As filed with the Securities and Exchange Commission on May 10, 2021.

Registration No. 333-255304

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

Amendment No. 1

FORM S-1

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

Sagimet Biosciences Inc.

(Exact name of registrant as specified in its charter)

Delaware	**2834**	**20-5991472**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

Sagimet Biosciences Inc.
155 Bovet Road, Suite 303
San Mateo, California 94402
(650) 561-8600

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

George Kemble, Ph.D.
President and Chief Executive Officer
155 Bovet Road, Suite 303
San Mateo, California 94402
(650) 561-8600

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Carlton Fleming **Marianne Sarrazin** **Cooley LLP** **3175 Hanover Street** **Palo Alto, California 94304** **(650) 843-5000**	**Dennis Hom** **Chief Financial Officer** **155 Bovet Road, Suite 303** **San Mateo, California 94402** **(650) 561-8600**	**B. Shayne Kennedy** **Cheston J. Larson** **Chris G. Geissinger** **Latham & Watkins LLP** **650 Town Center Drive, 20th Floor** **Costa Mesa, California 92626** **(714) 540-1235**

Approximate date of commencement of proposed sale to the public: As soon as practicable after this registration statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box: ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☐

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

Subject to Completion
Preliminary Prospectus dated May 10, 2021

PROSPECTUS

Shares

Class A Common Stock

This is Sagimet Biosciences Inc.'s initial public offering. We are selling shares of our Class A common stock.

We expect the public offering price to be between $ and $ per share. Currently, no public market exists for the shares. After the pricing of the offering, we expect that the shares will trade on The Nasdaq Global Market under the symbol "SGMT."

We are an "emerging growth company" as defined under the federal securities laws and, as such, have elected to comply with certain reduced reporting requirements.

Following this offering, we will have two classes of common stock: Class A common stock and Class B common stock. The rights of the holders of Class A common stock and Class B common stock are identical, except with respect to voting and conversion. Each share of Class A common stock will be entitled to one vote and shares of Class B common stock will be non-voting, except as may be required by law. Each share of Class B common stock may be converted at any time into one share of Class A common stock at the option of its holder, subject to the ownership limitations provided for in our amended and restated certificate of incorporation to be in effect upon the completion of this offering.

Investing in the Class A common stock involves risks that are described in the "Risk Factors" section beginning on page 15 of this prospectus.

	Per share	Total
Initial public offering price	$	$
Underwriting discounts and commissions(1)	$	$
Proceeds, before expenses, to us	$	$

(1) See the section titled "Underwriting" for additional information regarding the compensation payable to the underwriters.

The underwriters may also exercise their option to purchase up to an additional shares of Class A common stock from us, at the initial public offering price, less the underwriting discounts, for 30 days after the date of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The shares will be ready for delivery on or about , 2021.

BofA Securities **Cowen** **Piper Sandler**

Oppenheimer & Co.

The date of this prospectus is , 2021.

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Neither we nor the underwriters have authorized anyone to provide you any information or make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our Class A common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside of the United States: we have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of our Class A common stock and the distribution of this prospectus outside of the United States.

Sagimet Biosciences Inc. and our logo are our trademarks and are used in this prospectus. This prospectus also includes trademarks, tradenames and service marks that are the property of other organizations. Solely for convenience, our trademarks and tradenames referred to in this prospectus appear without the ™ symbol, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor, to these trademarks and tradenames.

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our Class A common stock. You should read this entire prospectus carefully, including the sections of this prospectus titled "Risk Factors," "Selected Financial Data," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and our financial statements and the related notes included elsewhere in this prospectus, before making an investment decision. Unless otherwise indicated, all references in this prospectus to "Sagimet," the "company," "we," "our," "us" or similar terms refer to Sagimet Biosciences Inc.

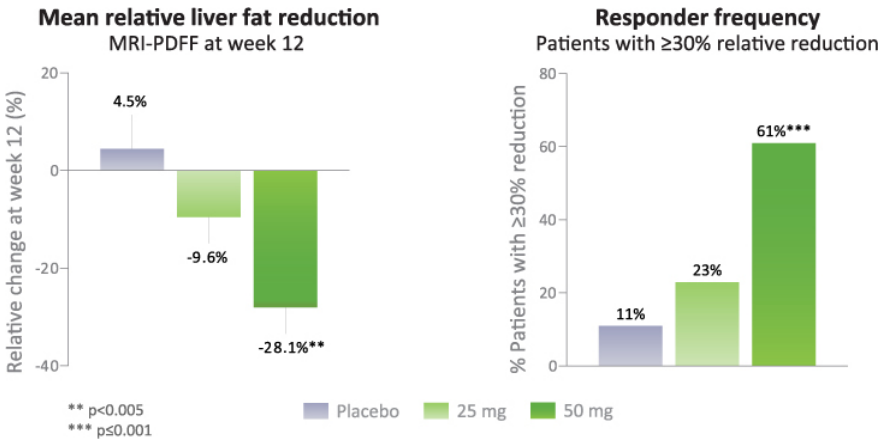
Overview

We are a clinical-stage biopharmaceutical company focused on developing a portfolio of internally-discovered, selective fatty acid synthase (FASN) inhibitors for the treatment of several diseases that result from the overproduction of the fatty acid, palmitate. Based on our clinical and preclinical data, we believe that our wholly-owned pipeline of oral FASN inhibitors has the potential to offer treatments for indications in several therapeutic areas of high unmet medical need including liver diseases and cancers. TVB-2640, which we are developing as an oral, once-daily pill, is our lead drug candidate that we selected from more than 1,200 compounds in our library of FASN inhibitors and has been studied in over 260 subjects, including healthy volunteers and patients with non-alcoholic steatohepatitis (NASH) or cancer. In our FASCINATE-1 Phase 2a clinical trial, TVB-2640 demonstrated statistically significant improvements across steatosis, inflammation/lipotoxicity, fibrosis and metabolic biomarkers important in NASH, and was well-tolerated. We believe that these attributes provide TVB-2640 the potential to treat a broad range of patients in this multifactorial disease. In the second quarter of 2021, we plan to initiate enrollment of our FASCINATE-2 Phase 2b clinical trial in NASH patients with moderate to advanced fibrosis to evaluate the impact of TVB-2640 on disease improvement by assessing liver biopsies after 52 weeks of treatment. We also plan to conduct an interim analysis after a portion of the patients complete 26 weeks of treatment. Within oncology, in the second half of 2021, we plan to initiate a randomized, controlled Phase 2 clinical trial for glioblastoma multiforme (GBM) and a Phase 1b/2 basket clinical trial in several solid tumors where FASN inhibition may have promising utility. In addition, we plan to advance our second FASN inhibitor, TVB-3567, into a first-in-human clinical trial in the second half of 2021.

In healthy adults, FASN is a key enzyme involved in the production of saturated fatty acids in the liver and other organs and is the only enzyme in the human body capable of converting metabolized sugars into palmitate. Palmitate is a saturated fatty acid that serves as a building block for longer chain, polyunsaturated fatty acids and can directly interact with other proteins to sustain normal cell signaling and metabolic function. The overproduction of palmitate is a critical driver of cellular metabolic dysfunction that can drive development or progression of several different diseases. In patients with NASH, increased FASN-mediated palmitate synthesis in the liver is the source of three key drivers of the disease: excess accumulation of liver fat, inflammation and fibrosis. If left untreated, these can lead to cirrhosis of the liver, liver cancer and/or liver transplantation.

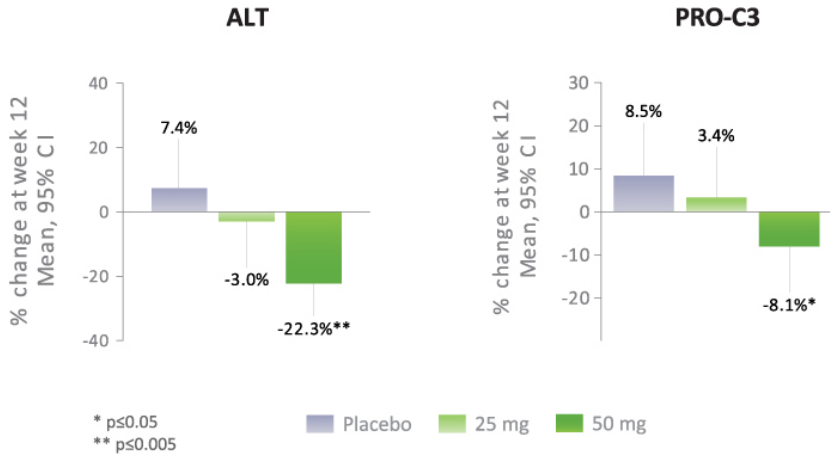
We are developing TVB-2640 as an oral, once-daily, selective FASN inhibitor for the treatment of NASH, an aggressive form of non-alcoholic fatty liver disease (NAFLD). In our FASCINATE-1 Phase 2a clinical trial, TVB-2640 demonstrated a statistically significant, dose-dependent relative reduction of liver fat of 28.1% in patients treated with 50mg over 12 weeks, compared to the 4.5% relative increase in liver fat observed with patients in the placebo group as measured by magnetic resonance imaging—proton density fat fraction (MRI-PDFF). A statistically significant 61% of patients treated with 50mg of TVB-2640 achieved a ≥30% relative reduction of liver fat, as shown below.

Liver Fat Changes at Week 12



Additionally, TVB-2640 demonstrated statistically significant improvement across steatosis, inflammation/lipotoxicity, fibrosis and metabolic biomarkers important in NASH. In one inflammatory biomarker, alanine transaminase (ALT), 50mg of TVB-2640 decreased levels by 22.3% ($p<0.005$) in a dose-dependent manner. ALT is often elevated in NASH patients and indicative of hepatic inflammation and damage. Decreasing ALT levels in NASH patients has been shown by liver biopsy to correlate with improvement of fibrosis. Similarly, 50mg of TVB-2640 decreased the fibrosis biomarker, PRO-C3 by 8.1% ($p<0.05$) in a dose-dependent manner. PRO-C3 is a protein fragment of procollagen and is indicative of active hepatic fibrogenesis when found in the blood. Decreases of PRO-C3 suggest reduced levels of fibrosis in the liver. The data showing a reduction in these biomarker levels are shown below:

Biomarker Changes at Week 12



Additionally, TVB-2640 was well-tolerated. Adverse events were similar among the cohorts, with most being Grade 1 (mild) and no adverse events above Grade 3. There were no TVB-2640-related serious adverse events, and the only serious adverse event in the study occurred in a subject randomized to the placebo group.

The prevalence of NASH is increasing both in the United States and globally, and is correlated with increasing rates of obesity, type 2 diabetes and metabolic syndrome. Metabolic syndrome is characterized by high blood sugar and lipid levels, insulin resistance and obesity. NASH is a significant unmet medical need for which no treatments have been approved in the United States or European Union. In the United States, the prevalence of NASH was estimated to total approximately 17.3 million patients in

2016, of which approximately 5.7 million have had NASH with moderate to advanced fibrosis (fibrosis stage F2-F3, on a scale of F0-F4). People with NAFLD have an increased risk of cardiovascular disease, liver failure, cancers of the liver and extrahepatic cancers. NASH is currently the leading cause of liver transplantation in women and second only to alcoholic liver disease in men. NASH is also the leading indication for liver transplantation in patients older than 54 years and in Medicare recipients, and is expected to become the leading cause of liver transplantation in men as well.

In addition to NASH, dysregulation of fatty acid metabolism is a hallmark of certain cancers. In our Phase 1 trial, high doses of TVB-2640 achieved human proof-of-concept and a manageable tolerability profile in cancer patients with solid tumors. TVB-2640 demonstrated prolonged stable disease in patients when the drug was used alone and in combination with a taxane. TVB-2640 also demonstrated confirmed partial responses when combined with a taxane, even in patients who had been previously treated with a taxane. In August 2020, positive data were also shared in an oral presentation at European Society of Medical Oncology (ESMO) from a Phase 2 clinical trial with TVB-2640 and bevacizumab in relapsed GBM, one of the most aggressive forms of brain cancer. TVB-2640 and bevacizumab demonstrated an encouraging 65% objective response rate, as measured by Response Assessment in Neuro-Oncology (RANO) criteria on brain MRI and 47% progression free survival at six months, exceeding those reported for bevacizumab alone. The safety results showed that the combination was generally well-tolerated. In the second half of 2021, we plan to initiate a randomized, controlled Phase 2 clinical trial of TVB-2640 for GBM and a Phase 1b/2 basket clinical trial of TVB-2640 in several solid tumors where FASN inhibition may have promising utility.

Our team

We have assembled a team with extensive experience in drug discovery and development in the fields of hepatology, metabolic disease and oncology. Collectively, our team has been directly involved in a broad spectrum of research and development and commercial activities leading to successful outcomes, including US Food and Drug Administration (FDA) approvals and marketed drugs. Our president and chief executive officer, George Kemble, Ph.D., has broad experience in the biopharmaceutical industry and brings over 20 years of drug discovery and development experience. Before becoming our chief executive officer in October 2015, Dr. Kemble served as our chief scientific officer since August 2011. Prior to Sagimet, Dr. Kemble was senior vice president and head of research at MedImmune, LLC (now a subsidiary of AstraZeneca PLC), where he was responsible for a large group of scientists dedicated to the research and development of programs across a number of therapeutic areas, including launch of the intranasal vaccine FluMist, the first innovation in influenza vaccines in over 60 years. Our chief medical officer, Eduardo Bruno Martins, M.D., D.Phil., has deep expertise in clinical development with previous leadership positions at AbbVie Inc., Allergan, Inc., Eiger BioPharmaceuticals, Inc., Gilead Sciences, Inc., Genentech, Inc., Dynavax Technologies Corporation, Intermune, Inc., and SciClone Pharmaceuticals, Inc., where he led clinical development and medical affairs activities from translational research to Phase IV trials in various therapeutic areas, including in hepatology, vaccines and oncology. Our chief financial officer and head of corporate development, Dennis Hom, has been instrumental to a variety of financing events and corporate transactions at leading pharmaceutical and biotechnology companies including Achaogen, Inc., Amgen Inc., and Novartis AG, and was previously an investment banker at J.P. Morgan Chase & Co. and predecessor firm Hambrecht & Quist. In addition, we are backed by a group of renowned and leading investors including Altium Capital Management, the Invus Group, LLC, Kleiner Perkins Caufield & Byers, LLC, New Enterprise Associates Inc., PFM Health Sciences, LP, Rock Springs Capital LP, other undisclosed investors, and Ascletis BioScience Co. Ltd. (Ascletis), our strategic partner in the People's Republic of China (China), Hong Kong, Macau and Taiwan (collectively, Greater China).

Our FASN inhibitor pipeline

We believe FASN inhibition holds promise in several diseases, including certain liver diseases, cancers, skin diseases, fibrotic diseases and viral infections. We are advancing a portfolio of small molecule FASN inhibitors, selected from our library of over 1,200 internally-discovered and wholly-owned compounds, designed for convenient oral administration and high selectivity for the FASN enzyme, with the goal of limiting off-target activity and unwanted side effects. Additionally, we believe our drug candidates are positioned to overcome limitations of early generation FASN inhibitors developed by others, including poor potency, off-target activity, or suboptimal physiochemical or pharmacokinetic properties.

The following table summarizes our wholly-owned drug candidates in development for multiple diseases with high unmet need:

TEAE classification	Placebo n=31	25mg cohort n=33	50mg cohort n=35
Any TEAE	Gr. 1: 11 (35.5%) Gr. 2: 8 (25.8%)	Gr. 1: 18 (54.5%) Gr. 2: 7 (21.2%)	Gr. 1: 11 (31.4%) Gr. 2: 7 (20.0%)
TEAE leading to drug withdrawal	0	2 (6.1%)	0
Treatment Emergent Serious Adverse	0	0	0
Drug related TEAE	Gr. 1: 3 (9.7%) Gr. 2: 1 (3.2%)	Gr. 1: 10 (30.3%) Gr. 2: 2 (6.1%)	Gr. 1: 9 (25.7%) Gr. 2: 1 (2.9%)
TEAE leading to death	0	0	0

TVB-2640 for NASH

In patients with NASH, FASN-mediated palmitate synthesis is increased in the liver leading to excess accumulation of liver fat and stimulation of inflammation and fibrosis resulting in poor liver function. Our lead candidate, TVB-2640, is designed to bind to FASN and specifically inhibits one of the enzymatic subdomains (ß-ketoacyl reductase), thereby reducing the body's overproduction of palmitate. We believe that this reduction can lead to meaningful clinical benefits in NASH patients. In the diseased liver, TVB-2640 is designed to reduce the dysfunctional, high level of lipid synthesis and to directly blunt activated inflammatory and fibrotic pathways.

In June 2020, we announced top-line results from our FASCINATE-1 Phase 2a clinical trial in NASH patients where TVB-2640 demonstrated a statistically significant 28.1% relative reduction of liver fat in patients treated with 50mg over 12 weeks, compared to the 4.5% relative increase in liver fat observed with patients in the placebo group as measured by MRI-PDFF. A statistically significant 61% of patients treated with 50mg of TVB-2640 achieved a ≥30% relative reduction of liver fat, who we refer to as MRI-PDFF responders. A meta-analysis of several studies demonstrated that MRI-PDFF responders have a 7-fold higher likelihood of a ≥2 point improvement in NAFLD Activity Score (NAS) and a 5-fold higher rate of NASH resolution, both measured by liver biopsy, compared to nonresponders. A completed clinical trial for another drug candidate has also demonstrated a predictive, positive correlation between MRI-PDFF response and improvement of fibrosis that was higher compared to nonresponse. Additionally, TVB-2640 demonstrated statistically significant improvement consistent across steatosis, inflammation/lipotoxicity, fibrosis and metabolic biomarkers important in NASH, and was well-tolerated. In the second quarter of 2021, we plan to enroll an open-label cohort in the FASCINATE-1 Phase 2a clinical trial to assess the safety and efficacy of TVB-2640 in patients treated with 75mg for 12 weeks. We expect data from this cohort in the fourth quarter of 2021.

We plan to initiate enrollment of our FASCINATE-2 Phase 2b clinical trial in the second quarter of 2021 in NASH patients with moderate to advanced fibrosis (F2-F3) to evaluate the impact of TVB-2640 assessed by biopsy. We expect to enroll 330 patients and administer oral, daily doses for 52 weeks. We will randomize patients to receive placebo, 50mg of TVB-2640 or 75mg of TVB-2640. The co-primary endpoints will be: (1) ≥2 point improvement in NAS that results from reduction of necro-inflammation (inflammation or ballooning) and (2) improvement in fibrosis. These two endpoints are accepted by the FDA for Phase 2b studies in NASH. Liver biopsy data will also be evaluated to assess NASH resolution without worsening of fibrosis and/or improvement in fibrosis without worsening of NASH, both of which are endpoints accepted by the FDA for accelerated approval. We will also measure liver fat, assessed using MRI-PDFF, and other serum biomarkers in a portion of patients at 26 weeks of treatment in an interim analysis. We expect to initiate dosing of the 75mg dose cohort in FASCINATE-2 following results from the planned 75mg, open-label cohort in our FASCINATE-1 Phase 2a clinical trial. If results from this open-label cohort do not

support use of 75mg in our FASCINATE-2 trial, we expect to complete the trial with the 50mg and placebo arms. We expect interim results in the second half of 2022 and top-line liver biopsy results in 2023. We received Fast-Track designation for TVB-2640 for the treatment of NASH in March 2021. See "Government Regulation and Product Approval—Expedited Development and Review Programs."

We believe TVB-2640 has the potential to be a backbone therapy for NASH with the ability to combine with a broad set of other mechanisms. We also intend to conduct exploratory clinical trials evaluating combinations of TVB-2640 and other complementary mechanisms with relatively short treatment duration of ≤12 weeks. These trials should allow us to evaluate improvements in noninvasive biomarkers directly in NASH patients and select combinations for further development.

TVB-2640 for oncology

Dysregulation of lipid metabolism is also a hallmark of cancer. Most normal cells get their palmitate from dietary sources and do not rely on FASN for palmitate production. However, cancer cells have a rapid proliferation rate and a high lipid requirement for cell signaling and membrane synthesis, and rely upon de novo lipogenesis (DNL) as an internal source of fatty acids, a process known as neoplastic lipogenesis. FASN is overexpressed in many cancer cell types including GBM, lung, breast, ovarian, prostate, hepatocellular, colorectal and malignant melanoma with increased expression of FASN being associated with poor prognosis and reduced survival in several tumor cell types.

In our Phase 1 clinical trial, high doses of TVB-2640 demonstrated activity and a manageable tolerability profile in cancer patients with solid tumors. TVB-2640 led to prolonged stable disease in patients when the drug was used alone and in combination with a taxane. TVB-2640 also demonstrated confirmed partial responses when combined with a taxane, even in patients who had been previously treated with a taxane.

