Clawback Policy.	10-Q	11/14/2023	10.3#	
101.INS	Inline XBRL Instance 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.

† Certain portions of this document that constitute confidential information have been redacted in accordance with Regulation S-K, Item 601(b)(10).

^ The certification that accompanies this Annual Report on Form 10-K pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, is not deemed “filed” by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

TERNS PHARMACEUTICALS, INC.

Date: March 20, 2025

By: /s/ Amy Burroughs
Amy Burroughs
Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Amy Burroughs and Andrew Gengos as his or her true and lawful attorney-in-fact and agent, with the full power of substitution, for him or her in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed below by the following persons on behalf of the registrant in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
/s/ Amy Burroughs Amy Burroughs	Chief Executive Officer and Director *(Principal Executive Officer)*	March 20, 2025
/s/ Andrew Gengos Andrew Gengos	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 20, 2025
/s/ David Fellows David Fellows	Chairman of the Board of Directors	March 20, 2025
/s/ Robert Azelby Robert Azelby	Director	March 20, 2025
/s/ Jeffrey Kindler Jeffrey Kindler, Esq.	Director	March 20, 2025
/s/ Hongbo Lu Hongbo Lu, Ph.D	Director	March 20, 2025
/s/ Jill Quigley Jill Quigley, Esq.	Director	March 20, 2025
/s/ Radhika Tripuraneni Radhika Tripuraneni, M.D., M.P.H.	Director	March 20, 2025
/s/ Heather Turner Heather Turner, J.D.	Director	March 20, 2025