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, 2020

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, 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. ☐

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

The registrant's common stock was not publicly traded as of the last business day of the registrant's most recently completed second fiscal quarter.

The number of shares of Registrant's Common Stock outstanding as of March 26, 2021 was 25,125,072.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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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 related to the global COVID 19 pandemic 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 regarding the potential market size and size of the potential patient populations for our single-agent and combination therapy candidates and any future single-agent and combination therapy candidates if approved for commercial use;
- our clinical and regulatory development plans;
- 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 timing of commencement of future nonclinical studies and clinical trials and research and development programs;
- our ability to acquire, discover, develop and advance single-agent and combination therapy 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 single-agent and combination therapy candidates;
- our commercialization, marketing and manufacturing capabilities and expectations;
- our intentions with respect to the commercialization of our single-agent and combination therapy candidates;
- the pricing and reimbursement of our single-agent and combination therapy candidates, if approved;
- the potential effects of COVID-19 on our preclinical and clinical programs and business;
- the implementation of our business model and strategic plans for our business and single-agent and combination therapy candidates, including additional indications for which we may pursue;
- the scope of protection we are able to establish, maintain, protect and enforce for intellectual property rights covering our single-agent and combination therapy 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;
- our future financial performance; and
- developments and projections relating to our competitors and our industry, including competing products.

Summary of material risks associated with our business

The principal risks and uncertainties affecting our business include the following:

- 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.
- Unfavorable global economic or political conditions (including a recession or depression resulting from the COVID-19 pandemic) could adversely affect our business, financial condition or results of operations.
- 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. Furthermore, NASH is an indication for which there is no approved therapy in the United States or Europe and for which other development challenges exist such as the lack of widely-accepted noninvasive diagnostic methods. If the development of our single-agent and combination therapy candidates is unsuccessful or delayed, we may be unable to obtain required regulatory approvals and we may be unable to commercialize our single-agent and combination therapy candidates on a timely basis, if at all.
- 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 single-agent and combination therapy candidates.
- We face significant competition for our drug discovery and development efforts in an environment of rapid technological and scientific change, and our single-agent and combination therapy 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 with them.
- 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 single-agent or combination therapy candidates on a timely basis or at all.
- 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 single-agent or combination therapy candidate, and our commercialization of any of our single-agent and combination therapy 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.
- Our current and any future single-agent and combination therapy 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 single-agent and combination therapies.
- 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.
- 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 summary risk factors described above should be read together with the text of the full risk factors below in the section entitled Item 1A. “Risk Factors” and the other information set forth in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes, as well as in other documents that we file with the U.S. Securities and Exchange Commission. The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not precisely known to us or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, results of operations, and future growth prospects.

PART I

Item 1. Business.

Company Overview

We are a clinical-stage biopharmaceutical company developing a portfolio of small-molecule single-agent and combination therapy candidates for the treatment of non-alcoholic steatohepatitis, or NASH, and other chronic liver diseases. Our programs are based on clinically-validated and complementary mechanisms of action to address the multiple hepatic disease processes of NASH in order to drive meaningful clinical benefits for patients. The mechanisms of action targeted by our current drug candidates are the same mechanisms of action targeted by other drug candidates that have achieved clinical proof-of-concept in NASH clinical trials and have demonstrated significant improvements on histological and non-invasive markers of the disease, though no drug has been approved for the treatment of NASH in the United States or Europe. Our most advanced program is TERN-101, a liver-distributed, non-bile acid Farnesoid X Receptor agonist that has demonstrated sustained liver FXR activation, as well as a favorable tolerability profile across multiple Phase 1 clinical trials. In our Phase 1 clinical trials, no pruritus, or itching, or increases in LDL cholesterol levels as compared to the control group were observed—unlike in Phase 1 clinical trials of other FXR agonists conducted by third parties. Our Phase 2a clinical trial of TERN-101 in NASH patients (the LIFT Study) was fully enrolled in January 2021 and we expect top-line data in July 2021. Our second clinical stage program, TERN-201, is a highly selective inhibitor of Vascular Adhesion Protein-1. We intend to start our Phase 1b clinical trial of TERN-201 in NASH patients in the first half of 2021 and expect top-line data in the first half of 2022. Our third clinical stage program is TERN-501, a Thyroid Hormone Receptor beta agonist with high metabolic stability, enhanced liver distribution and greater selectivity for THR-β compared to other THR-β agonists in development. In January 2021, the FDA cleared our investigational new drug application, or IND, for TERN-501. In March 2021, we announced the initiation of our Phase 1 first-in-human clinical trial of TERN-501 and we expect top-line data in the second half of 2021. We are also pursuing two combination therapy programs to address the multiple disease processes of NASH and expect to initiate a Phase 2a clinical proof-of-concept trial evaluating a combination of TERN-101 and TERN-501 in the first half of 2022.

NASH is a severe form of non-alcoholic fatty liver disease, or NAFLD, that affects up to 15 million people in the United States, and up to 6% of the global population, for which there is currently no approved therapy in the United States or Europe. In a study published in *Hepatology* in 2016, direct healthcare costs associated with NAFLD and NASH in the United States in 2016 were estimated to be approximately $100 billion, in the absence of approved therapies. Severe progression of NASH can lead to cirrhosis, decompensated liver disease and increased risk for hepatic carcinoma and liver-related mortality. NASH is a multifaceted disease that involves three distinct pathogenic hepatic disease processes: steatosis, inflammation and fibrosis. Our pipeline of programs is intended to address each of these distinct pathogenic disease processes. We believe that with our pipeline targeting steatosis (TERN-101 and TERN-501), inflammation (TERN-101 and TERN-201) and fibrosis (TERN-101 and TERN-201) in tandem, our programs have the potential to provide greater resolution of NASH and improvements in related clinical outcomes. Furthermore, by developing combination therapies to treat NASH, we are aiming to expand the reach of NASH therapeutics through improved response rates, better tolerability and improved compliance as compared to monotherapy regimens.

Our NASH Pipeline Programs

Our wholly owned NASH pipeline includes multiple single-agent and combination therapy candidates that provide several opportunities to address the multifaceted nature of NASH and drive meaningful clinical benefits for patients. We intend to advance single-agent and combination therapy candidates to increase the potential for improved response rates in NASH patients, for whom there are no approved treatment options.

- **TERN-101** is a liver-distributed, non-bile acid Farnesoid X Receptor, or FXR, agonist that has demonstrated a differentiated tolerability profile and improved target engagement due to its sustained FXR activation in the liver but only transient FXR activation in the intestine. FXR is a nuclear receptor primarily expressed in the liver, intestine and kidneys. FXR regulates hepatic expression of various genes involved in lipid metabolism, inflammation and fibrosis. Clinical trials of other FXR agonists have demonstrated significant histological NASH improvements but have also resulted in pruritus and adverse lipid changes. These safety and tolerability issues have been observed in Phase 1 clinical trials for other FXR agonists and have generally been regarded as dose-limiting toxicities, which are suboptimal for patients and can lead to treatment discontinuation. However, in all four Phase 1 clinical trials of TERN-101, none of the 119 subjects who received TERN-101 reported pruritus, and the serum lipid profiles among TERN-101 recipients were similar to placebo recipients at all doses. We are currently evaluating TERN-101 in a 12-week, randomized, placebo-controlled Phase 2a clinical trial in approximately 100 NASH patients (the LIFT Study). In January 2021, we completed the enrollment of patients into the LIFT Study and top-line data is expected in July 2021. We received Fast Track designation from the U.S. Food and Drug Administration, or the FDA, for TERN-101 for the treatment of NASH in October 2019. Fast Track designation does not guarantee an accelerated review by the FDA.
- **TERN-201** is a highly-selective inhibitor of Vascular Adhesion Protein-1, or VAP-1, that has demonstrated sustained target engagement in clinical trials without the off-target liabilities associated with other VAP-1 inhibitors in development. VAP-1 facilitates the deceleration, binding, and transmigration of leukocytes from the bloodstream into the liver and produces reactive oxygen species that promote liver inflammation and fibrosis. VAP-1 has been shown to be over-expressed in the livers of NASH patients in response to local lipotoxicity and liver injury. In a Phase 2a clinical trial of another developer's VAP-1 inhibitor in NASH patients, 12 weeks of administration demonstrated significant, dose-dependent improvements in NASH biomarkers, providing clinical proof of concept for VAP-1 inhibition in NASH. In our Phase 1a first-in-human (SAD/MAD) clinical trial in 61 healthy subjects, TERN-201 was shown to fully suppress plasma VAP-1 activity at all of the doses we evaluated. TERN-201 was selected for development over other discovery candidates because it is highly specific for VAP-1 inhibition and has minimal potential for off-target effects. We intend to start our Phase 1b clinical trial of TERN-201 in NASH patients in the first half of 2021 and expect top-line data in the first half of 2022. We received Fast

Track designation from the FDA for TERN-201 for the treatment of NASH in August 2020. Fast Track designation does not guarantee an accelerated review by the FDA.

- **TERN-501** is a Thyroid Hormone Receptor beta, or THR-β, agonist with high metabolic stability, enhanced liver distribution and greater selectivity for THR-β compared to other THR-β agonists in development. 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 ability to reduce hepatic steatosis and improve serum lipid parameters including LDL cholesterol and triglycerides. *In vivo* NASH studies in a rodent model have demonstrated that low-doses of TERN-501 achieved complete resolution of steatosis and reductions in serum lipids, hepatic inflammation and fibrosis. TERN-501 has high liver distribution and is 23-fold more selective for THR-β than for THR-α activation, thereby minimizing the risk of cardiotoxicity and other off-target effects associated with non-selective THR stimulation. Finally, TERN-501 has been designed to be metabolically stable and is therefore expected to have little pharmacokinetic variability and a low clinical dose, making it an attractive candidate for use in fixed-dose combinations for NASH treatment. In January 2021, the FDA cleared our IND for TERN-501. In March 2021, we announced the initiation of our Phase 1 first-in-human clinical trial of TERN-501 and we expect top-line data in the second half of 2021.
- **GLP-1R** is our small-molecule Glucagon-Like Peptide-1 Receptor agonist program that is intended to address metabolic processes involved in the pathogenesis of NASH. Our GLP-1R program has identified several potentially suitable small-molecule scaffolds. We plan to further optimize these series of compounds and identify structures that are suitable for orally administered combination with other NASH drug candidates within our pipeline. We are currently advancing this program through lead optimization and anticipate announcing a development candidate in the second half of 2021.

Combinations:

Several prior clinical trials evaluating single-agent therapies for NASH have shown only moderate histological improvements and exhibited tolerability issues with some of these agents at high doses. We believe that developing combination therapies targeting multiple mechanistic pathways will drive improved response rates for NASH patients while mitigating potential tolerability concerns and improving compliance as compared with monotherapy regimens. We are well-positioned to develop multiple combination therapies for NASH with our extensive experience in combination drug development and the ability to leverage our pipeline of wholly owned single-agents that we believe are suitable for orally administered combination development.

We believe that therapies targeting steatosis (TERN-101 and TERN-501), inflammation (TERN-101 and TERN-201) and fibrosis (TERN-101 and TERN-201) in tandem, have the potential to provide greater resolution of NASH and improvement in related clinical outcomes. We expect to initiate a Phase 2a clinical proof-of-concept trial evaluating a combination of TERN-101 and TERN-501 in NASH patients in the first half of 2022. We are also assessing the potential utility of combinations of TERN-201 with assets inside and outside of our pipeline. Given the strength of our internal resources and capabilities, we have the flexibility to independently advance our combination therapies without the need for a co-development partner at this time.

Our History

Terns was founded in 2017 with the goal of developing innovative therapies for patients with NASH and other liver diseases. We have assembled a team of industry veterans with extensive experience in drug discovery and development, especially in liver diseases. Collectively, our team is responsible for more than 20 FDA approved products, including eleven fixed-dose-combination drugs. Our executive team has a strong track record in leading successful biotechnology companies and research and development organizations. Senthil Sundaram, our Chief Executive Officer, has over 20 years of strategy, financial and leadership experience in the life sciences industry. Dr. Erin Quirk, our President and Chief Medical Officer, brings more than 15 years of experience in the pharmaceutical industry, and has personally contributed to the development of 14 approved drug products to date, including initial marketing applications for five novel fixed-dose combinations. Dr. Weidong Zhong, our founder and Chief Scientific Officer, is an accomplished industry veteran who brings 25 years of experience in drug discovery and development and has developed over 20 small-molecule and biologic drug candidates.

Our Strategy

Our goal is to develop and commercialize differentiated monotherapies and combination therapies for patients with NASH and other chronic liver diseases. Key elements of our strategy to achieve this goal include:

- **Develop improved drug candidates targeting clinically-validated mechanisms of action.** We are developing a portfolio of small molecule drug candidates targeting clinically-validated mechanisms of action for the treatment of NASH. The mechanisms of action targeted by our current drug candidates are the same mechanisms of action targeted by other drug candidates that have achieved clinical proof-of-concept in NASH clinical trials and have demonstrated significant improvements on histological and non-invasive markers of the disease, though no drug has been approved for the treatment of NASH in the United States or Europe. However, these clinical trials have also highlighted an opportunity for us to meaningfully improve the efficacy, safety and tolerability of therapies utilizing these mechanisms. Based on this premise, we are advancing multiple drug candidates we believe have the potential to deliver better clinical outcomes in a high proportion of NASH patients as either single-agent or combination therapies.
- **Leverage non-invasive biomarkers to rapidly advance our single-agent drug candidates through clinical proof-of-concept.** We are advancing our single-agent drug candidates through clinical proof-of-concept trials on an expedited basis by using relevant non-invasive biomarkers in our Phase 1 and Phase 2 clinical trials to efficiently confirm and benchmark target engagement or efficacy without the need for liver biopsies. We believe this approach enables us to accelerate enrollment in our clinical trials and achieve significantly shorter development timelines.
- **Advance our portfolio of combination therapy candidates for the treatment of NASH.** In addition to developing our single-agent drug candidates, we are evaluating and developing fixed-dose combination therapies to address the multiple disease processes of NASH. We believe developing combination therapies targeting multiple mechanistic pathways will drive improved response rates for NASH patients while mitigating potential tolerability concerns and improving compliance as compared with monotherapy regimens. The outcomes of our monotherapy biomarker-based clinical trials will further inform our decision to pursue the utility of our drug candidates as monotherapies or in fixed-dose-combinations that we believe have synergistic therapeutic effect and well-balanced safety profiles. We have identified and are advancing our first combination therapy candidate for NASH, involving a combination of TERN-101 and TERN-501, and expect to initiate a Phase 2a clinical proof-of-concept trial in the first half of 2022. We are also evaluating the potential to co-administer TERN-201, a potent anti-inflammatory and anti-fibrotic agent, in combination with a metabolically active NASH treatment.
- **Advance our earlier stage program and expand applications for our existing drug candidates.** We have identified a series of GLP-1R small molecule agonists with the potential to address metabolic processes involved in the pathogenesis of NASH. Our GLP-1R program is designed to enable oral administration, a limitation of existing GLP-1 agonists, for widespread use in NASH patients. We are currently advancing this program through lead optimization and anticipate announcing a development candidate in the second half of 2021. Beyond NASH, our goal is to maximize the commercial potential of our existing drug candidates by exploring additional indications supported by their underlying biology and mechanism. For example, we believe our NASH drug candidates may also have utility in other chronic liver diseases such as autoimmune hepatitis, primary biliary cholangitis and primary sclerosing cholangitis. We will maintain a focused and disciplined strategy in evaluating potential follow-on indications that may merit further advancement.
- **Independently develop and commercialize our drug candidates in indications and geographies where we believe we can maximize the value and benefit to patients.** We have a disciplined strategy to maximize the value of our pipeline by retaining development and commercialization rights to those drug candidates, indications and geographies that we believe we can ultimately commercialize successfully on our own if they are approved. We plan to collaborate on drug candidates that we believe have promising utility in disease areas, patient populations or geographies that are better served by the resources or specific expertise of other biopharmaceutical companies.

Background on NASH

NASH is a severe form of NAFLD, a common liver disease characterized by the accumulation of excess fat in the liver (steatosis). When hepatic steatosis results in liver inflammation and, in many cases, fibrosis, it results in NASH, a multifaceted disease that involves three distinct pathogenic hepatic disease processes: steatosis, inflammation and fibrosis. Severe progression of NASH leads to cirrhosis and decompensated liver disease, with the associated risks for hepatocellular carcinoma and liver-related death. NASH was recently identified as the second leading etiologic indication for liver transplantation in the United States, and it is projected to become the leading cause of liver transplantation in the coming years.

NAFLD is the most common cause of chronic liver disease in the United States, affecting 80 to 100 million individuals. Among persons with NAFLD, approximately 20% will progress to NASH, which is currently estimated to affect 15 million adults in the United States. Progression of liver fibrosis ultimately leads to cirrhosis in an estimated 20% of patients with NASH. With an aging population and the markedly increasing rates of obesity, diabetes, and dyslipidemia/metabolic syndrome worldwide, NAFLD and NASH have increased greatly in prevalence, posing a significant healthcare challenge. In a study published in *Hepatology* in 2016, direct healthcare costs associated with NAFLD and NASH in the United States in 2016 were estimated to be approximately $100 billion, in the absence of approved therapies.

Etiology of NASH

NAFLD and NASH are classified as progressive metabolic diseases, often correlated with chronic excess caloric intake, obesity and metabolic syndrome. Physiologically, hepatocytes in the liver can act as a repository for excess energy stored by the body. As humans consume disproportionate amounts of calories relative to those burned on a consistent basis, the body becomes overweight, and organs, including the liver, become burdened by fatty tissue. With the liver acting as the hub for excess energy and energy conversion, an imbalance develops with more delivery of fats and triglycerides to the liver, an increase in hepatic fatty acid synthesis, and impaired hepatic fatty acid oxidation and removal of liver fat, resulting in NAFLD.

Within the steatotic liver, fat deposits can create lipotoxic effects to the surrounding liver tissue, resulting in hepatocyte stress and injury and activating inflammatory Kupffer cells. Local increases in reactive oxygenation species can induce hepatocytes to undergo cell death and create an inflammatory response within the organ. VAP-1 is over expressed in affected areas of the liver, serving as an attachment point for inflammatory leukocytes and triggering their recruitment from the bloodstream into the liver. These leukocytes are stimulated by local lipotoxic effects and the presence of reactive oxygenation species to produce cytokines, further exacerbating local inflammatory cascades and activating resident Kupffer cells, thereby exacerbating local inflammation.

Inflammatory cascades in the liver activate hepatic stellate cells to excrete extracellular matrix resulting in liver fibrosis. Over time, fibrosis progresses, increasingly replacing diseased and normal liver tissue with scar tissue. Eventually, most of the liver is replaced by fibrotic tissue, which histologically is categorized as cirrhosis. While some cirrhotic patients have enough functional liver tissue to maintain hepatic activity, over time, the liver fails, resulting in decompensated liver disease and the need for liver transplantation to avoid liver related death. Furthermore, cirrhosis is a key risk factor for hepatocellular carcinoma.

NASH is currently diagnosed by histological findings on liver biopsy. In clinical trials, recommended scoring systems assess (i) liver fibrosis and (ii) steatosis and inflammation using the NAFLD Activity Score, or NAS, a composite score that grades the degree of three non-fibrotic histologic features of NASH: steatosis, hepatocyte ballooning, and lobular inflammation. Efficacious responses to treatment in NASH clinical trials are usually considered to be either an improvement in fibrosis score without worsening of the NAS, or an improvement of the NAS without worsening of fibrosis.

Increasingly, non-invasive blood and imaging tests are being used in clinical practice to diagnose NASH. Vibration controlled transient elastography combined with blood tests (serum chemistries, hematological parameters and other biomarkers) have shown good accuracy in diagnosing both steatosis and the degree of liver inflammation. As data from these non-invasive assessments continue to accumulate—for initial diagnosis of NASH, monitoring of disease progression over time, and monitoring response to treatment—these approaches may replace liver biopsy, both in clinical practice and clinical trials. In its December 2018 draft NASH guidance, the FDA encouraged sponsors to include non-invasive biomarkers in clinical studies of experimental NASH treatments in order to accelerate development and supplant liver biopsy.

Treatment of NASH

There currently are no FDA-approved therapies for the treatment of NASH, and available treatment options are limited to control of metabolic dysfunction, including weight loss, as well as lifestyle modifications such as exercise and dietary changes. However, many patients are unable to achieve or maintain significant weight loss or comply long-term with the dietary and lifestyle changes required to reverse NASH. In order to optimally treat NASH and reduce the risk of liver cancer and liver-related mortality, the three distinct disease processes may each need to be addressed–steatosis, inflammation and fibrosis. Single agents focusing on specific mechanisms contributing to one of these three processes, each involving multiple pathways, have demonstrated only modest results to date.

The following table summarizes some of the treatment approaches for NASH currently in clinical development, together with limitations observed and Terns' differentiated approach. Among the small-molecule programs with validated mechanisms, we believe FXR agonism, VAP-1 inhibition and THR-β agonism have great potential, not only as targets for single-agent therapy, but also as key components in combination therapies.

Treatment Approaches in NASH	Clinical Trial Findings(1)	Observed Limitations(1)	TERNS Differentiation
FXR agonists	Improvements in liver fibrosis and markers of liver function.	Pruritus and adverse lipid effects	TERN-101: high liver distribution, minimizing potential for pruritus and adverse lipid changes
VAP-1 inhibitors	Clinical PoC in NASH with significant dose dependent improvements in key markers of liver injury, inflammation and cell death	Off-target mono-amine oxidase, or MAO, inhibition can result in significant drug-drug interactions	TERN-201: highly specific for VAP-1 inhibition; minimal potential to inhibit MAO-A or MAO-B
THR-β agonists	Significant reductions in liver fat and in lipid levels in serum	Low THR-β selectivity can cause cardiac and other safety issues Variable PK and patient-specific dose adjustments	TERN-501: superior selectivity for THR-β over THR-α; enhanced metabolic stability
GLP-1 agonists	Activation of the GLP-1 pathway has shown to be effective in driving NASH resolution	Requires frequent injections which may limit potential for widespread use Tolerability concerns	Potential for once-daily oral administration and coformulation with other oral NASH therapies
FGF agonists	Histological NASH and fibrosis improvements in Phase 2	Requires frequent injections which may limit potential for widespread use Tolerability concerns	N/A
De Novo Lipogenesis Inhibitors (ACC, FASN, DGAT2)	NASH biomarker improvement in Phase 2	Serum triglyceride elevations Skin/hair toxicity	N/A

(1) Represents clinical trial findings from clinical trials conducted by other sponsors.

Our Programs

We are developing a portfolio of small molecules that address the multiple hepatic disease processes of NASH in order to drive meaningful clinical benefits. Our most advanced program, TERN-101, is a liver-distributed, non-bile acid FXR agonist that has demonstrated sustained liver FXR activation, as well as a favorable tolerability profile across multiple Phase 1 clinical trials. Our Phase 2a clinical trial of TERN-101 in NASH was fully enrolled in January 2021 and we expect top-line data in July 2021. Our second clinical stage program, TERN-201, is a highly selective inhibitor of VAP-1, which directly addresses hepatic inflammation. We intend to start our Phase 1b clinical trial of TERN-201 in NASH patients in the first half of 2021 and expect top-line data in the first half of 2022. Our third clinical stage program is TERN-501, a THR-β agonist with high metabolic stability, enhanced liver distribution and greater selectivity for THR-β compared to other THR-β agonists in development. In January 2021, the FDA cleared our IND for TERN-501 and we announced the initiation of our Phase 1 first-in-human clinical trial of TERN-501 in March 2021. We expect top-line data from this clinical trial in the second half of 2021. We are also pursuing two

combination therapy programs to address the multiple disease processes of NASH and expect to initiate a Phase 2a clinical proof-of-concept trial evaluating a combination of TERN-101 and TERN-501 in the first half of 2022. We believe developing combination therapies targeting multiple mechanistic pathways will drive improved response rates across the population of NASH patients while mitigating potential tolerability concerns associated with other drugs in development.

TERN-101—a liver-distributed FXR agonist

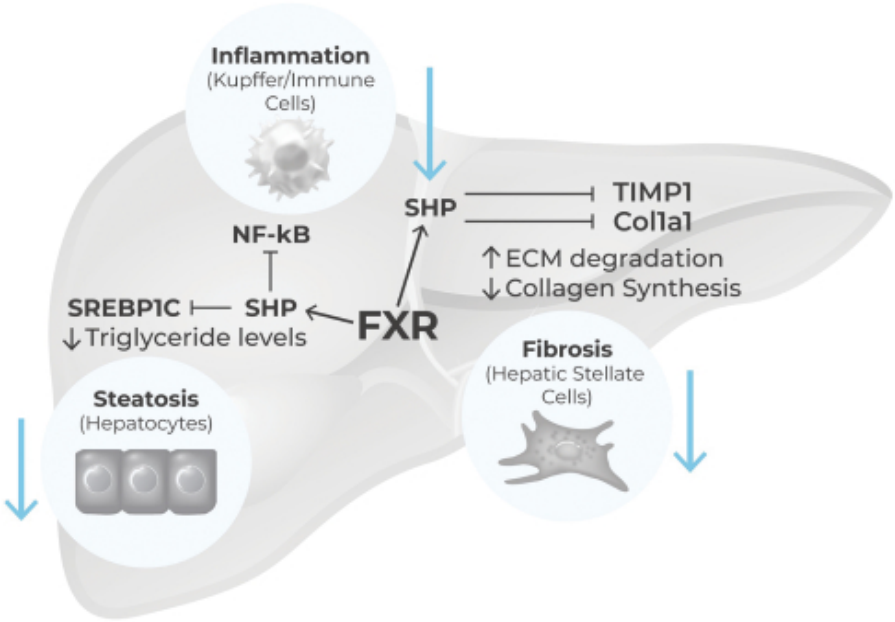
Drug candidate summary

TERN-101 is a liver-distributed, non-bile acid FXR agonist that has demonstrated a differentiated tolerability profile and improved target engagement; likely due to its sustained FXR activation in the liver but only transient FXR activation in the intestine. FXR is a nuclear receptor primarily expressed in the liver, intestine and kidneys. FXR regulates hepatic expression of various genes involved in lipid metabolism, inflammation and fibrosis. Clinical studies of other FXR agonists have demonstrated significant histological NASH improvements but have also resulted in pruritus and adverse lipid changes. These tolerability issues have generally been observed in Phase 1 clinical trials of other FXR agonists in development and have been regarded as dose-limiting toxicities, which are suboptimal for patients and can lead to treatment discontinuation. However, in all four Phase 1 clinical trials of TERN-101, none of the 119 subjects who received TERN-101 reported pruritus, and the serum lipid profiles among TERN-101 recipients were similar to placebo recipients even at high doses. We are currently evaluating TERN-101 in a Phase 2a, 12-week, randomized, placebo-controlled clinical trial in approximately 100 NASH patients (the LIFT Study), which was fully enrolled in January 2021, and we expect top-line data in July 2021. Our investigational new drug application, or IND, for TERN-101 went into effect in May 2019. We received Fast Track designation from the FDA for TERN-101 for the treatment of NASH in October 2019. Fast Track designation does not guarantee an accelerated review by the FDA.

FXR agonists may address NASH in different liver cell types

FXR is a nuclear receptor primarily expressed in the liver, intestine and kidneys. FXR regulates hepatic expression of various genes involved in lipid metabolism, inflammation and fibrosis. In the hepatocyte, FXR activation induces small heterodimer partner, or SHP, a key metabolic regulator. The upregulation of SHP by FXR reduces the expression of sterol-regulatory element-binding protein 1C, or SREBP1C, a master regulator of triglyceride synthesis. FXR-mediated inhibition of SREBP1C and subsequent reduction in triglyceride levels could result in reduced hepatic steatosis. FXR also plays a role in modulating hepatic inflammation. Activation of FXR in the hepatocyte represses nuclear factor-kB, or NF-kB, via induction of SHP, thereby reducing hepatic inflammation. FXR activation is also directly associated with reduction in hepatic inflammation in Kupffer cells. In hepatic stellate cells, FXR activation reduces fibrogenic markers such collagen type 1 alpha 1, or Col1a1, and tissue inhibitor of metalloproteinase 1, or TIMP1. Inhibition of Col1a1 and TIMP1 reduces collagen synthesis and increases the degradation of the extracellular matrix, or ECM, thereby reducing liver fibrosis.

A liver-distributed FXR agonist has the potential to address NASH by acting on the three key disease processes and cell types



Clinical validation of FXR agonists

FXR agonism has been investigated in large-scale clinical trials and has shown clinically relevant improvements in NASH. In these clinical trials, FXR agonists have shown significant histological NASH improvements in fibrosis, as well as improvement in markers of liver function.

Limitations of other FXR agonists: pruritus and adverse lipid changes

Clinical trials of other FXR agonists have demonstrated significant histological NASH improvements but have also resulted in pruritus and adverse lipid changes. These tolerability issues have been observed in early Phase 1 clinical trials for other FXR agonists as shown in the table below and have been regarded as dose-limiting toxicities, which are suboptimal for patients and can lead to treatment discontinuation. However, in all four Phase 1 clinical trials of TERN-101, none of the 119 subjects who received TERN-101 reported pruritus, and the serum lipid profiles among TERN-101 recipients were similar to placebo recipients even at high doses. An FXR agonist that can demonstrate improved liver health with minimal adverse effects would have great potential benefits for NASH patients.

FXR agonists: comparison of Phase 1 clinical trial results

			Observations in Phase 1 clinical trials[1]	
Drug candidate	**Developer**	**Dosing duration**	**Pruritus**	**Lipid profile change**
TERN-101	Terns Pharma	14d	None	None
MET409	Metacrine	14d	Yes	Yes
EDP-305	Enanta	14d	Yes	Yes
EYP001	Enyo	15d	Yes	Not disclosed
Obeticholic acid	Intercept	14d	Yes	Yes

(1) Includes findings from trials conducted by other sponsors. Denotes changes as compared to control group.

We believe the liabilities from the other FXR agonists may be due to their activation of FXR outside the liver, particularly in the intestine. FXR activation in intestinal enterocytes results in the secretion of Fibroblast Growth Factor 19, or FGF19, which has been associated with increased serum low-density lipoprotein, or LDL, cholesterol in published studies. Pruritus has been observed in clinical studies of other FXR agonists known to activate intestinal FXR. On the other hand, the use of bile acid sequestrants (such as cholestyramine or colesevelam) or ileal bile acid transporter, or IBAT, inhibitors has been demonstrated in several clinical studies to reduce plasma LDL, cholesterol in patients with hyperlipidemia and also to mitigate pruritus in patients with cholestatic liver disease, potentially through prevention of FXR activation. Therefore, we believe that an FXR agonist with sustained activity in the liver, but only minimal or transient intestinal or other extrahepatic FXR activity, would likely not be associated with pruritus or adverse lipid changes.

Our solution: TERN-101, a liver-distributed FXR agonist

We believe TERN-101 has been well-tolerated in completed clinical trials to date because of its high liver distribution, thereby minimizing activation of intestinal pathways that may be associated with pruritus and adverse lipid changes. The figure on the left below demonstrates in a preclinical model that administration of TERN-101 results in significantly higher distribution to the liver compared to other FXR agonists. The figure on the right below demonstrates that administration of TERN-101 is also associated with much higher activation of liver-related FXR gene expression, in contrast to intestinally-directed FXR agonists that have greater FXR gene activation in the intestine than in the liver. Studies have demonstrated that there is minimal overlap between liver and intestine FXR binding sites, indicating potentially a high degree of tissue-specific FXR function.

TERN-101 preferentially distributes to liver and induces liver-specific genes

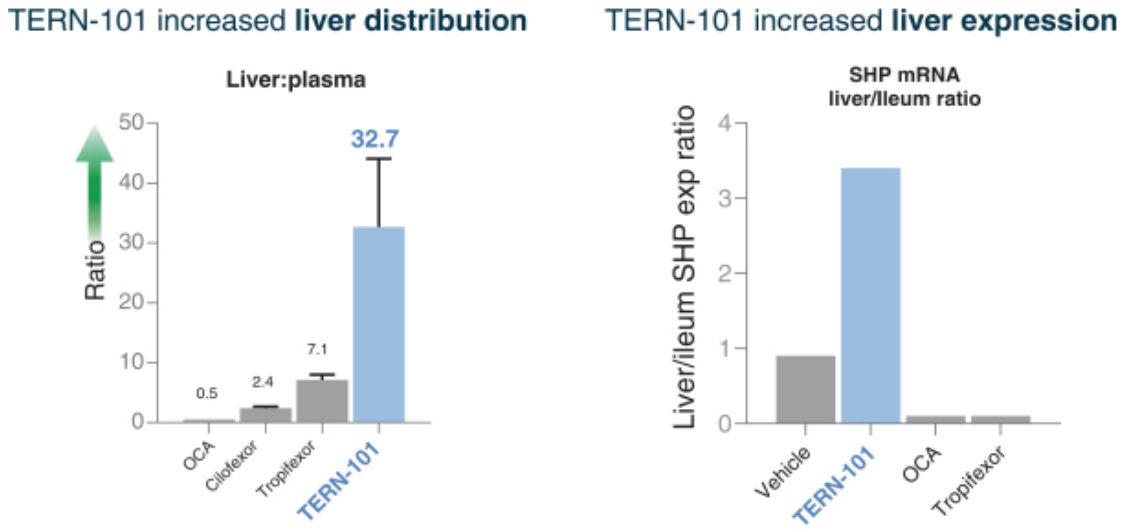


***Figure**: The information from the figure above (left) represents preclinical data derived from a rat model conducted by Terns (2 mg/kg of TERN-101, cilofexor or tropifexor); and data disclosed in regulatory filings for the 30 mg/kg of OCA. The information from the figure above (right) represents preclinical data derived from a mouse study model of SHP gene expression conducted by Terns after 7 days of dosing with TERN-101 (10 mg/kg), OCA (30 mg/kg) and tropifexor (0.3 mg/kg). SHP functions to inhibit bile acid synthesis.*

TERN-101 administration demonstrates sustained FXR activation in the liver

The liver-distributed profile of TERN-101 has been demonstrated in a Phase 1 clinical trial of the pharmacodynamics of TERN-101 in 36 human subjects. Sustained liver FXR activation in human subjects was demonstrated by dose-dependent decreases in 7 alpha-hydroxy-4-cholesten-3-one, or C4, concentrations that are among the most potent demonstrated with an FXR agonist to date. A decrease in C4 is a surrogate marker for FXR activation in the liver. In contrast to sustained liver FXR activation, repeated administration of TERN-101 over seven days resulted in only a transient increase of FGF19, suggesting transient intestinal FXR activation while the drug is being absorbed. Data from other FXR agonists in development demonstrate a much more sustained increase in FGF19 that persists through repeat administrations, which may indicate that sustained intestinal FXR activation is associated with their underlying tolerability issues.

TERN-101 induces sustained suppression of C4 but only transient increases of FGF19

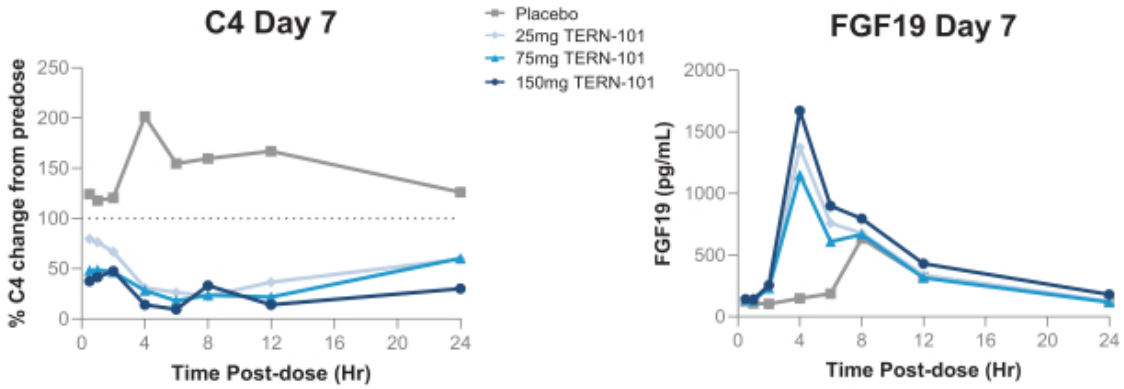


Figure: *Change in C4 relative to baseline (Day 1) on Day 7. FGF19 figure represents the mean FGF19 plasma concentration on Day 7.*

TERN-101 administration is not associated with liabilities of other FXR agonists

Across four completed Phase 1 clinical trials in 136 subjects, TERN-101 was administered to 119 subjects and was generally well-tolerated with no confirmed dose-related tolerability signals. Adverse events, or AEs, tended to be mild to moderate, with no dose-related increases in AEs. There was no pruritus among the 119 subjects treated with TERN-101, and lipid profiles in the TERN-101 dose groups were similar to placebo across each trial, including single administrations of TERN-101 at dose level of 600mg and repeated administrations at dose levels of 400mg for 14 days. The chart below plots serum LDL cholesterol concentrations from a Phase 1 pharmacodynamic clinical trial in 36 subjects and demonstrates that the lipid profiles are similar for subjects receiving TERN-101 or placebo. In one Phase 1 clinical trial, one subject receiving placebo and two subjects receiving 400 mg TERN-101 experienced elevations in alanine aminotransferase, or ALT, and aspartate transaminase, or AST, up to approximately five times the upper limit of normal. One of the TERN-101 recipients experienced transient transaminase elevations that decreased upon continued dosing through the duration of the trial, while the other TERN-101 recipient discontinued treatment. Transaminase elevations did not exceed 5.2x the upper limit of normal in any subject who received TERN-101, and none of these subjects had concomitant elevations in bilirubin. Transaminases for each of these subjects decreased to baseline at the end of the clinical trial. No transaminase elevations >1.5x upper limit of normal were observed in other TERN-101 clinical trials, including the single ascending dose trial (including doses of 600 mg) and a subsequent repeat dose trial (25 mg, 75 mg and 150 mg doses). Therefore, across the four completed Phase 1 clinical trials for TERN-101 it was concluded that the changes from baseline in ALT and AST were similar between TERN-101 and placebo recipients and the transaminase elevations that occurred in one Phase 1 clinical trial were not clinically relevant. ALT and AST elevations did not recur in subsequent trials.