In August 2020, positive data were also shared in an oral presentation at ESMO from a Phase 2 clinical trial with TVB-2640 and bevacizumab in GBM demonstrating an encouraging 65% objective response rate and 47% progression-free survival at six months. This investigator-sponsored clinical trial was conducted at University of Texas Health, San Antonio. In the second half of 2021, we plan to initiate a randomized, controlled Phase 2 clinical trial evaluating TVB-2640 for GBM and a Phase 1b/2 basket clinical trial for several solid tumors where FASN inhibition may have promising utility. The results of this Phase 1b/2 basket clinical trial will help identify additional tumor types we will pursue for further clinical development.

TVB-3567

We have shown that our FASN inhibitors demonstrated activity in preclinical models of NASH, skin and lung fibrosis, multiple solid tumors, hepatitis C virus infection and respiratory syncytial virus infection. In addition to our lead drug candidate, we are developing a second selective FASN inhibitor designated as TVB-3567. This compound also showed potent FASN inhibitory activity in certain preclinical models, including modulation of diacylglycerol metabolism and protein kinase C signaling in cancer models. We have completed preclinical safety studies with TVB-3567 that we believe support an IND submission, including safety pharmacology, genotoxicity and general toxicology studies in rats and dogs. We plan to file an IND for TVB-3567 and initiate a Phase 1 clinical trial in the second half of 2021 in an indication to be determined.

Our strategy

Our goal is to develop and commercialize our selective FASN inhibitors in therapeutic areas where FASN plays a central role in the development or progression of disease. We intend to achieve this goal by pursuing the following key strategic objectives:

- ***Advance TVB-2640 through clinical development for the treatment of NASH.***
- ***Establish TVB-2640 as a backbone therapy for the treatment of NASH.***
- ***Progress our FASN inhibitors in clinical development for the treatment of solid tumors.***

- ***Bring additional FASN inhibitors, such as TVB-3567, into clinical development.***
- ***Independently develop and commercialize our drug candidates in indications and geographies where we believe we can maximize the value and benefit to patients.***

Risks related to our business

Investing in our Class A common stock involves substantial risk. The risks described under the section titled "Risk Factors" immediately following this prospectus summary may cause us to not realize the full benefits of our strengths or may cause us to be unable to successfully execute all or part of our strategy. Some of the more significant risks include the following:

- Even if this offering is successful, we will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs or future commercialization efforts.
- Currently our business depends on the success of TVB-2640, which is still in clinical development. If we are unable to obtain regulatory approval for or successfully commercialize TVB-2640, our business will be materially harmed.
- Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. If clinical trials or regulatory approval processes for our drug candidates are prolonged, delayed or suspended, we may be unable to commercialize our drug candidates on a timely basis, which would require us to incur additional costs and delay our receipt of any revenue from potential product sales.
- 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.
- We may not be successful in our efforts to expand our pipeline by identifying additional indications for which to investigate TVB-2640 in the future. We may expend our limited resources to pursue a particular indication or formulation for TVB-2640 and fail to capitalize on drug candidates, indications or formulations that may be more profitable or for which there is a greater likelihood of success.
- We may attempt to secure approval from the FDA or comparable foreign regulatory authorities through the use of accelerated approval pathways. If we are unable to obtain such approval, we may be required to conduct additional clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw any accelerated approval we have obtained.
- 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.
- If we are unable to obtain, maintain and enforce sufficient patent protection for our drug candidates, or if the scope of the patent protection is not sufficiently broad, third parties, including our competitors, could develop and commercialize products similar or identical to ours, and our ability to commercialize our drug candidates successfully may be adversely affected.
- We have licensed rights to TVB-2640 to Ascletis, a significant stockholder with a board designee, for Greater China. Under the license agreement, Ascletis controls product development efforts in its territory, including conduct of clinical trials, which could have an impact on our clinical development programs.
- We have relied on, and we expect to continue to rely on, third-party manufacturers to produce our drug candidates.

- If clinical trials of a drug candidate fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of such drug candidate.
- Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.
- Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.
- Our amended and restated certificate of incorporation that will be in effect at the closing of this offering will provide that the Court of Chancery of the State of Delaware and, to the extent enforceable, the federal district courts of the United States of America will be the exclusive forums for substantially all 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.

Corporate information

We were incorporated in Delaware in December 2006 under the name 3-V Biosciences, Inc., and changed our name to Sagimet Biosciences Inc. in August 2019. Our principal executive offices are located at 155 Bovet Road, Suite 303, San Mateo, California 94402, and our telephone number is (650) 561-8600. Our website address is www.sagimet.com. Information contained on, or that can be accessed through, our website is not incorporated by reference into this prospectus and the inclusion of our website address in this prospectus is only an inactive textual reference.

Implications of being an emerging growth company and smaller reporting company

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 (the JOBS Act). An emerging growth company may take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

- Being permitted to present only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations in this prospectus.
- Not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended (the Sarbanes-Oxley Act).
- Reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements.
- Exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may take advantage of these provisions until the last day of our fiscal year following the fifth anniversary of the date of the first sale of our common equity securities pursuant to an effective registration statement under the Securities Act of 1933, as amended. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," which occurs when the market value of our Class A common stock and Class B common stock that is held by non-affiliates exceeds $700 million, our annual gross revenues exceed $1.07 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. We have elected to take advantage of these reduced disclosure obligations in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. As a result of these elections, the information that we provide to our stockholders may be different than you might receive from other public reporting companies.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows

an emerging growth company to delay adopting new or revised accounting standards until such time as those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and as a result, we will not be subject to the same new or revised accounting standards as other public companies that comply with the public company effective dates.

We are also a “smaller reporting company” as defined in the Securities Exchange Act of 1934, as amended (the Exchange Act). We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

The Offering

Class A common stock offered by us	shares
Option to purchase additional shares	shares
Class A common stock to be outstanding immediately after this offering	shares (or shares if the underwriters exercise their option to purchase additional shares in full)
Class B common stock to be outstanding immediately after this offering	shares
Total Class A and Class B common stock to be outstanding immediately after this offering	shares (or shares if the underwriters exercise their option to purchase additional shares in full)
Use of proceeds	We estimate that the net proceeds from the sale of our Class A common stock in this offering will be approximately $ million (or approximately $ million if the underwriters exercise their option to purchase additional shares in full), based on the assumed initial public offering price of $ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We currently intend to use the net proceeds we receive from this offering, together with our existing cash and cash equivalents, (i) to advance the development of TVB-2640, including clinical trials and manufacturing of additional drug supply, (ii) to advance the development of other drug candidates, including a first-in-human clinical trial of TVB-3567; and (iii) the remainder, for general corporate purposes, including working capital and operating expenses. See the section titled “Use of Proceeds” for additional information.
Voting Rights	Following this offering, we will have two classes of common stock: Class A common stock and Class B common stock. The rights of the holders of Class A common stock and Class B common stock are identical, except with respect to voting and conversion. Each share of Class A common stock will be entitled to one vote and shares of Class B common stock will be non-voting, except as may be required by law. Each share of Class B common stock may be converted into one share of Class A common stock at the option of its holder, subject to the ownership limitations provided for in our amended and restated certificate of incorporation to be in effect upon the completion of this offering. See the section titled “Description of Capital Stock” for additional information.
Risk factors	See the section titled “Risk Factors” for additional information.
Proposed trading symbol on The Nasdaq Global Market	“SGMT”

The number of shares of our Class A common stock and Class B common stock that will be outstanding after this offering is based on shares of our Class A common stock and shares of our Class B common stock outstanding as of March 31, 2021 after giving effect to (i) the reclassification and renaming of all outstanding shares of common stock into shares of Class A common stock, and (ii) the conversion of our outstanding shares of redeemable convertible preferred stock into shares of our Class A common stock and shares of our Class B common stock, and excludes:

- 8,108,225 shares of Class A common stock issuable upon exercise of outstanding options as of March 31, 2021 under our 2007 Equity Incentive Plan (the 2007 Plan) with a weighted average exercise price of $0.22 per share;
- 153,615,632 shares of Class A common stock issuable upon exercise of outstanding options as of March 31, 2021 under our 2017 Equity Incentive Plan (the 2017 Plan) with a weighted average exercise price of $0.08 per share;
- 8,145,193 shares of Class A common stock issuable upon exercise of outstanding options granted after March 31, 2021 under the 2017 Plan with a weighted average exercise price of $0.11 per share;
- shares of Class A common stock reserved for future issuance under our 2021 Equity Incentive Plan (the 2021 Plan) which will become effective once the registration statement of which this prospectus forms a part is declared effective, as well as any future automatic annual increases in the number of shares of Class A common stock reserved for issuance under the 2021 Plan and any shares underlying outstanding stock awards granted under (i) the 2007 Plan or (ii) the 2017 Plan, that expire or are repurchased, forfeited, cancelled or withheld, as more fully described in the section titled “Executive Compensation—Equity benefit plans”; and
- shares of Class A common stock reserved for issuance under our 2021 Employee Stock Purchase Plan (the ESPP) which will become effective once the registration statement of which this prospectus forms a part is declared effective, and any future automatic annual increases in the number of shares of Class A common stock reserved for future issuance under our ESPP.

Unless otherwise indicated, the information in this prospectus assumes:

- a -for- reverse stock split of our Class A common stock to be effected prior to the closing of this offering;
- an initial public offering price of $ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus;
- the reclassification and renaming of all outstanding shares of common stock into shares of Class A common stock;
- the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into an aggregate of shares of our Class A common stock and shares of our Class B common stock immediately upon the closing of this offering;
- the net exercise of (i) the outstanding warrant to purchase 79,545 shares of our Series D redeemable convertible preferred stock with an exercise price of $0.88 per share, and automatic conversion to Class A common stock, resulting in the issuance of shares of our Class A common stock and (ii) the outstanding warrant to purchase 8,361,424 shares of our Class A common stock with an exercise price of $0.01 per share, resulting in the issuance of shares of our Class A common stock, in each case, assuming an initial public offering price of $ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, which warrants will terminate if not exercised prior to the completion of this offering;
- no exercise of the outstanding options described above;

- no exercise of the underwriters' option to purchase up to an additional shares of our Class A common stock; and
- the filing and effectiveness of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws, each of which will occur upon the closing of this offering.

Summary Financial Data

The following tables set forth our summary statements of operations and comprehensive loss data for the years ended December 31, 2019 and 2020 and three months ended March 31, 2020 and 2021, and our summary balance sheet data as of March 31, 2021. The statements of operations and comprehensive loss data for the years ended December 31, 2019 and 2020 have been derived from our audited financial statements included elsewhere in this prospectus. We derived our summary statements of operations data for the three months ended March 31, 2020 and 2021 and the summary balance sheet data as of March 31, 2021 from our unaudited financial statements included elsewhere in this prospectus. In our opinion, the unaudited interim financial statements have been prepared on a basis consistent with our audited financial statements and contain all adjustments, consisting only of normal and recurring adjustments, necessary for a fair presentation of such interim financial statements. Our historical results are not necessarily indicative of the results that may be expected for any period in the future. You should read the following summary financial data together with the sections titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Selected Financial Data" and our financial statements and the related notes included elsewhere in this prospectus. The summary financial data included in this section are not intended to replace the financial statements and are qualified in their entirety by our financial statements and the related notes included elsewhere in this prospectus.

Statement of Operations Data:

(in thousands, except share and per share data)

	Years Ended December 31,		Three Months Ended March 31,	
	2019	2020	2020	2021
Operating expenses:				
Research and development	$ 8,391	$ 8,182	$ 3,025	$ 3,354
General and administrative	5,861	3,218	982	1,449
Total operating expenses	14,252	11,400	4,007	4,803
Other income (expense), net:				
Interest expense	(64)	—	—	—
Change in fair value of related parties convertible notes	321	—	—	—
Change in fair value of redeemable convertible preferred stock tranche liability	(390)	—	—	(751)
Change in fair value of redeemable convertible preferred stock warrants	(4)	—	(2)	—
Interest income and other	128	30	26	6
Total other income (expense), net	(9)	30	24	(745)
Net loss and comprehensive loss	$ (14,261)	$ (11,370)	$ (3,983)	$ (5,548)
Net loss per share attributable to common stockholders, basic and diluted[1]	$ (1.86)	$ (1.48)	$ (0.52)	$ (0.66)
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted[1]	7,674,259	7,674,259	7,674,259	8,350,834
Pro forma net loss per share attributable to common stockholders, basic and diluted[2]				
Weighted-average shares outstanding used in computing pro forma net loss per share attributable to common stockholders, basic and diluted[2]				

(1) See Notes to Financial Statements—Note 2 for an explanation of the calculations of our net loss per share attributable to common stockholders, basic and diluted.

(2) The unaudited pro forma basic and diluted weighted-average common shares outstanding used in the calculation of unaudited pro forma basic and diluted net loss per share attributable to common

stockholders for the year ended December 31, 2020 and the three months ended March 31, 2021 have been prepared to give effect to: (i) the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into our Class A common stock and Class B common stock upon the closing of this offering and (ii) the issuance of shares of our Class A common stock as a result of the expected net exercise of all outstanding warrants.

Balance Sheet Data:

(in thousands)

	As of March 31, 2021		
	Actual	Pro Forma(1)	Pro Forma, As Adjusted(2)(3)
Cash and cash equivalents	$ 74,944	$	$
Working capital(4)	73,887		
Total assets	77,200		
Total liabilities	3,161		
Redeemable convertible preferred stock warrant liabilities	9		
Redeemable convertible preferred stock	214,620		
Accumulated deficit	(172,475)		
Total stockholders' deficit	(140,581)		

(1) The pro forma balance sheet data gives effect to (i) the conversion of all of our outstanding shares of redeemable convertible preferred stock into an aggregate of shares of our Class A common stock and shares of our Class B common stock immediately upon the closing of this offering; (ii) the issuance of shares of our Class A common stock as a result of the expected net exercise of an outstanding warrant to purchase 79,545 shares of our Series D redeemable convertible preferred stock, subsequent conversion to Class A common stock, and the related reclassification of the redeemable convertible warrant liability to Class A common stock and additional paid-in capital, assuming an initial public offering price of $ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus; (iii) the issuance of shares of our Class A common stock as a result of the expected net exercise of an outstanding warrant to purchase 8,361,424 shares of our Class A common stock, assuming an initial public offering price of $ per share; and (iv) the filing and effectiveness of our amended and restated certificate of incorporation upon the closing of this offering.

(2) On a pro forma as adjusted basis to give further effect to our issuance and sale of shares of Class A common stock in this offering at an assumed initial public offering price of $ per share, the midpoint of the estimated offering price range listed on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

(3) Each $1.00 increase or decrease, as applicable, in the assumed initial public offering price of $ per share, the midpoint of the estimated offering price range listed on the cover page of this prospectus, would increase or decrease, as applicable, the pro forma as adjusted amount of each of cash and cash equivalents, working capital, total assets and total stockholders' equity by approximately $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease, as applicable, of 1,000,000 shares in the number of shares offered by us at the assumed initial public offering price per share, the midpoint of the estimated offering price range listed on the cover page of this prospectus, would increase or decrease, as applicable the pro forma as adjusted amount of each of cash and cash equivalents, working capital, total assets and total stockholders' equity by approximately $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. The

pro forma and pro forma as adjusted information discussed above is illustrative only and will depend on the actual initial public offering price and other terms of this offering determined at pricing.

(4) Working capital is defined as total current assets less total current liabilities. See our financial statements and the related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

RISK FACTORS

Investing in our Class A common stock involves a high degree of risk. You should consider and read carefully all of the risks and uncertainties described below, as well as the other information in this prospectus, including our financial statements and the related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" before deciding whether to invest in our Class A common stock. The risks described below are not the only ones facing us. The following risks or additional risks and uncertainties not presently known to us or that we currently believe to be immaterial could materially and adversely affect our business, financial condition, results of operations and growth prospects. In such an event, the trading price of our Class A common stock could decline, and you may lose all or part of your investment. This prospectus also contains forward-looking statements and estimates that involve risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. Our actual results could differ materially from those anticipated in our forward-looking statements as a result of specific factors, including the risks and uncertainties described below.

Risks Related to Our Business

Even if this offering is successful, we will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs or future commercialization efforts.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since our inception. We expect to continue to spend substantial amounts to continue the clinical development of, and seek regulatory approval for, TVB-2640, TVB-3567 and any future drug candidates. We will require significant additional amounts in order to prepare for commercialization, and, if approved, to launch and commercialize TVB-2640 or TVB-3567. Our expenses could increase beyond expectations if we are required by the US Food and Drug Administration (the FDA), or any comparable foreign regulatory authority to perform clinical trials or preclinical studies in addition to those that we currently anticipate. Other unanticipated costs may also arise.

In addition, if we obtain regulatory approval to market TVB-2640, TVB-3567 or any other drug candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Because the design and outcome of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of TVB-2640, TVB-3567 or any other drug candidate we develop. Following this offering, we also expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to maintain our continuing operations.

As of March 31, 2021, we had $74.9 million in cash and cash equivalents. Based on our current operating plans, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to fund our operating expenses and capital expenditures requirements for at least the next twelve months. Our estimate as to how long we expect the net proceeds from this offering, together with our existing cash and cash equivalents, to be able to continue to fund our operating expenses and capital expenditures requirements is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. Moreover, it is particularly difficult to estimate with certainty our future expenses given the dynamic nature of our business, the COVID-19 pandemic and the macro-economic environment generally. The net proceeds from this offering and our existing cash and cash equivalents will not be sufficient to fund all of the activities that are necessary to complete the development and commercialization of our drug candidates.

Until such time as we can generate significant revenue from sales of our drug candidates, if ever, we will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources, which may dilute our stockholders or restrict

our operating activities. Adequate additional financing may not be available to us on acceptable terms, or at all. Market volatility, including as a result of the COVID-19 pandemic, could also adversely impact our ability to access capital as and when needed. Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our research-stage programs, clinical trials or future commercialization efforts.

Currently our business depends on the success of TVB-2640, which is still in clinical development. If we are unable to obtain regulatory approval for or successfully commercialize TVB-2640, our business will be materially harmed.

Currently, our product development is primarily focused on TVB-2640, an inhibitor of the fatty acid synthase (FASN) enzyme, for potential treatment of NASH. Successful continued development and ultimate regulatory approval of TVB-2640 for NASH, or other indications that we may pursue, is critical to the future success of our business. We have invested, and will continue to invest, a significant portion of our time and financial resources in the clinical development of TVB-2640. We will need to raise sufficient funds to successfully complete the clinical development program for TVB-2640. The future regulatory and commercial success of TVB-2640 is subject to a number of risks, including the following:

- we may not have sufficient financial and other resources to complete the necessary clinical trials for TVB-2640, including but not limited to Phase 2 clinical trials and, later, registrational clinical trials to obtain drug approval;
- the mechanism of action of TVB-2640 is complex and we do not know the degree to which it will translate into a therapeutic benefit, if any, in NASH or any other indication or to which it may contribute to long term safety issues or adverse events, if any, when TVB-2640 is taken for prolonged periods such as in the treatment of NASH, or any other indication;
- patients in our clinical trials may die or suffer other adverse effects for reasons that may or may not be related to TVB-2640, which will be even more uncertain if we pursue clinical trials of TVB-2640 in combination with other drugs or drug candidates, which uncertainty could delay or prevent further clinical development;
- we may not be able to obtain adequate evidence from clinical trials of efficacy and safety for TVB-2640 in NASH, or any other indication;
- in our clinical programs for TVB-2640, we may experience variability in patients, adjustments to clinical trial procedures and the need for additional clinical trial sites, which could delay our clinical trial progress;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or comparable foreign regulatory authorities for marketing approval;
- the standards implemented by clinical or regulatory agencies may change at any time;
- the FDA or comparable foreign regulatory agencies may require efficacy endpoints for a Phase 3 clinical trial for the treatment of NASH, or any other indication, that differ from the endpoints of our current or future trials, which may require us to conduct additional clinical trials;
- we do not know the degree to which TVB-2640 will be accepted as a therapy by physicians, patients and third-party payors, even if approved;
- if approved for NASH, TVB-2640 will likely compete with the off-label use of currently marketed drugs and other therapies in development that may reach approval for NASH prior to TVB-2640; and
- we may not be able to obtain, maintain or enforce our patents and other intellectual property rights in a manner that prevents our competitors from developing and commercializing products similar or identical to TVB-2640 or that otherwise compete with TVB-2640.

Of the large number of drugs in development in the pharmaceutical industry, only a small percentage results in the submission of a new drug applications (NDA), to the FDA and even fewer are approved for

commercialization. Furthermore, even if we receive regulatory approval to market TVB-2640, any such approval may be subject to limitations on the indicated uses or patient populations for which we may market the drugs. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development programs, we may be unable to successfully develop or commercialize TVB-2640. If we or any of our future development partners are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize TVB-2640, we may not be able to generate sufficient revenue to continue our business.