TERN-101 shows comparable LDL changes to placebo in 7-day Pharmacokinetics/Pharmacodynamics Phase 1 trial

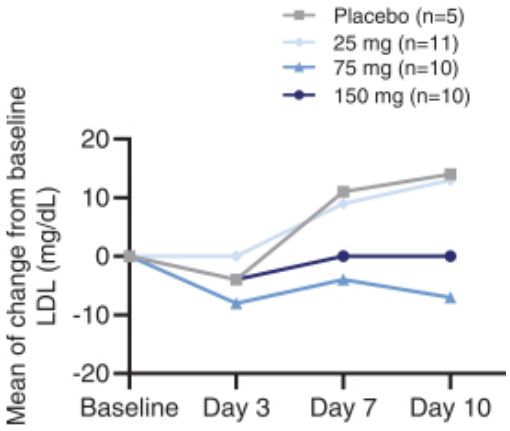


Figure*: Changes from baseline (Day -1) in mean LDL.*

We believe the favorable Phase 1 tolerability profile stems from the fact that TERN-101 is liver-distributed, with limited systemic and intestinal FXR activation that may be associated with the pruritus and adverse lipid changes seen with other FXR agonists. The solid line in the chart below shows the average plasma level on Day 7 of TERN-101 in human subjects administered 150 mg TERN-101 capsules. The dotted line represents projected TERN-101 liver concentration, which was calculated based on the TERN-101 rat tissue distribution study results. Plasma concentrations at this dose generally do not exceed the TERN-101 EC_{50} throughout the 24 hour dosing period, thereby avoiding the effects of FXR activation outside of the liver, which we believe explains the lower incidence of off-target effects typically associated with other FXR agonists in development. However, liver concentrations of TERN-101 are projected to be much higher than the TERN-101 EC_{50} throughout the dosing period, which we believe accounts for the potent C4 decreases observed with TERN-101. Together, these data suggest TERN-101 activity will mainly occur in the liver.

TERN-101 is projected to achieve sustained liver activation

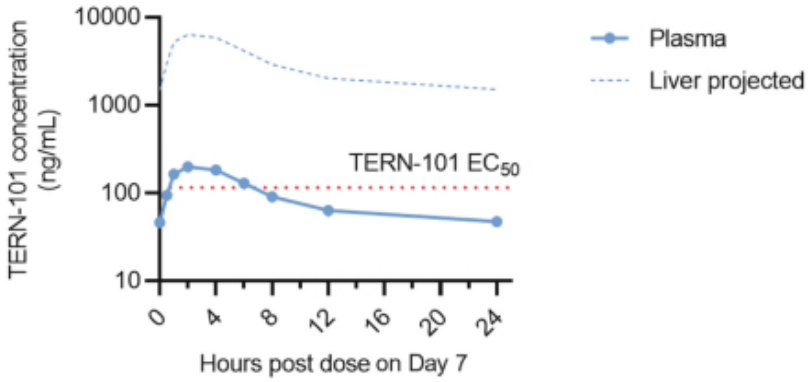
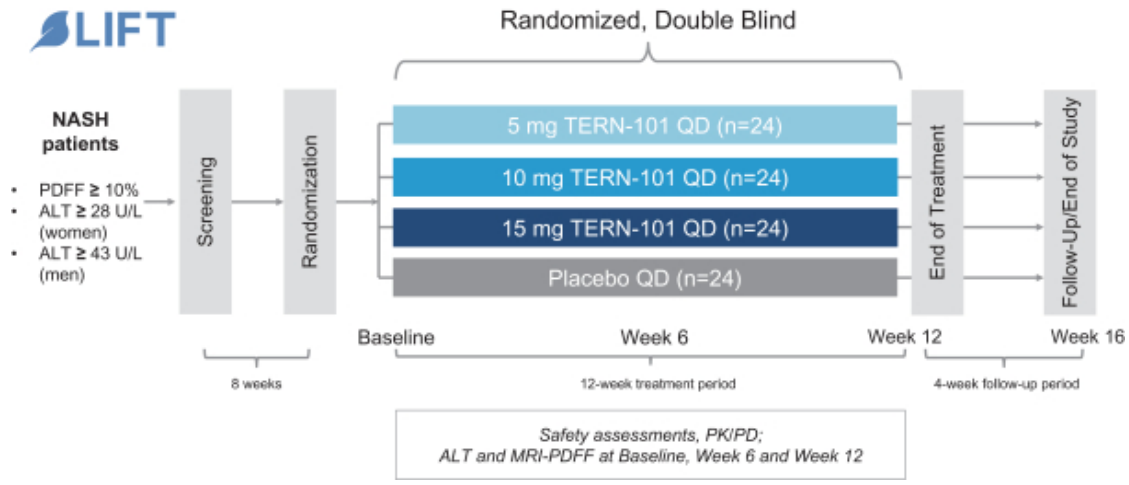


Figure*: TERN-101 150 mg capsule formulation mean plasma concentration and projected liver concentration over time on Day 7.*

Ongoing Phase 2a Clinical Trial of TERN-101 (LIFT Study) in NASH patients for 12 weeks

TERN-101 is currently being evaluated in the LIFT Study, a Phase 2a, 12-week, randomized, placebo-controlled clinical trial in approximately 100 patients with phenotypic or biopsy-diagnosed NASH, identified either by prior biopsy or clinical diagnosis (liver stiffness measured by transient elastography of 7.6—25 kPa and controlled attenuation parameter (CAP) > 300). In January 2021, we completed the enrollment of patients into the LIFT Study and top-line data are expected in July 2021. Clinical trial participants receive once-daily oral administration of placebo or TERN-101 tablet doses of 5 mg, 10 mg or 15 mg for 12 weeks. TERN-101 plasma concentrations resulting from these tablet doses are expected to fall within a comparable range as the plasma concentrations observed in Phase 1 studies of capsule formulation doses of 25 mg to 150 mg. The primary endpoint is the incidence of adverse events. Key secondary and exploratory outcome measures are percent change from baseline in ALT, change from baseline in hepatic fat fraction assessed by magnetic resonance imaging derived proton density fat fraction, or MRI-PDFF, as well as other biomarkers that have been associated with histologic improvements in NASH patients.

TERN-101 Phase 2a LIFT trial design



TERN-201 – a highly selective VAP-1 inhibitor

Drug candidate summary

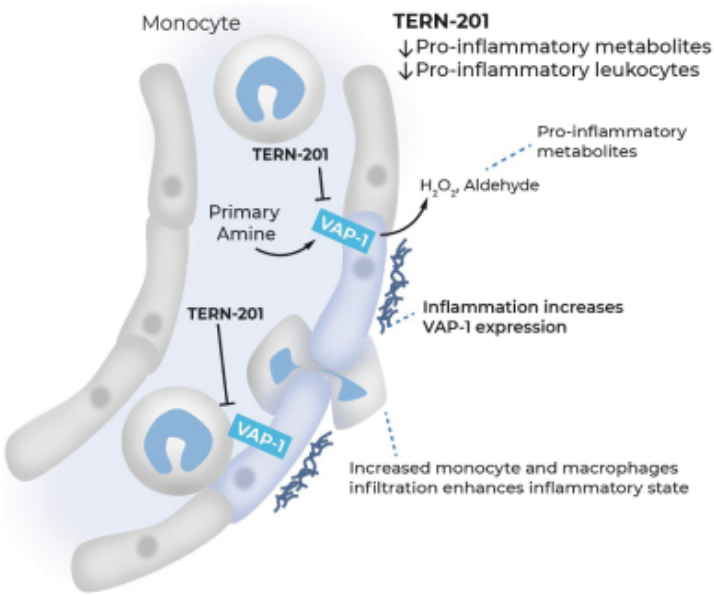
TERN-201 is a highly selective, irreversible, covalent inhibitor of VAP-1. In our Phase 1a first-in-human (SAD/MAD) clinical trial across 61 healthy subjects, TERN-201 was shown to fully suppress plasma VAP-1 activity at all of the doses that we evaluated and VAP-1 suppression was evident up to days after a single dose. In preclinical studies, TERN-201 reduced fibrosis in a model of liver injury in a dose-dependent manner, with inflammation and fibrosis significantly reduced after treatment. TERN-201 exhibits high selectivity for VAP-1 and enhanced liver distribution. Importantly, TERN-201 does not inhibit human MAO-A and MAO-B, thereby avoiding risks associated with MAO inhibition. We believe the sustained activity of TERN-201, with its VAP-1 selectivity and anticipated low therapeutic dose, make it suitable for coadministration with therapies directed at steatosis and other metabolic processes involved in NASH. We are currently preparing to initiate a Phase 1b clinical trial of TERN-201 in NASH patients in the first half of 2021 and expect top-line data in the first half of 2022. Our IND for TERN-201 went into effect in January 2019. We received Fast Track designation from the FDA for TERN-201 for the treatment of NASH in August 2020. Fast Track designation does not guarantee an accelerated review by the FDA.

Overview of VAP-1 biology in NASH

As liver damage accumulates in NAFLD and NASH patients, VAP-1 becomes increasingly expressed on the endothelium of blood vessels within the liver. Through its function as a leukocyte adhesion molecule, VAP-1 facilitates the deceleration, binding and transmigration of leukocytes from the blood stream into the liver, and recruits co-functioning proteins to aid in the transmigration process. These leukocytes respond to local liver tissue damage and multiple stimuli, reproducing and releasing cytokines which cause progressive liver inflammation. In addition,

VAP-1 acts as an enzyme to break down short-chain primary amines in the blood and produce reactive oxygen species, or ROS, aldehyde, ammonia and hydrogen peroxide in the liver, which in turn cause inflammation, hepatic oxidative stress and tissue damage. Together, the cytokine cascades resulting from white blood cell liver penetration and local ROS-mediated oxidative stress and tissue damage stimulate fibrosis, the synthesis of ECM by activating hepatic stellate cells. The following graphic illustrates this process.

VAP-1 increases oxidative stress, recruits white blood cells to the liver, increases inflammation and fibrosis



Clinical validation of VAP-1 inhibition in NASH

VAP-1 inhibition has the potential to address the inflammatory process in NASH patients. Preclinical data have demonstrated that VAP-1 inhibition improves liver histology and serum biomarkers. VAP-1 has been shown to be over-expressed in the livers of NASH patients in response to local lipotoxicity and liver injury. Increased levels of soluble VAP-1 in the plasma is also associated with the presence of NASH, and with increasing liver fibrosis. In a Phase 2a clinical trial, administration of a different VAP-1 inhibitor over 12 weeks in NASH patients demonstrated significant, dose dependent decreases from baseline in ALT, AST, GGT and CK-18, markers of liver injury and inflammation and cell death compared to placebo. Improvements in these markers provide clinical proof-of-concept for VAP-1 inhibition as a treatment approach in NASH.

Limitations of other VAP-1 inhibitors in development

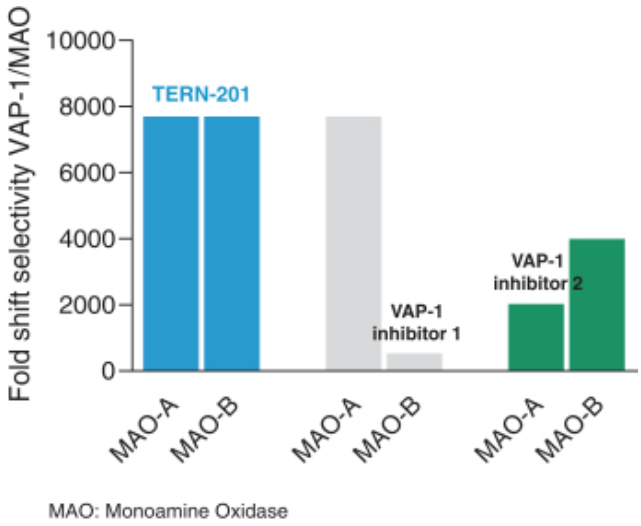
A clinical trial of another VAP-1 inhibitor in NASH patients demonstrated improvements in markers of liver injury, inflammation and cell death, including significant reductions in ALT. However, other VAP-1 inhibitors currently in development for NASH are associated MAO inhibition due to their lack of specificity for binding VAP-1. Drugs that inhibit MAO create the risk of life-threatening serotonin syndrome and hypertensive crisis when administered with commonly prescribed serotonergic drugs and with tyramine-containing foods. Therefore, we believe a VAP-1 inhibitor with improved selectivity for VAP-1 inhibition that lacks the potential to inhibit MAO-A or MAO-B could provide meaningful clinical benefit to NASH patients in reducing inflammation and liver fibrosis without risks related to MAO inhibition.

Our solution for VAP-1 inhibition: TERN-201

TERN-201 was selected over other discovery candidates because it is highly specific for VAP-1 inhibition and has minimal potential to inhibit MAO-A or MAO-B at clinically relevant concentrations. Preclinical studies showed that TERN-201 was greater than 7000-fold more selective for VAP-1 than for MAO-A or MAO-B. In clinical studies, TERN-201 has shown strong VAP-1 inhibition at all doses studied, and plasma TERN-201 concentrations, or Cmax, after 7 days of dosing were more than 300 times lower than the IC50 concentrations for MAO-A and MAO–B inhibition at the highest dose level studied. The graph below illustrates the selectivity of TERN-201 for VAP-1 inhibition over MAO inhibition shown in preclinical studies.

TERN-201 shows no apparent MAO inhibition

Fold selectivity for VAP-1 over
MAO-A or MAO-B



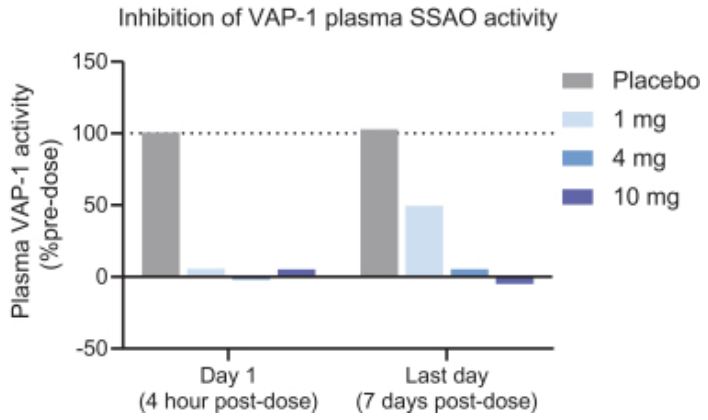
MAO: Monoamine Oxidase

Clinical development of TERN-201

We have completed a first-in-human, double-blind, randomized, placebo-controlled, Phase 1 clinical trial (SAD/MAD) of TERN-201 which assessed the safety, pharmacokinetics, or PK, and pharmacodynamics, or PD, in 61 healthy subjects. Single oral TERN-201 doses of 1, 3, 6 or 10 mg and repeat doses of 1 mg and 4 mg (once-daily for 7 days) and 10 mg (once-daily for 14 days) were administered. In the trial, TERN-201 target engagement was assessed by measuring decreases from baseline in the semi-carbazide sensitive amine oxidase, or SSAO, activity which results from VAP-1 enzymatic activity, and by changes from baseline in methylamine, a biomarker that increases in concentration in the blood as its metabolism by VAP-1 is inhibited.

TERN-201 demonstrated robust and sustained VAP-1 target engagement. Near complete inhibition of VAP-1 plasma SSAO activity was observed at four hours post-dose on Day One in all single and multiple dose groups. There was evidence of dose dependent sustained decreases in VAP-1 plasma SSAO activity for one week after completion of single and repeat dosing due to covalent binding of TERN-201 to VAP-1 and the rate of regeneration of VAP-1 over several days after completion of TERN-201 dosing. Near complete suppression of VAP-1 plasma SSAO activity persisted to 7 days after completion of a single TERN-201 dose of 10 mg and repeat doses of 4 mg and 10 mg. Changes from baseline in methylamine were also dose dependent, with the greatest increases from baseline observed in the TERN-201 10 mg dose group in both single and multiple dose cohorts.

TERN-201 demonstrates near complete inhibition of VAP-1 plasma SSAO activity in single ascending dose Phase 1 trial



In the Phase 1 SAD/MAD clinical trial, TERN-201 administered for up to 14 days was generally well-tolerated with no tolerability signals based on AEs, safety laboratory testing and electrocardiogram monitoring. Clinical and preclinical studies indicate that TERN-201 is not extensively metabolized and is unlikely to inhibit or induce major drug metabolism pathways or MAOs; therefore, it has a low potential for drug-drug interactions. This profile as well as its pharmaceutical properties and anticipated low therapeutic dose make it a very attractive candidate for co-formulation with other drugs as part of a single-tablet, fixed-dose combination treatment for NASH.

Preclinical data for TERN-201

In preclinical studies, TERN-201 demonstrated dose-dependent beneficial effects on liver histology and serum biomarkers comparable to other VAP-1 inhibitors in development. TERN-201 exhibited dose-dependent inhibition of rat hepatic stellate cells activation and reduction of fibrosis, inflammation, and ballooning in an *in vivo* rodent model of liver inflammation and fibrosis. TERN-201 also reduced inflammation and markers of fibrosis, leukocyte infiltration, and hepatic stellate cell activation in an *in vivo* NASH rodent model. Histological improvements were noted in inflammation and fibrosis scores as shown in the figure below. The animals in the TERN-201 dosing groups had a reduced inflammation score of 1.1, while placebo animals on average had an inflammation score of 2.3. This significant histological response correlates with the anti-inflammatory activity of TERN-201. Fibrosis scores were also reduced with an average score of 2.1 and 2.3 for the low and high TERN-201 dosing groups, respectively, compared to an average score of 2.9 in the placebo group.

TERN-201 reduces liver inflammation and fibrosis in an *in vivo* rodent model of NASH

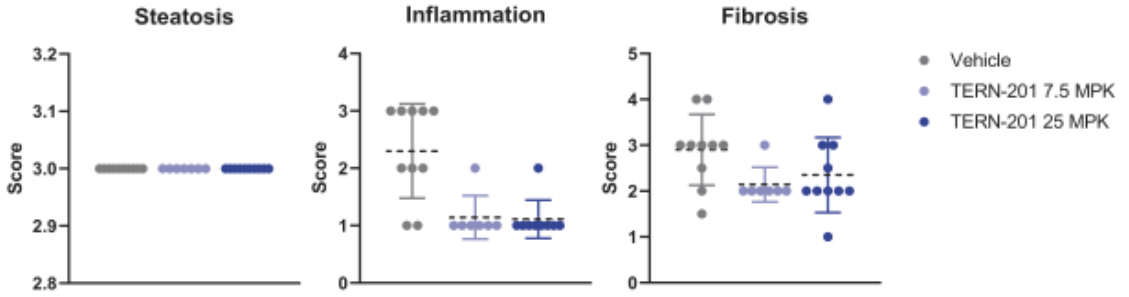


Figure: *Efficacy of TERN-201 in a rat model of NASH. Liver steatosis, inflammation and fibrosis assessed by histological scoring in treated groups (n=10). TERN-201 treatment groups had an ~1 point reduction in inflammation and fibrosis scores relative to the placebo group. Data for individual animals (dots) and mean (dashed line) are presented.*

Planned TERN-201 Phase 1b clinical trial

We intend to initiate a 12-week Phase 1b clinical trial of TERN-201 in patients with NASH in the first half of 2021 that will assess the tolerability of different doses of TERN-201 and the potential improvements in NASH biomarkers. We expect to enroll approximately 60 patients in this trial. The primary endpoint of this trial will be to assess the safety of TERN-201. We expect top-line data from this clinical trial to be available in the first half of 2022. Following this clinical trial, we will consider subsequent trials of TERN-201 as monotherapy or potentially in combination with a metabolically active NASH treatment.

TERN-501 – a selective THR-β agonist with enhanced metabolic stability and liver distribution

Drug candidate summary

TERN-501 is a selective THR-β agonist with enhanced metabolic stability and liver distribution, characteristics that are intended to improve safety and efficacy in NASH patients. 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. THR-β stimulation has been identified as a target for NASH on the basis of its potential to reduce hepatic steatosis and improve serum lipid parameters in NASH 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 has high metabolic stability and a low projected clinical dose, which we believe makes it an attractive candidate for fixed-dose combination co-formulations. In January 2021, the FDA cleared our IND for TERN-501 and we announced the initiation of our Phase 1 first-in-human clinical trial in March 2021. We expect top-line data from this clinical trial in the second half of 2021.

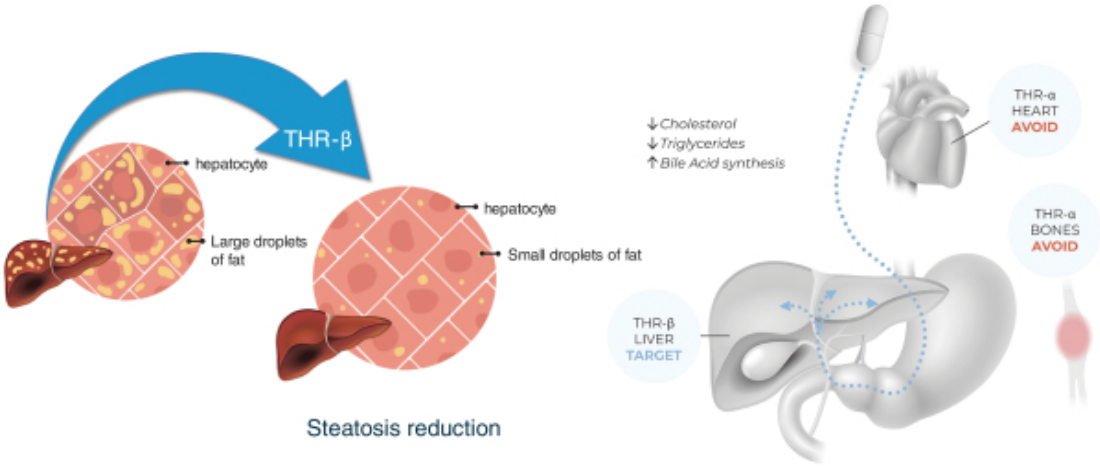
THR-β agonists for NASH

Thyroid hormone plays a central role in regulating metabolism, through its actions in multiple tissues, including fat, skeletal muscle, pancreas, and liver. THR-α and THR-β are nuclear receptors widely expressed in the body, but the two different isoforms are differentially expressed in different tissue types. 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. THR-α is the major form of thyroid hormone receptor in cardiac muscle, skeletal muscle and bone. Selective agonism of THR -β in the liver has been identified as a target for NASH and validated in clinical trials on the basis of its potential to improve hepatic steatosis and lipid profiles in NASH patients.

Clinical validation of THR-β agonism

Data from other NASH clinical studies validate the potential of THR-β agonism as a NASH treatment (the data from other NASH clinical studies described in this paragraph are from Madrigal Pharmaceuticals, Inc.'s Phase 2 Study of MGL-3196 and Viking Therapeutics, Inc.'s Phase 2 Study of VK2809). In these clinical studies, two different THR-β agonists showed significant reductions in liver fat measured by MRI-PDFF, as well as reduction in lipid levels in serum, which may offer additional benefits to NASH patients who are at high risk of cardiovascular comorbidities. One of these clinical trials correlated reductions in liver fat measured by MRI-PDFF with histological responses including NAS reduction, NASH resolution and fibrosis resolution. These types of histological responses may be suitable for accelerated approval under current draft guidance from the FDA titled "Noncirrhotic Nonalcoholic Steatohepatitis With Liver Fibrosis: Developing Drugs for Treatment Guidance for Industry."

Selectivity towards THR-β over THR-α is key to modulating the metabolic activities in the liver without triggering the unwanted effects of thyroid hormone outside of the liver



Limitations of THR-β targeting

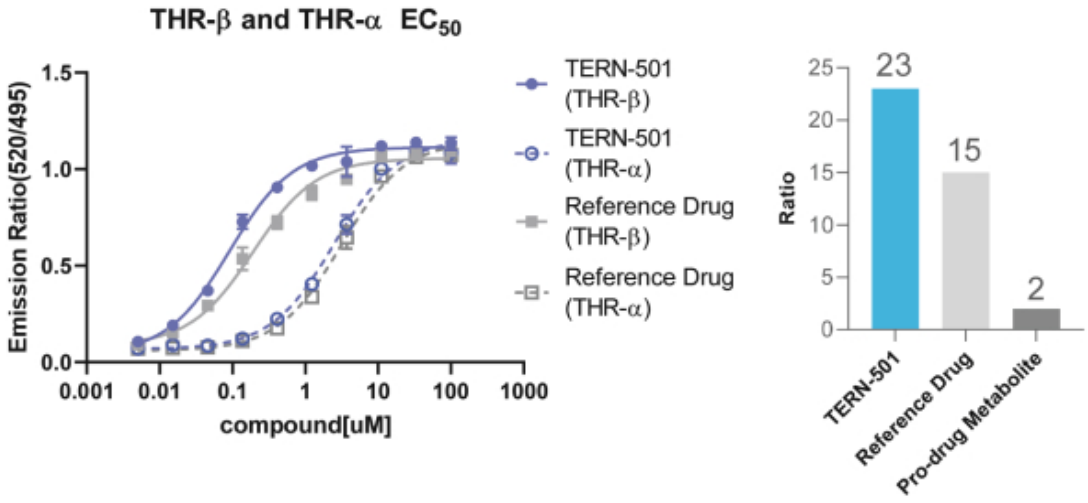
For THR agonists, a key safety concern is the potential for adverse effects from off-target thyroid hormone receptor stimulation that may stem from either lack of selectivity for THR-β or high variations in pharmacokinetics due to the lack of metabolic stability. Selectivity for THR-β over THR-α is key to modulating the metabolic activities in the liver without triggering the unwanted effects of THR-α activation outside of the liver. Stimulation of THR-α can adversely affect the cardiovascular and musculoskeletal system through increases in heart rate, cardiac arrhythmias, muscle wasting, and reduced bone mineral density. Therefore, the identification of a selective THR-β agonist particularly with enhanced liver distribution, would have the potential to improve hepatic steatosis and serum lipid profiles while potentially avoiding adverse effects of THR-α activation. However, the use of a liver-targeted pro-drug approach to overcome THR selectivity has not completely avoided cardiac adverse events in clinical trials.

In addition to THR-β selectivity, metabolic stability and predictable pharmacokinetics are important considerations in the development of thyroid hormone activators. In a Phase 2 clinical trial of another selective THR-β agonist, lack of metabolic stability resulted in significant inter-patient variability in drug exposure that required PK monitoring and dose adjustments. Dose adjustments in widespread clinical practice present potential challenges in terms of patient compliance, safety monitoring and additional burden on the healthcare system. Additionally, highly variable pharmacokinetics and unpredictable drug concentrations would hinder the potential for combination treatment in NASH patients.

Our solution for THR-β agonism: high THR-β-selectivity and improved metabolic stability

TERN-501 was selected over other discovery candidates because of its high selectivity for THR-β over THR-α, its improved metabolic stability and its enhanced liver-distribution, all of which are characteristics that are intended to improve efficacy and safety in NASH patients. TERN-501 has a similar structural backbone to other THR-β agonists in late stage development that are selective for THR-β. Furthermore, the TERN-501 chemical structure incorporates certain changes designed to enhance metabolic and pharmacokinetic stability, thereby limiting the need for individualized dose adjustments implemented in studies with other THR-β agonists. In a head-to-head comparison, TERN-501 has shown a 23-fold selectivity for THR-β over THR-α stimulation in a cell-free assay, which is higher than the selectivity for two other THR agonists currently in development. TERN-501 is not a pro-drug and does not rely on the metabolic process to make it pharmacologically active. The following chart illustrates the selectivity of TERN-501 as compared to a reference drug and the active metabolite of a pro-drug in clinical development for NASH.

TERN-501 demonstrates higher selectivity for THR-β over THR-α



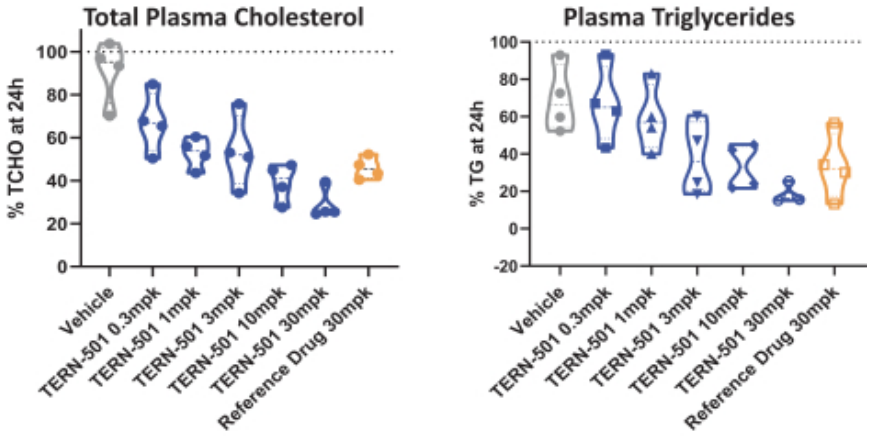
Non-clinical tissue distribution studies show that TERN-501 demonstrates enhanced liver distribution relative to plasma and other organs. From non-clinical studies, TERN-501 is projected to have a predictable human PK profile due to its improved metabolic stability. Due to its metabolic stability, we believe that TERN-501 is unlikely to require PK monitoring and individualized clinical dose adjustment in NASH patients, as was done with another THR-β agonist in development that lacks metabolic stability and has variable PK in humans, thereby avoiding potential challenges associated with monitoring and dose adjustment in clinical practice, including patient compliance, safety monitoring and additional burden on the healthcare system. Further, TERN-501 is projected to have a low clinically efficacious dose range which, along with its metabolic stability, makes it attractive for long-term NASH treatment and for co-formulation as part of a fixed-dose combination.

Preclinical data for TERN-501

In preclinical studies, TERN-501 showed potent activity in animal models of metabolic disease. TERN-501 produced rapid and significant reductions in serum lipids in an *in vivo* rat model; serum total cholesterol and triglycerides were significantly reduced up to 71% and 82%, respectively, 24 hours after a single intraperitoneal injection of TERN-501. In an *in vivo* mouse NASH model, histological analysis showed that TERN-501 resolved liver steatosis to healthy control levels at all doses and led to a dose-dependent reduction in liver triglycerides and fibrosis. TERN-501 treatment of these mice also led to significant reductions in serum cholesterol, triglycerides and ALT.

The graph below compares reductions in plasma cholesterol and plasma triglycerides in an *in vivo* rat model following a single intraperitoneal administration of various doses of TERN-501 as compared to a reference compound in late-stage clinical development.

TERN-501 demonstrates dose-dependent reductions in serum total cholesterol and triglycerides in an *in vivo* rodent model of hypercholesterolemia



The graphs below demonstrate the histological improvement in an *in vivo* mouse model of NASH following repeat administrations of various doses of TERN-501.

TERN-501 improves steatosis, inflammation and fibrosis in an *in vivo* mouse model of NASH

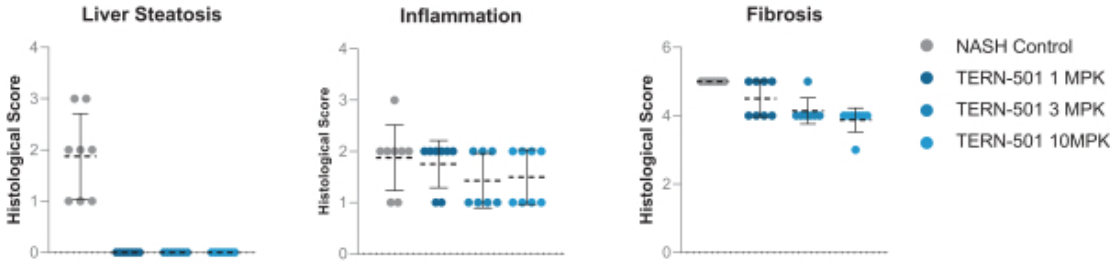


Figure: *Efficacy of TERN-501 in a mouse model of NASH. Liver steatosis, inflammation and fibrosis assessed by histological scoring in treated groups (n=8). Data for individual animals (dots) and mean (dashed line) are presented.*

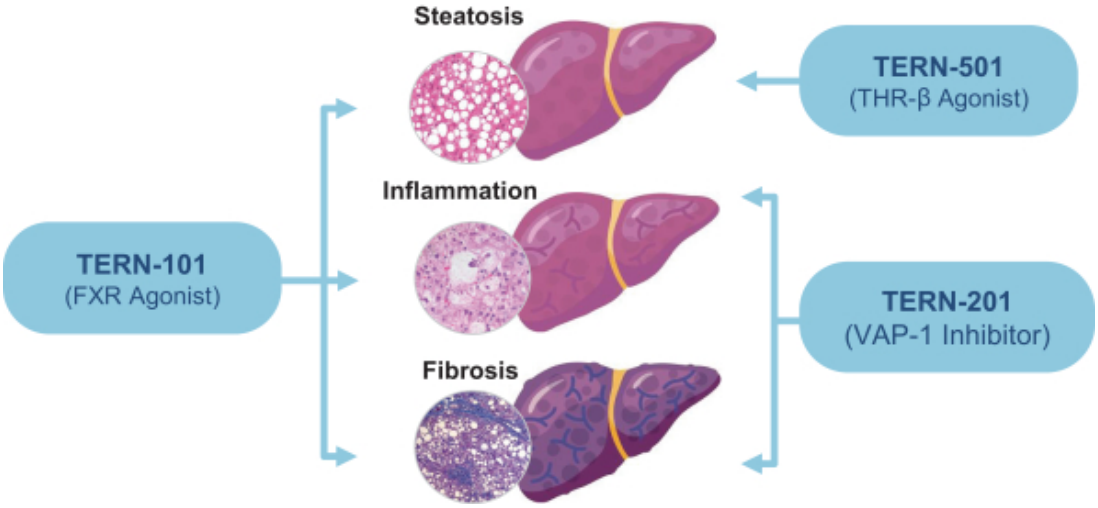
Phase 1 first-in-human clinical trial for TERN-501

In March 2021, we announced the initiation of our Phase 1 first-in-human clinical trial of TERN-501. As a Phase 1 first-in-human clinical trial, the primary purpose of this trial is to address the safety of TERN-501. We expect to enroll approximately 90 participants in this trial. As with our other clinical programs, this Phase 1 clinical trial is planned to include single ascending dose and multiple ascending dose cohorts in which we intend to assess TERN-501 safety, tolerability and PK, as well as the reduction in serum lipid levels which could serve as an early marker of target engagement. As part of this Phase 1 clinical trial, we also intend to assess drug-drug interactions, including the co-administration of our liver-distributed FXR agonist (TERN-101) and our metabolically stable THR-beta agonist (TERN-501), two mechanisms that have shown additive or synergistic improvements on histological endpoints and serum lipid parameters in our preclinical NASH studies. We expect top-line data from our Phase 1 clinical trial in the second half of 2021. Following this Phase 1 clinical trial, we plan to conduct a Phase 2a clinical trial in NASH patients assessing TERN-501 administered as monotherapy and potentially co-administered with TERN-101.

Combination Therapy Programs

Several prior clinical trials evaluating single-agent therapies for NASH have shown only moderate histological improvements and exhibited tolerability issues with some of these agents at high doses. We believe developing combination therapies targeting multiple mechanistic pathways will drive improved response rates for NASH patients while mitigating potential tolerability concerns and improving compliance as compared with monotherapy regimens. We are well-positioned to develop multiple combination therapies for NASH with our extensive experience in combination drug development and the ability to leverage from within our pipeline of wholly owned single-agents that we believe are attractive candidates for combination development. We are focused on developing combination therapies with clinically validated mechanisms of action to address the multifaceted nature of NASH. Given the strength of our internal resources and capabilities, we have the flexibility to independently advance our combination therapies without the need for a co-development partner at this time. We believe that therapies targeting steatosis (TERN-101 and TERN-501), inflammation (TERN-101 and TERN-201) and fibrosis (TERN-101 and TERN-201) in tandem, have the potential to provide greater resolution of NASH and improvement in related clinical outcomes.

Our combination approach: complementary mechanisms for the treatment of NASH



Preclinical data for combination therapies

We believe that a combination of TERN-101 and TERN-501 has the potential for improved therapeutic benefit for NASH patients. As a liver-distributed FXR agonist, TERN-101 is expected to have effects on multiple facets of NASH, including potential improvements in steatosis, inflammation and fibrosis. TERN-501 is a THR-β agonist that is expected to potently and rapidly reduce hepatic steatosis and normalize plasma lipid parameters through the modulation of metabolic pathways that are distinct from those modulated by liver FXR activation. A combination of TERN-101 and TERN-501 would therefore be expected to significantly reduce steatosis, inflammation and fibrosis in NASH patients through their complementary effects without the need to use maximal dose levels of either agent. The combination may also result in a positive serum lipid profile since TERN-501 is expected to reduce LDL cholesterol and triglyceride levels in NASH patients in whom FXR agonists have generally not demonstrated potentially therapeutic decreases in plasma cholesterol or triglycerides.

As seen in the charts below, the combination of the FXR agonist TERN-101 and the THR-β agonist TERN-501 showed robust efficacy in an *in vivo* mouse model of NASH by profoundly reducing steatosis and significantly improving fibrosis, serum triglycerides, serum total cholesterol and ALT. The combination treatment of TERN-101 and TERN-501 also resulted in the expression of more than 800 additional distinct genes as compared to either agent alone, supporting our hypothesis that additional biological processes are activated by combination treatment. Together these results suggest that the combination of the FXR agonist TERN-101 and the THR-β agonist TERN-501 may provide additional benefits for NASH patients than either treatment alone.