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

Successful and timely completion of clinical trials will require that we enroll a sufficient number of patients. We may not be able to initiate, continue, or complete clinical trials that may be required by the FDA or comparable foreign regulatory authorities to obtain regulatory approval for TVB-2640, TVB-3567 or any other future drug candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these clinical trials. Patient enrollment, a significant factor in the timing to conduct and complete clinical trials, is affected by many factors, including:

- the size and nature of the patient population;
- the severity of the disease under investigation;
- eligibility criteria for the trial;
- the proximity of patients to clinical sites;
- the design of the clinical protocol;
- the ability to obtain and maintain patient consents;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the risk that patients enrolled in clinical trials will drop out of the trials before the administration of our drug candidates or trial completion;
- the availability of competing clinical trials;
- the availability of new drugs approved for the indication the clinical trial is investigating;
- clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies; and
- the effects of the COVID-19 pandemic.

In certain of our proposed NASH clinical trials, patient willingness to undergo a liver biopsy may also impact patient enrollment. Potential patients for TVB-2640, TVB-3567 or any other future drug candidates may not be adequately diagnosed or identified with the diseases that we are targeting or may not meet the entry criteria for our trials.

We also may encounter difficulties in identifying and enrolling NASH patients with a stage of disease appropriate for ongoing or future clinical trials. In addition, the process of finding and diagnosing patients may prove costly. Additionally, other pharmaceutical companies with more resources and greater experience in drug development and commercialization are targeting treatments for NASH, and this competition reduces the number and types of patients available to us, as 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. Because the number of qualified clinical investigators and clinical trial sites is also limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites, and may delay or make it more difficult to fully enroll our clinical trials. We also rely on contract research organizations (CROs) and clinical trial sites to enroll subjects in our clinical trials and, while we have agreements governing their services, we will have limited influence over their actual performance.

These factors may make it difficult for us to enroll enough patients to complete our clinical trials in a timely and cost-effective manner. Delays in the completion of any clinical trial of our drug candidates will increase our costs, slow down our drug candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, some 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 drug candidates.

Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. If clinical trials or regulatory approval processes for our drug candidates are prolonged, delayed or suspended, we may be unable to commercialize our drug candidates on a timely basis, which would require us to incur additional costs and delay our receipt of any revenue from potential product sales.

Drug development has inherent risk. We will be required to demonstrate through adequate and well-controlled clinical trials that our drug candidates are safe and effective for use in their target indications before we can seek regulatory approvals for their commercial sale. Clinical studies are expensive, difficult to design and implement, can take many years to complete and are uncertain as to outcome. Delay or failure can occur at any stage of development, including after commencement of any of our clinical trials. In addition, success in early clinical trials does not mean that later clinical trials will be successful, because later-stage clinical trials may be conducted in broader patient populations and involve different study designs. For instance, the results from our Phase 2a study may not be predictive of the results from any future Phase 2b or Phase 3 studies. Furthermore, our future trials will need to demonstrate sufficient safety and efficacy in larger patient populations for approval by regulatory authorities. Companies frequently suffer significant setbacks in advanced clinical trials, even after earlier clinical trials have shown promising results. In addition, only a small percentage of drugs under development result in the submission of an NDA to the FDA and even fewer are approved for commercialization.

We cannot predict whether we will encounter problems with any completed, ongoing or planned clinical trials that will cause us or any regulatory authority to delay or suspend those clinical trials or delay the analysis of data derived from them. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials;
- delays in reaching a consensus with regulatory authorities on study design or implementation of the clinical trials;
- difficulties obtaining regulatory authorization to commence a clinical trial or complying with conditions imposed by a regulatory authority regarding the scope or term of a clinical trial;
- delays in reaching or failing to reach agreement on acceptable terms with prospective CROs, contract manufacturing organizations, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly;
- delays in identifying, recruiting and training suitable clinical investigators;
- insufficient or inadequate supply or quality of our drug candidates or other materials necessary to conduct and complete our clinical trials, or delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for clinical trials;
- delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of our drug candidates for use in clinical trials;
- difficulties obtaining institutional review board (IRB) or ethics committee approval to conduct a clinical trial at a prospective site;
- delays in recruiting, screening and enrolling patients and delays caused by patients withdrawing from clinical trials or failing to return for post-treatment follow-up;
- changes to the clinical trial protocols;

- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines;
- serious and unexpected drug-related side effects related to the drug candidate being tested;
- lack of adequate funding to continue the clinical trial;
- occurrence of severe adverse effects in clinical trials of the same class of agents conducted by other companies;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- selection of clinical endpoints that require prolonged periods of observation or analyses of resulting data;
- third-party vendors not performing manufacturing and distribution services in a timely manner or to sufficient quality standards;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, good clinical practice (GCP) or other regulatory requirements;
- third-party contractors not performing data collection or analysis in a timely or accurate manner;
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications; and
- failure of our third-party contractors, such as CROs and contract manufacturing organizations, or our investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner.

We do not know whether our clinical trials will begin as planned, will need to be restructured, or will be completed on schedule, if at all. Delays in the initiation, enrollment, or completion of our clinical trials will result in increased development costs for our drug candidates, and our financial resources may be insufficient to fund any incremental costs. If our clinical trials are delayed, our competitors may be able to bring products to market before we do and the commercial viability of our drug candidates could be limited.

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 or ethics committees of the institutions in which such trials are being conducted or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing, or successful completion of a clinical trial.

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

Moreover, principal investigators for our clinical trials may serve and have served 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 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, 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 drug candidates.

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 preliminary or top-line data from our preclinical studies and 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 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. Top-line 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, top-line data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock after this offering.

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 drug candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. 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 drug candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

We may not be successful in our efforts to expand our pipeline by identifying additional indications for which to investigate TVB-2640 in the future. We may expend our limited resources to pursue a particular indication or formulation for TVB-2640 and fail to capitalize on drug candidates, indications or formulations that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we are focused on specific indications for TVB-2640. As a result, we may fail to generate additional clinical development opportunities for TVB-2640 for a number of reasons, including, TVB-2640 may in certain indications, on further study, be shown to have harmful side effects, limited to no efficacy, or other characteristics that suggest it is unlikely to receive marketing approval and achieve market acceptance in such additional indications.

We plan to conduct several clinical trials for TVB-2640 and TVB-3567 in parallel over the next several years. If we make incorrect determinations regarding the viability or market potential of any of our

drug 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 forgo or delay pursuit of opportunities with other indications that could have had greater commercial potential or likelihood of success. However, we may focus on or pursue one or more of our target indications over other potential indications and such development efforts may not be successful, which would cause us to delay the clinical development and approval of TVB-2640. Furthermore, research programs to identify additional indications for TVB-2640 require substantial technical, financial, and human resources. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for specific indications may not yield any commercially viable products.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our drug candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a drug candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any drug candidate and it is possible that any drug candidates we may seek to develop in the future will never obtain regulatory approval. Neither we nor any future collaborator is permitted to market any of our drug candidates in the United States until we receive regulatory approval of an NDA from the FDA.

Prior to obtaining approval to commercialize a drug 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 foreign regulatory agencies, that such drug candidates are safe and effective for their intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for our drug candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. The FDA may also require us to conduct additional preclinical studies or clinical trials for our drug candidates either prior to or post-approval, or it may object to elements of our clinical development program.

The FDA and other regulatory agencies may delay, limit or deny approval of our drug candidates for many reasons, including:

- we may not be able to demonstrate to the satisfaction of the FDA or other regulatory agencies that TVB-2640, TVB-3567 or any of our other future drug candidates are safe and effective for any indication;
- the results of clinical trials may not meet the level of statistical significance or clinical significance required by the FDA or other regulatory agencies for approval;
- the FDA or other regulatory agencies may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the FDA or other regulatory agencies may not find the data from preclinical studies and clinical trials sufficient to demonstrate that TVB-2640's, TVB-3567's or any of our other future drug candidates clinical and other benefits outweigh its safety risks;
- the FDA or other regulatory agencies may disagree with our interpretation of data from preclinical studies or clinical trials, or may not accept data generated at our clinical trial sites;
- the data collected from preclinical studies and clinical trials of TVB-2640, TVB-3567 or any of our other future drug candidates may not be sufficient to support the submission of an NDA or other application for regulatory approval;
- the FDA may have difficulties scheduling an advisory committee meeting in a timely manner, or the advisory committee may recommend against approval of our application or may

recommend that the FDA require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling, or distribution and use restrictions;

- the FDA may require development of a risk evaluation and mitigation strategy (REMS) as a condition of approval;
- the FDA or other regulatory agencies may identify deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for clinical and commercial supplies;
- the FDA or other regulatory agencies may change their approval policies or adopt new regulations; and
- the FDA or other regulatory agencies may require simultaneous approval for both adults and for children and adolescents delaying needed approvals, or we may have successful clinical trial results for adults but not children and adolescents, or vice versa.

Before we can submit an application to the FDA for regulatory approval, we must conduct a pivotal trial that will be substantially broader than our planned Phase 2b trial. Phase 3 clinical trials frequently produce unsatisfactory results even though prior clinical trials were successful. Therefore, even if the results of our Phase 2 trials are successful, the results of the future trials that we conduct may or may not be successful. Further, our drug candidates may not be approved even if they achieve their primary endpoints in Phase 3 clinical trials.

In addition, any of these regulatory authorities may change requirements for the approval of a drug candidate even after reviewing and providing comments or advice on a protocol for a clinical trial. The FDA or other regulatory agencies may require that we conduct additional clinical, nonclinical, manufacturing validation or drug product quality studies and submit those data before considering or reconsidering the application. Depending on the extent of these or any other studies, approval of any applications that we submit may be delayed by several years or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA or other regulatory agencies.

In addition, the FDA or other regulatory agencies may also approve a drug candidate for fewer or more limited indications than we request, may impose significant limitations related to use restrictions for certain age groups, warnings, precautions or contraindications or may grant approval contingent on the performance of costly post-marketing clinical trials or risk mitigation requirements, such as the implementation of a REMS. The FDA or other regulatory agencies may not accept the labeling claims that we believe would be necessary or desirable for the successful commercialization of our drug candidates.

Obtaining and maintaining regulatory approval for a drug candidate in one jurisdiction does not mean that we will be successful in obtaining regulatory approval for that drug candidate in other jurisdictions.

Obtaining and maintaining regulatory approval for a drug candidate 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 for a drug candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the drug 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 trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a drug 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 TVB-2640, TVB-3567 or any of our other future drug candidates is also subject to approval.

Regulatory authorities in jurisdictions outside of the United States and the European Union also have requirements for approval for drug candidates with which we must comply prior to marketing in those jurisdictions. 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

TVB-2640, TVB-3567 or any of our other future drug candidates 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 TVB-2640, TVB-3567 or any of our other future drug candidates will be harmed, which would adversely affect our business, prospects, financial condition, and results of operations.

We currently have no marketing and sales organization and have no organizational experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell TVB-2640, TVB-3567 and any future drug candidates, we may not be able to generate product revenues.

We currently do not have a commercial organization for the marketing, sales, and distribution of pharmaceutical products. To commercialize TVB-2640, TVB-3567 and any future drug candidates, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services.

The establishment and development of our own sales force or the establishment of a contract sales force to market TVB-2640, TVB-3567 and any future drug candidates will be expensive and time-consuming and could delay any commercial launch. Moreover, we may not be able to successfully develop this capability. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train, and retain marketing and sales personnel. We also face competition in our search for third parties to assist us with the sales and marketing efforts of TVB-2640, TVB-3567 or any of our other future drug candidates. To the extent we rely on third parties to commercialize TVB-2640, TVB-3567 or any of our other future drug candidates, if approved, we may have little or no control over the marketing and sales efforts of such third parties and our revenues from product sales may be lower than if we had commercialized TVB-2640, TVB-3567 or any future drug candidates ourselves. In the event we are unable to develop our own marketing and sales force or collaborate with a third-party marketing and sales organization, we would not be able to commercialize TVB-2640, TVB-3567 or any future drug candidates.

Use of TVB-2640, TVB-3567 or any future drug candidates could be associated with side effects, adverse events or other properties that could delay or prevent regulatory approval or result in significant negative consequences following marketing approval, if any.

As is the case with pharmaceuticals generally, it is likely that there may be side effects and adverse events associated with the use of TVB-2640, TVB-3567 or any future drug candidates. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by TVB-2640, TVB-3567 and any future drug 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 other comparable foreign authorities. If drug-related serious adverse events are observed, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval for TVB-2640, TVB-3567 or any of our other future drug candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition, and prospects significantly.

Furthermore, only about 260 subjects have been treated with TVB-2640. It is possible that as we test our drug candidates in larger, longer and more extensive clinical trials, illnesses, injuries, discomforts and other adverse events that were observed in previous trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. Many times, side effects are only detectable after investigational products are tested in large-scale clinical trials or, in some cases, after they are made available to patients on a commercial scale following approval.

Additionally, if TVB-2640, TVB-3567 and any future drug candidates receive marketing approval, and we or others later identify undesirable side effects caused by such drug candidate, a number of potentially significant negative consequences could result, including:

- we may be forced to suspend marketing of that product, or decide to remove the product form the marketplace;
- regulatory authorities may withdraw approvals or change their approvals of such product, or seek an injunction against its manufacture or distribution;
- regulatory authorities may require additional warnings on the label, including "boxed" warnings, issue safety alerts or press releases, or may limit access of that product 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 create a REMS, which could include a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way the product is administered;
- we could be subject to fines, injunctions, or the imposition of criminal or civil penalties, or be sued and held liable for harm caused to subjects or patients; and
- the product may become less competitive, and our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of TVB-2640, TVB-3567 or any future drug candidates, if approved, and could significantly harm our business, results of operations, and prospects.

We may seek Fast-Track designation for our drug candidates, but we might not receive such designations, and even if we do, such designations may not actually lead to a faster development or regulatory review or approval process.

If a drug candidate is intended for the treatment of a serious condition and nonclinical or clinical data demonstrate the potential to address unmet medical need for this condition, a product sponsor may apply for FDA Fast-Track designation. The sponsor of a Fast-Track drug candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the drug candidate may be eligible for priority review if the relevant criteria are met. A Fast-Track drug candidate may also be eligible for rolling review, where the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA. We may seek Fast-Track designation for other indications for TVB-2640, TVB-3567 or any future drug candidates we may develop, but we might not receive such designations from the FDA. However, even if we receive Fast-Track designation, Fast-Track designation does not ensure that we will receive marketing approval or that approval will be granted within any particular timeframe. We may not experience a faster development or regulatory review or approval process with Fast-Track designation 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. Fast-Track designation alone does not guarantee qualification for the FDA's priority review procedures.

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

We may in the future seek an accelerated approval for our one or more of our drug candidates. Under the accelerated approval program, the FDA may grant accelerated approval to a drug candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies, upon a determination that the drug candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such

as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post- approval confirmatory studies to verity and describe the drug's clinical benefit. If such post-approval studies fail to confirm the drug's clinical benefit, the FDA may withdraw its approval of the drug on an expedited basis.

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

Any regulatory approvals that we may receive for our drug candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the drug candidate, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS in order to approve our drug candidates, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or foreign regulatory authorities approve our drug candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our drug candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. If we or a regulatory authority discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

Our drug candidates will remain subject to ongoing regulatory review even if they receive marketing approval, and if we fail to comply with continuing regulations, we could lose these approvals and the sale of any approved commercial products could be suspended.

If we fail to comply with the regulatory requirements of the FDA and other applicable domestic and foreign regulatory authorities, or previously unknown problems with any approved product, manufacturer, or manufacturing process are discovered, we could be subject to administrative or judicially imposed sanctions, including:

- restrictions on the products, manufacturers, or manufacturing processes;

- warning letters;
- civil or criminal penalties;
- fines;
- injunctions;
- product seizures or detentions;
- pressure to initiate voluntary product recalls;
- suspension or withdrawal of regulatory approvals; and
- refusal to approve pending applications for marketing approval of new products or supplements to approved applications.

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

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, and compliance with such regulation may be expensive and consume substantial financial and management resources. If we or any future marketing collaborators or contract manufacturers are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies or are not able to maintain regulatory compliance, it could delay or prevent the promotion, marketing or sale of our products, which would adversely affect our business and results of operations.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If any of our drug candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as our drug candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we receive marketing approval for a drug candidate, physicians may nevertheless prescribe it 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 US federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use 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 drug candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

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

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA 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 or modifications to approved 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 US government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products, and on March 18, 2020 the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 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. Additionally, on April 15, 2021, the FDA issued a guidance document in which the FDA described its plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites. According to the guidance, the FDA intends to request such remote interactive evaluations in situations where an in-person inspection would not be prioritized, deemed mission-critical, or where direct inspection is otherwise limited by travel restrictions, but where the FDA determines that remote evaluation would be appropriate. 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.

Our industry is highly competitive, and our drug candidates may become obsolete.

We are engaged in a rapidly evolving field. Competition from other pharmaceutical companies, biotechnology companies and research and academic institutions is intense and likely to increase. Many of those companies and institutions have substantially greater financial, technical and human resources than us. Those companies and institutions also have substantially greater experience in developing products, conducting clinical trials, obtaining regulatory approval and in manufacturing and marketing pharmaceutical products. Our competitors may succeed in obtaining regulatory approval for their products more rapidly than we do. Competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for competitive products. Some of these competitive products may have an entirely different approach or means of accomplishing the desired therapeutic effect than products being developed by us. Our competitors may succeed in developing products that are more effective and/or cost competitive than those we are developing, or that would render our drug candidates less competitive or even obsolete. In addition, one or more of our competitors may achieve product commercialization or patent protection earlier than us, which could materially adversely affect our business.

If TVB-2640 is approved for the treatment of NASH, future competition could also arise from products currently in development with multinational pharmaceutical companies, specialized biotechnology companies and universities and other research institutions, including Bristol-Myers Squibb Company, CymaBay Therapeutics, Inc., Enanta Pharmaceuticals, Inc., Galmed Pharmaceuticals Ltd., Gilead Sciences, Inc., Intercept Pharmaceuticals, Inc., Inventiva S.A., Madrigal Pharmaceuticals, Inc., Metacrine, Inc., NGM Biopharmaceuticals, Inc., Novartis AG, Pfizer Inc., and Viking Therapeutics, Inc. Smaller or earlier-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. 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.

Recently enacted legislation, future legislation and healthcare reform measures may increase the difficulty and cost for us to obtain marketing approval for and commercialize TVB-2640, TVB-3567 and any future drug candidates and may affect the prices we may set.

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

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the Affordable Care Act) was enacted in the United States. Among the provisions of the Affordable Care Act of importance to our potential drug candidates, the Affordable Care Act: established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; expanded eligibility criteria for Medicaid programs; increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; created a new Medicare Part D coverage gap discount program; established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare and Medicaid Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

There have been judicial, executive and Congressional challenges to certain aspects of the Affordable Care Act. By way of example, legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act of 2017 (the Tax Act) included a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act 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 US District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the US Court of Appeals for the 5th Circuit ruled that that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. The United States Supreme Court is currently reviewing this case, although it is unclear when or how the Supreme Court will rule.

On February 10, 2021, the Biden administration withdrew the federal government's support for overturning the Affordable Care Act. Further, although the Supreme Court has not yet ruled on the constitutionality of the Affordable Care Act, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. It is also unclear how the Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration will impact the Affordable Care Act or our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, included reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 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 1, 2020 through December 31, 2021, unless additional Congressional action is taken. In addition, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives.

At the state level, individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other

countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition, and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for TVB-2640 or TVB-3567, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition, and prospects.

We cannot predict the likelihood, nature, or extent of healthcare reform initiatives that may arise from future legislation or administrative action, particularly as a result of the new presidential administration. We expect that the Affordable Care Act and other healthcare reform measures, including those that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. In addition, it is possible that additional governmental action will be taken in response to the COVID-19 pandemic. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from third-party payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize TVB-2640, TVB-3567 or our other drug candidates, if approved.

Even if we are able to obtain regulatory approvals for any of our drug candidates, if they exhibit harmful side effects after approval, our regulatory approvals could be revoked or otherwise negatively impacted, and we could be subject to costly and damaging product liability claims.

Even if we receive regulatory approval for any of our other drug candidates, we will have tested them in only a small number of patients during our clinical trials. If our applications for marketing are approved and more patients begin to use our product, new risks and side effects associated with our products may be discovered. As a result, regulatory authorities may revoke their approvals. If any of our products is approved by the FDA based on a surrogate endpoint pursuant to accelerated approval regulations, we will be required to conduct additional clinical trials establishing clinical benefit on the ultimate outcome of NASH. Additionally, we may be required to conduct additional clinical trials, make changes in labeling of our product, reformulate our product or make changes and obtain new approvals for our and our suppliers' manufacturing facilities. We might have to withdraw or recall our products from the marketplace. We may also experience a significant drop in the potential sales of our product if and when regulatory approvals for such product are obtained, experience harm to our reputation in the marketplace or become subject to lawsuits, including class actions. Any of these results could decrease or prevent any sales of our approved product or substantially increase the costs and expenses of commercializing and marketing our product.