Combination of TERN-101 + TERN-501 demonstrates improvements in liver histology and serum biomarkers in an *in vivo* NASH mouse model

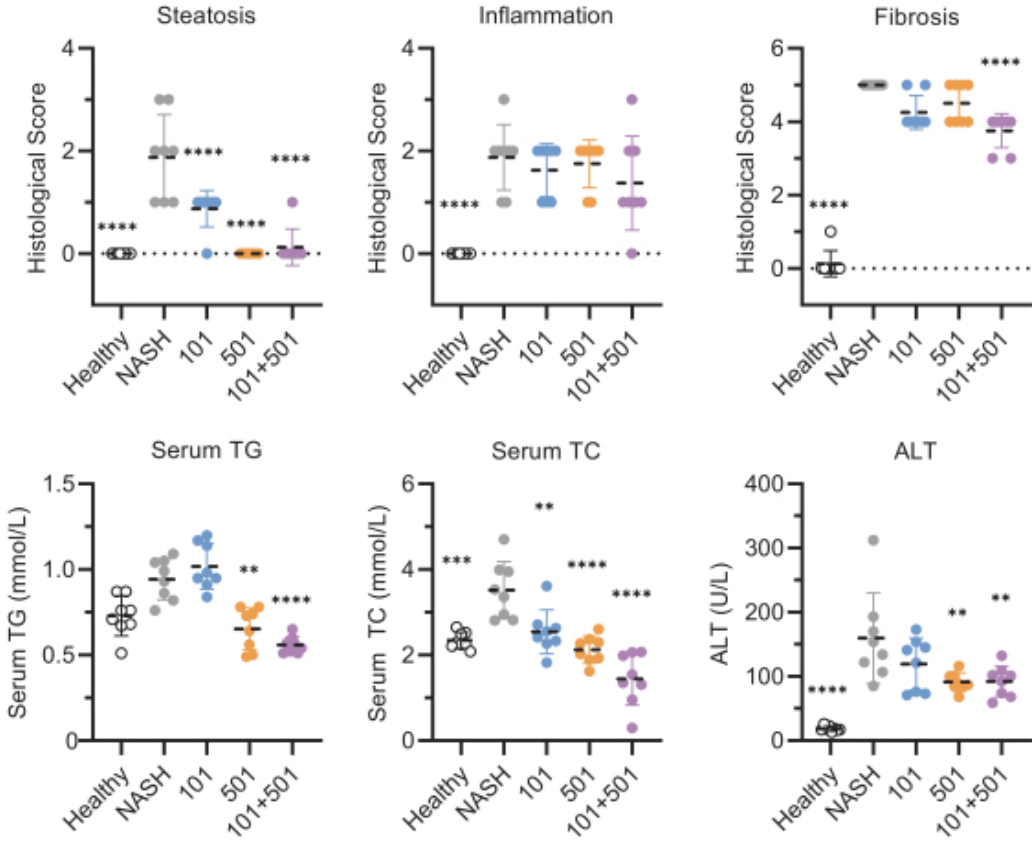


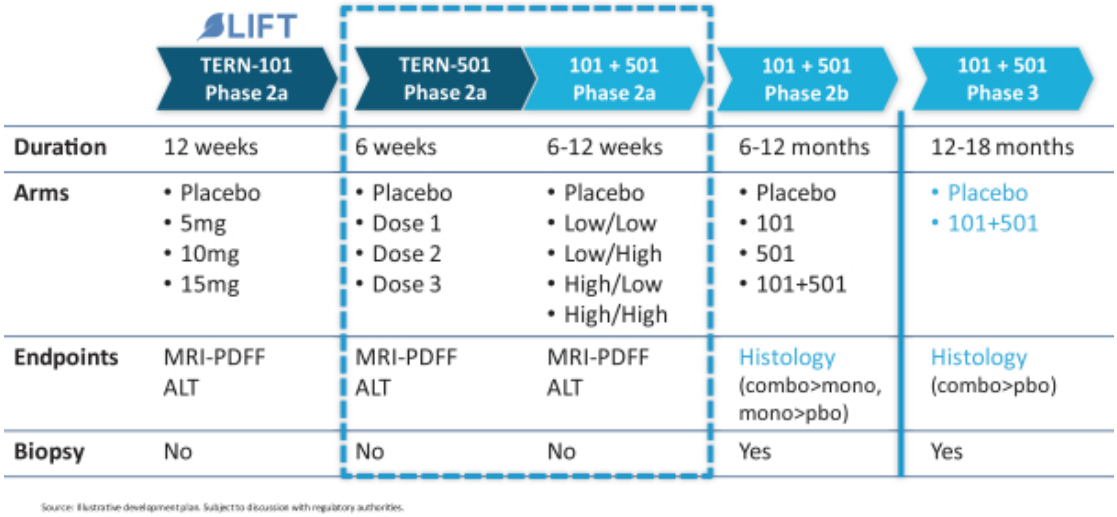
Figure: *Data from a NASH mouse model. TERN-101 dose 3 mg/kg; TERN-501 dose 1 mg/kg. Liver steatosis (upper left), inflammation (upper middle) and fibrosis (upper right) were quantified by histological analysis for degree of steatosis, lobular inflammation, and fibrosis. Serum was collected at termination and analyzed for triglycerides, or TG (lower left), total cholesterol, or TC, (lower middle) and a biomarker of liver damage, alanine aminotransferase, or ALT (lower right). Data for individual animals (dots) and mean (dashed line) are presented; **p <0.01, ***p <0.001, ****p <0.*

We are also evaluating the potential to combine our VAP-1 inhibitor, TERN-201, with a metabolically active NASH treatment. We believe the anti-inflammatory and anti-fibrotic effects, sustained target engagement, VAP-1 selectivity and anticipated low therapeutic dose of TERN-201 make it suitable for co-administration with therapies directed at steatosis and other metabolic processes involved in NASH. For example, the combination of our FXR agonist TERN-101 and TERN-201 demonstrated histological improvements in inflammation and GGT, an inflammation biomarker, in an *in vivo* rodent model of NASH.

Clinical development plan for NASH combination of TERN-101 and TERN-501

Our approach for developing a differentiated NASH combination regimen is to discover and develop promising drug candidates targeting clinically validated mechanisms of action, advance them first as monotherapies to evaluate safety and pharmacokinetics in healthy volunteers and subsequently conduct Phase 1b or 2a trials to assess safety in NASH patients and potentially efficacious dose ranges using known non-invasive biomarkers of efficacy for these mechanisms of action. Subsequently, we intend to proceed to Phase 2a studies with the coadministration of two or

more complimentary mechanisms of action—such as the FXR agonist TERN-101 and the THR-β agonist TERN-501—to assess the potential for combinations to generate additive or synergistic effects on these same non-invasive biomarkers relative to monotherapy and inform dose selection for later phase studies of the agents in combination. We then plan to proceed to longer duration Phase 2b and Phase 3 trials that can evaluate our individual monotherapies as well as promising combinations within the same trials to confirm treatment effects using liver biopsy and histological markers of efficacy. We believe this approach maximizes the chance of achieving higher NASH response rates compared to treatment approaches that rely exclusively on single-agent therapeutics and creates efficiencies through the evaluation of our individual monotherapies and combination treatments, allowing us to proceed to marketing authorization applications for those single-agent drug candidates and combination therapies that offer the clearest advantages to patients. The following graphic illustrates our potential combination development plan.



Preclinical Pipeline

Our small-molecule glucagon-like peptide-1 receptor, or GLP-1R, agonist program is intended to address metabolic processes involved in the pathogenesis of NAFLD and NASH. The natural endogenous ligand, glucagon-like peptide-1, or GLP-1, promotes insulin secretion from pancreatic β-cells in a glucose-dependent-manner following food ingestion. Activation of the GLP-1 pathway has shown to be effective in driving NASH resolution in studies of available GLP-1 agonists currently approved for the treatment of diabetes. However, these approved agents are synthetic peptides and potentially require higher doses more frequent subcutaneous injections for the potential treatment of NASH. This injectable route of administration is likely to limit their use in NASH patients, particularly if efficacious oral NASH treatments become available. Although an oral GLP-1 peptide formulation is available for the treatment of Type 2 diabetes, it requires high doses, is associated with adverse effects and lacks NASH efficacy data. A non-peptidic small-molecule oral GLP-1 receptor agonist may offer advantages over currently available peptide GLP-1R agonists that have been studied for the treatment of NASH.

Our GLP-1R program has identified several potentially suitable small-molecule scaffolds. We plan to further optimize these series of compounds and identify structures that have the potential for once daily oral administration and a profile suitable for combination with other NASH drugs within our pipeline. We aim to nominate a final candidate for further development in the second half of 2021.

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 for manufacturing 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

Given our stage of development, we have not yet established a commercial organization. We intend to establish a targeted commercial infrastructure in key geographies at the appropriate time prior to regulatory approval of our single-agent drugs and fixed-dose combination 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. Given the high incidence of NASH, it is likely that the number of companies seeking to develop products and therapies for the treatment of liver and cardio-metabolic diseases, including NASH, will increase. Most of our competitors are focused on single-agent product candidates; there are fewer competitors, of which we are aware, who are developing combination therapies for the treatment of NASH.

We are aware of both pharmaceutical and biotechnology companies with development programs in NASH. Large pharmaceutical companies participating in the development of NASH treatments include, but are not limited to, AbbVie, Inc., Amgen Inc., AstraZeneca PLC/MedImmune LLC, Bayer AG, Boehringer Ingelheim, Bristol-Myers Squibb Company, Eisai, Inc., Eli Lilly and Company, Gilead Sciences, Inc., GlaxoSmithKline plc, Johnson & Johnson, Merck & Co., Inc., Novartis Pharmaceuticals Corp., Novo Nordisk A/S, Pfizer Inc., Roche Holding AG, Sanofi, Sumitomo Dainippon Pharma Co., Ltd. and Takeda Pharmaceutical Co., Ltd.

In relation to TERN-101, companies who are currently conducting clinical trials with FXR in the context of NASH include AbbVie, Inc., Enanta Pharmaceuticals, Inc., ENYO Pharma SA, Gilead Sciences, Inc., Intercept Pharmaceuticals, Inc., Metacrine, Inc. and Novartis Pharmaceuticals Corp.

TERN-201, our VAP-1 inhibitor, is a relatively novel mechanism for the treatment of NASH, and thus has little competition we are aware of. The companies who are currently developing a SSAO/VAP-1 inhibitor with NASH as a lead indication are LG Chem Ltd. and Novo Nordisk A/S.

With regards to TERN-501, companies who are currently conducting clinical trials targeting THR-β in the context of NASH include Ascletis Pharma Inc., Madrigal Pharmaceuticals, Inc. and Viking Therapeutics, Inc.

Furthermore, pharmaceutical and biotechnology companies who are developing clinical-stage drugs to treat NASH, using mechanisms not mentioned above, include 89Bio, Inc., Akero Therapeutics, Inc., Arrowhead Pharmaceuticals, Inc., Axcella Health, Inc., Carmot Therapeutics, Inc., Cirius Therapeutics, Inc., CohBar, Inc., Coherus Biosciences Inc., Corcept Therapeutics, Inc., CymaBay Therapeutics, Inc., Esperion Therapeutics, Inc., Galectin Therapeutics Inc., Galmed Pharmaceuticals Ltd., Hanmi Pharmaceutical Co., Ltd., Inventiva Pharma SA,

Ionis Pharmaceuticals, Inc., MediciNova, Inc., NGM Biopharmaceuticals, Inc., NorthSea Therapeutics, Inc., Pliant Therapeutics, Inc., Poxel SA, Sagimet Biosciences, Inc., T3D Therapeutics, Inc. and Zydus Cadila Healthcare.

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, 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 drug and combination therapy 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 March 15, 2021, our owned and exclusively licensed patent portfolio includes:

- For TERN-101, our FXR agonist, we own five patent families and exclusively license from Eli Lilly and Company, or Eli Lilly, two patent families, which collectively are directed to composition-of-matter coverage of TERN-101, its formulations, and its methods of use (including combination therapy) in the treatment of certain liver, metabolic and other diseases and conditions. The composition-of-matter patent family includes one issued U.S. patent and over 35 granted foreign patents. The issued U.S. patent in the composition-of-matter patent family is projected to expire, inclusive of patent term adjustment, in 2029, not including any patent term extensions that may be available. Corresponding foreign patents are generally projected to expire in 2028, not including any patent term extensions that may be available. For more information regarding this exclusive license agreement with Eli Lilly, please see "—Licensing and Other Intellectual Property-Related Agreements."
- For TERN-201, our VAP-1 inhibitor, we own two patent families and exclusively license from Eli Lilly two patent families, which collectively are directed to composition-of-matter coverage of TERN-201 and its methods of use (including combination therapy) in the treatment of certain liver, metabolic and other diseases and conditions. The composition-of-matter patent family includes three issued U.S. patents and 25 pending patent applications in foreign jurisdictions, including Australia, Brazil, Canada, China, the EPO, India, Japan and Korea. The patents in this patent family and any patents issuing from patent applications therein are projected to expire in 2036, not including any patent term extensions that may be available. For more information regarding this exclusive license agreement with Eli Lilly, please see "—Licensing and Other Intellectual Property-Related Agreements."
- We do not currently own or have a license to any issued patent with claims directed to TERN-501, our THR-β agonist. However, we own two patent families with applications collectively directed to

composition-of-matter coverage of TERN-501 and its methods of use (including combination therapy) in the treatment of various diseases, including certain liver, metabolic and other diseases and conditions. The composition-of-matter patent family is being pursued in the United States and in certain foreign jurisdictions, including under the Patent Cooperation Treaty. Any patents that may issue from applications in the composition-of-matter patent family are generally projected to expire in 2039, not including any patent term adjustments and any patent term extensions that may be available.

- For TRN-000632, our small-molecule allosteric inhibitor of the BCR-ABL fusion gene, we own one patent family directed to composition-of-matter coverage of TRN-000632 and its methods of use in the treatment of leukemia and other diseases and conditions. The patent family includes one issued U.S. patent and is being pursued in the U.S. and in certain foreign jurisdictions, including under the Patent Cooperation Treaty. 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 (Shanghai) Healthtech Co., Ltd. and Jiangsu Hansoh Pharmaceutical Group Company Ltd., or collectively, Hansoh. For more information regarding this exclusive option and license agreement with Hansoh, please see "—Licensing and Other Intellectual Property-Related Agreements."

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, 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.

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-101 License Agreement with Eli Lilly

In February 2018, we entered into an exclusive license agreement with Eli Lilly, or the TERN-101 License Agreement, pursuant to which we have been granted an exclusive, worldwide, sublicensable (subject to certain conditions), royalty-bearing license under certain intellectual property rights, including patents applications filed in both the United States and foreign jurisdictions claiming the composition of the compound Eli Lilly has designated as LY2562175 and methods of using the same and certain know-how related to the manufacture of LY2562175 owned or controlled by Eli Lilly to develop, manufacture and commercialize therapeutic products containing LY2562175, or TERN-101 Products, for all uses and indications in humans. Eli Lilly also has the right, on a country-by-country and TERN-101 Product-by-TERN-101 Product basis, to negotiate an agreement governing the co-promotion of TERN-101 Products if we, or our sublicensees, decide to commercialize a TERN-101 Product in the People’s Republic of China, Hong Kong, Macau or Taiwan.

Pursuant to the terms of the TERN-101 License Agreement, we must use commercially reasonable efforts to develop, manufacture, apply for regulatory approval of and commercialize TERN-101 Products in the People’s Republic of China. In addition, Eli Lilly provided us, at its expense, certain support in connection with the transfer of the licensed materials.

As consideration for the exclusive license, we are required to pay Eli Lilly up to an aggregate of $56 million upon the achievement of pre-specified clinical, regulatory and commercial milestone events for TERN-101 Products; no such milestones have been achieved to date under the TERN-101 License Agreement.

We are also required to pay tiered royalties calculated on a calendar year basis, ranging from mid-single digit to mid teen percentages, on net sales of TERN-101 Products. The royalty rate is subject to customary reductions, including reductions based on certain generic competition to a TERN-101 Product or amounts paid to any third party under a necessary license to such third party’s patent rights in order to develop, manufacture, commercialize or use a TERN-101 Product. The royalty term will terminate on a country-by-country, TERN-101 Product-by-TERN-101 Product basis on the later of (i) the expiration date of the last valid claim within the licensed patent rights infringed by the sale of such TERN-101 Product in such country, (ii) the loss of regulatory exclusivity for such TERN-101 Product in such country, and (iii) the tenth anniversary of the first commercial sale of such TERN-101 Product in such country.

Any intellectual property or inventions developed solely by either party in connection with activities conducted pursuant to the TERN-101 License Agreement shall be owned solely by that party, and any jointly-developed intellectual property or inventions shall be jointly owned (although no joint development activities are anticipated). We have the first right to prosecute, maintain, defend and enforce certain patents licensed under the TERN-101 License Agreement, including any patents that are solely and directly related to LY2562175 or TERN-101 Products.

The TERN-101 License Agreement shall expire upon the expiration of the last-to-expire royalty term for the TERN-101 Products on a country-by-country basis. Upon expiration of the TERN-101 License Agreement, the license granted to us shall be considered fully paid-up, irrevocable, perpetual and non-exclusive. Either we or Eli Lilly may terminate the TERN-101 License Agreement if the other party commits a material breach of the agreement or defaults in the performance thereunder and fails to cure that breach within 90 days after written notice is provided, or in the event of insolvency of the other party. We may terminate the TERN-101 License Agreement in its entirety or on a country-by-country and TERN-101 Product-by-TERN-101 Product basis upon 180 days' prior written notice. Eli Lilly may terminate the TERN-101 License Agreement if we, our affiliates or our sublicensees challenge the licensed patents or if we assist any third party in challenging such patents.

TERN-201 License Agreement with Eli Lilly

In March 2018, we entered into an exclusive license agreement with Eli Lilly, or the TERN-201 License Agreement, pursuant to which we have been granted an exclusive, worldwide, sublicensable (subject to certain conditions), royalty-bearing license under certain intellectual property rights, including patents applications filed in both the United States and foreign jurisdictions claiming the composition of the compound Eli Lilly has designated as LY3379274, and methods of using the same and certain know-how related to the manufacture of LY3379274 owned or controlled by Eli Lilly to develop, manufacture, and commercialize therapeutic products containing LY3379274, or TERN-201 Products, for all uses and indications in humans. Eli Lilly has a right of first negotiation to negotiate an agreement covering the commercialization of any TERN-201 Product before we negotiate the same with a third party. Eli Lilly also has the right, on a country-by-country and TERN-201 Product-by- TERN-201 Product basis, to negotiate an agreement governing the co-promotion of TERN-201 Products if we, or our sublicensees, decide to commercialize a TERN-201 Product in the People's Republic of China, Hong Kong, Macau or Taiwan.

Pursuant to the terms of the TERN-201 License Agreement, we must use commercially reasonable efforts to develop, manufacture, apply for regulatory approval of and commercialize TERN-201 Products in the People's Republic of China, the United States, Japan, France, Germany, Italy, Spain and the United Kingdom. In addition, Eli Lilly provided us, at its expense, certain support in connection with the transfer of the licensed materials.

As initial consideration for the license under the TERN-201 License Agreement, we paid Eli Lilly a non-refundable, upfront payment of $4 million. As additional consideration for the exclusive license, we are required to pay Eli Lilly up to an aggregate of $104 million upon the achievement of specified clinical and regulatory milestone events for TERN-201 Products. No development milestones have been achieved to date under the TERN-201 License Agreement.

We are also required to pay tiered royalties, ranging from mid-single digit to mid-teen percentages, on annual net sales of TERN-201 Products. The royalty rate is subject to customary reductions, including reductions based on certain generic competition to a TERN-201 Product or amounts paid to any third party under a necessary license to such third party's patent rights in order to develop, manufacture, commercialize or use a TERN-201 Product. The royalty term will terminate on a country-by-country, TERN-201 Product-by-TERN-201 Product basis on the later of (i) the expiration date of the last valid claim within the licensed patent rights infringed by the sale of such TERN-201 Product in such country, (ii) the loss of regulatory exclusivity for such TERN-201 Product in such country, and (iii) the tenth anniversary of the first commercial sale of such TERN-201 Product in such country.

Any intellectual property or inventions developed solely by either party in connection with activities conducted pursuant to the TERN-201 License Agreement shall be owned solely by that party, and any jointly-developed intellectual property or inventions shall be jointly owned (although no joint development activities are anticipated). We have the first right to prosecute, maintain, defend and enforce certain patents licensed under the TERN-201 License Agreement, including any patents that are solely and directly related to LY3379274 or TERN-201 Products.

The TERN-201 License Agreement shall expire upon the expiration of the last-to-expire royalty term for the TERN-201 Products on a country-by-country basis. Upon expiration of the TERN-201 License Agreement, the license granted to us shall be considered fully paid-up, irrevocable, perpetual and non-exclusive. Either we or Eli Lilly may terminate the TERN-201 License Agreement if the other party commits a material breach of the agreement or defaults in the performance thereunder and fails to cure that breach within 90 days after written notice is provided, or in the event of insolvency of the other party. We may terminate the TERN-201 License Agreement in its entirety or on a

country-by-country and TERN-201 Product-by-TERN-201 Product basis upon 180 days prior written notice. Eli Lilly may terminate the TERN-201 License Agreement if we, our affiliates or our sublicensees challenge the licensed patents or if we assist any third party in challenging such patents.

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 that are directed to THR-β agonists. In particular, we have been assigned a Chinese patent application and potentially certain other patents or patent applications and know-how relating to our THR-β program. We are also entitled to license the rights granted to us under the assignment agreement. Pursuant to the terms of the assignment agreement, 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 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 to negotiate an assignment or license to exclusively develop, manufacture, commercialize or otherwise exploit such agonist.

As initial consideration for the assignment, we paid Vintagence an upfront payment of CNY 5 million (approximately $0.75 million). As additional consideration, we are required to pay Vintagence up to an aggregate CNY 205 million (approximately $30 million) upon the achievement of specified developmental, clinical and regulatory milestone events with respect to products covered by the agreement.

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, and we must assign such assigned patent back to Vintagence. We also have the first right to enforce the assigned patents and know-how. If we do not bring an action to enforce any of the assigned patents or know-how against infringing activities, Vintagence has the right to bring such an action.

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 insolvency. 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.

TRN-000632 Exclusive Option and License agreement with Hansoh Pharmaceuticals

In July 2020, we, along with our subsidiaries, CaspianTern LLC and Terns, Inc., entered into an exclusive option and license agreement with Hansoh pursuant to which we have granted an exclusive option, exercisable during a specified period, to Hansoh to obtain an exclusive, royalty-bearing license under certain patent and other intellectual property rights owned or controlled by us, including patents claiming the composition of TRN-000632, 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 TRN-000632, 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. Notwithstanding the foregoing, we would 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. If Hansoh exercises its option and at our request, the parties will enter into a manufacturing and technology transfer agreement under which Hansoh will provide technical assistance and support related to the manufacture of Hansoh Products containing TRN-000632 as the sole active ingredient, at our cost. Pursuant to the terms of the option and license agreement, upon Hansoh's exercise of its option, 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 (if Hansoh does not exercise the option) payment of $1 million. Under the license, if Hansoh exercises its option, Hansoh has agreed to pay us up to an aggregate $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 or royalties paid to any third party under a license to such third party's patent rights necessary in order 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.

Upon the effectiveness of the license, intellectual property developed out of the activities under this option and license agreement, and that is necessary or useful to exploit TRN-000632 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.

Hansoh's right to exercise the option shall expire upon the earlier of 30 days after certain studies are completed or 16 months from the effective date of the option and license agreement. Hansoh can terminate its option at any time. If Hansoh exercises its option, 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 if the option has been exercised. 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 assign our entire right, title and interest in and to the Hansoh Products, including all intellectual property rights therein, in the Hansoh Territory to Hansoh and Hansoh shall provide us the fair market value of such assignment.

Government Regulation and Product Approval

Among others, the FDA, the European Medicines Agency, or EMA, 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 drug and combination therapy 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. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or

distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in accordance with FDA's good laboratory practice requirements and other applicable regulations;
- 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; and
- FDA review and approval of the NDA to permit commercial marketing of the product for particular indications for use in the United States.

Prior to beginning the first clinical trial with a product candidate in the United States, 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, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA 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 safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

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

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

The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB’s requirements or if the drug has been associated with unexpected serious harm to patients. In addition, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial.

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 and before approval, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or *in vitro* testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

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 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 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 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 may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing.

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

Before approving an NDA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates an NDA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A Complete Response Letter usually describes the specific deficiencies in the NDA identified by the FDA and may require additional clinical data, such as an additional pivotal Phase 3 trial or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a Complete Response

Letter 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 and the specific indication for which it is being studied. The sponsor of a Fast Track product 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.

Any product submitted to the FDA for approval, including a product with a Fast Track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A product is eligible for priority review if it 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 for a new drug 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 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 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. 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.

The Food and Drug Administration Safety and Innovation Act established a category of drugs referred to as "breakthrough therapies" that may be eligible to receive breakthrough therapy designation. A sponsor may seek FDA designation of a product candidate as a "breakthrough therapy" if the product 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. The breakthrough therapy designation is a distinct status from both accelerated approval and priority review, which can also be granted to the same drug if relevant criteria are met. If a product is designated as breakthrough therapy, the FDA will work to expedite the development and review of such drug.

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 qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. We may explore some of these opportunities for our drug and combination therapy candidates as appropriate.

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. 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 adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or untitled letters;
- clinical holds on clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product 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. 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.

Marketing Exclusivity

Market exclusivity provisions authorized under the FDCA can delay the submission or the approval of certain marketing applications. The FDCA provides a five-year period of non-patent marketing 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 marketing 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.

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, Europe, which may include, for instance, applicable 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.

In order to market our future product candidates in the European Economic Area (which is comprised of the 28 Member States of the EU plus Norway, Iceland and Liechtenstein), or the EEA, and many other foreign jurisdictions, we must obtain separate regulatory approvals. More concretely, in the EEA, medicinal product candidates can only be commercialized after obtaining a Marketing Authorization, or MA, There are two types of marketing authorizations:

- the "Community MA," which is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Product candidates for Human Use of the EMA and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of product candidates, such as biotechnology medicinal product candidates, orphan medicinal product candidates and medicinal product candidates indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for product candidates containing a new active substance not yet authorized in the EEA, or for product candidates that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU; and
- "National MAs," which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for product candidates not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, 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 above described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

Data and marketing exclusivity. In the EEA, new product candidates authorized for marketing, or reference product candidates, qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. 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 marketing authorization 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 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 marketing authorization 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.

Adaptive pathways. The EMA has an adaptive pathways program which allows 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 in cases of high unmet medical need. 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 life-threatening conditions); 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 marketing authorization.

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 includes 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.

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 physician sunshine laws and regulations. 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, civil and criminal penalties, damages, fines, 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 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.

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 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, in 2017, Congress enacted the Tax Cuts and Jobs Act, or the Tax Act, which eliminated the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a Texas U.S. District Court Judge ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. In December 2019, the U.S. Court of Appeals for the 5th Circuit ruled that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing the case, although it is unclear when the Supreme Court will make a decision. In addition, there may be other efforts to challenge, repeal or replace the ACA.

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 and reduced payments to several types of Medicare providers, which will remain in effect through 2030 absent additional congressional action, with the exception of a temporary suspension from May 2020 through March 2021. 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. 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 and marketing cost disclosure and 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.

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 state data breach notification laws, state 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 could apply to our operations or the operations of our partners. State laws may be more stringent, broader in scope or offer greater individual rights with respect to protected health information, or PHI, than the Health Insurance Portability and Accountability Act of 1996, or HIPAA, and state laws may differ from each other, which may complicate compliance efforts. Entities that are found to be in violation of HIPAA, as the result of a breach of unsecured PHI, a complaint about privacy practices, or an audit by U.S. Department of Health and Human Services, or HHS, may be subject to significant civil, criminal, and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance.

Even when HIPAA does not apply, according to the Federal Trade Commission, or FTC, violating consumers' privacy rights or failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the FTC Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards.

In addition, certain state and non-U.S. laws, such as the GDPR, govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, California recently enacted legislation, the CCPA, which went into effect in January 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and

provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Further, the CPRA was recently voted into law by California residents, which significantly amends the CCPA, and imposes additional data protection obligations on companies doing business in California, including additional consumer rights processes and opt outs for certain uses of sensitive data. It also creates a new California data protection agency specifically tasked to enforce the law, which would likely result in increased regulatory scrutiny of California businesses in the areas of data protection and security. The substantive requirements for businesses subject to the CPRA will go into effect in January 2023, and become enforceable in July 2023.

In Europe, we are subject to laws relating to our and our suppliers', vendors', partners' and subcontractors' collection, control, processing and other use of personal data (i.e., any data relating to an identifiable living individual, whether that individual can be identified directly or indirectly). We are subject to the supervision of local data protection authorities in those jurisdictions where we are established, where we offer goods or services to EEA and United Kingdom residents and where we monitor the behavior of individuals within the EEA or the United Kingdom (i.e., undertaking clinical trials). We and our suppliers, partners and subcontractors process personal data including in relation to our employees, employees of customers, clinical trial patients, healthcare professionals and employees of suppliers including health and medical information. The data privacy regime in the EEA and the United Kingdom includes the GDPR, the e-Privacy Directive and the e-Privacy Regulation (once in force) and the national laws and regulations implementing or supplementing each of them.

The GDPR requires that personal data is only collected for specified, explicit and legal purposes as set out in the GDPR or local laws, and the data may then only be processed in a manner consistent with those purposes. The personal data collected and processed must be adequate, relevant and not excessive in relation to the purposes for which it is collected and processed, it must be held securely, not transferred outside of the EEA (unless certain steps are taken to ensure an adequate level of protection), and must not be retained for longer than necessary for the purposes for which it was collected. In addition, the GDPR requires companies processing personal data to take certain organizational steps to ensure that they have adequate records, policies, security, training and governance frameworks in place to ensure the protection of data subject rights, including as required to respond to complaints and requests from data subjects. For example, the GDPR requires us to make more detailed disclosures to data subjects, requires disclosure of the legal basis on which we can process personal data, makes it harder for us to obtain valid consent for processing, requires the appointment of a data protection officer where sensitive personal data (*e.g.*, health data) is processed on a large scale, introduces mandatory data breach notification throughout the EEA and imposes additional obligations on us when we are contracting with service providers.

In addition, to the extent a company processes, controls or otherwise uses "special category" personal data (including patients' health or medical information, genetic information and biometric information), more stringent rules apply, further limiting the circumstances and the manner in which a company is legally permitted to process that data. Finally, the GDPR provides a broad right for EU and EEA member states to create supplemental national laws which may result in divergence across Europe making it harder to maintain a consistent operating model or standard operating procedures. Such laws, for example, may relate to the processing of health, genetic and biometric data, which could further limit our ability to use and share such data or could cause our costs to increase, and harm our business and financial condition.

We depend on a number of third parties in relation to the provision of our services, a number of which process personal data on our behalf. It is our policy to enter into contractual arrangements with each such provider to ensure that they only process personal data according to our instructions, and that they have sufficient technical and organizational security measures in place. Where we transfer personal data outside the EEA, we do so in compliance with the relevant data export requirements from time to time. We take our data protection obligations seriously, as any improper, unlawful or accidental disclosure, loss, alteration or access to, personal data, particularly sensitive personal data (i.e., special category), could negatively impact our business and/or our reputation.

We are also subject to EU laws on personal data export, as we may transfer personal data from the EEA to other jurisdictions which are not considered by the European Commission to offer adequate protection of personal data. Such transfers need to be legitimized by a valid transfer mechanism under the GDPR. Recent legal developments in Europe have created complexity and uncertainty regarding transfers of personal data from the EEA to 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, under which personal data could be transferred from the EEA to US entities who had self-certified under the Privacy Shield scheme. While the CJEU upheld the adequacy of the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism, and potential alternative to the Privacy Shield), it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. GDPR increases financial penalties for noncompliance (including possible fines of up to four percent of global annual revenue for the preceding financial year or €20 million (whichever is higher) for the most serious violations). Relatedly, following the departure of the United Kingdom from the EU after the expiry of the transition period in January 2021, the United Kingdom will operate a separate but similar regime to the EU which we will have to comply with (with respect to any United Kingdom activities) and allows for fines of up to £17.5 million or 4% of the total worldwide annual turnover of the preceding financial year (whichever is higher).

Employees and Human Capital Management

As of December 31, 2020, we had 30 employees, all of whom were full-time, all of whom are engaged in research and development activities, operations, finance and administration. Sixteen of our employees hold doctorate degrees (Ph.D., M.D. or Pharm.D.). None of our employees is 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 (by means of filing a certificate of domestication with the Secretary of State of Delaware), 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 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. Many of the following risks and uncertainties are, and will be, exacerbated by the coronavirus disease 2019, or COVID-19, pandemic and any worsening of the global business and economic environment as a result. 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.

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 single-agent and combination therapy 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 have had significant operating losses since our inception. Our net loss attributable to common stockholders for the years ended December 31, 2020 and 2019 was approximately $29.4 million and $68.6 million, respectively. As of December 31, 2020, we had an accumulated deficit of $131.9 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 single-agent and combination therapy 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 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.

Since our inception, we have invested a significant portion of our efforts and financial resources in research and development activities. Our single-agent and combination therapy candidates will require additional clinical development, and we intend to conduct additional research and development activities to discover and develop new single-agent and combination therapy 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 single-agent and combination therapy candidates or any future single-agent and combination therapy candidates.

As of December 31, 2020, we had capital resources consisting of cash and cash equivalents of approximately $74.9 million. In December 2020, we issued and sold shares of our convertible preferred stock for gross proceeds of

approximately $87.4 million (including conversion of the $15.0 million of convertible notes and effective conversion of $1.8 million in a bridge loan, plus accrued interest). In February 2021, we issued and sold 8,625,000 shares of our common stock in our initial public offering, or IPO, for net proceeds of approximately $132.9 million, after deducting underwriting discounts and commissions and offering expenses. We expect our existing capital resources, which includes the gross proceeds from the issuance and sale of our convertible preferred stock and the net proceeds from our IPO, will fund our planned operating expenses into 2024. 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, 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, results and costs of researching and developing our current single-agent and combination therapy candidates or any other future single-agent and combination therapy candidates we choose to pursue, and conducting preclinical studies and clinical trials, including our planned clinical trials of TERN-101, TERN-201, TERN-501 and the coadministration of TERN-101 and TERN-501 and any delays related to the COVID-19 pandemic;
- the timing of, and the costs involved in, obtaining regulatory approvals for our single-agent and combination therapy candidates or any future single-agent and combination therapy candidates;
- the number and characteristics of any additional single-agent or combination therapy 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 single-agent and combination therapy candidates or any future single-agent and combination therapy candidates and any single-agent or combination therapies we successfully commercialize;
- the cost of pre-commercial activities and, if approved, commercialization activities related to our single-agent and combination therapy 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;
- any product liability or other lawsuits related to our single-agent and combination therapy 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;
- the timing, receipt and amount of sales of any future approved drugs; and
- the impact of the COVID-19 pandemic, which may exacerbate the magnitude of the factors discussed above.

Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. 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 single-agent and combination therapy candidates or any future single-agent or combination therapy 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 single-agent and combination therapy candidates or any future single-agent or combination therapy 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 single-agent and combination therapy 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 single-agent and combination therapy 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 will 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. 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 single-agent and combination therapy candidates, we must prioritize development of certain single-agent and combination therapy candidates and/or certain disease indications, which initially will be NASH. We may expend our limited resources on candidates or indications that do not yield a successful product and fail to capitalize on single-agent and combination therapy candidates or indications that may be more profitable or for which there is a greater likelihood of success.

We are currently focused on developing a portfolio of small-molecule single-agent and combination therapy candidates for the treatment of non-alcoholic steatohepatitis, or NASH, and other chronic liver diseases. We seek to maintain a process of prioritization and resource allocation among our programs to maintain a balance between advancing our three clinical-stage programs, TERN-101, TERN-201 and TERN-501, in identified indications and exploring additional indications or mechanisms as well as developing future single-agent and combination therapy candidates. We also aim to conduct combination trials of our single-agent drug candidates. However, due to the significant resources required for the development of our single-agent and combination therapy candidates, we must focus on specific diseases and disease pathways and decide which single-agent and combination therapy candidates to pursue and the amount of resources to allocate to each such single-agent or combination therapy candidate.

Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular single-agent and combination therapy candidates or therapeutic areas may not lead to the development of any viable commercial drug and may divert resources away from better opportunities. 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 single-agent and combination therapy candidates or misread trends in NASH or in the pharmaceutical, biopharmaceutical or biotechnology industry, our business, financial condition and results of operations could be materially adversely affected. As a result, we may fail to

capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other single-agent and combination therapy 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 single-agent and combination therapy 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.

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:

- the timing and cost of, and level of investment in, research, development, pre-commercial and, if approved, commercialization activities relating to our single-agent and combination therapy candidates, which may change from time to time;
- the timing and status of enrollment for our clinical trials;
- the cost of manufacturing our single-agent and combination therapy 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 single-agent and combination therapy 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 single-agent and combination therapy candidates or competing single-agent and combination therapy 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 single-agent and combination therapy candidates from regulatory authorities in the United States and internationally;
- coverage and reimbursement policies with respect to our single-agent and combination therapy candidates, if approved, and potential future drugs that compete with our single agent and combination therapies;
- the level of demand for our single-agent and combination therapy 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.

Risks related to the discovery and development of our single-agent and combination therapy 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 single-agent and combination therapy candidates.