If any product liability lawsuits are successfully brought against us or any of our collaborative partners, we may incur substantial liabilities and may be required to limit commercialization of our drug candidates.

We face an inherent risk of product liability lawsuits related to the testing of our drug candidates in seriously ill patients and will face an even greater risk if drug candidates are approved by regulatory authorities and introduced commercially. Product liability claims may be brought against us or our partners by participants enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling any of our future approved products. If we cannot successfully defend against any such claims, we may incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any of our future approved products;
- injury to our reputation;
- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- significant litigation costs;
- substantial monetary awards to or costly settlements with patients or other claimants;
- product recalls or a change in the indications for which products may be used;

- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize our drug candidates.

If any of our drug candidates are approved for commercial sale, we will be highly dependent upon consumer perceptions of our company and the safety and quality of our products. We could be adversely affected if we are subject to negative publicity. We could also be adversely affected if any of our products or any similar products distributed by other companies prove to be, or are asserted to be, harmful to patients. In addition, because of our dependence upon consumer perceptions, any adverse publicity associated with illness or other adverse effects resulting from patients' use or misuse of our products or any similar products distributed by other companies could have a material adverse impact on our results of operations.

We do not currently hold product liability insurance coverage. Prior to commercialization of our drug candidates, we will need to purchase insurance coverage. As a result, we may be unable to maintain or obtain sufficient insurance at a reasonable cost to protect us against losses that could have a material adverse effect on our business. These liabilities could prevent or interfere with our product development and commercialization efforts. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our available insurance coverage, could decrease our cash resources and adversely affect our business, financial condition and results of operations.

Our employees, contractors and partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, contractors or partners. Misconduct by these parties could include failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with federal and state healthcare fraud and abuse laws and regulations, to report financial information or data timely, completely or accurately, or to 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. Third-party misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter 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 resulting from this misconduct and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, and the curtailment or restructuring of our operations.

We enter into various contracts in the normal course of our business in which we indemnify the other party to the contract. In the event we have to perform under these indemnification provisions, it could have a material adverse effect on our business, financial condition and results of operations.

In the normal course of business, we periodically enter into academic, commercial, service, collaboration, licensing, consulting and other agreements that contain indemnification provisions. With respect to our academic and other research agreements, we typically indemnify the institution and related parties from losses arising from claims relating to the products, processes or services made, used, sold or performed pursuant to the agreements for which we have secured licenses, and from claims arising from our or our potential sublicensees' exercise of rights under the agreement. With respect to our commercial agreements, we indemnify our vendors from any third-party product liability claims that could result from the production, use or consumption of the product, as well as for alleged infringements of any patent or other intellectual property right by a third party.

Should our obligation under an indemnification provision exceed applicable insurance coverage or if we were denied insurance coverage, our business, financial condition and results of operations could be adversely affected. Similarly, if we are relying on a collaborator to indemnify us and the collaborator is denied insurance coverage or the indemnification obligation exceeds the applicable insurance coverage, and if the collaborator does not have other assets available to indemnify us, our business, financial condition and results of operations could be adversely affected.

If we fail to develop and commercialize other drug candidates, we may be unable to grow our business.

Although the development and commercialization of TVB-2640 is 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, FASN inhibition, and other diseases. We will evaluate internal opportunities from our compound libraries, and also may choose to in-license or acquire other drug candidates as well as commercial products to treat patients suffering from NASH or other disorders with high unmet medical needs and limited treatment options. These other drug candidates may require additional, time-consuming development efforts prior to commercial sale, including preclinical studies, clinical trials and approval by the FDA and/or applicable foreign regulatory authorities. All drug candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the drug 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.

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.

Our business has been and could continue to be adversely affected by the evolving COVID-19 pandemic, which was declared by the World Health Organization as a global pandemic. As COVID-19 continues to spread, 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;
- 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;
- 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;
- interruptions or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- risk that participants enrolled in our clinical trials 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;

- refusal of the FDA to accept data from clinical trials in affected geographies; and
- increased costs relating to mitigating the impact of COVID-19 on any of the foregoing factors.

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 in our planned Phase 1 and Phase 2 clinical trials. In particular, some sites may 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, according to the Centers for Disease Control and Prevention, people who have serious medical conditions, including those such as NASH, are at higher risk of getting very sick from COVID-19. As a result, current or potential patients in our ongoing and planned clinical trials may choose to not enroll, not participate in follow-up clinical visits, or drop out of the trial 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 interrupt healthcare services.

If patient enrollment is delayed for an extended period of time, our ongoing and planned 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.

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 clinical trials depends on retrieving laboratory data from patients. Any failure by the laboratories with which we work 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 CROs or third-party manufacturing facilities upon which we rely, or the availability or cost of materials, which could disrupt the supply chain for TVB-2640 or TVB-3567. 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 TVB-2640 or otherwise advancing development of TVB-2640 or TVB-3567 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 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 Class A common stock or other equity securities or such sales may be on unfavorable terms.

COVID-19 and actions taken to reduce its spread continue to evolve. The extent to which COVID-19 may impede the development of TVB-2640, 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 “Risk Factors” section.

Risks related to our intellectual property

If we are unable to obtain, maintain and enforce sufficient patent protection for our drug candidates, or if the scope of the patent protection is not sufficiently broad, third parties, including our competitors, could develop and commercialize products similar or identical to ours, and our ability to commercialize our drug candidates successfully may be adversely affected.

Our success depends in large part on our ability to protect our proprietary technologies that we believe are important to our business, including pursuing and maintaining patent protection intended to cover the composition of matter of our drug candidates, including TVB-2640 and TVB-3567, their methods of use, related technologies and other inventions that are important to our business. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our technologies and drug candidates that are important to our business. In addition to patent protection, we also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection, including our proprietary platform of selective FASN inhibitors. If we do not adequately obtain, maintain, protect or enforce our intellectual property, third parties, including our competitors, may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability.

The patent application and approval process is expensive, time-consuming and complex. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

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 United States Patent and Trademark Office (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 pharmaceutical compounds commonly involves complex legal and factual questions, which has 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 drug candidates.

Our pending patent applications may not result in issued patents if other parties invented or filed patent applications on the same technology prior to our invention or filing of patent applications on our technology.

Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. Because patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file any patent application related to our drug candidates. Further, in cases where a particular compound of interest is in the public domain, third parties may be able to obtain patents on improvements or other inventions relating to such compound if they were to discover the same patentable inventions relating to such compounds after us but manage to file a patent application before we do. In addition, we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, including our polymorphs and variants, such as our employees, collaborators, consultants, advisors and other third parties; however, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to obtain patent protection. Furthermore, if third parties have filed patent applications related to our drug candidates or technology, an interference proceeding in the United States can be initiated by the USPTO or a third party to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

We cannot ensure that patent rights relating to inventions described and claimed in our pending patent applications will issue, or that our issued patents or patents that issue in the future will not be challenged and rendered invalid and/or unenforceable.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our drug candidates by obtaining and defending patents. We have pending and issued US and foreign patent applications in our portfolio; however, we cannot predict:

- if and when patents may issue based on our patent applications;
- the scope of protection of any patent issuing based on our patent applications;
- whether the claims of any issued patent will provide protection against competitors;
- whether or not third parties will find ways to invalidate or circumvent our patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications;
- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose; and/or
- whether the patent applications will result in issued patents with claims that cover each of our drug candidates or uses thereof in the United States or in other foreign countries.

We may be subject to a third-party preissuance submission of prior art to the USPTO or become involved in post-grant review procedures, oppositions, derivations, revocation, reexaminations, inter partes review or interference proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such challenge may result in loss of exclusivity or in our patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products or limit the duration of the patent protection of our technology and products. Such challenges also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects. Furthermore, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future drug candidates.

Our pending and future patent applications may not result in patents being issued that protect our drug candidates, in whole or in part, or which effectively prevent others from commercializing competitive products.

Given the amount of time required for the development, testing and regulatory review of new drug candidates, our patents protecting such drug candidates might expire before or shortly after such drug candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical ours. Our competitors and other third parties may also seek approval to market their own products similar to or otherwise competitive with our products. Alternatively, our competitors or other third parties may seek to market generic or biosimilar versions of any approved products and in so doing, claim that patents owned by us are invalid, unenforceable or not infringed. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or that our competitors are competing in a non-infringing manner. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

Moreover, some of our patents may in the future be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third

parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Our patents may be subject to a reservation of rights by one or more third parties.

If any of our technologies are developed in the future with government funding, the government may obtain certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention or to have others use the invention on its behalf. If the US government then decides to exercise these rights, it is not required to engage us as its contractor in connection with doing so. These rights may also permit the government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The government may also exercise its march-in rights if it determines that action is necessary because we failed to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to US industry. In addition, our rights in such government-funded inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government of aforementioned proprietary rights could harm our competitive position, business, financial condition, results of operations, and prospects.

Changes to the patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Recent patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act (the Leahy-Smith Act) signed into law in September 2011, could increase those uncertainties and costs and it is not yet clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could make it more difficult to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the prosecution of our or our collaboration partners' patent applications and the enforcement or defense of our or our collaboration partners' issued patents, all of which could harm our business, results of operations, financial condition and prospects.

The US 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. Additionally, there have been recent proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to enforce our proprietary technology. Depending on future actions by the US Congress, the US courts, the USPTO and the relevant law-making bodies in other countries, 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 that we might obtain in the future. See section titled "*Business—Intellectual property*" for description of the intellectual property regulatory framework.

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

Competitors may infringe our patents, trademarks, copyrights, trade secrets or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents or their intellectual property, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from manufacturing and selling the

competing product at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover said product. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, 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.

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 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 shares of our Class A common stock. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Furthermore, third parties may also raise invalidity or unenforceability claims before administrative bodies in the United States or comparable foreign authorities, even outside the context of litigation. Such mechanisms include re-examination, inter partes review, post-grant review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation, cancellation or amendment to our patents in such a way that they no longer cover and protect our drug candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity of our patents, for example, we cannot be certain that there is no invalidating prior art of which we, our licensors, our patent counsel and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our drug candidates. Any such loss of patent protection could have a material adverse impact on our business, financial condition, results of operations and prospects.

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

Filing, prosecuting and defending patents with respect to our drug candidates in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. The requirements for patentability may differ in certain countries, particularly in developing countries. Consequently, competitors and other third parties may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents or where any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing with us.

Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, 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 rights in certain foreign jurisdictions. The legal systems of some countries, including India, China and other developing countries, do not favor the enforcement of patents and other intellectual property 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 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, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Furthermore, while we intend to protect our intellectual property rights in major markets for our products, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

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 products.

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 drug 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. For example, we may incorrectly determine that our products 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. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

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

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our drug candidates without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. If any third-party patents or patent applications are found to cover our drug candidates or their 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 drug candidates without obtaining a license, which may not be available on commercially reasonable terms, or at all.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our drug candidates. Third parties may assert infringement, misappropriation or other claims against us based on existing or future intellectual property rights. The outcome of intellectual property litigation and other disputes is subject to uncertainties that cannot be adequately quantified in advance. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of using or manufacturing products. 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 drug candidates, products or methods of use, manufacturing or other applicable activities either do not infringe the patent claims of the

asserted patent or that the patent claims are invalid or unenforceable, and we may not be successful in doing so. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity that applies to all 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. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm our business and operating results. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

If we are found to infringe, misappropriate or otherwise violate a third party's intellectual property rights and we are unsuccessful in demonstrating that such intellectual property rights are invalid or unenforceable, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing drug candidate or product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing drug candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our drug candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects.

We may be subject to claims by third parties asserting that our employees or consultants or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property, or we may need to bring similar claims against third parties.

Some of our employees and consultants are currently or have been previously employed at universities or at other biotechnology or pharmaceutical 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 be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of third parties. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights 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 products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management. Any of the foregoing would have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, while we typically require our employees, consultants and contractors who may be involved in the 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 develops intellectual property that we regard as our own. 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, related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. 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.

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

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

The term of our patents may be inadequate to protect our competitive position on our products.

Patent rights are of limited duration. In the United States, if all maintenance fees are paid timely, the natural expiration of a patent is generally 20 years after its first effective filing date. Upon issuance in the United States, the term of a patent can be increased by patent term adjustment, which is based on certain delays caused by the USPTO, but this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. The term of a United States patent may also be shortened if the patent is terminally disclaimed over an earlier-filed patent. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Depending upon the timing, duration and other factors relating to any FDA marketing approval we receive for any of our drug candidates, one or more of our US patents may be eligible for limited patent term extension (PTE) under the Drug Price Competition and Patent Term Restoration Action of 1984 (the Hatch-Waxman Amendments). We plan to seek PTE in the United States and, if available, in other countries where we are prosecuting patents. However, only a single patent can be extended for each marketing approval, and any patent can be extended only once, for a single product. Moreover, the scope of protection during the period of the PTE does not extend to the full scope of the claim, but instead only to the scope of the product as approved. Laws governing analogous PTEs in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Additionally, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process. If we are unable to obtain PTE or the term of any such extension is less than we request, our competitors and other third parties may be able to obtain approval of competing products following our patent expiration and take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. Any of the foregoing would have a material adverse effect on our business, financial condition, results of operations and prospects. For more information about obtaining extensions, see section titled "*Business—Intellectual property*".

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and patent offices in foreign countries in several stages over the lifetime of the patent. The USPTO and patent offices in foreign countries require compliance with a number of procedural, documentary, fee payment and other requirements during the patent application process. While an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of a patent or patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors and other third parties might be able to

enter the market with similar or identical products of technology, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our trade secrets and proprietary know-how, the value of our technology could be materially adversely affected and our business would be harmed.

While we have obtained composition of matter patents with respect to certain of our drug candidates, we also rely on proprietary know-how and trade secret protection and confidentiality agreements to protect proprietary know-how or trade secrets that are not patentable or that we elect not to patent. For example, we may not elect to not patent some composition matter from our proprietary library of selective FASN inhibitors and therefore rely on protecting the proprietary aspects of our platform as a trade secret. We seek to protect our trade secrets and proprietary know-how in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, consultants, independent contractors, advisors, contract manufacturers, suppliers, collaborators and other third parties. We also enter into confidentiality and invention or patent assignment agreements with employees and certain consultants. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary know-how. Additionally, our confidentiality agreements and other contractual protections may not be adequate to protect our intellectual property from unauthorized disclosure, third-party infringement or misappropriation. Any party with whom we have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. Courts outside the United States are sometimes less willing to protect proprietary information, technology and know-how. Further, we may need to share our trade secrets and confidential know-how with current or future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. In addition, 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 third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us. If any of our trade secrets, including with respect to our proprietary platform of selective FASN inhibitors, were to be disclosed to or independently developed by a competitor or other third party, our business, financial condition, results of operations and prospects our business and competitive position could be materially harmed.

If we fail to comply with our obligations under any license, collaboration or other agreement, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our drug candidates.

We rely, in part, on license, collaboration and other agreements. We may need to obtain additional licenses from others to advance our research or allow commercialization of our drug candidates and it is possible that we may be unable to obtain additional licenses at a reasonable cost or on reasonable terms, if at all. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment.

In addition, our present and future licenses, collaborations and other intellectual property related agreements, currently impose, and are likely to further impose development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement or other obligations on us. If we breach any of these obligations, or use any future intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and our licensors may have the right to terminate the license. If any future license or other intellectual property related agreements are terminated, we may be required to cease developing and commercializing drug candidates that are covered by the licensed

intellectual property. Disputes may arise regarding intellectual property subject to a licensing, collaboration or other agreement, including:

- the scope of rights granted under the agreement and other interpretation related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators; and
- the priority of invention of patented technology.

In addition, the agreements under which we license intellectual property or technology to third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering the technology that we have licensed or assigned to third parties. Therefore, we cannot be certain that these patents and applications will be prosecuted, maintained and enforced in a manner consistent with the best interests of our business. If our licensees or assignees fail to obtain or maintain such intellectual property, or lose rights to such intellectual property, our right to develop and commercialize any of our products that are subject to such licensed rights could be adversely affected.

If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or drug candidate and our business, financial condition, results of operations and prospects could suffer.

Intellectual property rights do not necessarily address all potential threats.

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

- others may be able to make products similar to any drug candidates we may develop or utilize similarly related technologies that are not covered by the claims of the patents that we license or may own in the future;
- we, or our license partners or current or future collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future;
- we, or our license partners or current or future collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating any of our owned or licensed intellectual property rights;
- it is possible that our pending licensed patent applications or those that we may own in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;

- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business;
- we may choose not to file a patent in order to maintain certain trade secrets or proprietary know-how, and a third party may subsequently file a patent covering such intellectual property; and
- our trade secrets or proprietary know-how may be unlawfully disclosed, thereby losing their trade secret or proprietary status.
- Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

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 or 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. Although 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 drug candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, 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.

Risks related to third parties

We have licensed rights to TVB-2640 to Ascletis, a significant stockholder with a board designee, for Greater China. Under the license agreement, Ascletis controls product development efforts in its territory, including conduct of clinical trials, which could have an impact on our clinical development programs.

Under our license agreement with Ascletis, Ascletis is responsible for the design and conduct of clinical trials for the licensed drug candidate, TVB-2640, which is referred to as ASC40 in the People's

Republic of China, Hong Kong, Macau and Taiwan (referred to collectively as Greater China). As a result, these clinical trials may not be conducted in the manner or on the timeline we desire or may not be designed in a manner that will demonstrate a statistically significant result, any of which may negatively impact our development efforts outside of Greater China. We do not have any right to control trial design or interactions with regulatory authorities in Greater China. In addition, if Ascletis elects not to continue development of ASC40 or abandons clinical trials, it could have a negative effect on our business and our drug candidate development efforts outside of Greater China. Our lack of control over aspects of drug candidate development in our agreement with Ascletis, or any other future license partner, could cause delays or other difficulties in the development and commercialization of our drug candidates, which could harm our business and prospects.

Independent clinical investigators and CROs, that we engage to conduct our clinical trials may not devote sufficient time or attention to our clinical trials.

We currently rely on, and intend to continue relying on third parties, including independent clinical investigators and third-party CROs, to conduct certain aspects of our preclinical studies and clinical trials for TVB-2640, TVB-3567 and any other future drug candidates. We control or will control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with applicable protocol, legal, regulatory, and scientific standards, and our reliance on our CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for drug candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these CROs fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing products. Upon inspection, such regulatory authorities may determine that our clinical trials do not comply with the GCP regulations. In addition, our clinical trials must be conducted with drug product produced under current good manufacturing practice (cGMP), regulations and will require a large number of test subjects. Our failure or any failure by our CROs to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of our CROs violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Our CROs are not our employees, and, except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical, clinical and nonclinical programs. These CROs 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, which could affect their performance on our behalf. If our CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed, or terminated and we may not be able to complete development of, obtain regulatory approval for or successfully commercialize TVB-2640, TVB-3567 or any other future drug candidates. As a result, our financial results and the commercial prospects for TVB-2640, TVB-3567 and any future drug candidates could be harmed, our costs could increase and our ability to generate revenues could be delayed.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. Switching or adding CROs involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Although we carefully manage our

relationships with our CROs, we may encounter challenges or delays in the future and these delays or challenges may have a material adverse impact on our business, prospects, financial condition, and results of operations.

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 CROs, which could disrupt our clinical timelines, which could have a material adverse impact on our business, prospects, financial condition, and results of operations.

We have relied on, and we expect to continue to rely on, third-party manufacturers to produce our drug candidates.

We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of our drug candidates, and we lack the resources and the capabilities to do so. As a result, we currently rely, and expect to rely for the foreseeable future, on third-party manufacturers to supply our drug candidates. Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured our drug candidates ourselves, including:

- the failure of the third party to manufacture our drug candidates according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over our drug candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the reduction or termination of production or deliveries by suppliers, or the raising of prices or renegotiation of terms;
- the breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements;
- the failure of the third party to manufacture our drug candidates according to our specifications;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or study drug or placebo not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or non-renewal of manufacturing agreements by third parties, at a time that is costly or inconvenient to us.

If we do not maintain our key manufacturing relationships, we may fail to find replacement manufacturers or develop our own manufacturing capabilities, which could delay or impair our ability to obtain regulatory approval for our products and substantially increases our costs or deplete profit margins, if any. If we do find replacement manufacturers, we may not be able to enter into agreements with them on terms and conditions favorable to us and there could be a substantial delay before new facilities could be qualified and registered with the FDA and other foreign regulatory authorities. To date, we have relied on a single manufacturer based in China to produce TVB-2640 drug substance and two manufacturers in the United States and China to produce TVB-2640 drug product. We believe we have sufficient supply to conduct our planned NASH Phase 2b and glioblastoma multiforme Phase 2 trials and will need to manufacture additional material to support other planned studies. However, under the terms of our license agreement with a subsidiary of Ascletis, further drug substance will need to be supplied by Ascletis or another manufacturer outside Greater China.