We have no drugs or combination therapies approved for sale, and our two clinical-stage 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 single-agent and combination therapy candidates and, in particular, the advancement of our current clinical-stage programs, which are in early stages of clinical development. 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 single-agent or combination therapy candidate sufficient to warrant approval for commercialization. We cannot be certain that our single-agent and combination therapy 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 single-agent or combination therapy candidate. An NDA or other relevant regulatory filing must include extensive preclinical and clinical data and supporting information to establish that the single-agent or combination therapy 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 single-agent and combination therapy candidates will be successful in clinical trials or receive regulatory approval. Further, even if they are successful in clinical trials, our current or future single-agent and combination therapy candidates may not receive regulatory approval. If we do not receive regulatory approvals for current or future single-agent and combination therapy candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approval to market a single-agent or combination therapy 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 plan to seek regulatory approval to commercialize our single-agent and combination therapy candidates both 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 single-agent and combination therapy candidates that we may develop or acquire. The clinical and commercial success of our single-agent and combination therapy candidates and future single-agent and combination therapy 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;
- the COVID-19 pandemic, which may result in clinical site closures, delays to patient enrollment, patients discontinuing their treatment or follow-up visits or changes to trial protocols;
- 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 single-agent and combination therapy 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 single-agent and combination therapy candidates or any future single-agent and combination therapy candidates;
- acceptance of our proposed indications and primary endpoint assessments relating to the proposed indications of our single-agent and combination therapy 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 single-agent and combination therapy 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 single-agent and combination therapy candidates or any future single-agent and combination therapy candidates;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our single-agent and combination therapy 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 single-agent and combination therapy candidates or any future single-agent and combination therapy 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 single-agent and combination therapy candidates or any future single-agent and combination therapy 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;
- our ability to successfully develop a commercial strategy and thereafter commercialize our single-agent and combination therapy candidates or any future single-agent and combination therapy 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 single-agent and combination therapy candidates or any future single-agent and combination therapy 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 single-agent or combination therapy candidates or any future single-agent and combination therapy candidates, if approved;
- patients' willingness to enroll or continue to participate in a clinical trial during the COVID-19 pandemic;
- patient demand for our current or future single-agent and combination therapy 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 are able to execute on our strategy to develop fixed-dose combination therapy candidates that have desirable profiles;
- our ability to establish and enforce intellectual property rights in and to our single-agent and combination therapy candidates or any future single-agent and combination therapy 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 single-agent and combination therapy candidates. Even if regulatory approvals are obtained, we may never be able to successfully commercialize any of our single-agent or combination therapy candidates. Accordingly, we cannot provide assurances that we will be able to generate sufficient revenue through the sale of our single-agent and combination therapy candidates or any future single-agent and combination therapy 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 single-agent and combination therapy candidates is unsuccessful or delayed, we may be unable to obtain required regulatory approvals and we may be unable to commercialize our single-agent and combination therapy 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 adverse events. The results of preclinical, nonclinical and early clinical studies of our single-agent and combination therapy candidates may not be predictive of the results of later-stage clinical trials. Single-agent and combination therapy 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 single-agent and combination therapy 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 single-agent and combination therapy 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, 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 the course of a trial;

- addressing any conflicts with new or existing laws or regulations;
- adding a sufficient number of clinical trial sites; or
- manufacturing sufficient quantities of our single-agent and combination therapy candidates for use in clinical trials.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting, or completing our planned and ongoing 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, as the case may be, and may ultimately lead to the denial of marketing approval of our single-agent and combination therapy candidates.

If we experience delays in the completion of any clinical trial of our single-agent and combination therapy candidates or the termination of any such clinical trial, the commercial prospects of our single-agent and combination therapy candidates may be harmed, and our ability to generate drug revenues from any of these single-agent and combination therapy 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 single-agent and combination therapy 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 single-agent and combination therapy candidates.

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 single-agent and combination therapy 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 single-agent or combination therapy 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 single-agent or combination therapy 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 single-agent and combination therapy candidates that are in the same therapeutic areas as our single-agent and combination therapy 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 single-agent and combination therapy candidates.

We face significant competition for our drug discovery and development efforts in an environment of rapid technological and scientific change, and our single-agent and combination therapy 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 in particular 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 NASH. Large pharmaceutical companies participating in the development of NASH treatments include, but are not limited to, AbbVie, Inc., Amgen Inc., AstraZeneca PLC/MedImmune LLC, Bayer AG, Boehringer Ingelheim, Bristol-Myers Squibb Company, Eisai, Inc., Eli Lilly and Company, Gilead Sciences, Inc., GlaxoSmithKline plc, Johnson & Johnson, Merck & Co., Inc., Novartis Pharmaceuticals Corp., Novo Nordisk A/S, Pfizer Inc., Roche Holding AG, Sanofi, Sumitomo Dainippon Pharma Co., Ltd. and Takeda Pharmaceutical Co., Ltd.

In relation to TERN-101, companies conducting NASH clinical trials with FXR agonists include AbbVie, Inc., Enanta Pharmaceuticals, Inc., ENYO Pharma SA, Gilead Sciences, Inc., Intercept Pharmaceuticals, Inc., Metacrine, Inc. and Novartis Pharmaceuticals Corp.

TERN-201, our VAP-1 inhibitor, is a relatively novel mechanism for the treatment of NASH, and thus has little competition we are aware of. The companies who are currently developing a SSAO/VAP-1 inhibitor with NASH as a lead indication are LG Chem Ltd. and Novo Nordisk A/S.

With regards to TERN-501, companies conducting NASH clinical trials with THR-β agonists include Ascletis Pharma Inc., Madrigal Pharmaceuticals, Inc. and Viking Therapeutics, Inc.

Furthermore, pharmaceutical and biotechnology companies who are developing clinical-stage drugs to treat NASH using mechanisms not mentioned above include 89Bio, Inc., Akero Therapeutics, Inc., Arrowhead Pharmaceuticals, Inc., Axcella Health, Inc., Carmot Therapeutics, Inc., Cirius Therapeutics, Inc., CohBar, Inc.,

Coherus Biosciences Inc., Corcept Therapeutics, Inc., CymaBay Therapeutics, Inc., Esperion Therapeutics, Inc., Galectin Therapeutics Inc., Galmed Pharmaceuticals Ltd., Hanmi Pharmaceutical Co., Ltd., Inventiva Pharma SA, Ionis Pharmaceuticals, Inc., MediciNova, Inc., NGM Biopharmaceuticals, Inc., NorthSea Therapeutics, Inc., Pliant Therapeutics, Inc., Poxel SA, Sagimet Biosciences, Inc., T3D Therapeutics, 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 metabolic diseases, such as NASH, 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 single-agent and combination therapy candidates, which could give such products significant regulatory and market timing advantages over any of our single-agent and combination therapy candidates. Our competitors also may obtain FDA, European Medicines Agency, or EMA, or other 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 single-agent and combination therapy candidates are targeting, which could result in our competitors establishing a strong market position before we are able to enter the market. For additional information regarding our competition, see the section of this Annual Report on Form 10-K captioned Item 1. “Business—Competition.”

We are initially developing single-agent and combination therapy candidates for the treatment of NASH, an indication for which there is currently no approved therapy in the United States or Europe. 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 makes it difficult to predict the timing and costs of the clinical development of our single-agent and combination therapy candidates for the treatment of NASH.

Our current research and development efforts are focused on developing our single-agent and combination therapy candidates for the treatment of NASH, an indication for which there is currently no approved therapy in the United States or Europe. 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. As other companies are in later stages of clinical trials for their potential NASH therapies, we expect that the path for regulatory approval for NASH therapies may continue to evolve as these other 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 single-agent and combination therapy 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 single-agent and combination therapy 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 single-agent or combination therapy candidate. As an example, the FDA recently returned a complete response to an NDA submitted by Intercept Pharmaceuticals, Inc. for the drug candidate obeticholic acid, or OCA, for the treatment of NASH. The efficacy of OCA for the treatment of NASH was based on the surrogate histologic endpoint of improvement of fibrosis as shown by liver biopsy with no worsening of NASH in lieu of clinical outcomes in the NASH patients enrolled in the trial, such as overall survival and time to liver transplant. Such decisions may impact our future clinical trial designs, including trial size and approval endpoints, in ways that we cannot predict today. 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.

Even if we receive accelerated approval for any of our single-agent or combination therapy candidates, we anticipate we will be required to conduct or complete a post-approval clinical outcomes trial to confirm the clinical benefit of such single-agent and combination therapy 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.

Our anticipated development costs would likely increase if development of any current or future single-agent or combination therapy candidate is delayed because we are required by the FDA 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 single-agent and combination therapy candidates in combination with one or more therapies that have not yet been approved for marketing by the FDA, EMA or similar foreign regulatory authorities. We may not be able to market and sell any single-agent or combination therapy 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 single-agent and combination therapy candidates currently in development, including the potential for serious adverse effects, delay in their clinical trials and lack of FDA or EMA approval. If the FDA, EMA 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 single-agent and combination therapy candidates, we may be unable to obtain approval of or market any such single-agent or combination therapy candidate.

The lack of widely-accepted non-invasive methods for the diagnosis of NASH is likely to present a major challenge to the market penetration of our single-agent and combination therapy candidates for the treatment of NASH.

Liver biopsy is the standard approach for the diagnosis of inflammation and fibrosis associated with NASH. However, the procedure-related morbidity and, in rare cases, mortality, sample errors, costs, patient discomfort and thus lack of patient interest in undergoing the procedure limit its use. As such, only patients with a high risk of NASH, which includes patients with metabolic syndrome and an indication of non-alcoholic fatty liver disease, or NAFLD, are generally referred for liver biopsy. Because NASH tends to be asymptomatic until the disease progresses, many individuals with NASH remain undiagnosed until the disease has reached its late stages. The lack of widely-accepted non-invasive methods for the diagnosis of NASH is likely to present a major challenge to the market penetration of our single-agent and combination therapy candidates for the treatment of NASH, if ever commercialized, as many practitioners and patients may not be aware that a patient suffers from NASH and requires treatment. As such, use of our single-agent and combination therapy candidates for the treatment of NASH might not be as wide-spread as our

actual target market and this may limit the commercial potential of such single-agent and combination therapy candidates.

A further challenge to the market penetration for our NASH single-agent and combination therapy candidates is that currently a liver biopsy is the standard approach for measuring improvement in NASH patients. Because it would be impractical to subject all patients that take our single-agent and combination therapy candidates, if approved, to regular and repeated liver biopsies, it will be difficult to demonstrate effectiveness to practitioners and patients unless and until widely-accepted non-invasive methods for the diagnosis and monitoring of NASH become available in clinical practice and clinical trials, as to which there can be no assurance.

While non-invasive diagnostic approaches are being advanced, their use in the diagnosis of NASH and monitoring of response to treatment has not been broadly recommended in professional treatment guidelines. Moreover, some diagnostics in development have not yet been clinically validated, have uncertain timetables for clinical validation, and may also be subject to regulation by FDA or other regulatory authorities as medical devices and may require premarket clearance or approval.

Our single-agent and combination therapy 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 single-agent and combination therapy 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. To date, both TERN-101 and TERN-201 have been well-tolerated though we did observe transient elevations in transaminases in one of our Phase 1 clinical trials of TERN-101. Drugs with similar mechanism of actions to those we are developing have shown tolerability issues, including pruritus and adverse lipid changes in other FXR agonists, non-selective MAO inhibition in other VAP-1 inhibitors and potential cardiac toxicity in other THR-β agonists. As a result, it is possible that our drug candidates will display similar safety and tolerability issues and adverse events when evaluated in longer clinical trials in larger patient populations despite the results we have observed in our clinical trials to date.

If unacceptable side effects arise in the development of our single-agent and combination therapy 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 single-agent and combination therapy 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 single-agent and combination therapy candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our single-agent or combination therapy candidates. Inadequate training in recognizing or managing the potential side effects of our single-agent and combination therapy 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 single-agent or combination therapy 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 single-agent or combination therapy, or decide to remove the single-agent or combination therapy from the marketplace;
- regulatory authorities may withdraw or change their approvals of that single-agent or combination therapy;

- regulatory authorities may require additional warnings on the label or limit access of that single-agent or combination therapy 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 single-agent or combination therapy for patients, or to conduct post-marketing studies;
- we may be required to change the way the single-agent or combination therapy 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 single-agent or combination therapy 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 single-agent or combination therapy 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 single-agent or combination therapy 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 single-agent or combination therapy 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 single-agent and combination therapy 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 single-agent and combination therapy candidates under applicable regulatory requirements. The denial or delay of any such approval would delay commercialization of our single-agent and combination therapy 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 single-agent or combination therapy candidates in the United States until we receive regulatory approval of an NDA from the FDA.

Obtaining regulatory approval of an NDA can be a lengthy, expensive and uncertain process. Prior to obtaining approval to commercialize a single-agent or combination therapy 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 single-agent and combination therapy 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 single-agent or combination therapy candidate, the disease or condition that the single-agent or combination therapy candidate is designed to address, and the regulations applicable to any particular single-agent or combination therapy 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 single-agent and combination therapy candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. Administering single-agent and combination therapy 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 single-agent or combination therapy candidate for any or all indications. The FDA may also require us to conduct additional studies or trials for our single-agent and combination therapy 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 bodies can delay, limit or deny approval of our single-agent and combination therapy 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 single-agent or combination therapy candidates;
- our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory authority that our single-agent and combination therapy 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 single-agent and combination therapy 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 single-agent and combination therapy 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 single-agent and combination therapy candidates, which would significantly harm our business, financial condition, results of operations and prospects.

Even if we eventually complete clinical testing and receive approval of an NDA or foreign marketing application for our single-agent and combination therapy 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 single-agent or combination therapy 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 single-agent or combination therapy 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 single-agent or combination therapy candidate as we desire, would delay, prevent or otherwise limit commercialization of that single-agent or combination therapy candidate and would materially adversely impact our business and prospects.

Our business has been and could continue to be adversely affected by the evolving and ongoing COVID-19 global pandemic in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites or other business operations. The COVID-19 pandemic could adversely affect our operations, as well as the business or operations of our manufacturers or other third parties with whom we conduct business.

Our business has been and could continue to be adversely affected by the effects of the recent and evolving COVID-19 pandemic, which was declared by the World Health Organization as a global pandemic. As the COVID-19 pandemic continues, we may experience ongoing disruptions that could severely impact our business and clinical trials, including:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials, including interruption in global shipping that may affect the transport of clinical trial materials;
- changes in local regulations as part of a response to the COVID-19 outbreak which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- the diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- the interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;

- the interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- the risk that participants enrolled in our clinical trials or study staff conducting the clinical trial visits will acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events, or the ability to complete study visits and collect data; and
- the refusal of the FDA to accept data from clinical trials in affected geographies.

These and other disruptions in our operations and the global economy could negatively impact our business, operating results and financial condition.

Our clinical trials have been, and may in the future be, affected by the COVID-19 pandemic. For example, the COVID-19 pandemic may impact patient enrollment, visits or continued participation in our ongoing trials, including our Phase 2a clinical trial of TERN-101 (LIFT Study) and our Phase 1 clinical trial of TERN-501, and our planned trials, such as our Phase 1b clinical trial for TERN-201. In particular, some sites have in the past or may in the future pause enrollment to focus on, and direct resources to, COVID-19, while at other sites, patients may choose not to enroll or continue participating in the clinical trial as a result of the pandemic. In addition, patient visits to medical providers in the United States have slowed as a result of the COVID-19 pandemic. Further, according to the Centers for Disease Control and Prevention, people who have serious chronic medical conditions are at higher risk of getting very sick from COVID-19. As a result, 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 as a precaution against contracting COVID-19. Further, some patients may not be able or willing to comply with clinical trial protocols if quarantines impede patient movement or interrupts healthcare services.

We are unable to predict with confidence the duration of such patient enrollment delays and difficulties. If patient enrollment is delayed for an extended period of time, our clinical trials could be delayed or otherwise adversely affected. Similarly, our ability to recruit and retain principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, 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. For example, we have also made 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, and may need to make further adjustments in the future. For example, we have initiated our clinical trial protocols to enable remote visits to mitigate any potential impacts as a result of the COVID-19 pandemic. Many of these adjustments are new and untested, may not be effective, may affect the integrity of data collected, and may have unforeseen effects on the progress and completion of our clinical trials and the findings from such clinical trials.

In addition, we may 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 LIFT Study and our other clinical trials depend on retrieving laboratory, imaging and other data from patients. Any failure by the vendors with which 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.

In addition, 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, related to COVID-19 or other infectious diseases could impact personnel at our study sites or third-party manufacturing facilities upon which we rely, or the availability or cost of materials, which could disrupt the supply chain for our drug and combination therapy candidates. 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 the COVID-19 pandemic, our ability to continue meeting clinical supply demand for our drug and combination therapy candidates or otherwise advancing development of our single-agent and combination therapy candidates may become impaired.

The spread of COVID-19 and actions taken to reduce its spread may also materially affect us economically. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, there could be a significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity and financial position. In addition, the trading prices for other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms.

COVID-19 and actions taken to reduce its spread continue to rapidly evolve. The extent to which COVID-19 may impede the development of our single-agent and combination therapy candidates, reduce the productivity of our employees, disrupt our supply chains, delay our clinical trials, reduce our access to capital or limit our business development activities, will depend on future developments, which are highly uncertain and cannot be predicted with confidence.

In addition, to the extent the ongoing COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described in this Item 1A. “Risk Factors” section.

We have received Fast Track designation for TERN-101 and TERN-201 for the treatment of NASH, and we may seek Fast Track designation for some or all of our other single-agent and combination therapy candidates. We may not receive such designation, and even for those single-agent and combination therapy 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 single-agent and combination therapy candidates will receive marketing approval.

We have received Fast Track designation from the FDA for TERN-101 and TERN-201 for the treatment of NASH, and we may seek Fast Track designation and priority review for some of our other single-agent and 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 FDA has broad discretion whether or not to grant this designation. Thus, even if we believe a particular single-agent or combination therapy 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 single-agent and combination therapy candidates, may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our single-agent and combination therapy candidates will receive marketing approval.

We may seek a Breakthrough Therapy designation for one or more of our single-agent and combination therapy candidates if the clinical data support such a designation for one or more single-agent and combination therapy 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.

Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe one of our single-agent or combination therapy 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 single-agent or combination therapy 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 single-agent or combination therapy 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.

Obtaining and maintaining regulatory approval of our single-agent and combination therapy candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our single-agent and combination therapy candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our single-agent and combination therapy 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 single-agent or combination therapy candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the single-agent or combination therapy 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. In many jurisdictions outside the United States, a single-agent or combination therapy 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 single-agent and combination therapy candidates will be harmed.

Even if we receive regulatory approval of our single-agent and combination therapy candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our single-agent and combination therapy 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 single-agent and combination therapy candidates, when and if any of them are approved.

Any regulatory approvals that we receive for our single-agent and combination therapy 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 single-agent or combination therapy candidate. The FDA may also require us to adopt a REMS to ensure that the benefits of treatment with such single-agent or combination therapy 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 single-agent or combination therapy candidate, the manufacturing, quality control, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for the approved drug will be subject to extensive and ongoing regulatory requirements. The FDA also requires submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP requirements and good clinical practice, or GCPs, for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with a single-agent or combination therapy candidate, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- 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.

Advertising and promotion of any single-agent or combination therapy candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the U.S. Federal Trade Commission, the Department of Justice, the U.S. Department of Health and Human Services Office of Inspector General, state attorneys general, members of the U.S. Congress and the public. Additionally, advertising and promotion of any single-agent or combination therapy candidate that obtains approval outside of the United States will be heavily scrutinized by comparable foreign entities and stakeholders. Violations, including actual or alleged promotion of our drugs for unapproved or off-label uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA or comparable foreign bodies. Any actual or alleged failure to comply with labeling and promotion requirements may result in fines, warning letters, mandates to corrective information to healthcare practitioners, injunctions or civil or criminal penalties.

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 single-agent and combination therapy 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 results of the 2020 Presidential election may impact our business and industry. Namely, the Trump administration took several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these executive actions will be implemented or whether they will be rescinded or replaced under the Biden Administration. The policies and priorities of the new Administration are unknown and could materially impact 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.

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 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 agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and 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, including for 35 days beginning on December 22, 2018, the U.S. government has shut down

several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Separately, in response to the global COVID-19 pandemic, in March 2020, the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products through April 2020, and subsequently in March 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, in July 2020 the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. 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.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. If we are found or alleged to have improperly promoted off-label uses, we may become subject to significant liability.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription drugs, as our single-agent and combination therapy candidates would be, if approved. In particular, a drug may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the drug's approved labeling. Physicians may nevertheless prescribe such drugs to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our single-agent and combination therapy candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

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 single-agent or combination therapy candidate, and our commercialization of any of our single-agent or combination therapy 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 single-agent or combination therapy candidates on a clinical or commercial scale. The facilities used by our contract manufacturers to manufacture our single-agent and combination therapy candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs 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 single-agent and combination therapy 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 single-agent and combination therapy candidates, if approved.

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 single-agent and combination therapy 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 single-agent and combination therapy 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 single-agent and combination therapy 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 single-agent and combination therapy 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 single-agent or combination therapy candidate to complete the clinical trial, any significant delay in the supply of a single-agent or combination therapy 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 single-agent and combination therapy candidates. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our single-agent and combination therapy candidates, the commercial launch of our single-agent and combination therapy 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 single-agent and combination therapy candidates.

We, or our manufacturing partners, may be unable to successfully increase the manufacturing capacity for any of our single-agent or combination therapy 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 single-agent and combination therapy candidates in sufficient quality and quantity, the development, testing and clinical trials of that single-agent or combination therapy 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 single-agent or combination therapy 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 single-agent and combination therapy 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 our GLP-compliant preclinical and nonclinical studies and GCP-compliant clinical trials, 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 single-agent or combination therapy candidate, our financial results and the commercial prospects for our single-agent and combination therapy 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 single-agent and combination therapy 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 TRN-000632, 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 single-agent and combination therapy 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 single-agent and combination therapy 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 single-agent and combination therapy 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 single-agent and combination therapy 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 single-agent or combination therapy candidate, repeat or conduct new clinical trials or require a new formulation of a single-agent or combination therapy candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, drugs that compete directly or indirectly with our single-agent and combination therapy 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 single-agent and combination therapy 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 single-agent and combination therapy 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 single-agent and combination therapy candidates. Any of these developments could harm our product development efforts.

Risks related to commercialization of our single-agent and combination therapy candidates

The successful commercialization of our single-agent and combination therapy 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 single-agent and combination therapy 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 single-agent and combination therapy 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 single-agent and combination therapy candidates. Assuming we obtain coverage for our single-agent and combination therapy 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 single-agent and combination therapy 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 single-agent and combination therapy 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 single-agent and combination therapy candidates, pricing of existing third-party therapeutics may limit the amount we will be able to charge for our single-agent and combination therapy 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 single-agent and combination therapy candidates. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our single-agent and combination therapy candidates, and may not be able to obtain a satisfactory financial return on our single-agent and combination therapy 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 single-agent and combination therapy 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 we believe that changes in these rules and regulations are likely.

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 single-agent and combination therapy 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, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our single-agent and combination therapy candidates. Accordingly, in markets outside the United States, the reimbursement for our single-agent and combination therapy 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 single-agent and combination therapy candidates. We expect to experience pricing pressures in connection with the sale of our single-agent and combination therapy 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 intense. As a result, increasingly high barriers are being erected to the entry of new products.

Even if our current or future single-agent and combination therapy 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 single-agent or combination therapy candidates receive FDA or other regulatory approvals, the commercial success of any of our current or future single-agent and combination therapy 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 in development for the treatment of NASH, if we are unsuccessful in achieving a differentiated profile with our single-agent and combination therapy candidates based on efficacy, safety and tolerability, dosing and administration, market acceptance will be limited. Our single-agent and combination therapy 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 single-agent and combination therapy candidates. If approved, the commercial success of our single-agent and combination therapy candidates will depend on a number of factors, including:

- the clinical indications for which the single-agent or combination therapy is approved and patient demand for approved drugs that treat those indications;
- the safety and efficacy of our single-agent or combination therapy 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 single-agent and combination therapy candidates that may be approved;
- acceptance by physicians, operators of clinics and patients of the single-agent or combination therapy 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 single-agent and combination therapy 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 single-agent and combination therapy candidates and overall treatment experience, including, for example, the convenience of any dosing regimen;
- the cost of treatment with our single-agent and combination therapy 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 drugs and combination therapies may offer a physician as compared to alternative therapies;
- the prevalence and severity of side effects;
- limitations or warnings contained in the FDA-approved labeling for our drugs;

- the willingness of physicians, operators of clinics and patients to utilize or adopt our drugs and combination therapies as a solution;
- any FDA requirement to undertake a REMS;
- the effectiveness of our sales, marketing and distribution efforts;
- adverse publicity about our drugs and combination therapies or favorable publicity about competitive drugs; and
- potential product liability claims.

We cannot assure you that our current or future single-agent and combination therapy candidates, if approved, will achieve broad market acceptance among physicians and patients. Any failure by our single-agent and combination therapy 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 single-agent and combination therapy candidates, if approved, effectively in the United States and foreign jurisdictions or generate drug revenue.

We currently do not have a marketing or sales organization. In order to commercialize our single-agent and combination therapy 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 single-agent or combination therapy candidates receive regulatory approval, we expect to establish a sales organization with technical expertise and supporting distribution capabilities to commercialize each such single-agent or combination therapy 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 single-agent and combination therapy candidates. If we are not successful in commercializing our single-agent and combination therapy candidates or any future single-agent and combination therapy 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.

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 single-agent and combination therapy 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) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members. Beginning in 2022, such obligations will include payments and other transfers of value provided in the previous year to certain other healthcare professionals, including physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants and certified nurse midwives;
- 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.

Enacted and future healthcare legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our single-agent and combination therapy 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, and we expect there will be additional challenges and amendments to the ACA in the future. The U.S. Supreme Court is currently reviewing the case, although it is unclear when the Supreme Court will make a decision. It is also unclear how other efforts to challenge, repeal or replace the ACA will affect the law or our business.

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 2030, with the exception of a temporary suspension from May 2020 through March 2021, unless additional action is taken by Congress. 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.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, the Centers for Medicare and Medicaid Services, or CMS, may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our single-agent and combination therapy candidates or additional pricing pressures.

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 single-agent and combination therapy candidates or put pressure on our product pricing.

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 single-agent and combination therapy 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 single-agent or combination therapy 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 single-agent and combination therapy candidate development on therapies for the treatment of NASH and other liver and other chronic liver diseases. Our projections of addressable patient populations that have the potential to benefit from treatment with our single-agent and combination therapy 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 single-agent and combination therapy candidates may not ultimately be amenable to treatment with our single-agent and combination therapy 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 single-agent and combination therapy candidates could be significantly diminished and have an adverse material impact on our business.

Risks Related to Intellectual Property

Our current and any future single-agent and combination therapy 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 single-agent and combination therapy 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 single-agent and combination therapy 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 single-agent and combination therapy 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 risk increases 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.

From time to time, we may be subject to legal proceedings and claims with respect to intellectual property with respect to our single-agent and combination therapy candidates and technologies we use in our business. 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. 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 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. Results of any such litigation are difficult to predict and may require us to cease developing, manufacturing, or commercializing the infringing single-agent and combination therapy candidate, stop treating certain conditions, 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 single-agent and combination therapy candidates unless the third party licenses rights to us, which it is not 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 single-agent and combination therapy candidates.

Although we have reviewed certain third-party patent filings that we believe may be relevant to certain of our single-agent and combination therapy candidates, we have not conducted a freedom-to-operate search or analysis for all of our single-agent and combination therapy 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 single-agent and combination therapy candidates. Thus, we cannot guarantee that our single-agent and combination therapy 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 single-agent and combination therapy 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 single-agent and combination therapy 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 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 initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

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 drugs or combination therapies 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 single agent or combination therapy 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 single-agent or combination therapy 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 single agent or combination therapy candidates we may sell without incurring the sizeable development and 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 file patent applications in the United States and abroad related to our single-agent and combination therapy 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 single-agent and combination therapy 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 single-agent or combination therapy candidates or any future drugs or combination therapies 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 single-agent or combination therapy 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 single-agent or combination therapy 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 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 license agreements with Eli Lilly and Company with respect to TERN-101 and TERN-201 and 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 single-agent and combination therapy 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. 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 single-agent and combination therapy 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 single-agent and combination therapy 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. 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 single-agent and combination therapy 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, 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 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 international patents and patent applications, 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 single-agent and combination therapy 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 single-agent and combination therapy 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 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 single-agent or combination therapy 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 protection, particularly those relating to pharmaceuticals and biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally.

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, China 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, 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 application in the United States and abroad that is relevant to or necessary for the commercialization of our single-agent and combination therapy 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 application may be incorrect, which may negatively impact our ability to market our single-agent and combination therapy candidates. We may incorrectly determine that our single-agent and combination therapy candidates are not covered by a third-party patent or may incorrectly predict whether a third-party's pending 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 single-agent and combination therapy candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our single-agent and combination therapy 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 single-agent and combination therapy 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 single-agent and combination therapy 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. 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 single-agent and combination therapy candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. 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 single-agent and combination therapy candidates are obtained, once the patent life has expired for a single-agent or combination therapy 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 single-agent and combination therapy candidates, patents directed

towards such single-agent and combination therapy candidates might expire before or shortly after such single-agent and combination therapy candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing single-agent and combination therapy 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 single-agent and combination therapy 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 single-agent or combination therapy 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 single-agent and combination therapy 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 single-agent or combination therapy candidates is approved and a patent covering that single-agent or combination therapy 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 single-agent or combination therapy 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 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 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 U.S. or in other countries could diminish the value of patents in general, thereby impairing our ability to protect our single-agent and combination therapy 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 recent 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 a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also 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 will be 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.

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 single-agent and combination therapy 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 initiate 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, 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, particularly our Chief Executive Officer, Senthil Sundaram, and President and Chief Medical Officer, Erin Quirk, M.D., as well as our senior scientists and other members of our senior management team. 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 single-agent and combination therapy candidates.

Competition for qualified personnel in the pharmaceutical, biopharmaceutical and biotechnology field is intense due to the limited number of individuals who possess the 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. 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, 2020, we had 30 full-time employees. We will need to continue to expand our managerial, operational, finance and other resources in order to manage our operations and clinical trials, continue our development activities and, if approved, commercialize our preclinical and clinical-stage single-agent and combination therapy candidates or any future single-agent and combination therapy 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 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.

If we are not successful in identifying, developing and commercializing additional single-agent and combination therapy candidates, our ability to expand our business and achieve our strategic objectives would be impaired.

Although the development and commercialization of TERN-101, TERN-201 and TERN-501 is currently our primary focus, as part of our longer-term growth strategy, we plan to evaluate the development and commercialization of other therapies related to NASH and other chronic liver diseases. The success of this strategy depends primarily upon our ability to identify and validate new therapeutic candidates, and to identify, develop and commercialize new drugs and biologics. Our research efforts may initially show promise in discovering potential new drugs and biologics, yet fail to yield single-agent and combination therapy candidates for clinical development for a number of reasons, including:

- we may need to rely on third parties to generate molecules for some of our single-agent or combination therapy candidate programs;
- we may encounter drug manufacturing difficulties that limit yield or produce undesirable characteristics that increase the cost of manufacturing our single-agent and combination therapy candidates, cause delays or make our single-agent and combination therapy candidates unmarketable;
- our single-agent and combination therapy candidates may cause adverse effects in patients or subjects, even after successful initial toxicology studies, which may make the single-agent and combination therapy candidates unmarketable;
- our single-agent and combination therapy candidates may not demonstrate a meaningful benefit to patients or subjects; and
- our future collaboration partners may change their development profiles or plans for potential single-agent and combination therapy candidates or abandon a therapeutic area or the development of a partnered single-agent or combination therapy candidate.

If any of these events occur, we may be forced to abandon our development efforts for one or more programs, which could have a material adverse effect on our business, operating results and prospects and could potentially cause us to cease operations. Future research programs to identify new single-agent and combination therapy candidates may require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or single-agent and combination therapy candidates that ultimately prove to be unsuccessful.

Single-agent and combination therapy candidates may require additional, time-consuming development efforts prior to commercial sale, including preclinical studies, clinical trials and approval by the FDA and/or comparable foreign regulatory authorities. All single-agent and combination therapy candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the single-agent or combination therapy candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot assure you that any such products that are approved will be manufactured or produced economically, be successfully commercialized, be widely accepted in the marketplace, or be more effective than other commercially available alternatives.

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 single-agent and combination therapy candidates.

We face an inherent risk of product liability as a result of the clinical testing of our single-agent and combination therapy 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 single-agent and combination therapy 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 single-agent and combination therapy 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 single-agent and combination therapy 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 single-agent and combination therapy 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, in the future, 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 single-agent or combination therapy candidates, we intend to expand our insurance coverage to include the sale of such single-agent or combination therapy 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 in China, 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;

- 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 2017 Equity Incentive Plan or our 2021 Incentive Award Plan;
- 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, 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 single-agent and combination therapy 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 or 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 may be expensive, 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.

We face potential liability related to the privacy of health information we utilize in the development of products, as well as information we obtain from clinical trials sponsored by us from research institutions and directly from individuals.

We and our partners and vendors are subject to various federal, state and foreign data protection laws and regulations (*i.e.*, laws and regulations that address data privacy and security). If we or our partners or vendors fail to comply with these laws and regulations we may be subject to litigation, regulatory investigations, enforcement notices, enforcement actions, fines, and criminal or civil penalties, as well as negative publicity and a potential loss of business.

In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state 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 Federal Trade Commission Act.

In addition, once we commence clinical trials, 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. These state laws include the recently enacted California Consumer Privacy Act, or the CCPA, which establishes additional data privacy rights for residents of the State of California, including expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used. The CCPA also provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA has been amended from time to time, and it remains unclear what, if any, further modifications will be made to this legislation or how it will be interpreted. Further, in November 2020, the California Privacy Rights Act, or the CPRA, was voted into law by California residents. The CPRA significantly amends the CCPA, and imposes additional data protection obligations on companies doing business in California, including additional consumer rights processes and opt outs for certain uses of sensitive data. It also creates a new California data protection agency specifically tasked to enforce the law, which would likely result in increased regulatory scrutiny of California businesses in the areas of data protection and security. The substantive requirements for businesses subject to the CPRA will go into effect in January 2023, and become enforceable in July 2023. Similar laws have been proposed in other states and at the federal level, and if passed, such laws may have potentially conflicting requirements that would make compliance challenging.

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 Europe, the General Data Protection Regulation, or 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 detailed notices and consent requirements for clinical trial subjects and investigators and other data subjects, 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 honoring and providing for the rights of individuals within the EEA and the United Kingdom in relation to their personal data, including the right to access, correct and delete their 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. Further, following the United Kingdom's withdrawal from the EU effective as of December 31, 2020, we will have to comply with the GDPR and the GDPR as incorporated into United Kingdom national law, which may have differing requirements. If we fail to comply with any such data protection laws, we may be subject to litigation, regulatory investigations, enforcement notices, and/or enforcement actions, as well as negative publicity and a potential loss of business.

We are also subject to evolving EEA laws on data export, as we may transfer personal data from the EEA to other jurisdictions. Recent legal developments in Europe have created complexity and uncertainty regarding transfers of personal data from the EEA to the United States. For example, in July 2020, the Court of Justice of the European Union, or CJEU, invalidated the EU-US Privacy Shield Framework, or Privacy Shield, under which personal data could be transferred from the EEA to United States entities who had self-certified under the Privacy Shield scheme. Moreover, it is uncertain whether the standard contractual clauses will also be invalidated by the European courts or legislature. As government authorities issue further guidance on personal data export mechanisms 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. These laws and regulations may apply, not only to us, but also to vendors that store or otherwise process data on our behalf, such as information technology vendors. If such a vendor misuses data we have provided to it, or fails to safeguard such data, we may be subject to litigation, regulatory investigations, enforcement notices, and/or enforcement actions, as well as negative publicity and a potential loss of business.

We are likely to 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 adverse events. 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 a number of 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 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. As a result of the COVID-19 pandemic, we may face increased risks of a security breach or disruption due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. The costs to us to investigate, mitigate and remediate security incidents, breaches, disruptions, network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service, negative publicity and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Any security compromise affecting us, our partners or our industry, whether real or perceived, could harm our reputation, erode confidence in the effectiveness of our security measures and lead to regulatory scrutiny. Moreover, if a computer security breach affects our systems or results in the unauthorized access to or unauthorized use, disclosure, release or other processing of personally identifiable information or clinical trial data, it may be necessary to notify individuals, governmental authorities, supervisory bodies, the media and other parties pursuant to privacy and security laws, and our reputation could be materially damaged. We would also be exposed to a risk of loss, governmental investigations or enforcement, or litigation and potential liability, which could materially adversely affect our business, results of operations and financial condition.

Our internal computer systems, or those used by our third-party research institution collaborators, CROs or other contractors or consultants, may fail or suffer security breaches.

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to intellectual property, proprietary business information and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have

outsourced elements of our operations to third parties, and as a result we manage a number of third-party contractors who have access to our confidential information.

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 to our knowledge we have not experienced any such 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. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in 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 single-agent and combination therapy candidates and other third parties for the manufacture of our single-agent and combination therapy candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. 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 single-agent and combination therapy candidates could be delayed.

While we have not experienced any such system failure, accident or security breach to date, 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. For example, 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 programs and the development of our single-agent and combination therapy candidates could be delayed. In addition, the loss of clinical trial data for our single-agent and combination therapy candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions of our internal information technology systems, or those of our third-party CROs, vendors and other contractors and consultants, or security breaches could result in the loss, misappropriation, and/or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information, and personal information), which could result in financial, legal, business, and reputational harm to us. For example, any such 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 directly, 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.

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.

The costs related to significant security breaches or disruptions could 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.

Risks Related to Doing Business in China

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

Some of our research and development operations and manufacturing facilities are in the People's Republic of China, which we refer to as China or PRC. 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 single-agent and combination therapy 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 single-agent and combination therapy candidates. We engage competent third-party contractors for the transfer and disposal of these materials and wastes. 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.

China's economic, political and social conditions, as well as governmental policies, could affect the business environment and financial markets in China, our ability to operate our business, our liquidity and our access to capital.

Substantially all of our manufacturing operations are 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 over the past 40 years, growth

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 benefit the overall economy in China, but 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.

Failure to comply with PRC regulations regarding the registration requirements for employee stock ownership plans or share option 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 share-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 as a result of the COVID-19 pandemic. 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 two clinical-stage drug candidates or any other future clinical development programs, including any delays related to the COVID-19 pandemic;
- announcements of regulatory approval or disapproval of our current or any future single-agent and combination therapy 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 single-agent and combination therapy candidates;

- public misperception regarding the use of our single-agent and combination therapy candidates;
- acquisitions and sales of new products or single-agent and combination therapy candidates, technologies or businesses;
- manufacturing and supply issues related to our single-agent and combination therapy candidates for clinical trials or future single-agent and combination therapy 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;
- 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 single-agent and combination therapy candidates;
- product liability claims or other litigation or public concern about the safety of our single-agent and combination therapy 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 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 applicable to other public companies that are not 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 $1.07 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.

Our principal stockholders and management own a significant percentage of our stock and are able to exert significant control over matters subject to stockholder approval.