We do not currently have any long-term agreement with a manufacturer to produce raw materials, active pharmaceutical ingredients (APIs) and the finished products of TVB-2640 and we may rely on single

source suppliers for clinical supply of API and drug product of TVB-2640. Our reliance on third-party suppliers and manufacturers could harm our ability to develop TVB-2640 and any future drug candidates or to commercialize any drug candidates that are approved. Further, any delay in identifying and qualifying a manufacturer for commercial production could delay the potential commercialization of TVB-2640 and any future drug candidates, and, in the event that we do not have sufficient product to complete our clinical trials, it could delay such trials.

The FDA and other foreign regulatory authorities require manufacturers to register manufacturing facilities. The FDA and corresponding foreign regulators also inspect these facilities to confirm compliance with cGMPs. Contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP requirements. Any failure to comply with cGMP requirements or other FDA, European Medicines Agency (EMA) and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our drug candidates and market our products following approval, if obtained.

We currently do not control the manufacturing process of TVB-2640 and are completely dependent on our contract manufacturing partners for compliance with the FDA's cGMP requirements for manufacture of both the active drug substances and finished drug product. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the FDA's strict regulatory requirements, they will not be able to secure or maintain FDA approval for the 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 any other applicable regulatory authority does not approve these facilities for the manufacture of TVB-2640, TVB-3567 or any future drug candidates, or if it withdraws any such approval in the future, or if our suppliers or contract manufacturers decide they no longer want to supply or manufacture for us, we may need to find alternative manufacturing facilities, in which case we might not be able to identify manufacturers for clinical or commercial supply on acceptable terms, or at all, which would significantly impact our ability to develop, obtain regulatory approval for, or market TVB-2640, TVB-3567 and any future drug candidates.

In addition, the manufacture of pharmaceutical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up and validating initial production and absence of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state, and foreign regulations. Furthermore, if contaminants are discovered in our supply of TVB-2640, TVB-3567 or any future drug candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Any stability or other issues relating to the manufacture of TVB-2640, TVB-3567 or any future drug candidates may occur in the future. 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 the COVID-19 pandemic or other infectious diseases could impact personnel at our third-party manufacturing facilities upon which we rely, or the availability or cost of materials, which could disrupt the supply chain for our drug candidates. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide our drug candidate to patients in clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely.

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

Disputes under key agreements or conflicts of interest with our scientific advisors or clinical investigators could delay or prevent development or commercialization of our drug candidates.

Any agreements we have or may enter into with third parties, such as collaboration, license, formulation supplier, manufacturing, clinical research organization or clinical trial agreements, including our license agreement with Ascletis, may give rise to disputes regarding the rights and obligations of the parties. Disagreements could develop over contract interpretation, rights to ownership or use of intellectual property, the scope and direction of research and development, the approach for regulatory approvals or commercialization strategy. Any disputes or commercial conflicts could lead to the termination of agreements, delay progress of our product development programs, compromise our ability to renew agreements or obtain future agreements, lead to the loss of intellectual property rights, result in increased financial obligations for us or result in costly litigation.

Risks related to our industry and the regulatory environment in which we operate

If clinical trials of a drug candidate fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of such drug candidate.

Before obtaining regulatory approvals for the commercial sale of a drug candidate, we or our partners must demonstrate through lengthy, complex, and expensive preclinical studies and clinical trials that a drug candidate is both safe and effective for use in each target indication. Clinical trials often fail to demonstrate safety and efficacy of the drug candidate studied for the target indication. Most drug candidates that commence clinical trials are never approved by regulatory authorities for commercialization.

Preclinical studies and clinical trials are expensive, will take several years to complete and may not yield results that support further clinical development or product approvals. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical studies and early clinical trials may not predict the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety profiles, notwithstanding promising results in earlier trials.

Notwithstanding data in early preclinical studies, clinical trials in humans may show that a drug candidate is not safe and effective, in which event we may need to abandon development of such drug candidate. It is impossible to predict when a drug candidate will prove effective or safe in humans or will receive regulatory approval. Owing in part to the complexity of biological pathways, these compounds might not demonstrate in patients the biochemical and pharmacological properties we anticipate based on laboratory studies or earlier-stage clinical trials, and they may interact with human biological systems or other drugs in unforeseen, ineffective or harmful ways.

If we are unable to successfully discover, develop or enable our partners to develop drugs that are effective and safe in humans, we will not have a viable business.

A drug candidate may not achieve adequate market acceptance among physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Even if a drug candidate receives regulatory approval, it may not gain adequate market acceptance among physicians, patients, third-party payors, pharmaceutical companies and others in the medical community. Demonstrating the safety and efficacy of a drug candidate and obtaining regulatory approvals will not guarantee future revenue. Our commercial success also depends on obtaining and maintaining coverage and adequate reimbursement of a drug candidate by third-party payors, including government payors, which may be difficult or time-consuming to obtain, may be limited in scope and may not be obtained in all jurisdictions in which we may seek to market our products. Governments and private third-party payors closely examine medical products to determine whether they should be covered and reimbursed and, if so, the level of reimbursement that will apply. In the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. We cannot be certain that third-party payors

will sufficiently reimburse sales of a product or enable us to sell a product at profitable prices. Similar concerns could also limit the reimbursement amounts that health insurers or government agencies in other countries are prepared to pay for our products. In many regions, including Europe, Japan and Canada, where we may market a product, either directly or with a collaborator, the pricing of prescription drugs is controlled by the government or regulatory agencies. Regulatory agencies in these countries could determine that the pricing for a product should be based on prices of other commercially available drugs for the same disease, rather than allowing us to market a drug at a premium as new drugs.

Sales of medical products also depend on the willingness of physicians to prescribe the treatment, which is likely to be based on a determination by these physicians that the products are safe, therapeutically effective and cost effective. In addition, the inclusion or exclusion of products from treatment guidelines established by various physician groups and the viewpoints of influential physicians can affect the willingness of other physicians to prescribe the treatment. We cannot predict whether physicians, physicians' organizations, hospitals, other healthcare providers, government agencies or private third-party payors will determine that our products are safe, therapeutically effective and cost effective as compared with competing treatments. If any drug candidate is approved but does not achieve an adequate level of acceptance by such parties, we may not generate or derive sufficient revenue from that drug candidate and may not become or remain profitable.

Even if we commercialize any drug candidate, alone or with our partners, such product may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which could harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay or limit our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenue we generate from the sale of the product in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more drug candidates, even if our drug candidates obtain marketing approval.

Our ability to commercialize any products successfully will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations.

Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage and reimbursement will be available for any product that we or our partners commercialize or, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any drug candidate for which we or our partners obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we and our partners may not be able to successfully commercialize any drug candidate for which marketing approval is obtained.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary

according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or third-party payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Changing regulatory environments could negatively impact our business.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our drug candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from drug candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop drug candidates.

Product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of drug candidates in human clinical trials and will face an even greater risk if we or any future collaborator commercializes any resulting products. Product liability claims may be brought against us by subjects enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against claims that our drug candidates or products that we may develop caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any drug candidates or products that we may develop;
- termination of clinical trial sites or entire trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial subjects or patients;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize any products that we may develop.

Our clinical trial liability insurance coverage may not adequately cover all liabilities that we may incur. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Our inability to obtain product liability insurance at an acceptable cost or to otherwise protect against potential product liability claims could prevent or delay the commercialization of any products or drug candidates that we develop. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain marketing approval for our drug candidates in development, or any future drug candidates, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. Large judgments have been awarded in

class action lawsuits based on drugs that had unanticipated side effects. If we are sued for any injury caused by our products, drug candidates or processes, our liability could exceed our product liability insurance coverage and our total assets. Claims against us, regardless of their merit or potential outcome, may also generate negative publicity or hurt our ability to obtain physician endorsement of our products or expand our business.

Our relationships with customers, healthcare providers, and third-party payors may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, transparency laws, and other healthcare laws and regulations. If we or our employees, independent contractors, consultants, commercial partners, or vendors violate these laws, we could face substantial penalties.

Our relationships with customers, healthcare providers, and third-party payors may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, transparency laws with respect to drug pricing and payments and other transfers of value made to physicians and other healthcare providers, and other healthcare laws and regulations. These laws may impact, among other things, our clinical research program, as well as our proposed and future sales, marketing, and education programs. In particular, the promotion, sales and marketing of healthcare items and services is subject to extensive laws and regulations designed to prevent fraud, 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, and other business arrangements. In addition, we may be subject to federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

We may also be subject to state and foreign equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope. For example, we may be subject to the following: state anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental, third-party payors, including private insurers, or that apply regardless of payor; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures, or drug pricing; and state and local laws requiring the registration of pharmaceutical sales and medical representatives.

See section titled "Business—Government Regulation and Product Approval" for a description of the US healthcare laws and regulations that may affect our ability to operate.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities, or our arrangements with physicians, some of whom have been granted stock options, could be subject to challenge under one or more of such laws. It is not always possible to identify and deter employee misconduct or business noncompliance, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If we or our employees, independent contractors, consultants, commercial partners and vendors violate these laws, we may be subject to investigations, enforcement actions and/or significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, disgorgement, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of TVB-2640, TVB-3567 or any of our future drug candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Our internal computer systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security and back-up measures, our internal computer, server, and other information technology systems as well as those of our third-party collaborators, consultants, contractors, suppliers, and service providers, may be vulnerable to damage from physical or electronic break-ins, computer viruses, malware, ransomware, natural disasters, terrorism, war, telecommunication and electrical failure, denial of service, and other cyberattacks or disruptive incidents that could result in unauthorized access to, use or disclosure of, corruption of, or loss of sensitive, and/or proprietary data, including personal information, including health-related information, and could subject us to significant liabilities and regulatory and enforcement actions, and reputational damage. For example, the loss of clinical trial data from completed or ongoing clinical trials could result in delays in any regulatory approval or clearance efforts and significantly increase our costs to recover or reproduce the data, and subsequently commercialize the product. Additionally, theft of our intellectual property or proprietary business information could require substantial expenditures to remedy. Such theft could also lead to loss of intellectual property rights through disclosure of our proprietary business information, and such loss may not be capable of remedying. If we or our third-party collaborators, consultants, contractors, suppliers, or service providers were to suffer an attack or breach, for example, that resulted in the unauthorized access to or use or disclosure of personal or health information, we may have to notify consumers, partners, collaborators, government authorities, and the media, and may be subject to investigations, civil penalties, administrative and enforcement actions, and litigation, any of which could harm our business and reputation. Likewise, we rely on third parties to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. The COVID-19 pandemic has generally increased the risk of cybersecurity intrusions. Our reliance on internet technology and the number of our employees who are working remotely may create additional opportunities for cybercriminals to exploit vulnerabilities. For example, there has been an increase in phishing and spam emails as well as social engineering attempts from “hackers” hoping to use the recent COVID-19 pandemic to their advantage. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate or unauthorized access to or disclosure or use of confidential, proprietary, or other sensitive, personal, or health information, we could incur liability and suffer reputational harm, and the development and commercialization of TVB-2640, TVB-3567, or future drug candidates could be delayed.

Failure to comply with data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.

We and our partners may be subject to federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). 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. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Depending on the facts and circumstances, we could be subject to penalties if we violate HIPAA.

Even when HIPAA does not apply, according to the Federal Trade Commission, or the FTC, failing to take appropriate steps to keep consumers’ personal information secure may constitute unfair acts or practices in or affecting commerce in violation of the Federal Trade Commission 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 laws govern the privacy and security of health-related and other personal information in certain circumstances, some of which may be more stringent, broader in scope or offer greater individual rights with respect to protected health information than HIPAA, many of which may differ from each other, 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 the California Consumer Privacy Act (CCPA) which creates new individual privacy rights for California consumers (as defined in the law), including the right to opt out of certain disclosures of their information, and places increased privacy and security obligations on entities handling certain personal data of consumers or households. 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. As currently written, the CCPA may impact our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information. Further, the California Privacy Rights Act (CPRA) recently passed in California. The CPRA will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required.

Foreign data protection laws, including the General Data Protection Regulation, or GDPR, which went into effect in May 2018, may also apply to our processing of health-related and other personal data regardless of where the processing in question is carried out.

The GDPR imposes stringent requirements for controllers and processors of personal data of individuals within the European Economic Area, or EEA. The GDPR applies to any company established in the EEA as well as to those outside the EEA if they collect and use personal data in connection with the offering of goods or services to individuals in the EEA or the monitoring of their behavior. The GDPR, together with national legislation, regulations and guidelines of the EEA Member States and the United Kingdom (or UK) governing the processing of personal data, impose strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. In particular, these obligations and restrictions concern the consent of the individuals to whom the personal data relates, the information provided to the individuals, the transfer of personal data out of the EEA or the UK, security breach notifications, security and confidentiality of the personal data and imposition of substantial potential fines for breaches of the data protection obligations. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Further, from January 1, 2021, companies have to comply with the GDPR and also the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, e.g. fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. The relationship between the UK and the European Union in relation to certain aspects of data protection law remains unclear, and it is unclear how UK data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the UK will be regulated in the long term. These changes will lead to additional costs and increase our overall risk exposure. Currently there is a four to six-month grace period agreed in the EU and UK Trade and Cooperation Agreement, ending June 30, 2021 at the latest, whilst the parties discuss an adequacy decision. The European Commission published a draft adequacy decision on February 19, 2021. If adopted, the decision will enable data transfers from EU Member States to the UK for a four-year period, subject to subsequent extensions.

Implementing mechanisms to endeavor to ensure compliance with the GDPR and relevant local legislation in EEA Member States and the UK may be onerous and may interrupt or delay our development activities, and adversely affect our business, financial condition, results of operations, and prospects. In addition to the foregoing, a breach of the GDPR or other applicable privacy and data protection laws and regulations could result in regulatory investigations, reputational damage, and orders to cease/change our use of data, enforcement notices, or potential civil claims including class action-type litigation. While we have taken steps to comply with the GDPR where applicable, including by reviewing our security procedures,

engaging data protection personnel, and entering into data processing agreements with relevant contractors, our efforts to achieve and remain in compliance may not be fully successful.

Compliance with US and foreign privacy and security laws, rules and regulations could require us to take on more onerous obligations in our contracts, require us to engage in costly compliance exercises, restrict our ability to collect, use and disclose data, or in some cases, impact our or our partners' or suppliers' ability to operate in certain jurisdictions. Each of these constantly evolving laws can be subject to varying interpretations. Failure to comply with US and foreign data protection laws and regulations could result in government investigations and enforcement actions (which could include civil or criminal penalties), fines, private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, patients about whom we or our partners obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection 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.

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

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. Our ability to use our federal and state net operating losses, or NOLs, and other tax attributes to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our NOLs, or other tax attributes. Unused NOLs for taxable years beginning before January 1, 2018, may be carried forward to offset future taxable income, if any, until such unused NOLs expire. Under the Tax Act, as modified by the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, US federal NOLs incurred in taxable years beginning after December 31, 2017, can be carried forward indefinitely, but the ability to use such US federal NOLs to offset taxable income in taxable years beginning after December 31, 2020, is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to the Tax Act or the CARES Act.

As of December 31, 2020, we had US federal NOL carryforwards of approximately $108.2 million which may be available to offset future US federal income. Our US federal NOLs incurred prior to January 1, 2018 of approximately $91.0 million expire beginning in 2026 while federal NOLs incurred after December 31, 2017 of approximately $17.2 million will have an indefinite carryforward period, subject to annual limitations. As of December 31, 2020, we also had state NOL carryforwards of approximately $26.6 million which may be available to offset future state income and expire at various years beginning with 2028. Our NOL carryforwards and R&D credits are subject to review and possible adjustment by the US and state tax authorities.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50 percentage point change (by value) in its equity ownership over a rolling three-year period, the corporation's ability to use its pre-change NOL carryforwards, R&D credits and certain other tax attributes to offset its post-change income or taxes may be limited. This could limit the amount of NOLs, R&D credit carryforwards or other applicable tax attributes that we can utilize annually to offset future taxable income or tax liabilities. Subsequent ownership changes and changes to the US tax rules in respect of the utilization of NOLs, R&D credits and other applicable tax attributes carried forward may further affect the limitation in future years. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, California recently imposed limits on the usability of California state NOL carryforwards to offset taxable income in tax years beginning after 2019 and before 2023. As a result, we may be unable to use all or a material portion of our NOL carryforwards and other tax attributes, which could adversely affect our future cash flows.

The requirements of being a public company may strain our resources, result in more litigation and divert management's attention.

As a public company, we will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes-Oxley Act of 2002 (the Sarbanes-Oxley Act) the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Global Market and other applicable securities rules and regulations. Complying with these rules and regulations has increased and will increase our legal and financial compliance costs, make some activities more difficult, time consuming or costly and increase demand on our systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are required to disclose changes made in our internal control and procedures on a quarterly basis. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could significantly harm our business, financial condition, results of operations and prospects. We have a very small team with only five full-time employees. We may need to hire additional financial reporting, internal controls and other finance personnel or consultants in order to develop and implement appropriate internal controls and reporting procedures, which will increase our costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business, financial condition, results of operations and prospects may be significantly harmed.

These rules and regulations may make it more expensive for us to obtain director and officer liability insurance and, in the future, we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

By disclosing information in this prospectus and in future filings required of a public company, our business and financial condition will become more visible, which we believe may result in threatened or actual litigation, including by competitors and other third parties. If those claims are successful, our business could be seriously harmed. Even if the claims do not result in litigation or are resolved in our favor, the time and resources needed to resolve them could divert our management's resources and seriously harm our business, financial condition, results of operations and prospects.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

At the time the registration statement of which this prospectus forms a part is declared effective, we will be subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, and the rules and regulations of Nasdaq. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal controls over financial reporting. Commencing with our fiscal year ending December 31, 2022, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Form 10-K filing for that year, as required by Section 404 of the

Sarbanes-Oxley Act. This will require that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. Prior to this offering, we have never been required to test our internal controls within a specified period, and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner.

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

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

Public company compliance may make it more difficult to attract and retain officers and directors.

The Sarbanes-Oxley Act and new rules subsequently implemented by the SEC have required changes in corporate governance practices of public companies. As a public company, we expect these new rules and regulations to increase our compliance costs in 2021 and beyond and to make certain activities more time consuming and costly. As a public company, we also expect that these new rules and regulations may make it more difficult and expensive for us to obtain director and officer liability insurance in the future and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our board of directors or as executive officers.

Risks related to our class A common stock

Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expense related to the ongoing development of our drug candidates or future development programs;
- results of clinical trials, or the addition or termination of clinical trials or funding support by us or potential future partners;
- our execution of any collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under potential future arrangements or the termination or modification of any such potential future arrangements;
- any intellectual property infringement, misappropriation or violation lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- if any of our drug candidates receives regulatory approval, the terms of such approval and market acceptance and demand for such drug candidates;
- regulatory developments affecting our drug candidates or those of our competitors; and
- changes in general market and economic conditions.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our Class A common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Our stock price may be volatile and purchasers of our Class A common stock could incur substantial losses.

Our stock price is likely to be volatile. As a result of this volatility, investors may not be able to sell their Class A common stock at or above the initial public offering price. The market price for our Class A common stock may be influenced by many factors, including the other risks described in this section of the prospectus titled "Risk Factors" and the following:

- our ability to advance TVB-2640, TVB-3567 or potential future drug candidates;
- results of preclinical studies and clinical trials of TVB-2640, TVB-3567 or potential future drug candidates, or those of our competitors or potential future partners;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our drug candidates;
- the success of competitive products;
- introductions and announcements of new products by us, our future commercialization partners, or our competitors, and the timing of these introductions or announcements;
- actions taken by regulatory agencies with respect to our drug candidates, potential products, clinical trials, manufacturing process or sales and marketing terms;
- actual or anticipated variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional technologies, products or drug candidates;
- developments concerning any future collaborations, including, but not limited to, those with our sources of manufacturing supply and our commercialization partners;
- market conditions in the pharmaceutical sector;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products;
- our ability or inability to raise additional capital and the terms on which we raise it;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- actual or anticipated changes in earnings estimates or changes in securities analyst recommendations regarding our Class A common stock, other comparable companies or our industry generally;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- announcement and expectation of additional financing efforts;
- speculation in the press or investment community;
- trading volume of our Class A common stock;

- sales of our Class A common stock by us or our stockholders;
- the concentrated ownership of our Class A common stock;
- changes in accounting principles;
- terrorist acts, acts of war or periods of widespread civil unrest;
- natural disasters and other calamities; and
- general economic, industry and market conditions.

In addition, the stock markets in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme volatility that has been often unrelated to the operating performance of the issuer. These broad market and industry factors may seriously harm the market price of our Class A common stock, regardless of our operating performance.

You will experience immediate and substantial dilution as a result of this offering and may experience additional dilution in the future.

If you purchase our Class A common stock in this offering at the initial public offering price of $ per share, you will incur immediate and substantial dilution of $ per share, representing the difference between the initial public offering price of $ per share and our pro forma as adjusted net tangible book value per share as of after giving effect to this offering, and to (i) the conversion of all of our outstanding shares of redeemable convertible preferred stock into an aggregate of 1,322,399,477 shares of our Class A common stock immediately upon the closing of this offering, and (ii) the issuance of shares of our Class A common stock as a result of the expected net exercise of an outstanding warrant to purchase 79,545 shares of our Series D redeemable convertible preferred stock, conversion to Class A common stock and the related reclassification of the redeemable convertible warrant liability to Class A common stock and additional paid-in capital. After this offering, we will also have outstanding options to purchase our Class A common stock with exercise prices lower than the assumed initial public offering price. To the extent that any of these outstanding securities are ultimately exercised or we issue equity derivatives in the future, you will incur further dilution.

We expect that significant additional capital may be needed in the future to continue our planned operations, including further development of our drug candidates, conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating a public company. To raise capital, we may sell Class A common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell Class A common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our Class A common stock, including shares of Class A common stock sold in this offering.

The dual class structure of our common stock may limit your ability to influence corporate matters and may limit your visibility with respect to certain transactions.

The dual class structure of our common stock may limit your ability to influence corporate matters. Holders of our Class A common stock are entitled to one vote per share, while holders of our Class B common stock are not entitled to any votes. Nonetheless, each share of our Class B common stock may be converted at any time into one share of our Class A common stock at the option of its holder by providing written notice to us, subject to the limitations provided for in our amended and restated certificate of incorporation to become effective upon the closing of this offering. Consequently, if holders of our Class B common stock following this offering exercise their option to make this conversion, this will have the effect of increasing the relative voting power of those prior holders of our Class B common stock, and correspondingly decreasing the voting power of the holders of our Class A common stock, which may limit your ability to influence corporate matters. Additionally, stockholders who hold, in the aggregate, more than 10% of our Class A common stock and Class B common stock, but 10% or less of our Class A common stock, and are not otherwise an insider, may not be required to report changes in their ownership due to

transactions in our Class B common stock pursuant to Section 16(a) of the Exchange Act, and may not be subject to the short-swing profit provisions of Section 16(b) of the Exchange Act.

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Global Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors. However, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

The future issuance of equity or of debt securities that are convertible into equity would dilute our share capital.

We may choose to raise additional capital in the future, depending on market conditions, strategic considerations and operational requirements. To the extent that additional capital is raised through the issuance of shares or other securities convertible into shares, our stockholders will be diluted. Future issuances of our Class A common stock or other equity securities, or the perception that such sales may occur, could adversely affect the trading price of our Class A common stock and impair our ability to raise capital through future offerings of shares or equity securities. No prediction can be made as to the effect, if any, that future sales of Class A common stock or other equity securities or the availability of Class A common stock for future sales will have on the trading price of our Class A common stock.

Pursuant to our 2021 Plan, our management is authorized to grant stock options to our employees, directors and consultants. Initially, the aggregate number of shares of our Class A common stock that may be issued pursuant to stock awards under our 2021 Plan is shares. Additionally, the number of shares of our Class A common stock reserved for issuance under our 2021 Plan will automatically increase on January 1st of each year, beginning on January 1, 2022 and continuing through and including January 1, 2030, by % of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

An active trading market for our Class A common stock may not develop.

Prior to this offering, there has been no public market for our Class A common stock. The initial public offering price for our Class A common stock was determined through negotiations with the underwriters. Although our Class A common stock will trade on The Nasdaq Global Market, an active trading market for our shares may never develop or be sustained following this offering. If an active market for our Class A common stock does not develop or is not sustained, it may be difficult for you to sell shares you purchase in this offering without depressing the market price for the shares or at all.

Because our management will have flexibility in allocating the net proceeds from this offering, you may not agree with how we use them and the proceeds may not be invested successfully.

We intend to use the net proceeds to us from this offering to continue developing novel therapeutics for the treatment of a range of diseases, including NASH and certain cancers, further development of

TVB-2640 and TVB-3567, pay costs of operating as a public company and fund other general purposes, including working capital, operating expenses and capital expenditures. We may also use a portion of the net proceeds from this offering to in-license, acquire or invest in complementary businesses, technologies, products or assets. However, we have no current commitments or obligations to do so. Therefore, our management will have flexibility in allocating the net proceeds from this offering. Accordingly, you will be relying on the judgment of our management with regard to the allocation of these net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being allocated appropriately. It is possible that the proceeds will be invested in a way that does not yield a favorable, or any, return for our company.

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

Based on the beneficial ownership of our capital stock as of , 2021, prior to this offering, our executive officers and directors, together with holders of 5% or more of our capital stock before this offering and their respective affiliates, beneficially owned approximately % of our Class A common stock and Class B common stock. Following this offering, our executive officers and directors, together with holders of 5% or more of our capital stock and their respective affiliates, will beneficially own approximately % of our Class A common stock and Class B common stock, assuming no exercise of the underwriters' option to purchase additional shares and assuming no exercise of outstanding options. As a result, these stockholders, if acting together, will continue to have significant influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets and any other significant corporate transaction. In addition, pursuant to a nominating agreement between us and Baker Brothers Life Sciences L.P. and 667, L.P., or together, Baker Brothers, following the closing of this offering and so long as Baker Brothers together with its affiliates beneficially owns at least shares of our Class A common stock and Class B common stock, we will have the obligation to support the nomination of, and to cause our board of directors to include in the slate of nominees recommended to our stockholders for election, two individuals designated by Baker Brothers (each a Baker Designee) subject to customary conditions and exceptions, as well as the obligation to invite two board of directors observer designees of Baker Brothers to attend all meetings of our board of directors and all meetings of the committees of our board of directors as a nonvoting observer, if there is no Baker Designee on our board of directors, subject to customary conditions and exceptions. For more information regarding this agreement, see the section titled "Certain Relationships and Related Person Transactions—Baker Brothers nominating agreement". Baker Brothers and its affiliates may therefore have influence over management and control over matters requiring stockholder approval, including the annual election of directors and significant corporate transactions, such as a merger or other sale of our company or its assets, following the closing of this offering and for the foreseeable future.

The interests of these stockholders may not be the same as, and may even conflict with, your interests. For example, these stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their Class A common stock as part of a sale of our company or our assets and might affect the prevailing market price of our Class A common stock. The significant concentration of stock ownership may adversely affect the trading price of our Class A common stock due to investors' perception that conflicts of interest may exist or arise.

Sales of a substantial number of shares of our Class A common stock or Class B common stock by our existing stockholders 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 Class A common stock or Class B common stock in the public market after the lock-up and other legal restrictions on resale discussed in this prospectus lapse, the trading price of our Class A common stock could decline. Based on shares of Class A common stock and Class B common stock outstanding at , and after giving effect to the conversion of our outstanding redeemable convertible preferred stock, immediately upon the closing of this offering we will have outstanding a total of shares of Class A common stock and Class B common stock, including 79,545 shares that will be issued upon the exercise of a warrant for our Series D redeemable convertible preferred stock and 8,361,424 shares of Class A common

stock that will be issued upon the exercise of Class A common stock warrants, but excluding the shares of our Class B common stock that may be converted into an aggregate of shares of our Class A common stock. Of these shares, only the shares of Class A common stock sold in this offering by us, plus any shares sold upon exercise of the underwriters' option to purchase additional shares, will be freely tradable without restriction in the public market immediately following this offering.

We expect that the lock-up agreements pertaining to this offering will expire after 180 days from the date of this prospectus. BofA Securities, Inc., Cowen and Company, LLC and Piper Sandler & Co., however, may, 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, shares of Class A common stock that are either subject to outstanding options under our 2007 Plan and 2017 Plan or reserved for future issuance under our 2017 Plan and 2021 Plan, will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act of 1933, as amended (the Securities Act). If these additional shares of Class A common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our Class A common stock could decline.

After this offering, the holders of shares of our Class A common stock (including Class A common stock issuable upon conversion of Class B common stock) at will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the 180-day lock-up agreements described above. See section titled "Description of Capital Stock—Registration rights". Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our Class A common stock.

We are an "emerging growth company" and our election of reduced reporting requirements applicable to emerging growth companies may make our Class A common stock less attractive to investors.

We are an "emerging growth company" as defined in the Tax Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, or Section 404, reduced disclosure obligations regarding executive compensation in this prospectus and 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, we are only required to provide two years of audited financial statements and two years of selected financial data in this prospectus. We could be an emerging growth company for up to five years following the completion of this offering, although circumstances could cause us to lose that status earlier, including if we are deemed to be a "large accelerated filer," which occurs when the market value of our Class A common stock and Class B common stock that is held by non-affiliates exceeds $700 million as of the prior June 30, or if we have total annual gross revenue of $1.07 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31, or if we issue more than $1.0 billion in non-convertible debt during any three-year period before that time, in which case we would no longer be an emerging growth company immediately. Even after we no longer qualify as an emerging growth company, we could still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 and reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements. We cannot predict if investors will find our Class A common stock less attractive because we may rely on these exemptions. If some investors find our Class A common stock less attractive as a result, there may be a less active trading market for our Class A common stock and our share price may be more volatile.

Under the Tax Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves to the same. As a result, we will not be subject to the same new or revised accounting standards as other public

companies that comply with the public company effective dates, including but not limited to the new lease accounting standard. We have also elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. As a result of these elections, the information that we provide to our stockholders may be different than you might receive from other public reporting companies. However, if we later decide to opt out of the extended period for adopting new accounting standards, we would need to disclose such decision and it would be irrevocable.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. As a result, capital appreciation, if any, of our Class A common stock will be your sole source of gain for the foreseeable future.

We may incur significant costs from class action litigation due to our expected stock volatility.

Our stock price may fluctuate for many reasons, including as a result of public announcements regarding the progress of our development efforts for our discovery platform and our drug candidates, the development efforts of future partners or competitors, the addition or departure of our key personnel, variations in our quarterly operating results and changes in market valuations of biopharmaceutical and biotechnology companies. This risk is especially relevant to us because biopharmaceutical and biotechnology companies have experienced significant stock price volatility in recent years. When the market price of a stock has been volatile as our stock price may be, holders of that stock have occasionally brought securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit of this type against us, even if the lawsuit is without merit, we could incur substantial costs defending the lawsuit. The lawsuit could also divert the time and attention of our management.

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

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws may delay or prevent an acquisition of our company or a change in our management. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. These provisions include:

- a prohibition on actions by our stockholders by written consent;
- a requirement that special meetings of stockholders, which our company is not obligated to call more than once per calendar year, be called only by the chairman of our board of directors, our chief executive officer, or our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors;
- advance notice requirements for election to our board of directors and for proposing matters that can be acted upon at stockholder meetings;
- division of our board of directors into three classes, serving staggered terms of three years each; and
- the authority of the board of directors to issue preferred stock with such terms as the board of directors may determine.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, as amended, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years

after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. These provisions would apply even if the proposed merger or acquisition could be considered beneficial by some stockholders.

Our amended and restated certificate of incorporation that will be in effect at the closing of this offering will provide that the Court of Chancery of the State of Delaware and, to the extent enforceable, the federal district courts of the United States of America will be the exclusive forums for substantially all 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 that will be in effect at the closing of this offering will provide that 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 claim or cause of action brought on our behalf;
- any claim or cause of action for a breach of fiduciary duty owed by any of our current or former directors, officers, or other employees to us or our stockholders;
- any claim or cause of action against us or any of our current or former directors, officers or other employees arising out of or pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation, or our bylaws (as each may be amended from time to time);
- any claim or cause of action seeking to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws (as each may be amended from time to time, including any right, obligation, or remedy thereunder);
- any claim or cause of action as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; and
- any claim or cause of action against us or any of our current or former directors, officers, or other employees governed by the internal-affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the US federal courts have exclusive jurisdiction.

In addition, our amended and restated certificate of incorporation to be effective immediately prior to the closing of this offering will provide that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause or causes of action arising under the Securities Act, including all causes of action asserted against any defendant to such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering.

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. We note that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Additionally, our amended and restated certificate of incorporation to be effective immediately prior to the closing of this offering will provide that any person or entity holding, owning or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions.

General Risk Factors

Our operations are vulnerable to interruption by earthquake, fire, power loss, telecommunications failure, terrorist activity and other events beyond our control, which could harm our business.

Our facility is located in a seismically active region. We have not undertaken a systematic analysis of the potential consequences to our business and financial results from a major earthquake, fire, power loss, terrorist activity or other disasters and do not have a complete recovery plan for such disasters. In addition, we do not carry sufficient insurance to compensate us for actual losses from interruption of our business that may occur, and any losses or damages incurred by us could harm our business.

If securities or industry analysts do not publish research or reports about our company, 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 Class A common stock will be influenced by the research and reports that securities or industry analysts publish about us or our business. We do not currently have and may never obtain research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of our company, the trading price for our Class A common stock would be negatively impacted. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property rights or our Class A common stock performance, or if our target studies and operating results fail to meet the expectations of the analysts, our stock price would likely decline. If one or more of these analysts cease coverage of our company 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.

We have incurred significant operating losses since our inception and we expect to incur significant operating losses for the foreseeable future. We may never become profitable or, if profitability is achieved, be able to sustain profitability.

We have incurred significant operating losses since our inception and we expect to incur significant operating losses for the foreseeable future as we continue our clinical trials and development programs for TVB-2640, TVB-3567 and other future drug candidates. As of March 31, 2021, we had an accumulated deficit of $172.5 million, and we had cash and cash equivalents of $74.9 million. In the future, we intend to continue to conduct research and development, clinical testing, regulatory compliance and, if TVB-2640, TVB-3567 or other future drug candidates are approved, sales and marketing activities that, together with anticipated general and administrative expenses, will likely result in the incurrence of further significant operating losses for the foreseeable future.

As an organization, we have not yet demonstrated an ability to successfully complete clinical development, obtain regulatory approvals, manufacture a commercial-scale product, or conduct sales and marketing activities necessary for successful commercialization. We have no products approved for commercial sale and have not generated any revenue to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred significant net losses since our inception. We may never be able to commercialize TVB-2640, TVB-3567 or other future drug candidates.

We may not be profitable even if we or any of our future development partners succeed in commercializing any of our drug candidates. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our clinical development of, and seek regulatory approvals for, TVB-2640, TVB-3567 and any future drug candidates. We may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. Our prior net losses and expected future net losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. Because of the numerous risks and uncertainties associated with drug development, we are unable to accurately predict the timing or amount of increased expenses, or when, if at all, we will be able to achieve profitability.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position, business strategy, drug candidates, planned preclinical studies and clinical trials, results of preclinical studies, clinical trials, research and development costs, regulatory approvals, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that are in some cases beyond our control and may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "would," "expect," "plan," "anticipate," "could," "intend," "target," "project," "believe," "estimate," "predict," "potential," or "continue" or the negative of these terms or other similar expressions. Forward-looking statements contained in this prospectus include, but are not limited to, statements about:

- our financial performance;
- our ability to obtain additional cash and the sufficiency of our existing cash to fund our future operating expenses and capital expenditure requirements;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements, and needs for additional financing;
- the scope, progress, results and costs of developing TVB-2640, TVB-3567 or any other drug candidates we may develop, and conducting preclinical studies and clinical trials, including our TVB-2640 Phase 2 clinical trial;
- the timing and costs involved in obtaining and maintaining regulatory approval of TVB-2640 or any other drug candidates we may develop, and the timing or likelihood of regulatory filings and approvals, including our expectation to seek special designations for our drug candidates for various diseases;
- our plans relating to commercializing TVB-2640, TVB-3567 and any other drug candidates we may develop, if approved, including the geographic areas of focus and our ability to grow a sales team;
- the impact of the COVID-19 pandemic on our business and operations, including enrollment in our clinical trials, manufacturing suppliers, collaborators, use of CROs and employees;
- the rate and degree of market acceptance of TVB-2640, TVB-3567 and any other future drug candidate, as well as the reimbursement coverage for such drug candidates;
- current and future agreements with third parties in connection with the commercialization of TVB-2640, TVB-3567 or any other future approved candidate;
- the beneficial characteristics, safety, efficacy and therapeutic effects of TVB-2640, TVB-3567 and any other drug candidates we may develop;
- our estimates of the number of patients in the United States who suffer from the diseases we target, including non-alcoholic fatty liver disease, and the number of subjects that will enroll in our clinical trials;
- the progress and focus of our current and future clinical trials, and the reporting of data from those trials;
- our ability to advance drug candidates into and successfully complete clinical trials;
- the ability of our clinical trials to demonstrate the safety and efficacy of TVB-2640, TVB-3567 and any other drug candidates we may develop, and other positive results;
- the success of competing therapies that are or may become available;

- developments relating to our competitors and our industry, including competing drug candidates and therapies;
- our plans relating to the further development and manufacturing of TVB-2640, TVB-3567 and any other drug candidates we may develop, including additional indications that we may pursue;
- existing regulations and regulatory developments in the United States and other jurisdictions;
- our potential and ability to successfully manufacture and supply TVB-2640, TVB-3567 and any other drug candidates we may develop for clinical trials and for commercial use, if approved;
- the rate and degree of market acceptance of TVB-2640, TVB-3567 and any other drug candidates we may develop, as well as the pricing and reimbursement of TVB-2640, TVB-3567 and any other drug candidates we may develop, if approved;
- our expectations regarding our ability to obtain, maintain, protect and enforce intellectual property protection for TVB-2640, TVB-3567 and for any other future drug candidate;
- our ability to attract and retain the continued service of our key personnel and to identify, hire, and then retain additional qualified personnel and our ability to attract additional collaborators with development, regulatory and commercialization expertise;
- our expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act; and
- our anticipated use of our existing cash and cash equivalents and the proceeds from this offering.

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this prospectus and are subject to a number of risks, uncertainties and assumptions described in the section titled “Risk Factors” and elsewhere in this prospectus. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein until after we distribute this prospectus, whether as a result of any new information, future events or otherwise.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely upon these statements.

MARKET, INDUSTRY AND OTHER DATA

This prospectus contains estimates, statistical data and other information concerning our industry, market and competitive position, including data regarding the estimated size and patient populations of those and related markets, existing therapeutic options and the incidence of certain medical conditions, from our own internal estimates and research, as well as from independent market research, industry and general publications and surveys, governmental agencies and publicly available information in addition to research, surveys and studies conducted by third parties. Internal estimates are derived from publicly available information released by industry analysts and third-party sources, our internal research and our industry experience, and are based on assumptions made by us based on such data and our knowledge of our industry and market, which we believe to be reasonable. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires.

Industry data and other third-party information have been obtained from sources believed to be reliable, but we have not independently verified any third-party information. In addition, while we believe the industry, market and competitive position data included in this prospectus is reliable and based on reasonable assumptions, such data involve risks and uncertainties and are subject to change based on various factors, including those discussed in the section titled “Risk Factors.” These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties or by us.

USE OF PROCEEDS

We estimate that we will receive net proceeds from this initial public offering of approximately $ million (or approximately $ million if the underwriters exercise their option to purchase additional shares of our Class A common stock in full) based on an assumed initial public offering price of $ per share, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each $1.00 increase or decrease in the assumed initial public offering price of $ per share would increase or decrease, as applicable, the net proceeds to us from this offering by approximately $ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of 1.0 million shares in the number of shares of Class A common stock offered by us would increase or decrease, as applicable, the net proceeds to us from this offering by approximately $ million, assuming the assumed initial public offering price of $ per share remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We currently expect to use the net proceeds we receive from this offering, together with our existing cash and cash equivalents, as follows:

- approximately $ to advance the development of TVB-2640 including clinical trials and manufacturing of additional drug supply;
- approximately $ to advance the development of other drug candidates, including a first-in-human clinical trial of TVB-3567; and
- the remainder for general corporate purposes, including working capital and operating expenses.

We may also use a portion of the remaining net proceeds and our existing cash and cash equivalents to in-license, acquire, or invest in complementary businesses, technologies, products or assets. However, we have no current commitments or obligations to do so.

We believe, based on our current operating plan, that the net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to fund our operations for at least the next months. However, our expected use of proceeds from this offering described above represents our current intentions based on our present plans and business condition. The amounts and timing of our actual expenditures will depend on numerous factors, including the time and cost necessary to conduct our planned clinical trials, the results of our planned clinical trials and other factors described in the section titled “Risk Factors” in this prospectus, as well as the amount of cash used in our operations and any unforeseen cash needs. Therefore, our actual expenditures may differ materially from the estimates described above. We may find it necessary or advisable to use the net proceeds for other purposes.

We will have broad discretion over how to use the net proceeds to us from this offering. We intend to invest the net proceeds to us from the offering that are not used as described above in short-term, investment-grade, interest-bearing instruments.