Based upon the number of shares of common stock outstanding as of March 19, 2021, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 63.8% of our outstanding voting stock. These stockholders will have the ability to influence us through their ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

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

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up and other legal restrictions on resale lapse, the trading price of our common stock could decline. Based upon the number of shares outstanding as of March 19, 2021, we had outstanding a total of 25,125,072 shares of common stock.

The resale of 16,471,720 shares, or 65.6% of our outstanding shares of common stock, is currently prohibited or otherwise restricted as a result of securities law provisions, market standoff agreements entered into by certain of our stockholders with us or lock-up agreements entered into by our stockholders with the underwriters in connection with our IPO. The lock-up agreements pertaining to the IPO will expire in August 2021. After the lock-up agreements expire, these shares of common stock will be eligible for sale in the public market, including certain shares held by directors, executive officers and other affiliates which will be subject to Rule 144 under the Securities Act of 1933, as amended, or the Securities Act. The representatives may, however, in their sole discretion, permit our officers, directors and other stockholders who are subject to these lock-up agreements to sell shares prior to the expiration of the lock-up agreements.

In addition, we had an aggregate of 2,566,282 shares of common stock that are subject to outstanding options as of March 19, 2021. Any shares subject to vested options will become eligible for sale in the public market to the extent permitted by the provisions of the lock-up agreements and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

The holders of approximately 16,079,230 shares of our common stock, or approximately 64.0% of our total outstanding shares of common stock as of March 19, 2021, are entitled to rights with respect to the registration of their shares under the Securities Act, subject to the lock-up agreements described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

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 may have experienced ownership changes in the past and may experience ownership changes as a result of our IPO and/or 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.

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. There can be no assurance that analysts will continue to cover us or provide favorable coverage. In the event any of the analysts who cover us issue an adverse or misleading opinion regarding 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.

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.

As a California-domiciled public company, we are required to have at least two or three women and at least one director from an underrepresented community on our board of directors by the end of 2021, depending on the size of our board at the time.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified individuals to our board of directors. As a public company headquartered in California, we are required to have two or three women on our board of directors by the end of 2021, depending on the size of our board of directors at the time. We are also required to have at least one director from an underrepresented community by the end of 2021 and to have two or three two or three directors from an underrepresented community by the end of 2022, depending on the size of our board of directors at the time. We currently have two women and three directors from an underrepresented community on the board of directors. Recruiting and retaining board members carries uncertainty, and failure to comply with this California requirement will result in financial penalties.

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.

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.

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.

General Risk Factors

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, including a recession or depression resulting from the current COVID-19 pandemic, or political disruption could result in a variety of risks to our business, including weakened demand for our current or future single-agent and combination therapy 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.

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 single-agent and combination therapy 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 single-agent and combination therapy 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 single-agent and combination therapy 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.

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 Stock Market LLC and the rules of the Securities and Exchange Commission, or 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. Beginning with the second annual report that we will be required to file with the SEC, 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 applicable to public companies that are not 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, we may not detect 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.

Future sales and issuances of our common stock could 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.

Item 1B. Unresolved Staff Comments.

None.

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 June 2022. We also lease approximately 3,500 square feet of space for our current China office in Shanghai, China under an agreement that expires in May 2021, as well as approximately 6,000 square feet of space for our CMC chemistry, manufacturing and controls lab in Suzhou, China under an agreement that expires in September 2022. 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, 2020, 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 and other factors, and there can be no assurances that favorable outcomes will be obtained.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

Our common stock began trading on The Nasdaq Global Market on 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 19, 2021, there were approximately 31 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 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. In addition, our ability to pay cash dividends on our capital stock may be limited by the terms of any future debt or preferred securities we issue or any credit facilities we enter into.

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.

Recent Sales of Unregistered Securities

From January 1, 2020 through December 31, 2020, we sold and issued the following unregistered securities:

1. In May 2020, we issued and sold $15.0 million in aggregate principal amount of convertible promissory notes, or the 2020 Notes, and $1.8 million in aggregate principal amount of a bridge loan in China, or the China Bridge Loan.
2. In December 2020, we issued and sold an aggregate of 7,500,665 shares of Series C convertible preferred stock to 13 accredited investors at $11.65 per share for gross proceeds of approximately $87.4 million (inclusive of the conversion of the 2020 Notes and the effective conversion of the China Bridge Loan, plus accrued interest).
3. We granted to our directors, employees and consultants options to purchase 2,137,169 shares of our common stock with per share exercise prices ranging from $6.72 to $9.24 under our 2017 Equity Incentive Plan, as amended, or the 2017 Plan.
4. We issued to certain of our directors, employees and consultants an aggregate of 38,285 shares of our common stock at per share purchase prices ranging from $1.96 to $6.86 pursuant to exercises of options under the 2017 Plan for an aggregate purchase price of $0.1 million.

The offers, sales and issuances of the securities described in paragraphs (1) and (2) were deemed to be exempt from registration under Rule 701 promulgated under the Securities Act as transactions under compensatory benefit plans and contracts relating to compensation, or under Section 4(a)(2) of the Securities Act of 1933, as amended, or the Securities Act, as a transaction by an issuer not involving a public offering. The recipients of such securities were our directors, employees or bona fide consultants and received the securities under our equity incentive plans.

Appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment, business or other relationships, to information about us.

The offers, sales and issuances of the securities described in paragraphs (3) and (4) were deemed to be exempt under Section 4(a)(2) of the Securities Act or Rule 506 of Regulation D under the Securities Act as a transaction by an issuer not involving a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited investor within the meaning of Rule 501 of Regulation D under the Securities Act and had adequate access to information about us. No underwriters were involved in these transactions.

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 approximately $132.9 million, after deducting underwriting discounts and commissions of approximately $10.3 million and offering expenses of approximately $3.5 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.

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. Selected Financial Data.

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and are not required to provide the information required under this item.

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 single-agent and combination therapy candidates for the treatment of non-alcoholic steatohepatitis, or NASH, and other chronic liver diseases. Our programs are based on clinically-validated and complementary mechanisms of action to address the multiple hepatic disease processes of NASH in order to drive meaningful clinical benefits for patients. The mechanisms of action targeted by our current drug candidates are the same mechanisms of action targeted by other drug candidates that have achieved clinical proof-of-concept in NASH clinical trials and have demonstrated significant improvements on histological and non-invasive markers of the disease, though no drug has been approved for the treatment of NASH in the United States or Europe. Our most advanced program is TERN-101, a liver-distributed, non-bile acid Farnesoid X Receptor, or FXR, agonist that has demonstrated sustained liver FXR activation, as well as a favorable tolerability profile across multiple Phase 1 clinical trials. In our Phase 1 clinical trials, no pruritus, or itching, or increases in LDL cholesterol levels as compared to the control group were observed—unlike in Phase 1 clinical trials of other FXR agonists conducted by third parties. Our Phase 2a clinical trial of TERN-101 in NASH patients (the LIFT Study) was fully enrolled in January 2021 and we expect top-line data in July 2021. Our second clinical stage program, TERN-201, is a highly selective inhibitor of Vascular Adhesion Protein-1, or VAP-1. We intend to start our Phase 1b clinical trial of TERN-201 in NASH patients in the first half of 2021 and expect top-line data in the first half of 2022. Our third clinical stage program is TERN-501, a Thyroid Hormone Receptor beta, or THR-β, agonist with high metabolic stability, enhanced liver distribution and greater selectivity for THR-β compared to other THR-β agonists in development. In January 2021, the FDA cleared our investigational new drug application for TERN-501. In March 2021, we announced the initiation of our Phase 1 first-in-human clinical trial of TERN-501 and we expect top-line data in the second half of 2021. We are also pursuing two combination therapy programs to address the multiple disease processes of NASH and expect.

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 single-agent or combination therapy 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 single-agent or combination therapy 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 single-agent or combination therapy candidates. If we obtain regulatory approval for any of our single-agent or combination therapy candidates, we expect to incur significant expenses related to developing our internal commercialization capability to support product sales, marketing and distribution.

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of our single-agent and combination therapy candidates for preclinical and clinical testing, as well as for commercial manufacturing if any of our single-agent and combination therapy candidates obtain marketing approval. We believe that this strategy allows us to maintain a more efficient infrastructure by eliminating the need for us to invest in our own manufacturing facilities, equipment and personnel while also enabling us to focus our expertise and resources on the development of our single-agent and combination therapy candidates. The coronavirus disease 2019, or COVID-19, pandemic is rapidly evolving. The COVID-19

pandemic continues to impact countries worldwide, including the United States, or U.S., and China where we have business operations. The extent of the impact of the COVID-19 pandemic on our business, operations and development timelines and plans remains uncertain, and will depend on certain developments, including the duration and spread of the outbreak and its impact on our development activities, planned clinical trial enrollment, future trial sites, contract research organizations, or CROs, third-party manufacturers and other third parties with whom we do business, as well as its impact on regulatory authorities and our key scientific and management personnel. The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. To the extent possible, we are conducting business as usual, with necessary or advisable modifications to employee travel and with our employees working remotely. We will continue to actively monitor the rapidly evolving situation related to the COVID-19 pandemic and may take further actions that alter our operations, including those that may be required by federal, state or local authorities in the U.S. and China, or that we determine are in the best interest of our employees and other third parties with whom we do business. At this point, the extent to which the COVID-19 pandemic may affect our business, operations and development timelines and plans, including the resulting impact on our expenditures and capital needs, remains uncertain.

Components of our results of operations

Revenue

To date, we have not generated, and do not expect to generate, any revenue from the sale of products for the foreseeable future.

Operating expenses

Research and development

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 single-agent and combination therapy candidates. To date, our research and development expenses have related primarily to discovery efforts, preclinical and clinical development of our single-agent and combination therapy 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.

External expenses include:

- expenses incurred in connection with the discovery, preclinical and clinical development of our single-agent and combination therapy candidates, including those incurred under agreements with third parties, such as consultants and 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
- facility costs including rent, depreciation and maintenance expenses.

We may also incur in-process research and development expense as we acquire or in-license assets from other parties. 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.

Internal expenses include employee and personnel-related costs and expenses, including salaries, benefits and stock-based compensation expense for employees and personnel engaged in research and development functions.

We typically use our employee, consultant and infrastructure resources across our development programs. We track outsourced development costs by drug candidate or preclinical program, but we do not allocate personnel costs, other internal costs or external consultant costs to specific drug candidates or preclinical programs.

Our direct research and development expenses are tracked on a program-by-program basis for our drug and combination therapy candidates and consist primarily of external costs, such as fees paid to outside consultants, CROs and CMOs in connection with our preclinical development, manufacturing and clinical development activities. Our direct research and development expenses by program also include fees incurred under our license agreements. We do not allocate employee costs or facility expenses, including depreciation or other indirect costs, to specific programs because these costs are deployed across multiple programs and, as such, are not separately classified. 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. These employees work across multiple programs and, therefore, we do not track their costs by program.

We expect our research and development expenses to increase substantially in absolute dollars for the foreseeable future as we advance our single-agent and combination therapy candidates or any other future single-agent or combination therapy candidates we may develop into and through preclinical studies and clinical trials and pursue regulatory approval of our single-agent and combination therapy 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 single-agent and combination therapy candidates or any other future single-agent or combination therapy candidate that we may develop may be affected by a variety of factors including: the safety and efficacy of our single-agent and combination therapy candidates, early clinical data, investment in our clinical program, the ability of collaborators to successfully develop our licensed single-agent and combination therapy candidates, competition, manufacturing capability and commercial viability. We may never succeed in achieving regulatory approval for our single-agent and combination therapy 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 single-agent and combination therapy candidates or any other future single-agent and combination therapy candidates we may develop. The duration, costs and timing of preclinical studies and clinical trials and development of our single-agent and combination therapy candidates will depend on a variety of factors.

General and administrative

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 resource and other administrative functions. General and administrative expenses also include corporate facility costs not otherwise included in research and development expenses, 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 substantially 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. We also anticipate incurring additional expenses associated with operating as a public company, including increased expenses related to accounting, legal and regulatory matters, compliance, director and officer insurance, investor and public relations and tax-related services associated with maintaining compliance with the rules and regulations of the SEC and standards applicable to companies listed on a national securities exchange, additional insurance expenses, investor relations activities and other administrative and professional services.

Other income (expense)

Interest income

Interest income primarily consists of interest income on our marketable securities and short-term investments.

Change in fair value of loans payable

Change in fair value of loans payable primarily consists of the difference in fair value for our convertible loans payable between May 2020 and December 2020. As our U.S. convertible promissory notes and Chinese convertible bridge loan were converted in December 2020, remeasurement from the loans payable will no longer be required and we will no longer record such expenses (or income).

Foreign exchange gain (loss)

Foreign exchange gain (loss) primarily consists of foreign exchange gain or loss and government grants received by our majority-owned subsidiary Terns China Biotechnology Co., Ltd. (organized in Shanghai, People's Republic of China, or PRC), or Terns China. Our assets and liabilities from our subsidiaries Terns Biotechnology Co., Ltd. Suzhou PRC, or Terns Suzhou, and our majority-owned subsidiary Terns China are translated from their functional currency of the Chinese Yuan, or CNY, to the U.S. dollar reporting currency 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 income (loss) on the consolidated balance sheets.

Income Taxes

We account for income taxes using an asset and liability approach. Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Valuation allowances are provided when necessary to reduce net deferred tax assets to an amount that is more likely than not to be realized.

In determining whether a valuation allowance for deferred tax assets is necessary, we analyze both positive and negative evidence related to the realization of deferred tax assets and inherent in that, assess the likelihood of sufficient future taxable income. We also consider the expected reversal of deferred tax liabilities and analyze the period in which these would be expected to reverse to determine whether the taxable temporary difference amounts serve as an adequate source of future taxable income to support the realizability of the deferred tax assets. In addition, we consider whether it is more likely than not that the tax position will be sustained upon examination by taxing authorities based on the technical merits of the position.

We are subject to income taxes in the U.S. and foreign countries, and we are subject to routine corporate income tax audits in these jurisdictions. We believe that our tax return positions are fully supported, but tax authorities are likely to challenge certain positions, which may not be fully sustained. Our income tax expense includes amounts intended to satisfy income tax assessments that result from these challenges in accordance with the accounting for uncertainty in income taxes prescribed by U.S. generally accepted accounting principles, or U.S. GAAP. Determining the income tax expense for these potential assessments and recording the related assets and liabilities requires management judgments and estimates.

Results of operations

The following table summarizes our results of operations for the years ended December 31, 2020 and 2019:

(in thousands)	Year Ended December 31, 2020	2019	Change
Results of Operations			
Operating expenses:			
Research and development	$ 28,029	$ 61,534	$ (33,505)
General and administrative	8,996	8,663	333
Total operating expenses	37,025	70,197	(33,172)
Loss from operations	(37,025)	(70,197)	33,172
Other income (expense):			
Interest income	55	1,204	(1,149)
Change in fair value of loans payable	(2,887)	—	(2,887)
Other income, net	99	154	(55)
Total other (expense) income, net	(2,733)	1,358	(4,091)
Loss before income tax (expense) benefit	(39,758)	(68,839)	29,081
Income tax (expense) benefit	(813)	20	(833)
Net loss	$ (40,571)	$ (68,819)	$ 28,248

Revenue

To date, we have not generated, and do not expect to generate, any revenue from the sale of products for the foreseeable future.

Research and development expenses

Our research and development expenses are related primarily to discovery efforts, preclinical and clinical development of our single-agent and combination therapy candidates.

Research and development expenses for the twelve months ended December 31, 2020 were $28.0 million, compared to $61.5 million for the same period in 2019. The decrease in expenses of $33.5 million was primarily due to a $35.0 million one-time upfront payment made in connection with the Genfit collaboration agreement that occurred in 2019. Excluding such payment, research and development expenses increased by $1.5 million primarily due to a $0.8 million increase in employee-related expenses as higher headcount increased salaries, benefits, and stock-based compensation-related charges. In addition, there was a $0.7 million increase due to higher facility-related and depreciation expenses allocated to research and development 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 resource and other administrative functions.

General and administrative expenses for the twelve months ended December 31, 2020 were $9.0 million, compared to $8.7 million for the same period in 2019. The increase of $0.3 million was primarily due to a $0.9 million increase in employee-related expenses as higher headcount increased salaries, benefits, and stock-based compensation-related charges. In addition, there was a $0.1 million increase in IT-related and other professional services consulting. These increases were partially offset by a $0.7 million decrease due to higher facility-related and depreciation expenses allocated to research and development expenses.

Interest income

Interest income primarily consists of interest income on our marketable securities and short-term investments.

Interest income for the twelve months ended December 31, 2020 was $0.1 million, compared to $1.2 million for the same period in 2019. The decrease of $1.1 million was primarily due to the maturity of marketable securities during 2020.

Change in fair value of loans payable

The change in fair value of loans payable for the twelve months ended December 31, 2020 was a charge of $2.9 million. The change in the fair value of loans payable was due to the difference in fair value for our convertible loans payable between May 2020, when they were issued, and December 2020. Our U.S. convertible promissory notes and Chinese convertible bridge loan were converted in December 2020.

Other income, net

Other income, net for the twelve months ended December 31, 2020 was $0.1 million compared to less than $0.2 million for the same period in 2019.

Income tax (expense) benefit

Income tax expense for the twelve months ended December 31, 2020 was $0.8 million, compared to an income tax benefit of less than $0.1 million for the same period in 2019. The $0.7 million increase was primarily due to the recording of a full valuation allowance against our U.S. net deferred tax assets as we believe these deferred tax assets were not realizable on a more likely than not basis as of December 31, 2020.

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 expect to continue to incur net operating losses for at least the next several years, and we expect our research and development expenses, general and administrative expenses and capital expenditures will continue to increase. We expect our expenses and capital requirements will increase significantly in connection with our ongoing activities.

Sources of liquidity

We have principally funded our operations primarily through proceeds from the sale of shares of our common stock, convertible preferred stock and sale of our 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, 2020, we had an accumulated deficit of approximately $132.0 million, a net loss of approximately $40.6 million, negative cash flows from operations of approximately $29.6 million, and cash and cash equivalents of $74.9 million.

In May 2020, we received proceeds of $16.8 million from the issuance of convertible promissory notes (2020 Notes) and a bridge loan (Bridge Loan).

In December 2020, we issued and sold shares of our convertible preferred stock for gross proceeds of approximately $87.4 million (including conversion of the $15.0 million of 2020 Notes and effective conversion of the $1.8 million Bridge Loan, plus accrued interest).

In February 2021, we completed our initial public offering of 8,625,000 shares of our common stock, including the exercise in full by the underwriters of their option to purchase additional shares of common stock. The net proceeds from this offering were $132.9 million after deducting underwriting discounts and commissions and offering expenses.

We believe that the net proceeds from these transactions, together with our existing cash and cash equivalents, will be sufficient to fund our operating expenses and capital expenditure requirements into 2024. We will need substantial additional funding to support our operating activities.

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 single-agent and combination therapy candidates. We expect that our research and development and general and administrative costs will increase in connection with conducting additional preclinical studies and clinical trials for our current and future research programs and single-agent and combination therapy candidates, contracting with 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 single-agent and combination therapy candidates. In addition, if we obtain marketing approval for our single-agent and combination therapy 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. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we 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 single-agent and combination therapy 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 single-agent and combination therapy 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 single-agent and combination therapy candidates.

Identifying potential single-agent and combination therapy candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes many years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our single-agent and combination therapy candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of single-agent and combination therapy candidates that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

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 shareholder. 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 single-agent and combination therapy candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market single-agent and combination therapy candidates that we would otherwise prefer to develop and market ourselves.

Cash flows

Operating activities

Net cash used in operating activities during the year ended December 31, 2020 was $29.8 million and consisted primarily of our net loss of $40.6 million. This was partially offset by non-cash adjustments from a $2.9 million loss from the change in fair value of loans payable, $1.7 million of stock-based compensation expense, a $0.7 million change in deferred taxes and uncertain tax positions, and $0.4 million of depreciation expense, as well as a $5.1 million increase from changes in operating assets and liabilities primarily attributable to program related services incurred and payable as of December 31, 2020.

Net cash used in operating activities during the year ended December 31, 2019 was $66.2 million and consisted primarily of our net loss of $68.8 million. This was partially offset by non-cash adjustments from $0.7 million of stock-based compensation and $0.2 million of depreciation expense, as well as a $1.8 million increase from changes in operating assets and liabilities primarily attributable to program-related services incurred and payable as of December 31, 2019.

Investing activities

Net cash provided by investing activities during the year ended December 31, 2020 was $6.7 million and consisted primarily of $5.6 million in proceeds from the sale and maturity of marketable securities and $2.4 million of proceeds from the sale and maturity of short-term investments, offset by a $0.7 million purchase of short-term investments and a $0.6 million purchase of property and equipment.

Net cash used in investing activities during the year ended December 31, 2019 was $3.9 million and consisted primarily of $45.1 million in purchases of marketable securities, $13.3 million in purchases of short-term investments

and $0.9 million in purchases of property and equipment, offset by $39.5 million in proceeds from the sale and maturity of marketable securities and $15.9 million in proceeds from the sale and maturity of short-term investments.

Financing activities

Net cash provided by financing activities during the year ended December 31, 2020 was $85.5 million and consisted primarily of $69.4 million in proceeds from the issuance of Series C convertible preferred stock and $16.9 million in proceeds from the issuance of loans payable, partially offset by $0.8 million payments of deferred offering costs related to our IPO completed in February 2021.

Net cash provided by financing activities during the year ended December 31, 2019 was nominal.

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 2, 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.

Fair value of common stock prior to our IPO

Historically, for all periods in 2020, which is prior to the completion of our IPO in February 2021, the fair value of our common stock was estimated on each grant date by our board of directors. In order to determine the fair value, our board of directors considered, among other things, contemporaneous valuations of our common stock and preferred stock prepared by unrelated third-party valuation firms in accordance with the guidance provided by the American Institute of Certified Public Accountants 2013 Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, or the Practice Aid.

Given the absence of a public trading market of our shares of capital stock in 2020, our board of directors exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of our shares of common stock and preferred stock, including:

- the prices at which we sold shares of convertible preferred stock and the superior rights and preferences of the convertible preferred stock relative to its common stock;
- the progress of our research and development programs, including the status and results of preclinical studies for its single-agent and combination therapy candidates;
- our stage of development and commercialization and our business strategy;

- external market conditions affecting the biotechnology industry and trends within the biotechnology industry;
- our financial position, including cash on hand, and its historical and forecasted performance and operating results;
- the lack of an active public market for our common stock and convertible preferred stock;
- the likelihood of achieving a liquidity event, such as an IPO, or sale of our company in light of prevailing market conditions; and
- the analysis of IPOs and the market performance of similar companies in the biotechnology industry.

Significant changes to the key assumptions underlying the factors used could have resulted in different fair values of common stock at each valuation date.

Since becoming a public company in February 2021, we have used our stock price to determine fair value of our common stock.

Common stock valuation methodology prior to our IPO

We obtained contemporaneous third-party valuations of our common stock as of the dates on which our board of directors granted equity awards. In August 2017, June 2018, June 2019 and September 2020, we used third party valuations of our common stock prepared using the income approach, which focuses on the income-producing capability of a business. The income approach estimates value based on the expectation of future cash flows that a company will generate such as cash earnings, cost savings, tax deductions, and the proceeds from disposition. These cash flows are discounted to the present using a rate of return that incorporates the risk-free rate for the use of funds, the expected rate of inflation, and risks associated with the particular investment. The selected discount rate is generally based on rates of return available from alternative investments of similar type, quality, and risk. Once the value of our company was estimated it was allocated to our common shares using the Option Pricing Method, or OPM. This approach allows for the allocation of a company's equity value among the various equity capital owners (preferred and common stockholders). The OPM uses the preferred stockholders' liquidation preferences, participation rights, dividend policy, and conversion rights to determine how proceeds from a liquidity event shall be distributed among the various ownership classes at a future date.

The probability weighted expected return method (PWERM) involves the estimation of future potential outcomes for our company, as well as values and probabilities associated with each respective potential outcome. The common stock per share value determined using this approach is ultimately based upon probability-weighted per share values resulting from the various future scenarios, which can include an IPO, merger or sale, dissolution or continued operation as a private company.

These contemporaneous third-party valuations using the OPM method resulted in valuations of our common stock of $1.96 as of August 2017, $2.38 as of March 2018, $6.16 as of October 2018, $6.72 as of June 2019 and $6.86 as of June 2020. In October 2020, in connection with the preparation of our financial statements, we conducted a retrospective valuation of our common stock as of June 2019 and June 2020 and determined that the grant date fair value was $9.24 per share and $12.04 per share, respectively, solely for accounting purposes. In addition, in October 2020, in connection with the preparation of our financial statements, a third-party retrospective valuation of our common stock using the PWERM as of September 2020 resulted in a valuation of $23.38 per share. In November 2020, a third-party retrospective valuation of our common stock using the PWERM resulted in a valuation of $9.24 per share.

The assumptions underlying these valuations represented our board of directors' best estimates at the time they were made, which involve inherent uncertainties and the application of the judgment of our board of directors. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our stock-based compensation expense could be materially different.

Since becoming a public company in February 2021, we have used our stock price to determine fair value of our common stock.

Loans Payable

We have elected to record certain loans payable at fair value on the date of issuance, with gains and losses arising from changes in fair value recognized in the statements of operations at each period end while such loans payable are outstanding. Issuance costs are recognized in the statement of operations in the period in which they are incurred. The fair value of the loans payable was determined using a probability weighted expected return model, a scenario-based valuation model in which discrete future outcome scenarios for our company are projected and discounted to present value.

Accrued research and development expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing purchase orders and open contracts, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the services when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met; however, some require advance payments. We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. The significant estimates in our accrued research and development expenses include the costs incurred for services performed by CROs and CMOs among others, in connection with research and development activities for which we have not yet been invoiced.

We contract with CROs and CMOs to conduct clinical and manufacturing and other research and development services on our behalf. We base our expenses related to CROs and CMOs on our estimates of the services received and efforts expended pursuant to quotes and contracts with them. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our CROs or CMOs will exceed the level of services provided and result in a prepayment of the research and development expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or amount of prepaid expense accordingly. Non-refundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

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 cease to be an "emerging growth company" on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more, (ii) the last day of the fiscal year in which the fifth anniversary of the completion of the IPO occurs, (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years or (iv) the last day of the fiscal year in which we are deemed to be a large accelerated filer under the rules of the SEC, which generally is when we have more than $700.0 million in market value of our stock held by non-affiliates as of the last day of the second fiscal quarter and we have been a public company for at least 12 months and have filed one annual report.

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 2, 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.

Substantially all of our operations are within the United States and the People's Republic of China, or PRC, and we are exposed to market risks in the ordinary course of our business, including the effects of foreign currency fluctuations, interest rate changes and inflation. Information relating to quantitative and qualitative disclosures about these market risks is set forth below.

Interest rate risk

Cash, cash equivalents, marketable securities and short-term investments are held primarily in bank and time deposits. The fair value of our cash and short-term investments 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 substantial majority of our expense-related transactions are denominated in Chinese Yuan, or CNY, which is the functional currency of Terns Suzhou and Terns China. Our commercial transactions outside the PRC are primarily denominated in U.S. dollars. We do not hedge against currency risk. In the past years, CNY continued to appreciate against the U.S. dollar. To the extent that we need to convert U.S. dollars into CNY for our operations, appreciation of CNY against the U.S. dollar would reduce the CNY amount we receive from the conversion. Conversely, if we decide to convert CNY into U.S. dollars, appreciation of the U.S. dollar against the CNY would reduce the U.S. dollar amounts available to us.

Effects of inflation

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

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, 2020:

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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, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, noncontrolling interest, convertible preferred stock and stockholders' deficit and cash flows for each of the two years in the period ended December 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, 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 Jose, California
March 30, 2021

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

	December 31,	
	2020	2019
Assets		
Current assets:		
Cash and cash equivalents	$ 74,854	$ 12,327
Marketable securities	—	5,600
Short-term investments	—	1,723
Notes receivable	12,718	—
Deferred offering costs	2,137	—
Prepaid expenses and other current assets	1,160	2,574
Total current assets	90,869	22,224
Property and equipment, net	1,175	961
Other assets	246	719
Total assets	$ 92,290	$ 23,904
Liabilities, Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 935	$ 1,636
Accrued expenses and other current liabilities	9,006	3,314
Loans payable	12,880	—
Total current liabilities	22,821	4,950
Deferred rent, net of current portion	220	285
Taxes payable, noncurrent	657	345
Total liabilities	23,698	5,580
Commitments and contingencies		
Noncontrolling interest	—	14,117
Convertible preferred stock, $0.0001 par value; 188,029,084 and 76,409,088 shares authorized as of December 31, 2020 and 2019, respectively; 12,958,452 and 4,473,480 shares issued and outstanding as of December 31, 2020 and 2019, respectively; aggregate liquidation value of $197,468 and $95,371 as of December 31, 2020 and 2019, respectively	186,033	94,967
Stockholders' deficit:		
Common stock, $0.0001 par value, 299,700,000 and 100,000,000 shares authorized at December 31, 2020 and 2019, respectively; 337,508 and 215,890 shares issued and outstanding at December 31, 2020 and 2019, respectively	—	—
Additional paid-in capital	14,598	1,208
Accumulated other comprehensive loss	(124)	(106)
Accumulated deficit	(131,915)	(91,862)
Total stockholders' deficit	(117,441)	(90,760)
Total liabilities, noncontrolling interest, convertible preferred stock and stockholders' deficit	$ 92,290	$ 23,904

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,	
	2020	2019
Operating expenses:		
Research and development	$ 28,029	$ 61,534
General and administrative	8,996	8,663
Total operating expenses	37,025	70,197
Loss from operations	(37,025)	(70,197)
Other income (expense):		
Interest income	55	1,204
Change in fair value of loans payable	(2,887)	—
Other income, net	99	154
Total other (expense) income, net	(2,733)	1,358
Loss before income tax (expense) benefit	(39,758)	(68,839)
Income tax (expense) benefit	(813)	20
Net loss	(40,571)	(68,819)
Extinguishment of Series B convertible preferred stock	10,701	—
Net loss attributable to noncontrolling interest	(518)	(208)
Net loss attributable to common stockholders	$ (29,352)	$ (68,611)
Net loss per share attributable to common stockholders, basic and diluted	$ (102.93)	$ (374.39)
Weighted average common stock outstanding, basic and diluted	285,162	183,262
Other comprehensive income (loss):		
Net loss	$ (40,571)	$ (68,819)
Unrealized gain on available-for-sale securities, net of tax	—	2
Foreign exchange translation adjustment, net of tax	(18)	(166)
Comprehensive loss	(40,589)	(68,983)
Less: Comprehensive loss attributable to noncontrolling interest	(518)	(231)
Comprehensive loss attributable to common stockholders	$ (40,071)	$ (68,752)

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

TERNS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF NONCONTROLLING INTEREST, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(Amounts in thousands, except share data)

	Non-Controlling Interest	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Income (Loss) Comprehensive	Accumulated Deficit	Total Stockholders' Deficit
		Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balances at December 31, 2018	$ 14,325	2,089,285	$ 21,938	2,384,195	$ 73,029	—	$ —	104,761	$ —	$ 455	$ 59	$ (23,251)	$ (22,737)
Exercise of stock options	—	—	—	—	—	—	—	9,939	—	26	—	—	26
Vesting of restricted stock	—	—	—	—	—	—	—	101,190	—	59	—	—	59
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	668	—	—	668
Unrealized gain on available-for-sale securities	—	—	—	—	—	—	—	—	—	—	2	—	2
Unrealized loss on foreign currency translation	—	—	—	—	—	—	—	—	—	—	(167)	—	(167)
Net loss	(208)	—	—	—	—	—	—	—	—	—	—	(68,611)	(68,611)
Balances at December 31, 2019	$ 14,117	2,089,285	$ 21,938	2,384,195	$ 73,029	—	$ —	215,890	$ —	$ 1,208	$ (106)	$ (91,862)	$ (90,760)
Exercise of stock options	—	—	—	—	—	—	—	38,285	—	120	—	—	120
Vesting of restricted stock	—	—	—	—	—	—	—	83,333	—	23	—	—	23
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	1,691	—	—	1,691
LAV Option Exercise	(13,599)	767,857	8,062	216,450	6,667	—	—	—	—	(1,130)	—	—	(1,130)
Issuance of Series C convertible preferred stock, net of issuance costs of $330	—	—	—	—	—	5,966,686	69,170	—	—	—	—	—	—
Conversion of 2020 convertible promissory notes to Series C convertible preferred stock	—	—	—	—	—	1,366,820	15,921	—	—	1,769	—	—	1,769
Conversion of Bridge Loan to Series C convertible preferred stock	—	—	—	—	—	167,159	1,947	—	—	216	—	—	216
Extinguishment of Series B convertible preferred stock	—	—	—	(2,600,645)	(79,696)	—	—	—	—	10,701	—	—	10,701
Reissuance of Series B convertible preferred stock	—	—	—	2,600,645	68,995	—	—	—	—	—	—	—	—
Unrealized loss on foreign currency translation	—	—	—	—	—	—	—	—	—	—	(18)	—	(18)
Net loss	(518)	—	—	—	—	—	—	—	—	—	—	(40,053)	(40,053)
Balances at December 31, 2020	$ —	2,857,142	$ 30,000	2,600,645	$ 68,995	7,500,665	$ 87,038	337,508	$ —	$ 14,598	$ (124)	$ (131,915)	$ (117,441)

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,	
	2020	2019
Cash flows from operating activities:		
Net loss	$ (40,571)	$ (68,819)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,691	668
Depreciation and amortization expense	394	195
Amortization and accretion on marketable securities	37	(40)
Change in fair value of convertible notes	2,887	—
Change in deferred taxes and uncertain tax positions	693	(94)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,389	(987)
Other assets	102	(13)
Accounts payable	(1,146)	722
Accrued expenses and other current liabilities	4,780	1,858
Deferred rent	(65)	288
Net cash used in operating activities	(29,809)	(66,222)
Cash flows from investing activities:		
Purchase of property and equipment	(584)	(900)
Purchase of short-term investments	(715)	(13,314)
Proceeds from sale and maturity of short-term investments	2,431	15,919
Proceeds from sale and maturity of marketable securities	5,561	39,510
Purchase of marketable securities	—	(45,071)
Net cash provided by (used in) investing activities	6,693	(3,856)
Cash flows from financing activities:		
Net proceeds from issuance of Series C convertible preferred stock	69,377	—
Net proceeds from repayment of founders' loans	—	58
Payment of deferred offering costs	(858)	(22)
Proceeds from issuance of loans payable	16,876	—
Proceeds from stock option exercises	120	26
Net cash provided by financing activities	85,515	62
Effect of exchange rate changes on cash, cash equivalents and restricted cash	80	(131)
Net increase (decrease) in cash, cash equivalents and restricted cash	62,479	(70,147)
Cash, cash equivalents and restricted cash at beginning of period	12,375	82,522
Cash, cash equivalents and restricted cash at end of period	$ 74,854	$ 12,375
Supplemental disclosure of cash flow information:		
Cash paid for taxes	$ 178	$ 72
Supplemental disclosure of noncash investing and financing activities:		
LAV Option exercise	$ 13,599	$ —
Conversion of 2020 convertible promissory notes to Series C convertible preferred stock	$ 17,690	$ —
Conversion of Bridge Loan to Series C convertible preferred stock	$ 2,163	$ —
Extinguishment of Series B convertible preferred stock	$ 10,701	$ —
Deferred offering costs and Series C offering costs within accounts payable and accrued expenses	$ 1,519	$ —

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

1. Nature of the Business and Basis of Presentation

Terns Pharmaceuticals Inc. (Terns) is a clinical-stage biopharmaceutical company developing a portfolio of small-molecule single-agent and combination therapy candidates for the treatment of non-alcoholic steatohepatitis (NASH) and other chronic liver diseases. Terns was incorporated as an exempted company in the Cayman Islands with limited liability in December 2016. On December 29, 2020, the Company effected a de-registration of the Company in the Cayman Islands and a domestication in the State of Delaware (Domestication), pursuant to which it became a Delaware corporation and no longer subject to the laws of the Cayman Islands. Terns owns all of the share capital of Terns Pharmaceutical HongKong Limited (organized in Hong Kong) (Terns Hong Kong) and Terns, Inc., a Delaware corporation (Terns U.S. Opco). Terns Hong Kong holds the majority interest in Terns China Biotechnology Co., Ltd. (organized in Shanghai, People's Republic of China (PRC)) (Terns China) and its wholly owned subsidiary, Terns (Suzhou) Biotechnology Co., Ltd. (organized in Suzhou, PRC) (Terns Suzhou). Terns and its consolidated subsidiaries are hereinafter referred to as the "Company." The Company's principal office is in Foster City, California. Terns China and Terns Suzhou are collectively referred to as the "China Subsidiaries."

The Company is subject to risks and uncertainties common to early-stage companies in the biopharmaceutical industry, including, but not limited to, successful discovery and development of its drug candidates, the ability to secure additional capital to fund operations, regulatory approval of its drug candidates, development by competitors of new technological innovations, dependence on key personnel, the ability to attract and retain qualified employees, compliance with governmental regulations, the impact of the COVID-19 coronavirus and, ultimately, the commercial success of its drug candidates. Any drug candidates the Company may develop will require extensive nonclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel, and infrastructure and extensive compliance-reporting capabilities. Even if the Company's development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

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, its wholly owned subsidiary Terns Suzhou, and a variable interest entity (VIE) Terns China in which Terns has a majority interest and is the primary beneficiary. The noncontrolling interest attributable to the Company's VIE is presented as a separate component from stockholders' deficit in the consolidated balance sheets, and a noncontrolling interest in the consolidated statements of operations and comprehensive loss and consolidated statements of noncontrolling interest, convertible preferred stock and stockholders' deficit. 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.

Initial Public Offering

In February 2021, the Company completed an initial public offering (the "IPO") of 8,625,000 shares of its common stock, including the exercise in full by the underwriters of their option to purchase up to 1,125,000 additional shares of common stock, for net proceeds of $132.9 million, after deducting underwriting discounts and commissions and offering expenses, and its shares started trading on The Nasdaq Global Select Market under the ticker symbol "TERN." Upon closing of the IPO, all of the Company's outstanding shares of convertible preferred stock automatically converted into 16,079,230 shares of common stock.