DIVIDEND POLICY

We have never declared or paid cash dividends on our capital stock. We do not anticipate declaring or paying, in the foreseeable future, any cash dividends on our capital stock. We intend to retain all available funds and future earnings, if any, to fund the development and expansion of our business, and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination regarding the declaration and payment of dividends, if any, will be at the discretion of our board of directors, subject to applicable laws, and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

In addition, our ability to pay cash dividends on our capital stock in the future may be limited by the terms of any future debt or preferred securities we issue or any credit facilities we enter into.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of March 31, 2021 as follows:

- on an actual basis;
- on a pro forma basis, giving effect to (i) the conversion of all of our outstanding shares of redeemable convertible preferred stock into an aggregate of shares of our Class A common stock and shares of our Class B common stock immediately upon the closing of this offering; (ii) the issuance of shares of our Class A common stock as a result of the expected net exercise of an outstanding warrant to purchase 79,545 shares of our Series D redeemable convertible preferred stock, subsequent conversion to Class A common stock and the related reclassification of the redeemable convertible warrant liability to Class A common stock and additional paid-in capital, assuming an initial public offering price of $ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus; and (iii) the issuance of shares of our Class A common stock as a result of the expected net exercise of an outstanding warrant to purchase 8,361,424 shares of our Class A common stock, assuming an initial public offering price of $ per share; and
- on a pro forma as adjusted basis, giving effect to (i) the pro forma adjustments set forth above, (ii) the issuance and sale of shares of Class A common stock in this offering at the assumed initial public offering price of $ per share, the midpoint of the estimated offering price range listed on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us and (iii) the filing and effectiveness of our amended and restated certificate of incorporation upon the closing of this offering.

The pro forma as adjusted information below is illustrative only, and our capitalization following the closing of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing.

You should read this information in conjunction with our financial statements and the related notes included elsewhere in this prospectus and in the sections titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Selected Financial Data.”

(in thousands, except share and per share data)	Actual	Pro Forma (unaudited)	Pro Forma as Adjusted(1) (unaudited)
Cash and cash equivalents	$ 74,944	$	$
Redeemable convertible preferred stock warrant liability	9		
Redeemable convertible preferred stock, par value $0.0001 per share; 1,373,810,170 shares authorized, 1,373,730,625 shares issued and outstanding, actual; 1,373,810,170 shares authorized, no shares issued and outstanding, pro forma; no shares authorized, no shares issued and outstanding, pro forma as adjusted	214,620		
Stockholders’ (deficit) equity:			
Preferred stock, $0.0001 par value; no shares authorized, issued, and outstanding, actual and pro forma; and shares authorized, no shares issued and outstanding, pro forma as adjusted	—		
Common stock, par value $0.0001 per share; 1,590,550,754 shares authorized, 9,519,463 shares issued and outstanding, actual; 1,590,550,754 shares authorized, shares issued and outstanding, pro forma; shares authorized, shares issued and outstanding, pro forma as adjusted[(2)]	1		
Additional paid-in capital	31,893		
Accumulated deficit	(172,475)		
Total stockholders’ deficit	(140,581)		
Total capitalization	$ 74,048	$	$

(1) Each $1.00 increase or decrease, as applicable, in the assumed initial public offering price of $ per share, the midpoint of the estimated offering price range listed on the cover page of this prospectus, would increase or decrease, as applicable, the pro forma as adjusted amount of each of cash and cash equivalents, additional paid-in capital, total stockholders equity and total capitalization by approximately $, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease, as applicable, of shares in the number of shares offered by us at the assumed initial public offering price per share, the midpoint of the estimated offering price range listed on the cover page of this prospectus, would increase or decrease, as applicable the pro forma as adjusted amount of each of cash and cash equivalents, additional paid-in capital, total stockholders equity and total capitalization by approximately $.

(2) Immediately following this offering we will have two classes of common stock: shares of Class A common stock and shares of Class B common stock.

The number of shares of our Class A common stock and Class B common stock that will be outstanding after this offering is based on shares of our Class A common stock and shares of our Class B common stock outstanding as of March 31, 2021 (i) the reclassification and renaming of all outstanding shares of common stock into shares of Class A common stock, and (ii) the conversion of our outstanding shares of redeemable convertible preferred stock into shares of our Class A common stock and shares of our Class B common stock, and excludes:

- 8,108,225 shares of Class A common stock issuable upon exercise of outstanding options as of March 31, 2021 under the 2007 Plan with a weighted average exercise price of $0.22 per share;
- 153,615,632 shares of Class A common stock issuable upon exercise of outstanding options as of March 31, 2021 under the 2017 Plan with a weighted average exercise price of $0.08 per share;
- 8,145,193 shares of Class A common stock issuable upon exercise of outstanding options granted after March 31, 2021 under the 2017 Plan, with a weighted average exercise price of $0.11 per share;
- shares of Class A common stock reserved for future issuance under the 2021 Plan, which will become effective once the registration statement of which this prospectus forms a part is declared effective, as well as any future automatic annual increases in the number of shares of Class A common stock reserved for issuance under the 2021 Plan and any shares underlying outstanding stock awards granted under (i) the 2007 Plan or (ii) the 2017 Plan, that expire or are repurchased, forfeited, cancelled or withheld, as more fully described in the section titled “Executive Compensation—Equity benefit plans”; and
- shares of Class A common stock reserved for issuance under the ESPP, which will become effective once the registration statement of which this prospectus forms a part is declared effective, and any future automatic annual increases in the number of shares of Class A common stock reserved for future issuance under our ESPP.

DILUTION

If you invest in our Class A common stock in this offering, your ownership interest will be diluted to the extent of the difference between the initial public offering price per share of our Class A common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

Our historical net tangible book value as of March 31, 2021 was a deficit of $140.6 million, or $14.77 per share of our common stock. Our historical net tangible book value (deficit) represents the amount of our total tangible assets less our total liabilities and redeemable convertible preferred stock. Historical net tangible book value per share represents historical net tangible book value (deficit) divided by the number of shares of our common stock outstanding as of March 31, 2021.

Our pro forma net tangible book value as of March 31, 2021 was $ million, or $ per share. Pro forma net tangible book value per share represents the amount of our total tangible assets (net of deferred offering costs) less our total liabilities, divided by the number of shares of our common stock outstanding as of March 31, 2021, after giving effect to (i) the conversion of all of our outstanding shares of redeemable convertible preferred stock into an aggregate of 1,322,399,477 shares of our Class A common stock immediately upon the closing of this offering; (ii) the issuance of shares of our Class A common stock as a result of the expected net exercise of an outstanding warrant to purchase 79,545 shares of our Series D redeemable convertible preferred stock, conversion to Class A common stock and the related reclassification of the redeemable convertible warrant liability to Class A common stock and additional paid-in capital, assuming an initial public offering price of $ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus; and (iii) the issuance of shares of our Class A common stock as a result of the expected net exercise of an outstanding warrant to purchase 8,361,424 shares of our Class A common stock, assuming an initial public offering price of $ per share.

After giving further effect to the sale of shares of Class A common stock that we are offering at the assumed initial public offering price of $ per share, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of March 31, 2021 would have been approximately $ million, or approximately $ per share. This amount represents an immediate increase in pro forma net tangible book value of $ per share to our existing stockholders and an immediate dilution in pro forma net tangible book value of approximately $ per share to new investors purchasing shares of Class A common stock in this offering.

Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the initial public offering price per share paid by new investors. The following table illustrates this dilution (without giving effect to any exercise by the underwriters of their option to purchase additional shares):

Assumed initial public offering price per share		$
Historical net tangible book deficit per share as of March 31, 2021	$ (14.77)	
Pro forma increase in net tangible book value per share as of March 31, 2021 attributable to the pro forma adjustment described above		
Pro forma net tangible book value per share as of March 31, 2021		
Increase in pro forma net tangible book value per share attributable to this offering		
Pro forma as adjusted net tangible book value per share after this offering		
Dilution per share to new investors in this offering		$

The dilution information discussed above is illustrative only and may change based on the actual initial public offering price and other terms of this offering. Each $1.00 increase or decrease, as applicable, in the assumed initial public offering price of $ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would increase or decrease, as applicable,

the pro forma as adjusted net tangible book value per share after this offering by approximately $, and dilution in pro forma net tangible book value per share to new investors by approximately $, assuming that the number of shares of Class A common stock offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease, as applicable, of 1.0 million shares in the number of shares of Class A common stock offered by us would increase or decrease, as applicable, our pro forma as adjusted net tangible book value per share after this offering by approximately $ per share, in each case, and decrease or increase, as applicable, the dilution to investors participating in this offering by approximately $ per share, assuming that the assumed initial public offering price remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise their option to purchase up to additional shares of our Class A common stock in full, the pro forma as adjusted net tangible book value after the offering would be $ per share, the increase in pro forma net tangible book value per share to existing stockholders would be $ per share and the dilution per share to new investors would be $ per share, in each case assuming an initial public offering price of $ per share.

The following table summarizes on the pro forma as adjusted basis described above, as of March 31, 2021, the differences between the number of shares of common stock purchased from us by our existing stockholders and common stock by new investors purchasing shares in this offering, the total consideration paid to us in cash and the average price per share paid by existing stockholders for shares of common stock issued prior to this offering and the price to be paid by new investors for shares of common stock in this offering. The calculation below is based on the assumed initial public offering price of $ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

	Shares Purchased		Total Consideration		Weighted-Average Price Per Share
	Number	Percentage	Amount	Percentage	
Existing stockholders			$		$
New investors					$
Total			$		

Each $1.00 increase or decrease, as applicable, in the assumed initial public offering price of $ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would increase or decrease, as applicable, the total consideration paid by new investors by $ million and, in the case of an increase, would increase the percentage of total consideration paid by new investors to % and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors to %, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. Similarly, each increase or decrease, as applicable, of 1.0 million shares in the number of shares offered by us, would increase or decrease, as applicable, the total consideration paid by new investors by $ million and, in the case of an increase, would increase the percentage of total consideration paid by new investors to % and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors to %, assuming that the assumed initial public offering price of $ per share remains the same.

The number of shares of our Class A common stock and Class B common stock that will be outstanding after this offering is based on shares of our Class A common stock and shares of our Class B common stock outstanding as of March 31, 2021 after giving effect to (i) the reclassification and renaming of all outstanding shares of common stock into shares of Class A common stock, and (ii) the conversion of our outstanding shares of redeemable convertible preferred stock into shares of our Class A common stock and shares of our Class B common stock, and excludes:

- 8,108,225 shares of Class A common stock issuable upon exercise of outstanding options as of March 31, 2021 under the 2007 Plan with a weighted average exercise price of $0.22 per share;

- 153,615,632 shares of Class A common stock issuable upon exercise of outstanding options as of March 31, 2021 under the 2017 Plan with a weighted average exercise price of $0.08 per share;
- 8,145,193 shares of Class A common stock issuable upon exercise of outstanding options granted after March 31, 2021 under the 2017 Plan, with a weighted average exercise price of $0.11 per share;
- shares of Class A common stock reserved for future issuance under the 2021 Plan, which will become effective once the registration statement of which this prospectus forms a part is declared effective, as well as any future automatic annual increases in the number of shares of Class A common stock reserved for issuance under the 2021 Plan and any shares underlying outstanding stock awards granted under (i) the 2007 Plan or (ii) the 2017 Plan, that expire or are repurchased, forfeited, cancelled or withheld, as more fully described in the section titled “Executive Compensation—Equity benefit plans”; and
- shares of Class A common stock reserved for issuance under the ESPP, which will become effective once the registration statement of which this prospectus forms a part is declared effective, and any future automatic annual increases in the number of shares of Class A common stock reserved for future issuance under our ESPP.

To the extent any outstanding options or warrants are exercised, new options or other equity awards are issued under our equity incentive plans, or we issue additional equity or convertible debt securities in the future, there will be further dilution to new investors.

SELECTED FINANCIAL DATA

The following tables set forth our selected statements of operations and comprehensive loss data for the years ended December 31, 2019 and 2020, and the three months ended March 31, 2020 and 2021, and our selected balance sheet data as of December 31, 2019 and 2020 and March 31, 2021. The statements of operations and comprehensive loss data for the years ended December 31, 2019 and 2020 and the balance sheet data as of December 31, 2019 and 2020 have been derived from our audited financial statements included elsewhere in this prospectus. We derived our summary statements of operations data for the three months ended March 31, 2020 and 2021 and the summary balance sheet data as of March 31, 2021 from our unaudited financial statements included elsewhere in this prospectus. In our opinion, the unaudited interim financial statements have been prepared on a basis consistent with our audited financial statements and contain all adjustments, consisting only of normal and recurring adjustments, necessary for a fair presentation of such interim financial statements. Our historical results are not necessarily indicative of the results that may be expected for any period in the future. You should read the following selected financial data together with the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes included elsewhere in this prospectus. The selected financial data included in this section are not intended to replace the financial statements and are qualified in their entirety by our financial statements and the related notes included elsewhere in this prospectus.

Statement of Operations Data:

(in thousands, except share and per share data)

	Years Ended December 31,		Three Months Ended March 31,	
	2019	2020	2020	2021
Operating expenses:				
Research and development	$ 8,391	$ 8,182	$ 3,025	$ 3,354
General and administrative	5,861	3,218	982	1,449
Total operating expenses	14,252	11,400	4,007	4,803
Other income (expense), net:				
Interest expense	(64)	—	—	—
Change in fair value of related parties convertible notes	321	—	—	—
Change in fair value of redeemable convertible preferred stock tranche liability	(390)	—	—	(751)
Change in fair value of redeemable convertible preferred stock warrants	(4)	—	(2)	—
Interest income and other	128	30	26	6
Total other income (expense), net	(9)	30	24	(745)
Net loss and comprehensive loss	$ (14,261)	$ (11,370)	$ (3,983)	$ (5,548)
Net loss per share attributable to common stockholders, basic and diluted[(1)]	$ (1.86)	$ (1.48)	$ (0.52)	$ (0.66)
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted[(1)]	7,674,259	7,674,259	7,674,259	8,350,834
Pro forma net loss per share attributable to common stockholders, basic and diluted[(2)]				
Weighted-average shares outstanding used in computing pro forma net loss per share attributable to common stockholders, basic and diluted[(2)]				

(1) See the section titled "Notes to Financial Statements—Note 2" for an explanation of the calculations of our basic and diluted net loss per share, and the weighted-average number of shares used in the computation of the per share amounts.

(2) The unaudited pro forma basic and diluted weighted-average common shares outstanding used in the calculation of unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2020 and the three months ended March 31, 2021 have been prepared to give effect to: (i) the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into our Class A common stock and Class B common stock upon the closing of this offering and (ii) the issuance of shares of our Class A common stock as a result of the expected net exercise of all outstanding warrants.

Balance Sheet Data:

(in thousands)

	As of December 31,		As of March 31,
	2019	2020	2021
Cash and cash equivalents	$ 10,212	$ 68,702	$ 74,944
Working capital(1)	8,739	66,828	73,887
Total assets	11,160	68,959	77,200
Redeemable convertible preferred stock warrant liability	9	9	9
Redeemable convertible preferred stock	134,179	202,885	214,620
Total stockholders' deficit	(125,315)	(135,910)	(140,581)

(1) Working capital is defined as total current assets less total current liabilities. See our financial statements and the related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our audited financial statements as of and for the years ended December 31, 2019 and 2020 and unaudited condensed financial statements as of and for the three months ended March 31, 2020 and 2021, and related notes and other financial information included elsewhere in this prospectus. This discussion and analysis and other parts of this prospectus contain forward-looking statements based upon our current plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations, intentions and beliefs. Our actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under the section titled "Risk Factors" and elsewhere in this prospectus. You should carefully read the "Risk Factors" section of this prospectus to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section titled "Special Note Regarding Forward-Looking Statements."

Overview

We are a clinical-stage biopharmaceutical company focused on developing a portfolio of internally-discovered, selective fatty acid synthase (FASN) inhibitors for the treatment of several diseases that result from the overproduction of the fatty acid palmitate. Based on our clinical and preclinical data, we believe that our wholly-owned pipeline of oral FASN inhibitors has the potential to offer treatments for indications in several therapeutic areas of high unmet medical need including liver diseases and cancers. TVB-2640, an oral, once-daily pill, is our lead drug candidate that we selected from more than 1,200 compounds in our library of FASN inhibitors and has been studied in over 260 subjects including healthy volunteers and patients with non-alcoholic steatohepatitis (NASH) or cancer. In our FASCINATE-1 Phase 2a clinical trial, TVB-2640 demonstrated statistically significant improvements across widely-used steatosis, inflammation/lipotoxicity, fibrosis and metabolic biomarkers important in NASH, and was well-tolerated. We believe that these attributes provide TVB-2640 the potential to treat a broad range of patients in this multifactorial disease. In the second quarter of 2021, we plan to enroll an open-label cohort in the FASCINATE-1 Phase 2a clinical trial to assess the safety and efficacy of TVB-2640 in patients treated with 75mg for 12 weeks. Also in the second quarter of 2021, we plan to initiate enrollment of our FASCINATE-2 Phase 2b clinical trial in NASH patients with moderate to advanced fibrosis to evaluate disease improvement by assessing liver biopsies after 52 weeks of treatment and conducting an interim analysis after a portion of the patients complete 26 weeks of treatment. Within oncology, in the second half of 2021, we plan to initiate a randomized, controlled Phase 2 clinical trial for glioblastoma multiforme (GBM) and a Phase 1b/2 basket clinical trial in several solid tumors where FASN inhibition may have promising utility. In addition, we plan to advance our second FASN inhibitor, TVB-3567, into a first-in-human clinical trial in the second half of 2021.

Since our inception, we have devoted substantially all of our resources to researching, discovering and developing our pipeline of proprietary FASN inhibitors and other drug targets, organizing and staffing our company, performing business planning, establishing our intellectual property portfolio, raising capital and general and administration activities to support and expand such activities. We do not have any products approved for sale and have not generated any revenue from product sales. To date, we have financed our operations primarily with proceeds from the sales of our redeemable convertible preferred stock and convertible notes. Through March 31, 2021, we have raised $233.3 million in gross proceeds from the sale of our redeemable convertible preferred stock and convertible notes. We will continue to require additional capital to develop our drug candidates and fund operations for the foreseeable future. Accordingly, until such time as we can generate significant revenue from sales of our drug candidates, if ever, we expect to finance our cash needs through public or private equity or debt financings, third-party funding and marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches.

We have incurred net losses in each year since inception and expect to continue to incur net losses in the foreseeable future. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending in large part on the timing of our preclinical studies, clinical trials and manufacturing activities, and

our expenditures on other research and development activities. Our net loss was $11.4 million and $5.5 million for the year ended December 31, 2020 and the three months ended March 31, 2021, respectively. As of March 31, 2021, we had an accumulated deficit of $172.5 million.

As of March 31, 2021, we had cash and cash equivalents of $74.9 million. Based upon our current operating plan, we believe that our existing cash and cash equivalents as of the date of this prospectus, together with the net proceeds from this offering, will enable us to fund our operating expenses and capital expenditure requirements through . See the section titled "—Liquidity and Capital Resources" for additional information.

We do not expect to generate any revenue from commercial product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our drug candidates, which we expect will take a number of years, if ever. We expect our expenses will increase substantially in connection with our ongoing activities, as we:

- advance drug candidates through preclinical studies and clinical trials;
- require the manufacture of supplies for our preclinical studies and clinical trials;
- pursue regulatory approval of drug candidates;
- hire additional personnel;
- operate as a public company;
- acquire, discover, validate and develop additional drug candidates; and
- obtain, maintain, expand and protect our intellectual property portfolio.

We rely and will continue to rely on third parties in the conduct of our preclinical studies and clinical trials and for manufacturing and supply of our drug candidates. We have no internal manufacturing capabilities, and we will continue to rely on third parties, of which the main suppliers are single-source suppliers, for our preclinical study and clinical trial materials. Given our stage of development, we do not yet have a marketing or sales organization or commercial infrastructure. Accordingly, if we obtain regulatory approval for any of our drug candidates, we also expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate revenue from the sale of our products, if any, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and may be forced to reduce our operations.

COVID-19 impacts

We are continuing to closely monitor the impact of the global COVID-19 pandemic on our business and are taking proactive efforts designed to protect the health and safety of our employees, and to maintain business continuity. We believe that the measures we are implementing are appropriate, and we will continue to monitor and seek to comply with guidance from governmental authorities and adjust our activities as appropriate. In March 2020, based on guidance issued by federal, state and local authorities, we transitioned to a remote work model for all of our employees.

While the COVID-19 pandemic has not yet resulted in a significant impact to our development timelines, as the pandemic continues, we could see an impact on our ability to advance our programs, obtain supplies from our contract manufacturer or interact with regulators, ethics committees or other important agencies due to limitations in regulatory authority, employee resources or otherwise. In any event, if the COVID-19 pandemic continues and persists for an extended period of time, we could experience significant disruptions to our development timelines, which would adversely affect our business, financial condition, results of operations and growth prospects.