Certificate of Incorporation

In December 2020, in connection with the Domestication, the Company's Board of Directors and stockholders approved the certificate of incorporation in the State of Delaware. The total number of shares of all classes of stock which the Company is authorized to issue is (i) 299,700,000 shares of common stock, (ii) 40,000,000 shares of Series

A convertible preferred stock, (iii) 36,409,088 shares of Series B convertible preferred stock, and (iii) 111,619,996 shares of Series C convertible preferred stock. All classes of stock are authorized at a par value of $0.0001.

Upon the completion of the IPO, all the outstanding shares of convertible preferred stock converted into common stock and the Company does not have any shares of preferred stock outstanding. In February 2021, the Company's amended and restated certificate of incorporation filed with the Secretary of State of the State of Delaware became effective in connection with the closing of IPO. Under the amended and restated certificate of incorporation, 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 are authorized at a par value of $0.0001.

Reverse Stock Split

In January 2021, the Company filed the amended and restated certificate of incorporation to effectuate a reverse split of shares of the Company's common stock and convertible preferred stock on a 1-for-14 basis (the "Reverse Stock Split"). The par value and the number of authorized shares of the convertible preferred stock and common stock were not adjusted as a result of the Reverse Stock Split. All issued and outstanding common stock, options to purchase common stock and per share amounts contained in the condensed consolidated financial statements have been retroactively adjusted to give effect to the Reverse Stock Split for all periods presented.

Variable Interest Entity

The Company consolidates a VIE where it has been determined that the Company is the primary beneficiary of the entity's operations. The Company has considered its relationships with a certain entity to determine whether the Company has a variable interest in that entity, and if so, whether the Company is the primary beneficiary of the relationship. U.S. GAAP requires VIEs to be consolidated if an entity's interest in the VIE is a controlling financial interest. Under the variable interest model, a controlling financial interest is determined based on which entity, if any, has (i) the power to direct the activities of the VIE that most significantly impacts the VIE's economic performance and (ii) the obligations to absorb losses that could potentially be significant to the VIE or the right to receive benefits from the VIE that could potentially be significant to the VIE.

Management performs ongoing reassessments of whether changes in the facts and circumstances regarding the Company's involvement with a VIE will cause the consolidation conclusion to change. The consolidation status of a VIE may change as a result of such reassessments. Changes in consolidation status are applied prospectively in accordance with U.S. GAAP.

Impact of the COVID-19 Pandemic

The COVID-19 pandemic is rapidly evolving. The COVID-19 virus continues to impact countries worldwide, including the U.S. and China where the Company has business operations. The extent of the impact of the COVID-19 pandemic on business, operations and development timelines and plans remains uncertain, and will depend on certain developments, including the duration and spread of the outbreak and its impact on the Company's development activities, planned clinical trial enrollment, future trial sites, contract research organizations (CROs), third-party manufacturers and other third parties with whom the Company conducts business, as well as its impact on regulatory authorities and the Company's key scientific and management personnel. The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. To the extent possible, the Company is conducting business as usual, with necessary or advisable modifications to employee travel and with employees working remotely. The Company will continue to actively monitor the rapidly evolving situation related to the COVID-19 pandemic and may take further actions that alter the Company's operations, including those that may be required by federal, state or local authorities in the United States and China, or that the Company determines are in the best interest of its employees and other third parties with whom the Company conducts business. At this point, the extent to which the COVID-19 pandemic may affect the Company's business, operations and development timelines and plans, including the resulting impact on expenditures and capital needs, remains uncertain.

2. Summary of Significant Accounting Policies

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. Significant 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 differ from those estimates.

Cash, Cash Equivalents and Restricted Cash

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. Restricted cash represents a security deposit related to a lease.

The reconciliation of cash, cash equivalents and restricted cash reported within the applicable balance sheet line items that sum to the total of the same such amount shown in the consolidated statements of cash flows is as follows:

	December 31,	
(in thousands)	**2020**	**2019**
Cash and cash equivalents	$ 74,854	$ 12,327
Restricted cash, non-current	—	48
Total cash, cash equivalents and restricted cash	$ 74,854	$ 12,375

Marketable Securities

The Company classifies as available-for-sale marketable securities with a remaining maturity when purchased of greater than three months. Marketable securities with a remaining maturity date greater than one year are classified as non-current. The Company's marketable securities are maintained by investment managers and consist of U.S. Treasury securities and equity securities. Debt securities are carried at fair value with the unrealized gains and losses included in other comprehensive income (loss) as a component of stockholders' deficit 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. Equity securities with readily determinable fair values are also carried at fair value with unrealized gains and losses are included in other income (expense), net. Realized gains and losses on both debt and equity securities are determined using the specific identification method and are included in other income (expense), net.

The Company classifies equity securities with readily determinable fair values, which would be available for use in its current operations, as current assets even though the Company may not dispose of such marketable securities within the next 12 months. Equity securities are included in marketable securities on the Company's consolidated balance sheet.

If any adjustment to fair value reflects a decline in value of the investment, the Company considers all available evidence to evaluate the extent to which the decline is "other-than-temporary" and, if so, marks the investment to market through a charge to the Company's consolidated statements of operations and comprehensive loss.

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 income (loss) on the consolidated balance sheets.

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash, cash equivalents, marketable securities and short-term investments. The Company invests its excess cash with large financial institutions that management believes to be of high credit quality. The Company has not experienced any losses on such deposits.

The Company's drug candidates require approvals from the U.S. Food and Drug Administration and comparable foreign regulatory agencies prior to generating commercial sales in their respective jurisdictions. There can be no assurance that any drug candidates will receive the necessary approvals. If the Company is denied approval, approval is delayed or the Company is unable to maintain approval for any drug candidate, it could have a materially adverse impact on the Company.

Fair Value Measurements of Financial Instruments

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.

Classification of Convertible Preferred Stock and Presentation of Noncontrolling Interest

The holders of Series A and Series B convertible preferred stock have certain liquidation rights in the event of a deemed liquidation that, in certain situations, is not solely within the control of the Company and would call for the redemption of the then outstanding Series A and Series B convertible preferred stock. Therefore, the Series A and Series B convertible preferred stock are classified outside of shareholders' deficit on the consolidated balance sheets. The carrying value of the convertible preferred stock is not subsequently remeasured to the redemption value until the contingent redemption events are considered to be probable of occurring.

The Company recognizes noncontrolling interest related to VIEs, in which the Company is the primary beneficiary, as equity in the consolidated financial statements separate from the parent entity's equity. The net loss attributable to noncontrolling interest is included in net loss in the consolidated statements of operations and comprehensive loss. Changes in the parent entity's ownership interest in a subsidiary that do not result in

deconsolidation are treated as equity transactions if the parent entity retains its controlling financial interest. In addition, when a subsidiary is deconsolidated, any retained noncontrolling equity investment in the former subsidiary will be initially measured at fair value and the difference between the carrying value and fair value of the retained interest will be recorded as a gain or loss.

Terns China, the Company's VIE, was established as a financing subsidiary to allow investment by Lilly Asia Ventures (LAV) investment entities: Suzhou Litai Equity Investment Centre (Limited Partnership) (PRC) and Suzhou Lirui Equity Investment Centre (Limited Partnership) (PRC), collectively referred to as the "LAV PRC Entities". The Company's board of directors has the unilateral ability to control the Terns China board of directors. Net losses of the China Subsidiaries have been allocated based on their ownership percentage to the LAV PRC Entities' noncontrolling interest and are reflected in the consolidated statements of operations and comprehensive loss. The noncontrolling interest is classified outside of stockholders' deficit on the consolidated balance sheets as it is redeemable for cash based on an investor option after a specified date.

In December 2020, the LAV PRC Entities exercised their option resulting in the conversion of all of the equity interests in Terns China held by the LAV PRC Entities into shares of the Company's preferred stock (the "China Conversion"). Following the completion of the China Conversion, Terns China became a wholly owned subsidiary of the Company. The Company does not currently anticipate any further direct third party investments into Terns China and Terns China will only act as an operating subsidiary for the Company's business activities in China.

In February 2021, upon the completion of the IPO, the outstanding shares of preferred stock of the Company were converted into shares of common stock.

Segment Information

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

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.

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.

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.

Property and Equipment

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 are as follows:

	Estimated Useful Life
Furniture and fixtures	5 years
Computer equipment	3 years
Office equipment	5 years
Lab equipment	3 to 5 years
Leasehold improvements	Shorter of remaining life of the lease or useful life of asset

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.

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.

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 other than 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 follows the provisions of the authoritative guidance from the FASB, on accounting for uncertainty in income taxes. These provisions provide a comprehensive model for the recognition, measurement and disclosure in financial statements of uncertain income tax positions that a company has taken or expects to take on a tax return. Under these provisions, a company can recognize the benefit of an income tax position only if it is more likely than not (greater than 50%) that the tax position will be sustained upon tax examination, based solely on the technical merits of the tax position. Otherwise, no benefit can be recognized. Assessing an uncertain tax position begins with the initial determination of the sustainability of the position and is measured at the largest amount of benefit that is greater than 50% likely of being realized upon ultimate settlement. As of each balance sheet date, unresolved uncertain tax positions must be reassessed. Additionally, the Company must accrue interest and related penalties, if applicable, on all tax exposures for which reserves have been established consistent with jurisdictional tax laws.

Common Stock Valuation

Due to the absence of an active market for the Company's common stock prior to the completion of the IPO in February 2021, the Company utilized methodologies in accordance with the framework of the American Institute of Certified Public Accountants Technical Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*, to estimate the fair value of its common stock. In determining the fair value of options granted prior to the IPO, the Company has considered the estimated fair value of the common stock as of the measurement date. The estimated fair value of the common stock prior to the IPO has been determined at each grant date based upon a variety of factors, including:

- the prices at which the Company sold shares of convertible preferred stock and the superior rights and preferences of the convertible preferred stock relative to its common stock at the time of each grant;
- the progress of the Company's research and development programs, including the status and results of clinical and nonclinical studies for its drugs;
- the Company's stage of development and commercialization and its business strategy;
- external market conditions affecting the biotechnology industry and trends within the biotechnology industry;
- the Company's financial position, including cash on hand, and its historical and forecasted performance and operating results;
- the lack of an active public market for the Company's common stock and convertible preferred stock;
- the likelihood of achieving a liquidity event, such as an IPO or sale of the Company in light of prevailing market conditions; and
- the analysis of IPOs and the market performance of similar companies in the biotechnology industry.

Significant changes to the key assumptions underlying the factors used could have resulted in different fair values of common stock at each valuation date.

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. For the years ended December 31, 2020 and 2019, the Company had unrealized gains and foreign exchange translation adjustments, which were a component of comprehensive loss.

Stock-Based Compensation

Stock-based compensation expense, including grants of stock options and restricted stock awards issued under the Company's equity incentive plan, is 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. The Company's determination of the fair value of stock options with time-based vesting utilizes the Black-Scholes option-pricing model. The Company estimates volatility using stock prices of peer companies, 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. 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 of each stock option grant is calculated based upon the Company's common stock valuation on the date of the grant. The Company accounts for forfeitures of stock option grants as they occur.

Net Loss Per Common Share

The Company follows the two-class method when computing net income (loss) per share of common stock as the Company has issued shares that meet the definition of participating securities. The two-class method determines net income (loss) per common share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed.

Basic net income (loss) per common share is computed by dividing the net income (loss) per common share by the weighted average number of common shares outstanding for the period. Diluted net income (loss) per common share is computed by adjusting net income (loss) to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net loss per common share is computed by dividing the diluted net loss by the weighted average number of common shares outstanding for the period, including potential dilutive common shares. For purposes of this calculation, outstanding stock options and convertible preferred stock are considered potential dilutive common shares.

The Company's convertible preferred stock outstanding prior to the IPO contractually entitles the holders of such shares to participate in dividends but do not contractually require the holders of such shares to participate in losses of the Company. Accordingly, in periods in which the Company reports a net loss, such losses are not allocated to such securities. In periods in which the Company reports a net loss, diluted net loss per common share is the same as basic net loss per common share, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. The Company reported a net loss for the years ended December 31, 2020 and 2019.

Loans Payable

The Company has elected to record certain loans payable at fair value on the date of issuance, with gains and losses arising from changes in fair value recognized in the statements of operations at each period end while such loans payable are outstanding. Issuance costs are recognized in the statement of operations in the period in which they are incurred. The fair value of the loans payable was determined using a probability weighted expected return method (PWERM), a scenario-based valuation model in which discrete future outcome scenarios for the Company are projected and discounted to present value.

Revenue Recognition

In January 2017, the Company early adopted Accounting Standard Update (ASU) 2014-09, *Revenue from Contracts with Customers (Topic 606)*, on a modified retrospective basis. Topic 606 establishes a principle for recognizing revenue upon the transfer of promised goods or services to customers, in an amount that reflects the expected consideration received in exchange for those goods or services. The standard also provides guidance on the recognition of costs related to obtaining and fulfilling customer contracts. Additionally, the standard requires disclosures regarding the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. To determine revenue recognition for arrangements that the Company determines are within the scope of Topic 606, 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 that falls under the scope of Topic 606, 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. Topic 606 suggests 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.

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' deficit 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.

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 December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* (ASU 2019-12), which eliminates certain exceptions related to the approach for intra-period tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The new guidance also simplifies aspects of the accounting for franchise taxes and enacted changes in tax laws or rates and clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill. The Company early adopted ASU 2019-12 effective January 2019. ASU 2019-12 removes the exception to the incremental approach for intra-period tax allocation in the event of a loss from continuing operations and income or gain from other items such as other comprehensive income. The exception previously resulted in allocating a tax benefit to continuing operations and tax expense to other items, even when tax expense may have been zero. Under the simplification, no tax expense or benefit will be recorded to continuing operations. There is no impact on the Company's financial statements for this amendment under ASU 2019-12. The other provisions within ASU 2019-12 are not applicable to the Company.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820)—Changes to the Disclosure Requirements for Fair Value Measurement* (ASU 2018-13), which removed the following disclosure requirements: (1) the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy; (2) the policy for timing of transfers between levels; and (3) the valuation processes for Level 3 fair value measurements. Additionally, this update added the following disclosure requirements: (1) the changes in unrealized gains and losses for the period included in other comprehensive income and loss for recurring Level 3 fair value measurements held at the end of the reporting period; (2) the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. For certain unobservable inputs, an entity may disclose other quantitative information (such as the median or arithmetic average) in lieu of the weighted average if the entity determines that other quantitative information would be a more reasonable and rational method to reflect the distribution of unobservable inputs used to develop Level 3 fair value measurements. The Company early adopted ASU 2018-13 in January 2019. For the new disclosures regarding the Company's Level 3 fair value measurements, (see Note 6, Fair Value).

In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815)* (ASU 2017-11). Part I to ASU 2017-11 eliminates the requirement to consider "down round" features when determining whether certain equity-linked financial instruments or embedded features are indexed to an entity's own stock. In addition, entities have to make new disclosures for financial instruments with down round features and other terms that change conversion or exercise prices. Part I to ASU 2017-11 was effective for fiscal years beginning after December 31, 2018. The amendments in Part II of ASU 2017-11 do not have an effective date because the amendments do not have an accounting effect. The Company adopted ASU 2017-11 in January 2019 with no material impact on its consolidated financial statements.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*, (ASU 2014-09), which amended the existing FASB Accounting Standards Codification. ASU 2014-09 supersedes the revenue recognition requirements in Revenue Recognition (Topic 605) and establishes a principle for recognizing revenue upon the transfer of promised goods or services to customers, in an amount that reflects the expected consideration received in exchange for those goods or services. The standard also provides guidance on the recognition of costs related to obtaining and fulfilling customer contracts. Additionally, the standard requires

disclosures regarding the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers.

ASU 2014-09, as amended, is effective for fiscal 2019, including interim periods within that reporting period. The standard allows for two different methods of adoption. The full retrospective method allows the amendment to be applied retrospectively to each prior period presented, and the modified retrospective method allows the amendment to be applied with the cumulative effect recognized as of the date of initial application. The Company early adopted this standard in January 2017 and the adoption had no impact on the Company's consolidated financial statements as the Company does not currently have any revenue-generating arrangements.

Recently Issued Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* (ASU 2016-02), which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e., lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less may be accounted for similar to existing guidance for operating leases today. For non-public entities, ASU 2016-02 is effective for annual reporting periods beginning after December 15, 2020, including interim periods within those fiscal years, and early adoption is permitted. For private entities, ASU 2016-02 is effective for annual reporting periods beginning after December 15, 2021, including interim periods within those fiscal years, 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 ASU 2016-02 until such time as those standards apply to private companies. The Company is in the process of completing its review of its existing lease agreements under Topic 842 and does not expect the adoption of ASU 2016-02 to have a material impact on its financial position, results of operations or cash flows.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* (ASU 2016-13), which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. ASU 2016-13 replaces the existing incurred loss impairment model with an expected loss methodology, which will result in more timely recognition of credit losses. ASU 2016-13 is effective for annual private company reporting periods, and interim periods within those years, beginning after December 15, 2023. The Company is currently in the process of evaluating the impact of the adoption of ASU 2016-13 on its consolidated financial statements.

3. Marketable Securities

Marketable securities consist of the following:

	As of December 31, 2019:			
(in thousands)	Amortized cost/cost	Unrealized Gains	Unrealized Losses	Fair Value
U.S. Treasury securities	$ 3,498	$ 1	$ —	$ 3,499
Equity securities	2,100	1	—	2,101
Total marketable securities	$ 5,598	$ 2	$ —	$ 5,600

The Company did not have any marketable securities for the year ended December 31, 2020.

4. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

(in thousands)	December 31, 2020	December 31, 2019
Prepaid research and development costs	$ 829	$ 2,113
Other current assets	331	461
Total prepaid expenses and other current assets	$ 1,160	$ 2,574

5. Property and Equipment, net

Property and equipment, net consisted of the following:

(in thousands)	December 31, 2020	December 31, 2019
Leasehold improvements	$ 897	$ 772
Furniture and fixtures	218	201
Computer equipment	156	128
Office equipment	41	40
Lab equipment	552	89
Property and equipment, gross	1,864	1,230
Less: Accumulated depreciation	(689)	(269)
Total property and equipment, net	$ 1,175	$ 961

The Company recognized depreciation expense related to these assets of $0.4 million and $0.2 million during the years ended December 31, 2020 and 2019, respectively.

6. Fair Value

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

(in thousands)	As of December 31, 2020: Level 1	Level 2	Level 3	Total
Assets:				
Cash and cash equivalents	$ 74,854	$ —	$ —	$ 74,854
Total	$ 74,854	$ —	$ —	$ 74,854
Liabilities:				
Loans payable	$ —	$ —	$ 12,880	$ 12,880
Total	$ —	$ —	$ 12,880	$ 12,880

(in thousands)	As of December 31, 2019: Level 1	Level 2	Level 3	Total
Assets:				
Cash and cash equivalents	$ 12,327	$ —	$ —	$ 12,327
Marketable securities	5,600	—	—	5,600
Short-term investments—structured deposits	—	1,723	—	1,723
Total	$ 17,927	$ 1,723	$ —	$ 19,650

During the years ended December 31, 2020 and 2019, there were no transfers between Level 1, Level 2 and Level 3.

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities included the following:

(in thousands)	December 31, 2020	December 31, 2019
Research and development costs	$ 2,800	$ 1,852
Accrued professional fees	2,185	129
Accrued development milestone	1,531	—
Compensation and benefit costs	1,492	1,216
Refundable contract liability	836	—
Other	162	117
Total accrued expenses and other current liabilities	$ 9,006	$ 3,314

8. Loans Payable

The following table provides the loans payable reported at fair value and measured on a recurring basis:

(in thousands)	Loans Payable
Balance at December 31, 2019	$ -
Issuance of 2020 Notes and Bridge Loan	16,800
Issuance of repurchase payable for the LAV Option exercise	10,771
Issuance of loans payable for conversion settlement of the Bridge Loan	2,109
Conversion of 2020 convertible promissory notes to Series C convertible preferred stock	(17,690)
Conversion of Bridge Loan to Series C convertible preferred stock	(2,163)
Change in fair value of loans payable and other adjustments	3,053
Balance at December 31, 2020	$ 12,880

2020 Notes

In May 2020, the Company issued convertible promissory notes (2020 Notes) in the aggregate amount of approximately $15.0 million. The 2020 Notes bear interest at a rate of 10.0% per annum, are unsecured, and are due and payable, including accrued interest, in May 2021.

In the event of a qualified sale of equity securities resulting in gross proceeds to the Company of at least $22.5 million (excluding the principal amount and any interest accrued under the 2020 Notes), all principal and accrued and unpaid interest under the 2020 Notes would be automatically converted into shares issued in the next qualified equity financing in an amount equal to the outstanding principal and unpaid accrued interest divided by the price per share paid by investors in the next equity financing.

In connection with the Series C Convertible Preferred Stock Financing, the 2020 Notes, totaling unpaid principal and accrued interest of $15.9 million, converted into 1,366,820 shares of Series C convertible preferred stock based on the issuance price of $11.65 per share. Prior to the conversion, the fair value of the 2020 Notes was determined to be $17.7 million. The Company recorded the $1.8 million difference between the fair value of the 2020 Notes and the value of the preferred stock issued within Additional paid-in capital of the accompanying Consolidated Balance Sheets.

Bridge Loan

In May 2020, the Company entered into a bridge loan with Terns China (Bridge Loan) for aggregate proceeds of $1.8 million, payable in renminbi (RMB) at an established USD/RMB exchange rate, based on an average of the previous five working days before May 8, 2020. The Bridge Loan bears interest at a rate of 10% per year, which began to accrue on the date of drawdown, and is computed based on the actual number of days elapsed based on a year of 365 days. The Bridge Loan holders has the same conversion rights as the 2020 Notes holders.

In connection with the closing of the Series C convertible preferred stock financing in December 2020, entities that are a part of LAV agreed to effectively convert the Bridge Loan into shares of Series C preferred stock on the same terms as the 2020 Notes. The conversion will be based on an outstanding loan balance equal to $1.9 million, consisting of (i) the principal loan amount ($1.8 million) plus (ii) accrued interest through December 29, 2020 ($0.1 million).

To help facilitate the transfer of cash from China to the United States to effectively convert the Bridge Loan, the Company and Terns China agreed to enter into an agreement with LAV to (i) repay the Bridge Loan, and (ii) issue shares of Series C convertible preferred stock at the initial closing of the Series C financing to entities that are a part of Lilly Asia Ventures in exchange for a promissory note issued to the Company by LAV, or the LAV Affiliate Promissory Note.

On December 29, 2020, the Bridge Loan was amended to clarify that (i) interest will accrue up to and through December 29, 2020, with no additional interest accruing after December 29, 2020 and (ii) the Bridge Loan will be repaid in full by the Company following the requisite government approvals in China. Proceeds from the repayment of the Bridge Loan by Terns China will be used by LAV to repay the LAV Affiliate Promissory Note in full.

The fair value of the Bridge Loan was determined to be $2.1 million as of December 31, 2020, which was based on an outstanding loan balance consisting of the principal loan amount plus accrued interest through December 29, 2020. The Bridge Loan was paid and the LAV Affiliate Promissory Note was received in March 2021.

LAV Series A and Series B Promissory Notes

In November 2020, the Chinese government provided approval for entities affiliated with LAV to exercise the LAV Option. Terns Hong Kong agreed to repurchase all equity interests held by the LAV PRC Entities with proceeds to be used by LAV to purchase shares of Series A convertible preferred stock and Series B convertible preferred stock of the Company (Repurchase).

In December 2020, the Company issued 767,857 shares of Series A convertible preferred stock and 216,450 shares of Series B convertible preferred stock to an affiliate of LAV (LAV Affiliate) in exchange for a promissory note with a principal amount equal to the original investment by LAV in Terns China (LAV Series A and Series B Promissory Note). The carrying value of the LAV Series A and Series B Promissory Note approximates its fair value due to the short-term nature of the liability. The LAV Series A and Series B Promissory Note was repaid through proceeds of the Repurchase, which was completed in January 2021.

Change in Fair Value of Loans Payable

The fair value of the loans payable liability was determined based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The fair value of the loans payable liability is remeasured at each reporting period, with changes in fair value recognized in the condensed consolidated statements of operations.

During the year, the Company used the PWERM method to value the loans payable. This approach involved the estimation of future potential outcomes for the Company, as well as values and probabilities associated with each respective potential outcome. The Company considered two scenarios (i) a 60% probability of an IPO in the near-term and (ii) a 40% probability of the Company remaining private for approximately 1.75 years following the date of the valuation. The Company considered these two scenarios to calculate the (i) future value of the loans payable under each scenario and (ii) the present value of the loans payable under each scenario. The value of the Company’s equity used to determine the appropriate allocation of value to the stockholders was calculated using different methodologies for each scenario. For the first scenario, the value of the Company’s equity was estimated based on the Company’s estimates, as well as recent IPO indications of comparable companies. For the second scenario, the value of the Company’s equity was estimated using the income approach, which focuses on the income-producing capability of a business and estimates value based on the expectation of future cash flows, which are then discounted to the present using a rate of return that incorporates the risk-free rate for the use of funds, the expected rate of inflation, and risks associated with the particular investment. Under each scenario, the rights and preferences of each share class were

considered in order to determine the appropriate allocation of value to the common and preferred stockholders, as well as the loans payable. The value per common and preferred share, as well as the loans payable, under each scenario was multiplied by a present value factor, calculated based on the Company's cost of equity and the expected timing of each scenario. After taking into consideration the PWERM of each scenario, the Company arrived at the fair value of the loans payable.

The Company recorded other expense of $2.9 million related to the change in the fair value of loans payable for the year ended December 31, 2020.

9. Convertible Preferred Stock

All shares of preferred stock described below were converted into 16,079,230 shares of the Company's common stock at the time of the IPO in February 2021.

Series A Preferred Stock

In April 2017, the Company entered into a Series A convertible preferred stock purchase agreement (Series A Agreement) whereby the Company issued 2,089,285 shares of Series A convertible preferred stock at $10.50 per share for an aggregate purchase price of $21.9 million. The cash proceeds associated with the sale of the Series A convertible preferred stock were to be received by the Company over three tranches of payments. The Company received $7.3 million for tranche 1 in April 2017, $7.3 million for tranche 2 in February 2018 and $7.3 million for tranche 3 in July 2018.

Terns China received an aggregate $8.0 million from the LAV PRC Entities in three tranches over the same period, which is presented as a noncontrolling interest. In connection with the Series A Agreement and this Terns China investment, the Company also issued an option to the LAV PRC Entities to convert their interest in the China Subsidiaries into an interest in Terns Cayman (the LAV Option).

Series B Preferred Stock

In October 2018, the Company entered into a Series B convertible preferred share purchase agreement (Series B Agreement), whereby the Company issued 2,384,195 shares of Series B convertible preferred stock at $30.80 per share for an aggregate purchase price of $73.4 million.

Terns China received $6.7 million from the LAV PRC Entities in connection with the Series B financing, which is presented as a noncontrolling interest. In connection with the Series B Agreement and this Terns China investment, the LAV Option was to allow the LAV PRC Entities to convert this interest in the China Subsidiaries into an interest in Terns Cayman.

LAV Series A and Series B Preferred Stock Options

In November 2020, the Chinese government provided approval for entities affiliated with Lilly Asia Ventures (LAV) to exercise the LAV Option. Terns Hong Kong agreed to repurchase all equity interests held by the LAV PRC Entities with proceeds to be used by LAV to purchase shares of Series A convertible preferred stock and Series B convertible preferred stock of the Company (Repurchase).

In December 2020, the Company issued 767,857 shares of Series A convertible preferred stock and 216,450 shares of Series B convertible preferred stock to an affiliate of LAV (LAV Affiliate) in exchange for a promissory note with a principal amount equal to the original investment by LAV in Terns China (LAV Series A and Series B Promissory Note). The LAV Series A and Series B Promissory Note was repaid through proceeds of the Repurchase which was completed in January 2021.

Series C Preferred Stock

In December 2020, the Company entered into a Series C preferred stock purchase agreement (Series C Convertible Preferred Stock Financing) whereby it issued 7,500,665 shares of Series C convertible preferred stock at $11.65 per share for gross proceeds of $87.4 million, which includes shares issued upon conversion of the 2020 Notes.

In connection with the Series C Convertible Preferred Stock Financing, the 2020 Notes, totaling unpaid principal and accrued interest of $15.9 million, converted into 1,366,820 shares of Series C convertible preferred stock. Furthermore, in December 2020, as part of the effective conversion of the Bridge Loan, the Company issued LAV an aggregate of 167,159 shares of Series C convertible preferred stock.

In connection with the Series C Convertible Preferred Stock Financing, a down-round adjustment was triggered for Series B convertible preferred stock. Instead of adjusting the conversion price of the Series B convertible preferred stock to $25.63, the Company and its investors agreed to adjust it to $30.80. This resulted in an extinguishment of all outstanding shares of Series B convertible preferred stock that were recorded at their fair value of $79.7 million. Immediately following the extinguishment, the shares of Series B convertible preferred stock were reissued and recorded at their fair value of $69.0 million. As part of the extinguishment, the Company recorded an increase to additional paid-in capital of $10.7 million, representing the difference between the extinguished carrying value of Series B convertible preferred stock and the fair value of the net consideration transferred to stockholders. The $10.7 million is also treated as an increase to earnings attributable to common stockholders in the calculation of net income (loss) per share.

Series A convertible preferred stock, Series B convertible preferred stock and Series C convertible preferred stock are collectively referred to as "convertible preferred stock." As of each balance sheet date, convertible preferred stock consisted of the following:

	As of December 31, 2020				
(in thousands, except share amounts)	Convertible Preferred Stock Authorized	Convertible Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A convertible preferred stock	40,000,000	2,857,142	$ 30,000	$ 30,000	2,857,142
Series B convertible preferred stock	36,409,088	2,600,645	68,995	80,100	5,721,423
Series C convertible preferred stock	111,619,996	7,500,665	87,038	87,368	7,500,665
Total convertible preferred stock	188,029,084	12,958,452	$ 186,033	$ 197,468	16,079,230

	As of December 31, 2019				
(in thousands, except share amounts)	Convertible Preferred Stock Authorized	Convertible Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A convertible preferred stock	40,000,000	2,089,285	$ 21,938	$ 21,938	2,089,285
Series B convertible preferred stock	36,409,088	2,384,195	73,029	73,433	5,245,233
Total convertible preferred stock	76,409,088	4,473,480	$ 94,967	$ 95,371	7,334,518

In connection with the IPO, all the outstanding shares of convertible preferred stock converted into common stock and the Company does not have any shares of preferred stock outstanding.

As of December 31, 2020, the rights and privileges of the holders of the convertible preferred stock were as follows:

Conversion

Shares of preferred stock are convertible, at the option of the holder, at any time, into shares of common stock. The number of shares is determined by dividing the original issuance price by the conversion price, which is also equal to the original issuance price. The conversion price of the preferred stock is subject to adjustment to prevent dilution in the event that the Company issues additional shares of common stock at a price per share less than the Series A convertible preferred stock, Series B convertible preferred stock or Series C convertible preferred stock conversion price, as the case may be. These rights terminate in the event of a liquidation or winding up of the Company. No fractional shares will be issued.

Liquidation Preference

In the event of any liquidation, dissolution, winding up of the Company or deemed liquidation event, either voluntarily or involuntarily, all assets and funds of the Company legally available for distribution will be distributed to the members of the Company at an amount equal to the respective Series A convertible preferred stock issuance price of $10.50 per share, Series B convertible preferred stock issuance price of $30.80 per share and Series C convertible preferred stock issuance price of $11.65 per share, plus any declared but unpaid dividends, first to the Series C convertible preferred stockholders, then the Series B convertible preferred stockholders, then the Series A convertible preferred stockholders.

If there are any assets or funds remaining after the distribution to the convertible preferred stockholders, the remaining assets and funds of the Company will be distributed ratably among all members according to the number of shares of common stock held by each member, treating all shares of convertible preferred stock as if they had been converted to common stock immediately prior to the liquidation, dissolution or winding up of the Company.

Dividends

As of December 31, 2020, the holders of the convertible preferred stock are entitled to be paid non-cumulative dividends if and when declared by the Company’s board of directors. The Company may not pay any dividends on shares of common stock of the Company unless the holders of the convertible preferred stock then outstanding simultaneously receive dividends at the same rate and same time as dividends paid with respect to common stock. The holders of Series C convertible preferred stock are entitled to receive dividends prior and in preference to any payments to the holders of Series B convertible preferred stock and common stock. The holders of Series B convertible preferred stock are entitled to receive dividends prior and in preference to any payments to the holders of Series A convertible preferred stock and common stock. After payment of dividends to the holders of Series C convertible preferred stock, the holders of Series B convertible preferred stock are entitled to receive dividends prior and in preference to the holders of Series B convertible preferred stock and any payment to the holders of common stock. After payment of dividends to the holders of Series B convertible preferred stock, the holders of Series A convertible preferred stock are entitled to receive dividends prior and in preference to any payment to the holders of common stock. Any additional dividends paid in any fiscal year will be paid among the holders of preferred stock and common stock then outstanding on an as-converted basis. Upon issuance of the Series B convertible preferred stock in October 2018, the dividends became non-cumulative. Dividends shall be 8.0% of the price per share per annum, payable only when and if declared by the Company’s board of directors. Through December 31, 2020, no cash dividends have been declared or paid by the Company.

Voting Rights

Each holder of outstanding convertible preferred stock is entitled to cast the number of votes equal to the whole number of shares of common stock into which the shares of convertible preferred stock held by such holder are convertible as of the record date for determining stockholders entitled to vote on such matter. Fractional votes are not permitted, and any fractional voting rights available on an as-converted basis will be rounded to the nearest whole number. To the extent that convertible preferred stockholders are allowed to vote separately, that series of the convertible preferred stock will have the right to vote separately as a class or series.

Redemption

The holders of Series A, Series B and Series C convertible preferred stock have certain liquidation rights in the event of a deemed liquidation that, in certain situations, are not solely within the control of the Company and would call for the redemption of the then outstanding Series A, Series B and Series C convertible preferred stock. Therefore, the Series A, Series B and Series C convertible preferred stock are classified outside of stockholders' deficit on the unaudited condensed consolidated balance sheets. The carrying value of the convertible preferred stock is not subsequently remeasured to the redemption value until the contingent redemption events are considered to be probable of occurring.

10. Common Stock

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

	December 31,	
(in thousands)	**2020**	**2019**
Conversion of outstanding shares of convertible preferred stock	16,079,230	7,334,518
LAV Options issued and outstanding	—	984,306
Options outstanding under the 2017 stock plan	2,466,670	478,135
Shares available for future grant under the 2017 stock plan	17,556	503,741
Total shares reserved	18,563,456	9,300,700

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, 2020, no cash dividends have been declared or paid by the Company.

11. Stock-Based Compensation

The Company has two share-based compensation plans, the 2017 Incentive Award Plan (the "2017 Plan") and the 2021 Incentive Award Plan (the "2021 Plan") which was adopted in February 2021. The 2021 Plan is successor to the 2017 Plan and no additional awards may be issued from the 2017 Plan. As of December 31, 2020, 17,556 shares were available for future grants of the Company's common stock under the 2017 Plan.

Each plan, while effective, authorizes the granting of shares of common stock and options to purchase common stock to employees and directors of the Company, as well as non-employee consultants, and allows the holder of the option to purchase common stock at a stated exercise price. Stock options granted to employees and nonemployees under the plans generally vest over four years. 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.

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, restricted stock unit 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. The 2021 Plan is successor to the 2017 Incentive Award 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.

Stock Options

The following table summarizes the stock option activity for all stock plans during the year ended December 31, 2020:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
			(in years)	*(in thousands)*
Outstanding as of December 31, 2018	122,490	$ 2.07	9.80	$ 501
Granted	446,061	5.21		
Exercised	(9,939)	2.64		
Forfeited	(80,477)	5.14		
Outstanding as of December 31, 2019	478,135	$ 4.48	8.94	$ 2,277
Granted	2,137,169	8.57		
Exercised	(38,285)	3.09		
Forfeited	(110,349)	2.93		
Outstanding as of December 31, 2020	2,466,670	$ 8.03	9.61	$ 21,678
Exercisable, December 31, 2020	1,983,384	$ 8.20	9.70	$ 17,273
Vested and expected to vest, December 31, 2020	2,466,670	$ 8.03	9.61	$ 21,678

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, 2020 and 2019, respectively, there was $26.7 million and $1.7 million 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 3.81 years as of December 31, 2020.

The total fair value of options vested during the year ended December 31, 2020 and 2019 was $0.7 million and $0.3 million, respectively.

The Company estimated the fair value of options granted using a Black-Scholes option pricing model with the following assumptions presented on a weighted average basis:

	Year Ended December 31,	
	2020	2019
Expected option life	6.06 Years	5.98 Years
Expected volatility	62.02%	63.84%
Risk-free interest rate	0.49%	2.38%
Expected dividend yield	—%	—%
Fair value of underlying common stock	$ 17.97	$ 6.63
Fair value of option	$ 12.84	$ 4.53

Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

Restricted Stock

The following table summarizes the stock award activity for all stock plans during the year ended December 31, 2020:

	Number of Shares	Grant-Date Fair Value
Unvested restricted common stock as of December 31, 2018	303,571	$ 1.96
Vested	(101,190)	1.96
Forfeited	(35,714)	1.96
Unvested restricted common stock as of December 31, 2019	166,667	1.96
Vested	(83,333)	1.96
Unvested restricted common stock as of December 31, 2020	83,334	$ 1.96

As of December 31, 2020 and 2019, there was less than $0.1 million and $0.2 million of unrecognized stock-based compensation expense related to restricted stock granted by the Company, respectively. The unrecognized stock-based compensation expense is estimated to be recognized over a period of 0.27 years as of December 31, 2020. The total fair value of the restricted stock vested during the years ended December 31, 2020 and 2019 was $0.2 million.

Stock-Based Compensation Expense

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

	Year Ended December 31,	
(in thousands)	2020	2019
Research and development expense	$ 373	$ 228
General and administrative expense	1,318	440
Total stock-based compensation expense	$ 1,691	$ 668

12. Income Tax

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

	Year Ended December 31,	
(in thousands)	2020	2019
U.S.	$ 1,180	$ (770)
Foreign	(40,938)	(68,069)
Total	$ (39,758)	$ (68,839)

The following table presents the provision (benefit) for income taxes:

(in thousands)	Year Ended December 31, 2020	2019
Current		
Federal	$ 128	$ 42
State	1	1
Foreign	279	236
Total current	$ 408	$ 279
Deferred		
Federal	$ 449	$ (266)
Foreign	(44)	(33)
Total deferred	$ 405	$ (299)
Total income tax expense (benefit)	$ 813	$ (20)

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, 2020	2019
Tax benefit at U.S. statutory rate	21.00%	21.00%
State income taxes, net of Federal tax benefit	—	—
Foreign income taxed at non-U.S. rates	(22.10)	(20.32)
Foreign permanent benefits	—	2.78
Other permanent items	(0.16)	—
Stock-based compensation	(0.16)	(0.12)
Research and development credits	2.28	1.06
Unrecognized tax benefit	(0.71)	(3.85)
GILTI	(0.32)	-
Increase in valuation allowance	(2.01)	—
Other	0.14	(0.52)
	(2.04)%	0.03%

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

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

(in thousands)	As of December 31, 2020	2019
Deferred tax assets:		
Accruals and reserves	$ 619	$ 353
Stock-based compensation	340	110
Net operating loss	28	47
Research and development credits	683	448
Valuation allowance	(1,431)	(299)
Total deferred tax assets	$ 239	$ 659
Deferred tax liabilities:		
Fixed assets	$ (58)	$ (74)
Total deferred tax liabilities	(58)	(74)
Net deferred tax assets	$ 181	$ 585

In assessing the realization of deferred tax assets, the Company considers whether it is more likely than not that some portion or all the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. The Company considers the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies in making this assessment. 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 as of December 31, 2020. Based upon the weight of available evidence, including historical operating performance and the Company's change of structure due to domestication of its Cayman entity to the State of Delaware in 2020, a net loss will be expected to occur in the foreseeable future, the Company decided to put on full valuation allowance against its net U.S. deferred tax assets.

Utilization of the research and development credit carryforward may be subject to an annual limitation due to the ownership percentage change limitations provided by the Internal Revenue Code of 1986 and similar state provisions. The annual limitation may result in the expiration of the research and development credits before utilization. The amount of such elimination, if any, have not been determined.

As of December 31, 2020 and 2019, the Company had a federal Research and Experimentation (R&E) credit carryforward of approximately $1.1 million and $0.6 million, respectively, which begins to expire in 2039. The California R&E credit carryforward of approximately $0.9 million and $0.5 million, respectively, do not expire.

As of December 31, 2020 and 2019, the total amount of unrecognized tax benefits was $5.4 million and $4.7 million, respectively, $4.2 million and $4.5 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:

(in thousands)	Year Ended December 31, 2020	2019
Unrecognized tax benefit at beginning of year	$ 4,709	$ 1,884
Increases related to current year tax position	697	2,825
Unrecognized tax benefit at end of year	$ 5,406	$ 4,709

The Company includes interest and penalties related to unrecognized tax benefits within the provision for income taxes. As of December 31, 2020, and 2019, the total amount of gross interest accrued and penalties was nominal.

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, 2018, remain open to adjustment by U.S. and foreign authorities.

13. Net Loss Per Common Share

Basic and diluted net loss per common share were calculated as follows:

	Year Ended December 31,	
(in thousands, except share and per share amounts)	2020	2019
Numerator:		
Net loss	$ (40,571)	$ (68,819)
Extinguishment of Series B convertible preferred stock	10,701	—
Net loss attributable to noncontrolling interest	(518)	(208)
Net loss attributable to common stockholders	$ (29,352)	$ (68,611)
Denominator:		
Weighted average common stock outstanding, basic and diluted	285,162	183,262
Net loss per share attributable to common stockholders, basic and diluted	$ (102.93)	$ (374.39)

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 common share for the periods indicated because including them would have had an anti-dilutive effect:

	Year Ended December 31,	
	2020	2019
Options to purchase common stock	2,466,670	478,135
Restricted common stock	83,334	166,667
Convertible preferred stock (as converted to common stock)	16,079,230	7,334,518
Options to purchase convertible preferred stock (as converted to common stock)	—	984,306
Total	18,629,234	8,963,626

14. Commitments and Contingencies

Lease Agreements

In March 2018, the Company entered into a lease agreement for office space in Shanghai China, which expires in May 2021. Monthly lease payments are inclusive of base rent, property management fee and the respective value added tax to be paid. Monthly lease payments include base rent of approximately $15,000 through May 2021.

In March 2019, the Company entered into a lease agreement for office space in Foster City, California which expires October 2024. The Company has the option to extend the lease agreement for a period of five years. The

monthly lease payments include base rent charges of $48,000. The lease provides for a rent abatement and scheduled increases in base rent.

In June 2019, the Company entered into a lease agreement for office space in Suzhou China, which expires in September 2022. Monthly lease payments are inclusive of base rent, property management fee and the respective value added tax to be paid. Monthly lease payments include base rent of approximately $4,000 through September 2022.

Future minimum lease payments due under operating leases as of December 31, 2020 are as follows:

(in thousands)	Operating Leases
2021	$ 669
2022	668
2023	652
2024	559
2025 and thereafter	-
Total	$ 2,548

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.

15. Assignment, License and Collaboration Agreements

License Agreements

TERN-101 License Agreement with Eli Lilly

In February 2018, the Company entered a worldwide exclusive license agreement with Eli Lilly and Company (Lilly) (Lilly FXR 2018 License Agreement). Under the terms of the Lilly FXR 2018 License Agreement, Lilly granted the Company an exclusive, royalty-bearing license to make, have made, use, offer for sale, sell, import, and have imported, including all rights to develop, manufacture, and commercialize covered products in the field in the territory and a sublicensing right that allows the Company to grant sublicenses to affiliates and third parties to perform any portion of the development, manufacture, and commercialization of covered products. The Company is required to use commercially reasonable efforts to meet development event milestones, develop the covered product in the field in mainland China and commercialize the covered product in the field in mainland China.

The Company agreed to pay Lilly up to an aggregate of $6.0 million in pre-specified development milestones for the first covered product in mainland China, and up to an aggregate of $50.0 million in pre-specified development milestones for the first covered product in ex-mainland China. The Company also agreed to pay Lilly tiered royalties calculated on a calendar year basis, in the mid-single digits to low teens on net sales ranging from the low hundreds of millions of dollars to the low billions of dollars. The Lilly FXR 2018 License Agreement expires upon expiry of the last remaining royalty obligation for a licensed product. As of December 31, 2020, the Company has not paid any amounts under the agreement and no milestones have been achieved. The Company has not recorded any research and development expense during the years ended December 31, 2020 and 2019 related to this agreement.

TERN-201 License Agreement with Eli Lilly

In March 2018, the Company entered into an exclusive license agreement with Lilly (Lilly VAP-1 2018 License Agreement). Under the terms of the Lilly VAP-1 2018 License Agreement, Lilly granted the Company an exclusive, royalty-bearing license to make, have made, use, offer for sale, sell, import, and have imported, including all rights to develop, manufacture, and commercialize covered products and a sublicensing right that allows the Company to grant

sublicenses to affiliates and third parties to perform any portion of the development, manufacture, and commercialization of covered products. The Company will remain directly responsible for all amounts owed to Lilly, regardless of sublicenses. The Company is required to use commercially reasonable efforts to meet development events according to achievement due dates and commercialize the covered product in the field in the major markets.

The Company paid Lilly a non-refundable, non-creditable upfront payment of $4.0 million, which was recorded as research and development expense in the Company's statement of operations and comprehensive loss for the year ended December 31, 2018. In addition, pursuant to the terms of the Lilly VAP-1 2018 License Agreement, the Company agreed to pay Lilly up to an aggregate of $74.0 million in pre-specified development milestones for the first covered product, and up to an aggregate of $30.0 million in pre-specified development milestones for the second indication of a covered product. The Company must also pay Lilly tiered royalties calculated on a calendar year basis, in the mid-single digits to mid-teens on net sales ranging from the high tens of millions of dollars to the low billions of dollars. The Lilly VAP-1 2018 License Agreement expires upon expiry of the last remaining royalty obligation for a licensed product. As of December 31, 2020, the Company has paid $4.0 million to Lilly. No development milestones have been met as of the twelve months ended December 31, 2020. The Company has not recorded any research and development expense during the years ended December 31, 2020 and 2019 related to this agreement.

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.

The Company paid Vintagence a non-refundable, non-creditable upfront payment of $0.7 million, which was recorded as research and development expense in the Company's statements of operations and comprehensive loss for the year ended December 31, 2019. 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, 2020, the Company has paid $0.7 million to Vintagence. In connection with the Company's 501 IND filing in December 2020, a milestone payment of CNY 10.0 million was due to Vintagence under the agreement. The milestone payment of $1.5 million is included in the consolidated balance sheet as of December 31, 2020 and is presented with accrued expenses and other current liabilities. The Company has recognized research and development expense of approximately $1.5 million and $0.7 million during the years ended December 31, 2020 and 2019, respectively, 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 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). Upon Hansoh's exercising the option, the Company will grant to Hansoh and its affiliates, an irrevocable, royalty-bearing license, with the right to sublicense to exploit licensed compound and licensed products in the Field, defined as in the Territory.

Hansoh is required to pay the Company a refundable, non-creditable upfront payment of $1.0 million, provided that in the event Hansoh elects to not exercise the option, the Company shall refund the amount of the upfront payment within six months from the expiration or termination of the option period. If the Company does not pay the refund amount within six months, the refund amount will be regarded as a debt owed by the Company to Hansoh, secured against the number of common shares as is equal to the refund amount divided by the share price of such shares issued by the Company in the latest equity financing round before the refund amount is due. Interest on the refund amount is at a rate equal to 5% per annum over the then-current applicable federal rate, compounded annually and will continue to accrue until paid. Interest shall be computed on the basis of a year of 365 days for the actual number of days elapsed. The entire amount of accrued but unpaid interest and all outstanding principal shall be due and payable on or before the close of business on the fifth anniversary of the last day of the refund period. The Company received an upfront payment of $0.8 million during the year ended December 31, 2020, which is recognized as a refund liability on the balance sheet. The upfront payment is included in the Company's consolidated balance sheet as of December 31, 2020 and is presented within accrued expenses and other current liabilities. The upfront payment and future payments are all constrained as of December 31, 2020.

In addition, pursuant to the Hansoh 2020 Option and License Agreement, 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. No milestones have been received to date.

Genfit Collaboration Agreement

In June 2019, the Company entered into a collaboration agreement with Genfit SA (Genfit) (Genfit 2019 Collaboration Agreement). Under the Genfit 2019 Collaboration Agreement, Genfit agreed to grant the Company an exclusive license to develop, manufacture and commercialize any pharmaceutical product in any form suitable for oral administration to adults or children that contains elafibranor (drug product) in the Terns territory. Under the terms of the Genfit 2019 Collaboration Agreement, the Company paid Genfit a one-time, non-refundable, non-creditable upfront payment of $35.0 million, which was recorded as research and development expense in the Company's statement of operations and comprehensive loss for the year ended December 31, 2019. In addition, the Company agreed to pay to Genfit up to an aggregate of $18.0 million in pre-specified development milestones, and up to an aggregate of $175.0 million in pre-specified commercial milestones. The Company also agreed to pay Genfit non-creditable, non-refundable royalties in the mid-teens, calculated on a product-by-licensed product and region-by-region basis, of all net sales. As of December 31, 2020, the Company has paid $35.0 million to Genfit under the agreement. The Company did not recognize any research and development expense during the year ended December 31, 2020 and recognized $35.0 million of research and development expense during the year ended December 31, 2019 related to this agreement. In May 2020, Genfit terminated its development program in NASH and, subsequently, the Company terminated its plans for NASH development work in China pursuant to the Genfit 2019 Collaboration Agreement. As a result, the Company does not anticipate making any milestone payments under the Genfit 2019 Collaboration Agreement in the foreseeable future.

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, 2020, management, with the supervision and participation of our Chief Executive Officer and 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 Chief Financial Officer concluded that, as of December 31, 2020, the design and operation of our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting

We regularly review our system of internal control over financial reporting and make changes to our processes and systems to improve controls and increase efficiency, while ensuring that we maintain an effective internal control environment. Changes may include such activities as implementing new, more efficient systems, consolidating activities, and migrating processes. There were no changes during the quarter ended December 31, 2020 to our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control over Financial Reporting

This Annual Report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by the rules of the SEC for newly public companies.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The following table sets forth information regarding our executive officers and directors as of March 19, 2021:

NAME	AGE	POSITION(S)
Executive Officers		
Senthil Sundaram	42	Chief Executive Officer and Director
Erin Quirk, M.D.	50	President and Chief Medical Officer
Mark Vignola, Ph.D.	43	Chief Financial Officer and Treasurer
Bryan Yoon, Esq.	43	Chief Operating Officer, General Counsel and Secretary
Weidong Zhong, Ph.D.	55	Chief Scientific Officer and Director
Non-Employee Directors		
David Fellows(2)(3)	64	Chairman of the Board
Carl Gordon, Ph.D., C.F.A(3)	56	Director
Jeffrey Kindler, Esq.(1)(2)	65	Director
Hongbo Lu, Ph.D.(1)(2)	49	Director
Jill Quigley, Esq.(1)(3)	45	Director

(1) Member of our audit committee.
(2) Member of our compensation committee.
(3) Member of our nominating and corporate governance committee.

Executive Officers

Senthil Sundaram has served as a member of our board of directors and as our Chief Executive Officer since July 2020. Previously, he served as the Chief Financial Officer of Nightstar Therapeutics, plc, a publicly-traded biotechnology company, from April 2017 to June 2019. From February 2013 to March 2017, Mr. Sundaram served in roles of increasing responsibility at Intercept Pharmaceuticals, Inc., a publicly-traded biotechnology company, most recently as the Head of Business Development. He currently serves on the board of directors of Sio Gene Therapies, Inc. (formerly Axovant Gene Therapies Ltd.), a publicly-traded biotechnology company. Mr. Sundaram received his undergraduate degrees in Computer Engineering and Economics from Brown University. We believe Mr. Sundaram is qualified to serve on our board of directors due to his extensive experience as an executive and director of public companies in the biotechnology industry.

Erin Quirk, M.D. has served as our Chief Medical Officer since January 2019, and our President since June 2020. She previously served in roles of increasing responsibility at Gilead Sciences, Inc., a publicly-traded biopharmaceutical company, from July 2010 to September 2018, most recently as Vice President of HIV Clinical Research. Dr. Quirk received her undergraduate degree in Biology and English Literature from Drew University and her M.D. from the University of Colorado School of Medicine. She completed her Residency in Internal Medicine and a Fellowship in Infectious Diseases at Barnes-Jewish Hospital, Washington University.

Mark Vignola, Ph.D. has served as our Chief Financial Officer since August 2020 and Treasurer since January 2021. Previously, he served as the Chief Financial Officer of Applied Therapeutics, Inc., a publicly-traded biotechnology company, from April 2019 to May 2020. Before that, Dr. Vignola served in roles of increasing responsibility at Intercept Pharmaceuticals, Inc., a publicly-traded biotechnology company, most recently as the Head of Corporate and Investor Relations. Dr. Vignola received his undergraduate degree in Biology from Boston College and Ph.D. in Molecular Genetics & Microbiology from Duke University.

Bryan Yoon, Esq. has served as our Chief Operating Officer and General Counsel since November 2020 and Secretary since January 2021. From November 2019 to November 2020, he served as the Chief Administrative Officer, General Counsel and Secretary of LogicBio Therapeutics, Inc. a publicly-traded biotechnology company. Before that,

he served as the General Counsel and Corporate Secretary at Nightstar Therapeutics, plc, a publicly-traded biotechnology company, from November 2017 to June 2019. Prior to joining Nightstar, Mr. Yoon served in roles of increasing responsibility at Intercept Pharmaceuticals, Inc., a publicly-traded biotechnology company, where he most recently was Senior Vice President, Legal Affairs and Corporate Secretary. Mr. Yoon received his undergraduate degree in Economics and Master of Engineering in Operations Research and Industrial Engineering from Cornell University and his J.D. from University of Michigan Law School.

Weidong Zhong, Ph.D. has served as our Chief Scientific Officer since July 2020 and a member of our board of directors since April 2017, and is one of our founders. He previously served as our Chief Executive Officer from April 2017 to July 2020. Before that, Dr. Zhong served as the Head of Antiviral Research from September 2011 to March 2017 at Novartis Institute for BioMedical Research, a research division of Novartis International AG, a publicly-traded biotechnology company. Dr. Zhong received his undergraduate degree in Molecular Biology from the University of Science and Technology of China and his Ph.D. in Biochemistry from the University of Wisconsin, Madison. We believe Dr. Zhong is qualified to serve on our board of directors due to his scientific expertise and his experience as an executive in drug discovery and development in the biotechnology industry, as well as his experience as a founding member of our company.

Non-Employee Directors

David Fellows has served as a member of our board of directors since December 2020 and as chairman of our board of directors since February 2021. Mr. Fellows served as the Chief Executive Officer and board member of Nightstar Therapeutics plc, a publicly-traded biotechnology company, from January 2015, and as a member of its board of directors from September 2017, until its acquisition by Biogen Inc., a publicly-traded biotechnology company, in July 2019. Before that, he served as the Vice President of Vision Care at Johnson & Johnson, from September 2005 to December 2014. Mr. Fellows serves on the boards of directors of Gyroscope Therapeutics, Jaguar Gene Therapy and Oxular Ltd. Mr. Fellows has also served on the board of the non-profit Glaucoma Foundation since May 2006. Mr. Fellows received his undergraduate degree in Psychology from Butler University. We believe Mr. Fellows is qualified to serve on our board of directors due to his extensive experience as an executive of companies in the biotechnology industry.

Carl Gordon, Ph.D., CFA has served as a member of our board of directors since October 2018. Dr. Gordon is a founding member and has served as Managing Partner and Co-Head of OrbiMed Advisors LLC, an investment firm, since 1998. Dr. Gordon currently serves on the boards of directors of Adicet Bio, Inc., Compass Therapeutics Inc., Gemini Therapeutics Inc., Keros Therapeutics, Inc., Kinnate Biopharma, Inc., and ORIC Pharmaceuticals, Inc., all publicly-traded companies, as well as several private companies. Dr. Gordon previously served on the boards of directors of several biopharmaceutical companies, including Alector, Inc., ARMO Biosciences, Inc., Arsanis, Inc. (which merged with X4 Pharmaceuticals, Inc.), Intellia Therapeutics, Inc., Passage Bio, Inc., Prevail Therapeutics Inc., Selecta Biosciences, Inc., SpringWorks Therapeutics, Inc., and Turning Point Therapeutics, Inc. Dr. Gordon received his undergraduate degree in Chemistry from Harvard College, his Ph.D. in Molecular Biology from the Massachusetts Institute of Technology and was a Fellow at The Rockefeller University. We believe that Dr. Gordon is qualified to serve on our board of directors due to his scientific expertise, extensive business experience and experience in venture capital and the life science industry.

Jeffrey Kindler, Esq. has served as a member of our board of directors since December 2020. Mr. Kindler has served as an operating partner of ARTIS Ventures, a venture investment firm, since January 2020, Senior Advisor to Blackstone, an investment firm, since June 2020, and as the Chief Executive Officer of Centrexion Therapeutics, a private biopharmaceutical company, since October 2013. Mr. Kindler has served on the board of directors of Perrigo Company plc since February 2017, PPD, Inc. from March 2012 and Precigen, Inc. since November 2011, all publicly-traded companies. Mr. Kindler previously served on the board of vTv Therapeutics Inc., a publicly-traded biotechnology company, from July 2015 to December 2020 and SIGA Technologies, Inc., a publicly-traded pharmaceutical company, from March 2013 to June 2020. Mr. Kindler received his undergraduate degree from Tufts University and J.D. from Harvard University. We believe Mr. Kindler is qualified to serve on our board of directors due to his extensive experience as an executive and director of companies in the biotechnology industry.

Hongbo Lu, Ph.D. has served as a member of our board of directors since April 2020. She has served as a Managing Partner at Vivo Capital, a healthcare investment firm, since January 2021. She previously served as a

Managing Partner of Lilly Asia Ventures, a venture capital firm, from January 2017 to December 2020. From June 2011 to October 2016, she served as a Managing Director at OrbiMed Advisors LLC. Dr. Lu currently serves on the board of directors of several private biotechnology companies, such as PINS Medical, Inc., Elpiscience and Geneception. She previously served on the board of directors of public companies including Turning Point Therapeutics, Inc., a publicly-traded biotechnology company, from May 2017 to May 2019, and on the board of directors of Avedro, Inc., a publicly-traded biotechnology company, from May 2018 to February 2019. Dr. Lu received her undergraduate degree in Material Science and Engineering from Tsinghua University, China, her Ph.D. in Biological Engineering from the University of Washington and her MBA from the University of California, Berkeley. We believe Dr. Lu is qualified to serve on our board of directors due to her experience as a director of public and private companies in the biotechnology industry and experience in venture capital and the life science industry.

Jill Quigley, Esq. has served as a member of our board of directors since December 2020. Ms. Quigley has served as the Chief Operating Officer of Passage Bio, a publicly-traded biopharmaceutical company, since November 2018. Previously, she served as the Interim Chief Executive Officer and General Counsel of Nutrinia, Inc., from January 2016 to November 2018. From July 2012 to January 2016, Ms. Quigley served in various roles at Shire plc, most recently as Senior Legal Counsel. Ms. Quigley received her undergraduate degree in Communications, Legal Institutions, Economics & Governance (CLEG) from American University and J.D. from Rutgers School of Law. We believe Ms. Quigley is qualified to serve on our board of directors due to her extensive experience as an executive of companies in the biotechnology industry.

Family Relationships

There are no family relationships among any of our executive officers or directors.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires our directors, executive officers, and persons holding more than 10% of our common stock to report their initial ownership of the common stock and other equity securities and any changes in that ownership in reports that must be filed with the SEC. The SEC has designated specific deadlines for these reports, and we must identify in our Annual Report on Form 10-K those persons who did not file these reports when due.

We were not subject to the filing requirements of Section 16(a) of the Exchange Act in 2020.

Board Composition

Classified Board of Directors

In accordance with our amended and restated certificate of incorporation, our board of directors is divided into three classes with staggered three-year terms. At each annual general meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors are divided among the three classes as follows:

- The Class I directors are Carl Gordon, Hongbo Lu and Weidong Zhong, and their terms will expire at the annual meeting of stockholders to be held in 2022;
- The Class II directors are David Fellows and Jill Quigley, and their terms will expire at the annual meeting of stockholders to be held in 2023; and
- The Class III directors are Jeffrey Kindler and Senthil Sundaram, and their terms will expire at the annual meeting of stockholders to be held in 2024.

The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control.

Audit Committee

Our audit committee oversees our corporate accounting and financial reporting process. Among other matters, the audit committee:

- appoints our independent registered public accounting firm;
- evaluates the independent registered public accounting firm's qualifications, independence and performance;
- determines the engagement of the independent registered public accounting firm;
- reviews and approves the scope of the annual audit and pre-approves the audit and non-audit fees and services;
- reviews and approves all related party transactions on an ongoing basis;
- establishes procedures for the receipt, retention and treatment of any complaints received by us regarding accounting, internal accounting controls or auditing matters;
- discusses with management and the independent registered public accounting firm the results of the annual audit and the review of our quarterly financial statements;
- approves the retention of the independent registered public accounting firm to perform any proposed permissible non-audit services;
- discusses on a periodic basis, or as appropriate, with our management's policies and procedures with respect to risk assessment and risk management;
- consults with management to establish procedures and internal controls relating to cybersecurity;
- is responsible for reviewing our financial statements and our management's discussion and analysis of financial condition and results of operations to be included in our annual and quarterly reports to be filed with the SEC;
- investigates any reports received through the ethics helpline and reports to the board of directors periodically with respect to any information received through the ethics helpline and any related investigations; and
- reviews the audit committee charter and the audit committee's performance on an annual basis.

Our audit committee consists of Jill Quigley, Jeffrey Kindler and Hongbo Lu. Our board of directors has determined that all members are independent under the Nasdaq Listing Rules and Rule 10A-3(b)(1) of the Exchange Act. The chair of our audit committee is Ms. Quigley. Our board of directors has determined that Mr. Kindler is an "audit committee financial expert" as such term is currently defined in Item 407(d)(5) of Regulation S-K. Our board of directors has also determined that each member of our audit committee can read and understand fundamental consolidated financial statements, in accordance with applicable requirements.

Compensation Committee

Our compensation committee oversees policies relating to compensation and benefits of our officers and employees. The compensation committee reviews and approves or recommends corporate goals and objectives relevant to compensation of our executive officers (other than our Chief Executive Officer), evaluates the performance of these officers in light of those goals and objectives and approves the compensation of these officers based on such evaluations. The compensation committee also reviews and approves or makes recommendations to our board of directors regarding the issuance of stock options and other awards under our stock plans to our executive officers (other than our Chief Executive Officer). The compensation committee reviews the performance of our Chief Executive Officer and makes recommendations to our board of directors with respect to his compensation, and our board of directors retains the authority to make compensation decisions relative to our Chief Executive Officer. The compensation committee will review and evaluate, on an annual basis, the compensation committee charter and the compensation committee's performance.

Our compensation committee consists of Jeffrey Kindler, David Fellows and Hongbo Lu. Our board of directors has determined that all members are independent under the Nasdaq Listing Rules and are "non-employee directors" as defined in Rule 16b-3 promulgated under the Exchange Act. The chair of our compensation committee is Mr. Kindler.

Nominating and Corporate Governance Committee

The nominating and corporate governance committee is responsible for making recommendations to our board of directors regarding candidates for directorships and the size and composition of our board of directors. In addition, the nominating and corporate governance committee is responsible for overseeing our corporate governance policies and making recommendations to our board of directors concerning governance matters.

Our nominating and corporate governance committee consists of David Fellows, Jill Quigley and Carl Gordon. Our board of directors has determined that all members of the nominating and corporate governance committee are independent under the Nasdaq Listing Rules. The chair of our nominating and corporate governance committee is Mr. Fellows.

Code of Business Conduct and Ethics

Our board of directors has adopted a code of business conduct and ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. The full text of our code of business conduct and ethics is available on our website at ir.ternspharma.com under "Corporate Governance." Any substantive amendment to, or waiver of, a provision of the code of business conduct and ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions, will be disclosed on our website.

Item 11. Executive Compensation.

This section discusses the material components of the executive compensation program for our 2020 named executive officers. Our named executive officers for fiscal year 2020 were:

- Senthil Sundaram, our Chief Executive Officer;
- Mark Vignola, Ph.D., our Chief Financial Officer; and
- Erin Quirk, M.D., our President and Chief Medical Officer.

This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt may differ materially from the currently planned programs summarized in this discussion. As an "emerging growth company" as defined in the JOBS Act, we are not required to include a Compensation Discussion and Analysis section and have elected to comply with the scaled disclosure requirements applicable to emerging growth companies. The equity award share numbers and exercise prices presented in Item 11. have been adjusted to reflect the impact of the 1-for-14 reverse stock split.

2020 Summary Compensation Table

The following table sets forth information concerning the compensation of our named executive officers for the year ended December 31, 2020.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards ($)(1)	Non-Equity Incentive Plan Compensation	Total ($)
Senthil Sundaram(2)	2020	208,333	150,000(3)	13,135,650	223,437	13,717,420
Chief Executive Officer						
Mark Vignola, Ph.D.(4)	2020	110,000	—	3,060,550	72,150	3,242,700
Chief Financial Officer						
Erin Quirk, M.D.	2020	374,325	—	3,294,044	175,064	3,843,433
President and Chief Medical Officer						

(1) Amounts reflect the full grant date fair value of option awards granted during 2020 computed in accordance with ASC Topic 718, rather than the amounts paid to or realized by the named individual. See Note 11 of the consolidated financial statements included in this Annual Report for the assumptions used in calculating these amounts.

(2) Mr. Sundaram commenced his employment effective as of July 30, 2020.

(3) Amount represents a signing and relocation bonus paid to Mr. Sundaram in connection with the commencement of his employment with us as described in the section titled "—Signing and Relocation Bonus" below.

(4) Dr. Vignola commenced his employment with us on September 1, 2020.

Narrative to the Summary Compensation Table

2020 Annual Base Salaries

Our named executive officers each receive a base salary to compensate them for services rendered to our company. The base salary payable to each named executive officer is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role and responsibilities. During fiscal year 2020, our named executive officers' annual base salaries were as follows:

- Mr. Sundaram: $500,000;
- Dr. Vignola: $330,000; and
- Dr. Quirk: $374,325.

In December 2020, our board of directors approved increasing the base salaries of our named executive officers. Starting in February 2021, the annual base salaries for Mr. Sundaram, Dr. Vignola and Dr. Quirk are $515,000, $375,000 and $430,000, respectively.

2020 Annual Performance Bonuses

We maintain an annual performance-based cash bonus program in which each of our named executive officers participated in 2020. Each named executive officer's target bonus is expressed as a percentage of base salary, and bonus payments are determined based on achievement of certain performance goals approved by our board of directors. The 2020 annual bonus for Mr. Sundaram was targeted at 45% of annual base salary, the 2020 annual bonus for Dr. Vignola was targeted at 30% of his annual base salary and the 2020 annual bonus for Dr. Quirk was targeted at 35% of her base salary. For fiscal 2021, the target bonuses for our named executive officers are as follows: Mr. Sundaram: 50%; Dr. Quirk: 45%; and Dr. Vignola: 40%. In February 2021, our board of directors determined annual performance-based cash bonus amounts for 2020, and the 2020 annual bonuses earned by our named executive officers are set forth in the Summary Compensation Table above in the column entitled "Non-Equity Incentive Plan Compensation".

Signing and Relocation Bonus

In order to attract top talent, from time to time, we provide signing and relocation bonuses to external hires. In connection with the hire of Mr. Sundaram in July 2020, we approved a cash signing and relocation bonus in the aggregate amount of $150,000, which was paid within 30 days following his employment start date. In the event Mr. Sundaram resigns for "good reason" or we terminate his employment with us for "cause" (in each case as defined in his offer letter agreement) before the first anniversary of his employment start date, he will be required to repay a prorated portion of his signing and relocation bonus. We believe this signing and relocation bonus arrangement was appropriate as an incentive for Mr. Sundaram to join us and remain employed through the first anniversary of his employment start date.

Equity Compensation

We have granted stock options to our employees, including our named executive officers, in order to attract and retain them, as well as to align their interests with the interests of our stockholders. In order to provide a long-term incentive, these stock options generally vest over four years subject to continued service to the company.

In connection with our initial public offering, or IPO, we adopted the 2021 Incentive Award Plan, or the 2021 Plan, in order to facilitate the grant of cash and equity incentives to directors, employees (including our named executive officers) and consultants of our company and certain of its affiliates and to enable us to obtain and retain services of these individuals, which is essential to our long-term success.

Other Elements of Compensation

Retirement Savings and Health and Welfare Benefits

Our employees, including our named executive officers, who satisfy certain eligibility requirements are eligible to participate in a 401(k) plan maintained by TriNet, a professional employer organization that is the legal employer of our employees. Our named executive officers are eligible to participate in the 401(k) plan on the same terms as other full-time employees. For each participant, we make matching contributions to the 401(k) plan equal to 100% of the first 3% of eligible compensation contributed each year, up to $7,500. We believe that providing a vehicle for tax-deferred retirement savings though our 401(k) plan adds to the overall desirability of our executive compensation package and further incentivizes our employees, including our named executive officers, in accordance with our compensation policies.

All of our full-time employees, including our named executive officers, are eligible to participate in our health and welfare plans, which are provided through TriNet. These health and welfare plans include medical, dental and vision benefits; short-term and long-term disability insurance; and supplemental life and AD&D insurance.

Perquisites and Other Personal Benefits

We determine perquisites on a case-by-case basis and will provide a perquisite to a named executive officer when we believe it is necessary to attract or retain the named executive officer. However, in 2020, we did not provide any perquisites or personal benefits to our named executive officers not otherwise made available to our other employees.

Outstanding Equity Awards at Fiscal Year-End

The following table summarizes the number of shares of common stock underlying outstanding option awards for each named executive officer as of December 31, 2020.

			Option Awards			
Name	Grant Date	Vesting Commencement Date(1)	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date
Senthil Sundaram	8/13/2020	7/30/2020(2)(3)(4)	370,170	—	6.86	8/12/2030
	12/30/2020	12/30/2020(2)(3)(4)	579,027	—	9.24	12/29/2030
Mark Vignola, Ph.D.	9/10/2020	9/1/2020(2)(3)(4)	76,995	—	6.86	9/9/2030
	12/30/2020	12/30/2020(2)(3)(4)	150,812	—	9.24	12/29/2030
Erin Quirk, M.D.	1/11/2019	1/2/2019(2)	32,514	35,342	6.16	1/10/2029
	3/16/2020	1/17/2020	1,309	4,404	6.72	3/15/2030
	7/31/2020	7/1/2020	1,860	15,997	6.86	7/30/2030
	12/30/2020	12/30/2020(2)	—	288,250	9.24	12/29/2030

(1) Except as otherwise indicated, 1/48th of the shares subject to each option vest on each monthly anniversary of the vesting commencement date, subject to continued service with us through each vesting date.

(2) 1/4th of the shares subject to each option vest on the 12-month anniversary of the vesting commencement date and 1/48th of the shares subject to the option vest on each monthly anniversary of the vesting commencement date for three years thereafter, subject to continued service with us through each vesting date.

(3) Pursuant to the terms of the named executive officer's offer letter agreement, the shares subject to the option will vest in full in the event of a termination of the executive's employment by us without "cause" or the executive's resignation for "good reason" (each such term as defined in the named executive officer's offer letter agreement), in each case, that occurs after entering into a definitive agreement providing for a change in control and within three months prior to or 12 months following a change in control of our company.

(4) Pursuant to the terms of the named executive officer's offer letter agreement, the named executive officer may exercise the option prior to vesting and be issued restricted shares, subject to entering into a restricted shares agreement with the Company, provided that such restricted shares will be subject to the same vesting schedule applicable to the related option award.

Change in Control Policy

In July 2020, we adopted the Terns Pharmaceuticals, Inc. Change in Control Policy, or the "CIC Policy", in which our executed officers (including our named executive officers), senior executives with a title of "Vice President" or higher, and other employees designated by our board are eligible to participate. Pursuant to the CIC Policy, 100% of a participant's then-outstanding equity awards will vest in full in the event of a termination of the participant's employment without "cause" or the participant's resignation for "good reason" (each such term generally defined in the same way they are defined in Mr. Sundaram's offer letter agreement), in each case, that occurs after entering into a definitive agreement providing for a change in control and within three months prior to or 12 months following a change in control of our company, subject to the participant's timely execution and non-revocation of a general release of claims against our company. If equity awards are subject to performance-based vesting conditions and such performance criteria have not or cannot be determined as of the date of the qualifying termination, such performance criteria shall be deemed to have been achieved at target levels. If a qualifying termination occurs after entering into a definitive agreement providing for a change in control but before the occurrence of an actual change in control event, the acceleration of the participant's equity awards will occur upon the change in control event and not the qualifying termination.

Executive Compensation Arrangements

Offer Letter Agreements

Mr. Sundaram Offer Letter Agreement

In July 2020, we entered into an offer letter agreement with Mr. Sundaram setting forth the terms and conditions of his employment with us. This agreement provides that Mr. Sundaram will serve as our Chief Executive Officer with an annual base salary of $500,000, a target bonus opportunity of 45% of his annual base salary, a one-time signing and relocation bonus of $150,000 and an initial option to purchase 370,170 shares of our common stock. The offer letter also provided for Mr. Sundaram the opportunity to be granted an additional option in the event we completed certain financing transactions prior to our initial public offering or a change in control.

In the event Mr. Sundaram resigns for "good reason" or we terminate his employment with us without "cause" (in each case as defined in his offer letter agreement), he is entitled to receive the following benefits, in addition to any accrued obligations and subject to his timely execution and non-revocation of a general release of claims in our favor: (i) continuation of his then-current annual base salary for a period of 12 months, (ii) a prorated portion of his annual performance bonus at 100% of target, (iii) continuation of his healthcare insurance coverage (or an equivalent reimbursement from us) for a period of 12 months and (iv) extended exercisability of certain options for up to three years following his termination of employment. Additionally, in the event Mr. Sundaram resigns for "good reason" or we terminate his employment with us without "cause" following a "potential change in control" and within three months prior to or 12 months following a "change in control" of our company (in each case as defined in his offer letter agreement), he is entitled to receive the following benefits, in addition to any accrued obligations and subject to his timely execution and non-revocation of a general release of claims in our favor: (i) continuation of his then-current annual base salary for a period of 18 months, (ii) a prorated portion of his annual performance bonus at 150% of target, (iii) continuation of his healthcare insurance coverage (or an equivalent reimbursement from us) for a period of 12 months and (iv) full vesting acceleration of all his then-outstanding equity awards.

Mr. Sundaram's offer letter agreement generally defines "cause" to mean the occurrence of any one or more of the following, subject to certain notice and cure rights: (i) the commission of any crime involving fraud, dishonesty or moral turpitude, (ii) the attempted commission of or participation in a fraud or act of dishonesty against us that results in (or might have reasonably resulted in) material harm to the business of our company; (iii) the intentional, material violation of any contract or agreement between him and us or any statutory duty owed to us, or (iv) conduct that constitutes gross insubordination, incompetence or habitual neglect of duties and that results in (or might have reasonably resulted in) material harm to the business of our company.

Mr. Sundaram's offer letter agreement generally defines "good reason" to mean the occurrence of any one or more of the following, without his consent and subject to certain notice and cure rights: (i) the assignment of any duties or responsibilities that results in a material diminution in his function (as in effect immediately prior to the effective date of the change in control transaction, if applicable); (ii) a reduction of greater than 10% in his annual base salary (as in effect on the effective date of the change in control transaction, if applicable); provided, however, that good reason shall not be deemed to have occurred in the event of a reduction in his annual base salary that is pursuant to a salary reduction program affecting substantially all of our employees and that does not adversely affect him to a greater extent than other similarly situated employees; or (iii) a relocation of his primary business office to a location more than 30 miles from the location of his primary business office (as of the effective date of the change in control transaction, if applicable), except for required travel on our company's business (to an extent substantially consistent with his business travel obligations prior to the effective date of the change in control transaction, if applicable).

Dr. Vignola Offer Letter Agreement

In August 2020, we entered into an offer letter agreement with Dr. Vignola setting forth the terms and conditions of his employment with us. The offer letter provides for Dr. Vignola to serve as our Chief Financial Officer commencing on September 1, 2020 with an annual base salary of $330,000 and a target bonus opportunity of 30% of his annual base salary.

In the event Dr. Vignola resigns for "good reason" or we terminate his employment with us without "cause" (in each case as defined in his offer letter agreement), he is entitled to receive the following benefits, in addition to any accrued obligations and subject to his timely execution and non-revocation of a general release of claims in our favor: (i) continuation of his then-current annual base salary for a period of 12 months, (ii) a prorated portion of his annual performance bonus based on actual performance, (iii) continuation of his healthcare insurance coverage (or an equivalent reimbursement from us) for a period of 12 months, and (iv) the extended exercisability of his options for up to three years following his termination of employment. In the event such resignation or termination occurs following a "potential change in control" and within three months prior to or 12 months following a "change in control" of our company (in each case as defined in his offer letter agreement), then, in addition to the foregoing payments and benefits, Dr. Vignola is entitled to full vesting acceleration of all his then-outstanding equity awards.

Dr. Vignola's offer letter agreement generally defines "cause" and "good reason" in the same way they are defined in Mr. Sundaram's offer letter agreement.

Dr. Quirk Offer Letter Agreement

In August 2020, we entered into an offer letter agreement with Dr. Quirk setting forth the terms and conditions of her continued employment with us. The offer letter provides for Dr. Quirk to continue to serve as our President and Chief Medical Officer with an annual base salary of $374,325 and a target bonus opportunity of 35% of her annual base salary.

In the event Dr. Quirk resigns for "good reason" or we terminate her employment with us without "cause" (in each case as defined in her offer letter agreement), she is entitled to receive the following benefits, in addition to any accrued obligations and subject to her timely execution and non-revocation of a general release of claims in our favor: (i) continuation of her then-current annual base salary for a period of 12 months, (ii) a prorated portion of her annual performance bonus based on actual performance, and (iii) continuation of her healthcare insurance coverage (or an equivalent reimbursement from us) for a period of 12 months.

Dr. Quirk's offer letter agreement generally defines "cause" and "good reason" in the same way they are defined in Mr. Sundaram's offer letter agreement except that Dr. Quirk's offer letter requires a greater distance relocation to trigger "good reason".

Director Compensation

Prior to our IPO, we have not maintained a formal non-employee director compensation program. Our non-employee directors received no cash compensation from us during the year ended December 31, 2020. However, in 2020, we granted David Fellows, Jeffrey Kindler, and Jill Quigley each an option to purchase 28,475 stock options as set forth in the 2020 Director Compensation Table below. Additionally, we provide reimbursement to our non-employee directors for their reasonable expenses incurred in attending meetings of our board of directors and its committees. Mr. Sundaram and Dr. Zhong receive no additional compensation for their service as directors.

2020 Director Compensation Table

Name	Option Awards ($)(1)	Total ($)
David Fellows	309,641	309,641
Carl Gordon, Ph.D., C.F.A.	—	—
Jeffrey Kindler	309,641	309,641
Hongbo Lu, Ph.D.	—	—
Jill Quigley, J.D.	309,641	309,641
Yi Shi, Ph.D., MBA	—	—
Elise Wang, MBA	—	—

(1) Amounts reflect the full grant date fair value of option awards granted during 2020 computed in accordance with ASC Topic 718, rather than the amounts paid to or realized by the named individual. See Note 11 of the consolidated financial statements included in this Annual Report for the assumptions used in calculating these amounts.

The table below shows the aggregate numbers of stock options held as of December 31, 2020 by each non-employee director.

Name	Options Outstanding as of December 31, 2020 (#)
David Fellows	28,475
Carl Gordon, Ph.D., C.F.A.	—
Jeffrey Kindler	28,475
Hongbo Lu, Ph.D.	—
Jill Quigley, J.D.	28,475
Yi Shi, Ph.D., MBA	—
Elise Wang, MBA	—

In February 2021, subsequent to the completion of our IPO, Drs. Gordon and Lu were each awarded an option to purchase 25,000 shares of the Company's common stock in accordance with the non-employee director compensation program described further below.

Non-Employee Director Compensation Program

Pursuant to the compensation program for our non-employee directors, or the Director Compensation Program, which became effective in connection with our IPO, our non-employee directors will receive cash compensation as follows:

- Each non-employee director will receive an annual cash retainer in the amount of $40,000 per year.
- The non-executive chair will receive an additional annual cash retainer in the amount of $30,000 per year.
- The chairperson of the audit committee will receive additional annual cash compensation in the amount of $15,000 per year for such chairperson's service on the audit committee. Each non-chairperson member of the audit committee will receive additional annual cash compensation in the amount of $7,500 per year for such member's service on the audit committee.
- The chairperson of the compensation committee will receive additional annual cash compensation in the amount of $10,000 per year for such chairperson's service on the compensation committee. Each non-chairperson member of the compensation committee will receive additional annual cash compensation in the amount of $5,000 per year for such member's service on the compensation committee.
- The chairperson of the nominating and corporate governance committee will receive additional annual cash compensation in the amount of $8,000 per year for such chairperson's service on the nominating and corporate governance committee. Each non-chairperson member of the nominating and corporate governance committee will receive additional annual cash compensation in the amount of $4,000 per year for such member's service on the nominating and corporate governance committee.

Under the Director Compensation Program, each non-employee director will automatically be granted an option to purchase 25,000 shares of our common stock upon the director's initial appointment or election to our board of directors, referred to as the Initial Grant, and an option to purchase 12,500 shares of our common stock automatically on the date of each annual stockholder's meeting thereafter, referred to as the Annual Grant. The Initial Grant will vest as to 1/3rd of the total shares subject thereto on the first anniversary of the applicable date of grant and as to 1/36th of the total shares subject thereto on each monthly anniversary of the applicable date of grant over the next 24 months thereafter, subject to continued service through each applicable vesting date. The Annual Grant will vest on the earlier of the first anniversary of the date of grant or the date of the next annual stockholder's meeting to the extent unvested as of such date, subject to continued service through each applicable vesting date. Each Initial Grant and Annual Grant will vest in full in the event of a change in control.

Compensation Committee Interlocks and Insider Participation

None of the members of the compensation committee is currently, or has been at any time, one of our executive officers or employees. None of our executive officers currently serves, or has served during the last year, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or on our compensation committee.

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

Equity Compensation Plan Information

The following table provides information on our equity compensation plans as of March 19, 2020. Information is included for equity compensation plans approved by our stockholders. We do not have any equity compensation plans not approved by our stockholders.

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options	Weighted-Average Exercise Price of Outstanding Options	Number of Securities Remaining Available for Future Issuance under Equity Compensation Plans (2)(3)(4)
	(in thousands, except per share amount)		
Equity compensation plans approved by security holders(1)	2,566,282	$ 8.65	2,534,007

(1) Includes securities issuable under our 2017 Equity Incentive Plan (the "2017 Plan"), the 2021 Plan and our 2021 Employee Stock Purchase Plan (the "ESPP").

(2) Includes 2,294,007 and 240,000 shares of common stock available for issuance under the 2021 Plan and the ESPP, respectively, as of March 19, 2021. No shares are available for issuance under the 2017 Plan. Shares under the 2017 Plan that expire, terminate or are forfeited prior to exercise or settlement automatically become available for issuance under the 2021 Plan.

(3) The number of shares of common stock reserved for issuance pursuant to equity awards under the 2021 Plan will automatically increase January 1 of each year for a period of up to ten years, commencing on January 1, 2022 and continuing through and including January 1, 2031 by 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 Board of Directors.

(4) The number of shares of common stock reserved for issuance under the ESPP will increase January 1 of each year for a period of up to ten years commencing January 1, 2022 and continuing through and including January 1, 2031 by the lesser of (i) a number of shares equal to 1% of the total number of outstanding shares of common stock on December 31 immediately prior to the date of increase; (ii) such number of shares as may be determined by the Board of Directors; *provided, however*, no more than 3,300,009 shares may be issued under the ESPP.

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth, as of March 19, 2021, information regarding beneficial ownership of our capital stock by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock;
- each of our named executive officers;
- each of our directors; and
- all of our executive officers and directors as a group.

The percentage of is based on 25,125,072 shares of common stock outstanding as of March 19, 2021. This table is based upon information supplied by officers, directors and principal stockholders and Schedules 13D and Schedules 13G, if any, filed with the SEC.

Beneficial ownership is determined according to the rules of the SEC and generally means that a person has beneficial ownership of a security if he, she or it possesses sole or shared voting or investment power of that security. In addition, shares of common stock issuable upon the exercise of stock options or warrants that are currently exercisable or exercisable within 60 days of March 19, 2021 are included in the following table. These shares are deemed to be outstanding and beneficially owned by the person holding those options or warrants for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. The information contained in the following table does not necessarily indicate beneficial ownership for any other purpose. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Unless otherwise noted below, the address for each beneficial owner listed in the table below is c/o Terns Pharmaceuticals, Inc., 1065 East Hillsdale, Suite 100, Foster City, California 94404.

	Beneficial Ownership	
Name of Beneficial Owner	**Number of Shares Beneficially Owned (#)**	**Percent of Total (%)**
Greater than 5% Stockholders:		
Lilly Asia Ventures U.S.(1)	4,781,566	19.0%
Entities affiliated with OrbiMed Advisors LLC(2)	3,791,204	15.1%
Entities affiliated with Vivo Capital(3)	2,675,133	10.6%
Deerfield Partners, L.P.(4)	2,382,033	9.5%
Lilly Asia Ventures (PRC)(5)	1,411,206	5.6%
Named Executive Officers and Directors:		
Erin Quirk, M.D.(6)	333,457	1.3%
Senthil Sundaram(7)	949,197	3.6%
Mark Vignola, Ph.D.(8)	227,807	†
David Fellows	—	—
Carl Gordon, Ph.D., C.F.A.(9)	3,791,204	15.1%
Jeffrey Kindler, Esq.	—	—
Hongbo Lu, Ph.D.(10)	—	—
Jill Quigley, Esq.	—	—
Weidong Zhong, Ph.D.(11)	442,299	1.7%
All executive officers and directors as a group (10 persons)(*)(12)	6,009,739	22.2%

* Includes Bryan Yoon, our Chief Operating Officer and General Counsel, who is not named in the table above.

† Represents beneficial ownership of less than one percent.

(1) Consists of (i) 1,392,857 shares of common stock held directly by Hopewell Resources Holdings Limited, (ii) 696,428 shares of common stock held directly by Oriental Spring Venture Limited, (iii) 1,286,698 shares of common stock held directly by LAV Aqua Limited, and (iv) 1,405,583 shares of common stock held directly by LAV Biosciences Fund V, L.P. LAV Corporate GP, Ltd. is the general partner of LAV GP III, L.P., which is the general partner of the parent entity of Hopewell Resources Holdings Limited and Oriental Spring Venture Limited. LAV Corporate IV GP, Ltd., is the general partner of LAV GP IV, L.P., which is the general partner of the parent entity of LAV Aqua Limited. LAV Corporate V GP, Ltd., is the general partner of LAV GP V, L.P., which is the general partner of LAV Biosciences Fund V, L.P. Dr. Yi Shi is the managing partner of LAV Corporate GP, Ltd., LAV Corporate IV GP, Ltd., and LAV Corporate V, L.P. and has all voting and investment power with respect to shares beneficially held by each of Hopewell Resources Holdings Limited, Oriental Spring Venture Limited, LAV Aqua Limited and LAV Biosciences Fund V, L.P. The principal address for each of LAV Corporate GP, Ltd., LAV Corporate IV GP, Ltd., and LAV Corporate V, L.P., Hopewell Resources Holdings Limited, Oriental Spring Venture Limited, LAV Aqua Limited and LAV Biosciences Fund V, L.P. is Unit 902-904, Two ChinaChem Central, 26 Des Voeux Road Central, Hong Kong.

(2) Consists of (i) 2,274,723 shares of common stock held directly by OrbiMed Private Investments VII, LP, or OPI VII and (ii) 1,516,481shares of common stock held directly by OrbiMed Asia Partners III, LP, or OrbiMed Asia, Dr. Carl L. Gordon is a member of the management committee of OrbiMed Advisors LLC, or OrbiMed Advisors, and a member of our board of directors. OrbiMed Capital GP VII LLC, or

OrbiMed GP VII, is the general partner of OPI VII and OrbiMed Advisors is the managing member of OrbiMed GP VII. By virtue of such relationships, OrbiMed GP VII and OrbiMed Advisors may be deemed to have voting power and investment power over the securities held by OPI VII and as a result, may be deemed to have beneficial ownership over such securities. OrbiMed Advisors exercises voting and investment power through a management committee comprised of Dr. Gordon, Sven H. Borho, and Jonathan T. Silverstein, each of whom disclaims beneficial ownership of the shares held by OPI VII. Dr. Gordon a member of the management committee of OrbiMed Advisors III Limited, or OrbiMed Advisors III, and a member of our board of directors. OrbiMed Asia GP III, or OrbiMed Asia GP, is the general partner of OrbiMed Asia and OrbiMed Advisors III is the managing member of OrbiMed Asia GP. By virtue of such relationships, OrbiMed Asia GP and OrbiMed Advisors III may be deemed to have voting power and investment power over the securities held by OrbiMed Asia and as a result, may be deemed to have beneficial ownership over such securities. OrbiMed Advisors III exercises voting and investment power through a management committee comprised of Dr. Gordon, Sven H. Borho, Jonathan T. Silverstein, Jonathan Wang, David G. Wang, Sunny Sharma, Carter W. Nield and Samuel D. Isaly, each of whom disclaims beneficial ownership of the shares held by OrbiMed Asia. The address for each of the entities and individuals identified in this footnote is c/o OrbiMed Advisors, 601 Lexington Avenue 54th Floor, New York, NY 10022.

(3) Consists of (i) 2,036,557 shares of common stock held directly by Vivo Capital Fund VIII, L.P., or VCF, (ii) 281,223 shares of common stock held directly by Vivo Capital Surplus Fund VIII, L.P., or VCSF, and (iii) 357,353 shares of common stock held directly by Vivo Opportunity Fund, L.P., or Vivo Opportunity Fund. Vivo Capital VIII, LLC, or Vivo LLC, is the general partner of both VCF and VCSF. Dr. Hongbo Lu is a Managing Partner at Vivo Capital and a member of our board of directors. The voting members of Vivo LLC are Frank Kung, Edgar Engleman and Shan Fu, none of whom has individual voting or investment power with respect to these shares and each of whom disclaims beneficial ownership of such shares. Vivo Opportunity, LLC is the general partner of Vivo Opportunity Fund. The voting members of Vivo Opportunity, LLC are Gaurav Aggarwal, Shan Fu, Frank Kung and Michael Chang none of whom has individual voting or investment power with respect to these shares and each of whom disclaims beneficial ownership of such shares. Dr. Lu does not have individual voting or investment power with respect to these shares and disclaims beneficial ownership of such shares. The address for each of the entities and individuals identified in this footnote is 505 Hamilton Avenue, Suite 207, Palo Alto, California 94301.

(4) Consists of 2,382,033 shares of common stock held directly by Deerfield Partners, L.P., or Deerfield. The address for Deerfield Partners, L.P., is c/o Deerfield Management Company, L.P., 780 Third Avenue, 37th Floor, New York, New York 10017.

(5) Consists of 1,411,206 shares of common stock held directly by Auspice Limited. Shanghai Liyi Investment Management Partnership L.P. is the general partner of Auspice Limited. Dr. Fei Chen is the managing partner of Shanghai Liyi Investment Management Partnership L.P. Dr. Fei Chen holds all voting and investment power over all shares beneficially held by Auspice Limited. Dr. Fei Chen is a managing partner at Lilly Asia Ventures (PRC). The registered address of Shanghai Liyi Investment Management Partnership L.P. is Room 1409, Building 2, No.700 Jiahao Road, Jiading District, Shanghai 201802 P.R. China. The registered address of Auspice Limited is Room 2909-2914, #3 Corporate Avenue 168 Hubin Road, Huangpu, Shanghai, China.

(6) Consists of 333,457 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of March 19, 2021.

(7) Consists of 949,197 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of March 19, 2021.

(8) Consists of 227,807 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of March 19, 2021.

(9) Consists of the shares described in footnote (2) above. Dr. Gordon disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein, if any.

(10) Does not include the shares of common stock held by Vivo Capital described in footnote (3) above. Dr. Hongbo Lu is a Managing Partner at Vivo Capital and a member of our board of directors.

(11) Consists of (i) 285,714 shares of common stock held directly by Dr. Weidong Zhong and (ii) 156,585 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of March 19, 2021.

(12) Includes (i) 4,076,918 shares held by our current directors and executive officers and (ii) 1,932,821 shares subject to options exercisable within 60 days of March 19, 2021.

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

Other than compensation arrangements, including employment arrangements, with our directors and executive officers, including those discussed in "Item 11. Executive Compensation" of this Annual Report on Form 10-K, the following is a description of each transaction since January 1, 2020 in which:

- we were a party or will be a party;
- the amounts involved exceeded or will exceed $120,000; and
- any of our directors, executive officers or holders of more than 5% of our capital stock, or an affiliate or immediate family member thereof, had or will have a direct or indirect material interest.

2020 Bridge Loan

In May 2020, Terns China Biotechnology Co., Ltd. entered into a bridge loan, or the Bridge Loan, with certain entities that are a part of Lilly Asia Ventures, which beneficially owned more than 5% of our outstanding capital stock at the time of the bridge loan financing, for the aggregate principal amount of approximately $1.8 million.

In connection with the closing of the Series C convertible preferred stock financing, entities affiliated with Lilly Asia Ventures, or LAV, agreed to effectively convert the Bridge Loan into shares of our Series C preferred stock on the same terms as the 2020 Notes, as described in more detail below. The conversion will be based on an outstanding loan balance equal to $1.9 million, consisting of (i) the principal loan amount ($1.8 million) plus (ii) accrued interest through December 29, 2020 ($0.1 million).

To help facilitate the transfer of cash from China to the United States to effectively convert the Bridge Loan, we and Terns China agreed to enter into an agreement with LAV to (i) repay the Bridge Loan, and (ii) issue shares of Series C convertible preferred stock at the initial closing to entities that are a part of Lilly Asia Ventures in exchange for a promissory note issued to us by LAV, or the LAV Affiliate Promissory Note.

On December 29, 2020, the Bridge Loan was amended to clarify that (i) interest will accrue up to and through December 29, 2020, with no additional interest accruing after December 29, 2020 and (ii) the Bridge Loan will be repaid in full by us following the requisite government approvals in China. Proceeds from the repayment of the Bridge Loan by Terns China will be used by LAV to repay the LAV Affiliate Promissory Note in full to us.

Series C Preferred Stock Financing

In December 2020, we entered into a Series C convertible preferred stock purchase agreement with various investors, pursuant to which we issued an aggregate of 7,500,665 shares of Series C convertible preferred stock at $11.65 per share for gross proceeds of approximately $87.4 million, which amount includes the conversion of the 2020 Notes and effective conversion of the Bridge Loan.

The table below sets forth the number of shares of our Series C convertible preferred stock purchased by our executive officers, directors, holders of more than 5% of our capital stock and their affiliated entities or immediate family members. Each share of Series C convertible preferred stock in the table below converted into one share of our common stock immediately prior to the completion of our IPO.

Name(1)	Series C Convertible Preferred Stock (#)	Aggregate Cash Purchase Price ($)
Lilly Asia Ventures (U.S.)(2)	1,739,901	20,266,385
Entities affiliated with OrbiMed Advisors LLC(3)	1,530,491	17,827,190
Entities affiliated with Vivo Capital(4)	414,420	4,827,190
Deerfield Partners, L.P.(5)	1,717,033	20,000,000
Lilly Asia Ventures (PRC)(6)	167,159	1,947,073

(1) For additional information regarding these stockholders and their equity holdings, see Item 12. “Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.”

(2) Entities that are a part of Lilly Asia Ventures (U.S.) beneficially owned more than 5% of our outstanding capital stock at the time of the Series C convertible preferred stock financing. Dr. Yi Shi was at the time of the Series C convertible preferred stock financing, a member of our board of directors. Dr. Shi was designated to serve as a member of our board of directors by Lilly Asia Ventures (U.S.). Dr. Shi is a Managing Partner at Lilly Asia Ventures. (U.S.). Dr. Shi holds all voting and investment power over all shares beneficially held by entities that are part of Lilly Asia Ventures (U.S.). In addition, Dr. Hongbo Lu is currently, and was at the time of the Series C convertible preferred stock financing, a member of our board of directors. Dr. Lu was originally designated to serve as a member of our board of directors by Lilly Asia Ventures (U.S.). Dr. Lu was at the time of the Series C convertible preferred stock financing a Managing Partner at Lilly Asia Ventures (U.S.). Currently, Dr. Lu is a Managing Partner at Vivo Capital and is no longer affiliated with Lilly Asia Ventures (U.S.).

(3) Entities affiliated with OrbiMed Advisors LLC beneficially owned more than 5% of our outstanding capital stock at the time of the Series C convertible preferred stock financing. Dr. Carl Gordon is currently, and was at the time of the Series C convertible preferred stock financing, a member of our board of directors. Dr. Gordon was designated to serve as a member of our board of directors by OrbiMed Advisors LLC. Dr. Gordon is a Managing Partner at OrbiMed Advisors LLC.

(4) Entities affiliated with Vivo Capital beneficially owned more than 5% of our outstanding capital stock at the time of the Series C convertible preferred stock financing. Dr. Weidong Liu was at the time of the Series C convertible preferred stock financing, a member of our board of directors. Dr. Liu was designated to serve as a member of our board of directors by Vivo Capital. Dr. Liu is a Principal at Vivo Capital. In addition, Dr. Hongbo Lu is currently, and was at the time of the Series C convertible preferred stock financing, a member of our Board of Directors. Dr. Lu is a Managing Partner at Vivo Capital.

(5) Entities affiliated with Deerfield Partners, L.P. became beneficial owners of more than 5% of our outstanding capital stock at the time of the Series C convertible preferred stock financing. Ms. Elise Wang was designated to serve as a member of our board of directors by Deerfield Partners, L.P. after the closing of the Series C convertible preferred stock financing. Ms. Wang is a Principal at Deerfield Management Company.

(6) Entities that are a part of Lilly Asia Ventures (PRC) were beneficial owners of more than 5% of our outstanding capital stock at the time of the Series C convertible preferred stock financing. Dr. Fei Chen holds all voting and investment power over all shares beneficially held by entities that are a part of Lilly Asia Ventures (PRC). Dr. Fei Chen is a managing partner at Lilly Asia Ventures (PRC).

Investors’ Rights Agreement

We entered into an amended and restated investors’ rights agreement with the purchasers of our convertible preferred stock, which was subsequently converted into common stock in connection with the IPO, and certain of our other stockholders, including certain of our directors and executive officers, holders of more than 5% of our capital stock and entities with which certain of our directors are affiliated. As of December 31, 2020, the holders of approximately 16,079,230 shares of our common stock are entitled to rights with respect to the registration of their shares under the Securities Act.

Indemnification Agreements

We have entered into indemnification agreements with certain of our current directors, executive officers and certain other employees. Our amended and restated certificate of incorporation and our amended and restated bylaws provide that we will indemnify our directors and officers to the fullest extent permitted by applicable law.

Employment Agreements

We have entered into employment agreements with our named executive officers. For more information regarding these agreements, see Item 11. “Executive Compensation—Executive Compensation Arrangements—Offer Letter Agreements.”

Policies and Procedures for Related Person Transactions

Our board of directors adopted a written related person transaction policy setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy covers, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships in which we were or are to be a participant, where the amount involved exceeds $120,000 and a related person had or will have a direct or indirect material interest, including without limitation purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit committee is tasked to consider all relevant facts and circumstances, including but not limited to whether the transaction is on terms comparable to those that could be obtained in an arm’s length transaction with an unrelated third party and the extent of the related person’s interest in the transaction.

Director Independence

Our board of directors currently consists of 7 members. Our board of directors has determined that all of our directors, other than Mr. Sundaram and Dr. Zhong, qualify as “independent” directors in accordance with The Nasdaq Stock Market LLC, or Nasdaq, Marketplace Rules, or the Nasdaq Listing Rules. Mr. Sundaram and Dr. Zhong are not considered independent because they are executive officers of our company. Under the Nasdaq Listing Rules, the definition of independence includes a series of objective tests, such as that the director is not, and has not been for at least three years, one of our employees and that neither the director nor any of his or her family members has engaged in various types of business dealings with us. In addition, as required by the Nasdaq Listing Rules, our board of directors has made a subjective determination as to each independent director that no relationships exists that, in the opinion of our board of directors, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In making these determinations, our board of directors reviewed and discussed information provided by the directors and us with regard to each director’s relationships as they may relate to us and our management.

Item 14. Principal Accounting Fees and Services.

The following table represents aggregate fees billed to the Company by Ernst & Young LLP, for the fiscal years ended December 31, 2020 and 2019:

	2020	2019
Audit fees(1)	$ 1,691,800	$ 125,740
Tax fees	-	-
All other fees	-	-
Total fees	$ 1,691,800	$ 125,740

(1) Audit fees consist of fees for the audit of our annual financial statements, the review of our interim financial statements, and services provided in connection with the registration statement for the IPO of our common stock, which was completed in February 2021.

Audit Committee Pre-approval Policy and Procedures

Our audit committee has adopted policies and procedures relating to the approval of all audit and non-audit services that are to be performed by our independent registered public accounting firm. This policy provides that we will not engage our independent registered public accounting firm to render audit or non-audit services unless the

service is specifically approved in advance by our audit committee or the engagement is entered into pursuant to the pre-approval procedure described below.

From time to time, our audit committee may pre-approve specified types of services that are expected to be provided to us by our independent registered public accounting firm during the next 12 months. Any such pre-approval details the particular service or type of services to be provided and is also generally subject to a maximum dollar amount.

During our 2020 fiscal year, no services were provided to us by Ernst & Young LLP other than in accordance with the pre-approval policies and procedures described above.

PART IV

Item 15. Exhibits, 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.

Item 16. Form 10-K Summary

None.

		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	2/9/2021	3.2	
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
10.1	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	
10.2	Lease, dated March 1, 2019, by and between the Registrant and DWF IV Century Plaza, LLC.	S-1	1/15/2021	10.2	
10.3	Lease, dated June 15, 2018, by and between the Registrant and Changning Raffles Shanghai.	S-1	1/15/2021	10.3	
10.4(a)#	2017 Equity Incentive Plan, as amended.	S-1	1/15/2021	10.4(a)	
10.4(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)	
10.4(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)	
10.4(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)	
10.5(a)#	2021 Incentive Award Plan.	S-8	2/12/2021	99.2(a)	
10.5(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)	

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
10.5(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)	
10.5(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)	
10.6#	2021 Employee Stock Purchase Plan.	S-8	2/12/2021	99.3	
10.7#	Employment Agreement by and between the Registrant and Erin Quirk, M.D.	S-1/A	2/1/2021	10.7	
10.8#	Employment Agreement by and between the Registrant and Senthil Sundaram.	S-1/A	2/1/2021	10.8	
10.9#	Employment Agreement by and between the Registrant and Mark Vignola, Ph.D.	S-1/A	2/1/2021	10.9	
10.10#	Non-Employee Director Compensation Program.	S-1/A	2/1/2021	10.10	
10.11	Form of Indemnification Agreement for directors and officers.	S-1/A	2/1/2021	10.11	
10.12†	Exclusive License Agreement, dated as of February 9, 2018, between Terns Pharmaceuticals, Inc. and Eli Lilly and Company.	S-1	1/15/2021	10.13	
10.13†	Exclusive License Agreement, dated as of March 9, 2018, between Terns Pharmaceuticals, Inc. and Eli Lilly and Company.	S-1	1/15/2021	10.14	
10.14†	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	
10.15†	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	
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

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
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

# 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.

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 30, 2021

By: /s/ Senthil Sundaram
Senthil Sundaram
Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Senthil Sundaram as his or her true and lawful attorney-in-fact and agent, with the full power of substitution, for him 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/ Senthil Sundaram Senthil Sundaram	Chief Executive Officer and Director *(Principal Executive Officer)*	March 30, 2021
/s/ Mark Vignola Mark Vignola, Ph.D.	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 30, 2021
/s/ Weidong Zhong Weidong Zhong, Ph.D.	Chief Scientific Officer and Director	March 30, 2021
/s/ David Fellows David Fellows	Chairman of the Board of Directors	March 30, 2021
/s/ Carl Gordon Carl Gordon, Ph.D., C.F.A.	Director	March 30, 2021
/s/ Jeffrey Kindler Jeffrey Kindler, Esq.	Director	March 30, 2021
/s/ Hongbo Lu Hongbo Lu, Ph.D.	Director	March 30, 2021
/s/ Jill Quigley Jill Quigley, Esq.	Director	March 30, 2021

DESCRIPTION OF CAPITAL STOCK

The following summary describes the capital stock of Terns Pharmaceuticals, Inc. (the "Company," "we," "us" and "our") and the material provisions of our amended and restated certificate of incorporation and our amended and restated bylaws, the amended and restated investors' rights agreement to which we and certain of our stockholders are parties and of the Delaware General Corporation Law. Because the following is only a summary, it does not contain all of the information that may be important to you. For a complete description, you should refer to our amended and restated certificate of incorporation, amended and restated bylaws and amended and restated investors' rights agreement, copies of which are incorporated by reference as Exhibits 3.1, 3.2 and 10.1, respectively, to our Annual Report on Form 10-K.

General

Our authorized capital stock consists of 150,000,000 shares of common stock, par value $0.0001 per share, and 10,000,000 shares of preferred stock, par value $0.0001 per share.

Common Stock

Voting Rights

Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Our stockholders do not have cumulative voting rights in the election of directors. Accordingly, holders of a majority of the voting shares are able to elect all of the directors. In addition, the affirmative vote of holders of 66 2/3% of the voting power of all of the then outstanding voting stock is required to take certain actions, including amending certain provisions of our amended and restated certificate of incorporation, including the provisions relating to amending our amended and restated bylaws, the classified board and director liability.

Dividends

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of our common stock are entitled to receive dividends as may be declared from time to time by our board of directors out of legally available funds.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common stock are entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any then outstanding shares of preferred stock.

Rights and Preferences

Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

Fully Paid and Nonassessable

All of our outstanding shares of common stock are fully paid and nonassessable.

Preferred Stock

Our board of directors has the authority, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These

rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of our common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our company or other corporate action.

Registration Rights

Certain holders of shares of our common stock, are entitled to certain rights with respect to registration of such shares under the Securities Act of 1933, as amended, (the "Securities Act"). These shares are referred to as registrable securities. The holders of these registrable securities possess registration rights pursuant to the terms of our amended and restated investors' rights agreement and are described in additional detail below. The registration of shares of our common stock pursuant to the exercise of the registration rights described below would enable the holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective. We will pay the registration expenses, other than underwriting discounts, selling commissions and stock transfer taxes, of the shares registered pursuant to the demand, piggyback and Form S-3 registrations described below.

The demand, piggyback and Form S-3 registration rights described below will terminate upon the earliest of (i) with respect to each stockholder, such date, on or after the closing of our initial public offering in February 2021, on which all registrable shares held by such stockholder may immediately be sold during any 90-day period pursuant to Rule 144 of the Securities Act, or Rule 144, and (ii) the occurrence of a deemed liquidation event, as defined in our amended and restated certificate of incorporation, as currently in effect.

Demand Registration Rights

Certain holders of shares of our common stock are entitled to certain demand registration rights. Beginning August 3, 2021, certain investors holding, collectively, 20% of registrable securities may, on not more than two occasions, request that we register all or a portion of their shares, subject to certain specified exceptions. If any of these holders exercises its demand registration rights, then these holders will be entitled to register their shares, subject to specified conditions and limitations in the corresponding offering.

Piggyback Registration Rights

In the event that we propose to register any of our securities under the Securities Act, either for our own account or for the account of other security holders, certain holders of shares of our common stock will be entitled to certain "piggyback" registration rights allowing them to include their shares in such registration, subject to specified conditions and limitations.

S-3 Registration Rights

Certain holders of shares of our common stock are entitled to certain Form S-3 registration rights. Certain investors holding at least 10% of registrable securities may, on not more than two registrations on Form S-3 within any 12-month period, request that we register all or a portion of their shares on Form S-3 if we are qualified to file a registration statement on Form S-3, subject to specified exceptions. Such request for registration on Form S-3 must cover securities with an aggregate offering price which equals or exceeds $1.0 million, net of selling expenses. The right to have such shares registered on Form S-3 is further subject to other specified conditions and limitations.

Anti-Takeover Effects of Provisions of Delaware Law and Our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Certain provisions of Delaware law and our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that could make the following transactions more difficult: acquisition of us by means of a tender offer; acquisition of us by means of a proxy contest or otherwise; or removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter

transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions that might result in a premium over the market price for our shares.

These provisions, summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Delaware Anti-Takeover Statute

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits persons deemed "interested stockholders" from engaging in a "business combination" with a publicly-held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation's voting stock. Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors, such as discouraging takeover attempts that might result in a premium over the market price of our common stock.

Undesignated Preferred Stock

The ability to authorize undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to effect a change in control of our company. These and other provisions may have the effect of deterring hostile takeovers or delaying changes in control or management of our company.

Special Stockholder Meetings

Our amended and restated certificate of incorporation provides that a special meeting of stockholders may be called at any time by our board of directors, but such special meetings may not be called by the stockholders or any other person or persons.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our amended and restated bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

Elimination of Stockholder Action by Written Consent

Our amended and restated certificate of incorporation eliminates the right of stockholders to act by written consent without a meeting.

Classified Board; Election and Removal of Directors; Filling Vacancies

Our board of directors is divided into three classes, divided as nearly as equal in number as possible. The directors in each class will serve for a three-year term, one class being elected each year by our stockholders, with staggered three-year terms. Only one class of directors is elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Because our stockholders do not have cumulative voting rights, our stockholders holding a majority of the shares of common stock outstanding are able to elect all of our directors. Our amended and restated certificate of incorporation provides for the removal of any of our directors only for cause and requires a stockholder vote by the holders of at least a 66 2/3% of the voting power of the then

outstanding voting stock. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of the board, may only be filled by a resolution of the board of directors unless the board of directors determines that such vacancies shall be filled by the stockholders. This system of electing and removing directors and filling vacancies may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Choice of Forum

Our amended and restated certificate of incorporation and amended and restated bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: any derivative action or proceeding brought on our behalf; any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers or stockholders to us or to our stockholders; 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 (as either may be amended from time to time); or any action asserting a claim against us that is governed by the internal affairs doctrine. As a result, any action brought by any of our stockholders with regard to any of these matters will need to be filed in the Court of Chancery of the State of Delaware and cannot be filed in any other jurisdiction; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Securities Exchange Act of 1934 (the "Exchange Act"), as amended, 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 preclude stockholders that assert claims under the Exchange Act from bringing such claims in state or federal court, subject to applicable law.

If any action the subject matter of which is within the scope described above is filed in a court other than a court located within the State of Delaware, or a Foreign Action, in the name of any stockholder, such stockholder shall be deemed to have consented to the personal jurisdiction of the state and federal courts located within the State of Delaware in connection with any action brought in any such court to enforce the applicable provisions of our amended and restated certificate of incorporation and amended and restated bylaws and having service of process made upon such stockholder in any such action by service upon such stockholder's counsel in the Foreign Action as agent for such stockholder. Although our amended and restated certificate of incorporation and amended and restated bylaws contain the choice of forum provision described above, it is possible that a court could find that such a provision is inapplicable for a particular claim or action or that such provision is unenforceable.

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.

Amendment of Charter Provisions

The amendment of any of the above provisions in our amended and restated certificate of incorporation, except for the provision making it possible for our board of directors to issue undesignated preferred stock, would require approval by a stockholder vote by the holders of at least a 66 2/3% of the voting power of the then outstanding voting stock.

The provisions of the Delaware General Corporation Law, our amended and restated certificate of incorporation and our amended and restated bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing

changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Nasdaq Global Select Market Listing

Our common stock is listed on the Nasdaq Global Select Market under the trading symbol “TERN.”

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare, Inc. The transfer agent and registrar’s address is 250 Royall Street, Canton, Massachusetts 02021.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement (Form S-8 No 333-253085) of Terns Pharmaceuticals, Inc. of our report dated March 30, 2021, with respect to the consolidated financial statements of Terns Pharmaceuticals, Inc. included in this Annual Report (Form 10-K) of Terns Pharmaceuticals for the year ended December 31, 2020.

/s/ Ernst & Young LLP

San Jose, California
March 30, 2021

Exhibit 31.1

CERTIFICATION 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

I, Senthil Sundaram, certify that:

1. I have reviewed this Annual Report on Form 10-K of Terns Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 30, 2021

By: /s/ Senthil Sundaram

Senthil Sundaram
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION 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

I, Mark Vignola, certify that:

1. I have reviewed this Annual Report on Form 10-K of Terns Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 30, 2021

By: /s/ Mark Vignola

Mark Vignola
Chief Financial Officer
Principal Financial and Accounting Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Terns Pharmaceuticals, Inc. (the "Company") on Form 10-K for the period ending December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 30, 2021

By: /s/ Senthil Sundaram

Senthil Sundaram
Chief Executive Officer
Principal Executive Officer

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Terns Pharmaceuticals, Inc. (the "Company") on Form 10-K for the period ending December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 30, 2021

By: /s/ Mark Vignola

Mark Vignola
Chief Financial Officer
Principal Financial and Accounting Officer