In addition, while the potential economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, the pandemic could result in significant and prolonged disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the potential value of our common stock.

The extent of the impact of the COVID-19 pandemic on our development and regulatory efforts, our ability to raise sufficient additional capital on acceptable terms, if at all, and the future value of and market for our common stock will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the United States and in other countries, and the effectiveness of actions taken globally to contain and treat COVID-19.

License agreement with Ascletis

Ascletis BioScience Co. Ltd. In January 2019, we entered into a license agreement that became effective in February 2019 with Ascletis BioScience Co. Ltd. (Ascletis), a biotechnology company based in Hangzhou and Shaoxing, China and a significant stockholder. We entered into this agreement with the intention to develop, manufacture, and commercialize our FASN inhibitor TVB-2640, which is referred to as ASC40 in the People's Republic of China, Hong Kong, Macau and Taiwan (referred to collectively as Greater China). Under the terms of the license agreement, we granted Ascletis an exclusive right and license under our intellectual property to develop, manufacture, commercialize and otherwise exploit TVB-2640 and other FASN inhibitors in Greater China. We will bear all expenses related to patients enrolled in Greater China as part of an ongoing global Phase 2a trial and a Phase 1 clinical trial, except for clinical operations and regulatory staff provided by Ascletis. We and Ascletis have jointly applied for an investigational new drug (IND) in Greater China. Except for these Phase 1 and 2 trials and joint IND, Ascletis is solely responsible for all development activities and regulatory approvals for TVB-2640 in Greater China.

We are eligible to receive development and commercial milestone payments from Ascletis in an aggregate of up to $122 million as well as tiered royalties ranging from percentages in the high single digits to mid-teens on future net sales of TVB-2640, which is referred to as ASC40 in Greater China. Ascletis also led the Series E redeemable convertible preferred stock financing in February 2019. This license and Phase 2 research and development services components of the license agreement with Ascletis are representative of a "relationship with a customer" and therefore are subject to Accounting Standards Codification 606, *Revenue from Contracts with Customers* (ASC 606). As of December 31, 2020 and March 31, 2021, no revenue has been recognized from the license agreement with Ascletis and no milestone is probable of being achieved for at least the next twelve months.

Unless terminated earlier, the license agreement will continue until the expiration of the last expiring royalty term. Ascletis has the right to terminate the license agreement for convenience upon ninety-day written notice to us. In addition, either party may terminate the license agreement for uncured material breach by the other party, or upon the occurrence of insolvency-related events of the other party.

Components of results of operations

Revenue

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

Operating expenses

Research and development expenses. Research and development expenses represent costs incurred in performing research, development and manufacturing activities in support of our own product development efforts and include personnel-related costs (such as salaries, employee benefits and stock-based compensation) for our personnel in research and development functions; costs related to acquiring, developing and manufacturing supplies for preclinical studies, clinical trials and other studies, including fees paid to contract manufacturing organizations (CMOs); costs and expenses related to agreements with

contract research organizations, investigative sites and consultants to conduct non-clinical and preclinical studies and clinical trials; professional and consulting services costs; and facility and other allocated costs. We do not track research and development expenses by product candidate.

We expect our research and development expenses to increase substantially in absolute dollars for the foreseeable future as we advance our drug candidates into and through preclinical studies and clinical trials, pursue regulatory approval of our drug candidates and expand our pipeline of drug candidates. The process of conducting the necessary preclinical and clinical research to obtain regulatory approval is costly and time-consuming. The actual probability of success for our drug candidates may be affected by a variety of factors, including the safety and efficacy of our drug candidates, early clinical data, investment in our clinical programs, competition, manufacturing capability and commercial viability. We may never succeed in achieving regulatory approval for any of our drug 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 if, when and to what extent we will generate revenue from the commercialization and sale of our drug candidates.

Our clinical development costs may vary significantly based on factors such as:

- difficulties obtaining regulatory approval to commence a clinical trial or complying with conditions imposed by a regulatory authority regarding the scope or term of a clinical trial;
- conditions imposed on us by the FDA or other regulatory authorities regarding the scope or design of our clinical trials;
- delays in reaching or failing to reach agreement on acceptable terms with prospective CROs, CMOs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly;
- insufficient supply of our drug candidates or other materials necessary to conduct and complete our clinical trials;
- difficulties obtaining institutional review board (IRB), or ethics committee approval to conduct a clinical trial at a prospective site;
- slow enrollment and retention rate of subjects in our clinical trials;
- the FDA or other regulatory authority requiring alterations to any of our study designs, our pre-clinical strategy or our manufacturing plans;
- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines;
- serious and unexpected drug-related side effects related to the drug candidate being tested;
- lack of adequate funding to continue the clinical trial;
- subjects experiencing severe or unexpected drug-related adverse effects;
- occurrence of severe adverse effects in clinical trials of the same class of agents conducted by other companies;
- any changes to our manufacturing process, suppliers or formulation that may be necessary or desired;
- third-party vendors not performing manufacturing and distribution services in a timely manner or to sufficient quality standards;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, good clinical practice (GCP), or other regulatory requirements;
- third-party contractors not performing data collection or analysis in a timely or accurate manner;

- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications; and
- failure of our third-party contractors, such as CROs and CMOs, or our investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner.

General and administrative expenses. Our general and administrative expenses consist primarily of costs and expenses related to: personnel (including salaries, employee benefits and stock-based compensation) in our executive, legal, finance and accounting, human resources and other administrative functions; legal services, including relating to intellectual property and corporate matters; accounting, auditing, consulting and tax services; insurance; and facility and other allocated costs not otherwise included in research and development expenses.

We expect our general and administrative expenses to increase substantially in absolute dollars for the foreseeable future as we increase our headcount to support our continued research and development activities and grow our business. We also anticipate that we will incur increased expenses as a result of operating as a public company, including expenses related to audit, legal, regulatory and tax-related services associated with maintaining compliance with SEC rules and regulations and those of any national securities exchange on which our securities are traded, additional insurance expenses, investor relations activities and other administrative and professional services.

Other income (expense), net. Our other income (expense), net includes interest expense incurred, interest income earned and changes in the fair value of our redeemable convertible preferred stock related instruments. Interest expense consists primarily of interest expense related to convertible notes.

Results of operations

Comparison of the years ended December 31, 2019 and 2020

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

	Years Ended			
	2019	2020	Change	% Change
Operating expenses:				
Research and development	$ 8,391	$ 8,182	$ (209)	(2.5)%
General and administrative	5,861	3,218	(2,643)	(45.1)%
Total operating expenses	14,252	11,400	(2,852)	(20.0)%
Loss from operations	(14,252)	(11,400)	2,852	(20.0)%
Other income (expense), net:				
Interest expense	(64)	—	64	(100.0)%
Change in fair value of related parties convertible notes	321	—	(321)	(100.0)%
Change in fair value of redeemable convertible preferred stock tranche liability	(390)	—	390	(100.0)%
Change in fair value of redeemable convertible preferred stock warrants	(4)	—	4	(100.0)%
Interest income and other	128	30	(98)	(76.6)%
Total other income (expense), net	(9)	30	39	(433.3)%
Net loss and comprehensive loss	$(14,261)	$(11,370)	$ 2,891	(20.3)%

Research and development expense. Our research and development expense decreased by $0.2 million, or 2.5%, from the year ended December 31, 2019 compared to the year ended December 31,

2020. The decrease in our research and development expense was primarily due to the completion of the primary 25mg and 50mg cohorts of our FASCINATE-1 Phase 2a clinical trial in the United States in mid-2020, whereas the trial was ongoing for the full year of 2019, partially offset by the commencement of the FASCINATE-1 Phase 2a clinical trial in China.

General and administrative expenses. Our general and administrative expenses decreased by $2.6 million, or 45.1%, from the year ended December 31, 2019 compared to the year ended December 31, 2020 primarily due to a $2.2 million decrease in stock-based compensation expense related to the grants and milestone-based vesting of performance-based stock option grants in 2019 as compared to no grants in 2020 and a $1.0 million decrease in professional fees and IP-related costs, partially offset by a $0.6 million increase in personnel related bonus expense.

Other income (expense), net. Our other income (expense), net increased by $39 thousand from the year ended December 31, 2019 compared to the year ended December 31, 2020. The increase in our other income (expense), net was primarily due to an increase in non-cash fair value adjustments for the related parties convertible notes, redeemable convertible preferred stock tranche liability and redeemable convertible preferred stock warrants offset by a decrease in interest income in 2020 from declining cash balances, prior to the $68.7 million of net proceeds from the issuance of Series F redeemable convertible preferred stock in December 2020.

Comparison of the three months ended March 31, 2020 and 2021

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

	Three Months Ended March 31,			
	2020	2021	Change	% Change
Operating expenses:				
Research and development	$ 3,025	$ 3,354	$ 329	10.9%
General and administrative	982	1,449	467	47.6%
Total operating expenses	4,007	4,803	796	19.9%
Loss from operations	(4,007)	(4,803)	(796)	19.9%
Other income (expense), net:				
Change in fair value of redeemable convertible preferred stock tranche liability	—	(751)	(751)	100.0%
Change in fair value of redeemable convertible preferred stock warrants	(2)	—	2	(100.0)%
Interest income and other	26	6	(20)	(76.9)%
Total other income (expense), net	24	(745)	(769)	100.0%
Net loss and comprehensive loss	$(3,983)	$(5,548)	$(1,565)	(39.3)%

Research and development expense. Our research and development expense increased by $0.3 million, or 10.9%, from the three months ended March 31, 2020 compared to the three months ended March 31, 2021. The increase in our research and development expense was primarily due to $2.0 million in costs incurred in 2021 related to the start-up of our planned FASCINATE-2 Phase 2b clinical trial and a $0.2 million increase in costs to complete a small cohort under our FASCINATE-1 trial protocol in China. These increases were partially offset by a $1.7 million decrease in costs related to the completion of the primary 25mg and 50mg cohorts of our FASCINATE-1 Phase 2a clinical trial in the United States in mid-2020, as well as a $0.2 million decrease in pre-clinical activities.

General and administrative expenses. Our general and administrative expenses increased by $0.5 million, or 47.6%, from the three months ended March 31, 2020 compared to the three months ended March 31, 2021 primarily due to a $0.4 million increase in stock-based compensation expense related to stock options granted during the first quarter of 2021 and a $0.3 million increase in professional services. These increases were partially offset by a $0.2 million decrease in bonus expense.

Other income (expense), net. Our other income (expense), net decreased by $0.8 million from the three months ended March 31, 2020 compared to the three months ended March 31, 2021 due to the mark-to-market and subsequent extinguishment of the redeemable convertible preferred stock tranche liability from the second closing of our Series F financing in February 2021.

Liquidity and capital resources

We have incurred operating losses and negative cash flows from operations since inception and have relied on the sale and issuance of redeemable convertible preferred stock and convertible notes to fund our operations. For the years ended December 31, 2019 and 2020, our net loss was $14.3 million and $11.4 million, respectively. For the three months ended March 31, 2020 and 2021, our net loss was $4.0 million and $5.5 million, respectively. As of March 31, 2021, we had cash and cash equivalents of $74.9 million and an accumulated deficit of $172.5 million. To date, we have devoted the majority of our efforts on business planning, research and development of our drug candidates, including conducting preclinical studies and clinical trials, raising capital and recruiting management and technical staff to support these operations.

To date, none of our drug candidates have been approved for sale and we have not generated any revenue from product sales. We expect to incur increased research and development expenses as we develop existing and future drug candidates. We expect operating losses to continue to increase for the foreseeable future. Our prospects are subject to risks, expenses and uncertainties frequently encountered by companies in the biotechnology industry as discussed above.

In December 2020, we received gross subscriptions for $80.0 million of Series F redeemable convertible preferred stock financings from new and existing investors. $68.7 million of net proceeds were received in December 2020 and $11.0 million of net proceeds were received in February 2021.

Future funding requirements

Our primary uses of cash are to fund our operations, which consist primarily of research and development expenditures related to our programs and, to a lesser extent, general and administrative expenditures. We anticipate that we will continue to incur significant expenses for the foreseeable future as we continue to advance our drug candidates, expand our corporate infrastructure, including the costs associated with being a public company, further our research and development initiatives for our drug candidates, scale our laboratory and manufacturing operations, and incur marketing costs associated with potential commercialization. We are subject to all of the risks typically related to the development of new drug candidates, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We anticipate that we will need substantial additional funding in connection with our continuing operations.

We believe that our existing cash and cash equivalents as of the date of this prospectus will fund our current operating plans for at least twelve months from the issuance date of our unaudited condensed financial statements for the three months ended March 31, 2021. However, we will need to raise additional capital prior to commencing pivotal trials for any of our drug candidates. Until we can generate a sufficient amount of revenue from the commercialization of our drug candidates or from collaboration agreements with third parties, if ever, we expect to finance our future cash needs through public or private equity or debt financings, third-party (including government) funding and marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. The sale of equity or convertible debt securities may result in dilution to our stockholders and, in the case of preferred equity securities or convertible debt, those securities could provide for rights, preferences or privileges senior to those of our common stock. Debt financings may subject us to covenant limitations or restrictions on our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Our ability to raise additional funds may be adversely impacted by deteriorating 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. There can be no assurance that we will be successful in acquiring additional funding at levels sufficient to fund our operations or on terms favorable or acceptable to us. If we are unable to obtain adequate financing when needed or on terms favorable or acceptable to us, we may be forced to delay, reduce the scope of or eliminate one or more of our research and development programs.

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

- difficulties obtaining regulatory approval to commence a clinical trial or complying with conditions imposed by a regulatory authority regarding the scope or term of a clinical trial;
- conditions imposed on us by the FDA or other regulatory authorities regarding the scope or design of our clinical trials;
- delays in reaching or failing to reach agreement on acceptable terms with prospective CROs, CMOs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly
- insufficient supply of our drug candidates or other materials necessary to conduct and complete our clinical trials;
- difficulties obtaining IRB or ethics committee approval to conduct a clinical trial at a prospective site;
- slow enrollment and retention rate of subjects in our clinical trials;
- the FDA or other regulatory authority requiring alterations to any of our study designs, our pre-clinical strategy or our manufacturing plans;
- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines;
- serious and unexpected drug-related side effects related to the drug candidate being tested;
- lack of adequate funding to continue the clinical trial;
- subjects experiencing severe or unexpected drug-related adverse effects;
- occurrence of severe adverse effects in clinical trials of the same class of agents conducted by other companies;
- any changes to our manufacturing process, suppliers or formulation that may be necessary or desired;
- third-party vendors not performing manufacturing and distribution services in a timely manner or to sufficient quality standards;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, GCP, or other regulatory requirements;
- third-party contractors not performing data collection or analysis in a timely or accurate manner;
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications; and
- failure of our third-party contractors, such as CROs and CMOs, or our investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner.

A change in the outcome of any of these or other variables could significantly change our costs and timing associated with the development of our drug candidates. Furthermore, our operating plans may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such change.

Sources and uses of cash

The following table sets forth our primary sources and uses of cash for each of the periods presented below (in thousands):

	Years Ended December 31,	
	2019	2020
Net cash (used in) provided by:		
Operating activities	$(10,552)	$(10,416)
Investing activities	(27)	20
Financing activities	18,485	68,886
Net increase in cash	$ 7,906	$ 58,490

Cash flows from operating activities. Our net cash used in operating activities was $10.6 million for the year ended December 31, 2019. Our cash used in operating activities resulted from a net loss of $14.3 million primarily driven by the use of funds in our operations to develop our drug candidates offset by stock-based compensation for $3.0 million and an increase in our accounts payable and accruals of $1.3 million.

Our net cash used in operating activities was $10.4 million for the year ended December 31, 2020. Our cash used in operating activities resulted from a net loss of $11.4 million primarily driven by the use of funds in our operations to develop our drug candidates offset by stock-based compensation for $0.8 million and a decrease in our prepaid expenses of $0.6 million.

Cash flows from investing activities. Our net cash used in investing activities was $27,000 for the year ended December 31, 2019, which primarily related to a security deposit for a lease for office space.

Our net cash provided by investing activities was $20,000 for the years ended December 31, 2020, which primarily related to sales of equipment.

Cash flows from financing activities. Our net cash provided by financing activities was $18.5 million for the year ended December 31, 2019 which consisted primarily of net proceeds from our sale of redeemable convertible preferred stock of $21.8 million, offset by our repayment of debt in the amount of $3.4 million.

Our net cash provided by financing activities was $68.9 million for the year ended December 31, 2020 from net proceeds from the sale of Series F redeemable convertible preferred stock.

The following table sets forth our primary sources and uses of cash for each of the periods presented below (in thousands):

	Three Months Ended March 31,	
	2020	2021
Net cash (used in) provided by:		
Operating activities	$(2,598)	$ (4,903)
Financing activities	—	11,145
Net (decrease) increase in cash	$(2,598)	$ 6,242

Cash flows from operating activities. Our net cash used in operating activities was $2.6 million for the three months ended March 31, 2020. Our cash used in operating activities resulted from a net loss of $4.0 million primarily driven by the use of funds in our operations to develop our drug candidates offset by an increase in our accounts payable and accrued expenses of $0.9 million and stock-based compensation for $0.3 million.

Our net cash used in operating activities was $4.9 million for the three months ended March 31, 2021. Our cash used in operating activities resulted from a net loss of $5.5 million primarily driven by the use of funds in our operations to develop our drug candidates and a $1.2 million increase in prepaid expenses,

offset by a $0.3 million increase in accounts payable, a $0.8 million change in the fair value of the redeemable convertible preferred stock tranche liability and stock-based compensation for $0.7 million.

Cash flows from investing activities. We did not have cash provided by investing activities for the three months ended March 31, 2020 or 2021.

Cash flows from financing activities. We did not have cash provided by financing activities for the three months ended March 31, 2020.

Our net cash provided by financing activities was $11.1 million for the three months ended March 31, 2021 which consisted primarily of net proceeds from our sale of redeemable convertible preferred stock of $11.0 million in February 2021.

Off-balance sheet arrangements

During the periods presented we did not have, nor do we currently have, any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

Critical accounting policies

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses, redeemable convertible preferred stock tranche liabilities and stock-based compensation. We base our estimates on historical experience, known trends and events and various other factors that are believed to be 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. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in the section titled "Notes to Financial Statements—Note 2" included in our audited and unaudited financial statements elsewhere in this prospectus, we believe the following accounting policies and estimates to be most critical to the judgments and estimates used in the preparation of our financial statements.

Accrued research and development expense

As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our applicable 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 service when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers require advance payments; however, some invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in the financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of the estimates with the service providers and make adjustments if necessary.

We base our expenses related to preclinical studies, clinical trials and other studies on our estimates of the services performed pursuant to contracts with research institutions and clinical research organizations that conduct and manage preclinical studies, clinical trials and other studies on our behalf. 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 vendors will exceed the level of services provided and result in a prepayment of the expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. 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 the estimate, we adjust the accrual or prepaid expense accordingly. 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 reporting amounts that are too high or too low in any particular period. To date, we have not made any material adjustments to our prior estimates of accrued research and development expenses.

Stock-based compensation

We recognize stock-based compensation expense in an amount equal to the estimated grant date fair value of each option grant or stock award over the estimated period of service and vesting. This estimation of the fair value of each stock-based grant or issuance on the date of grant involves numerous assumptions by management. Although we calculate the fair value under the Black Scholes option pricing model, which is a standard option pricing model, this model still requires the use of numerous estimates, including, among others, the expected life of the award, the volatility of the underlying equity security, a risk free interest rate and expected dividends. The use of different values by management in connection with these estimates in the Black Scholes option pricing model could produce substantially different results.

For awards with service-based vesting conditions only, we recognize share-based compensation expense on a straight-line basis over the requisite service or vesting period. For awards with service- and performance-based vesting conditions, we recognize stock-based compensation expense using the graded vesting method over the requisite service period beginning in the period in which the awards are deemed probable to vest, to the extent such awards are probable to vest. We recognize the cumulative effect of changes in the probability outcomes in the period in which the changes occur.

Common stock valuations

We estimate the fair value of our common stock, utilizing our enterprise value determined with assistance from a third-party valuation expert, and in accordance with the guidance outlined in the American Institute of Certified Public Accountants Technical Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. Our management considered various objective and subjective factors to determine the fair value of our common stock as of each grant date, including:

- the prices at which we sold shares of redeemable convertible preferred stock and the superior rights and preferences of the redeemable convertible preferred stock relative to our common stock at the time of each grant;
- the progress of our research and development programs, including the status and results of preclinical studies for our drug candidates;
- our stage of development and commercialization and our business strategy;
- external market conditions affecting the biopharmaceutical industry and trends within the biopharmaceutical industry;
- our financial position, including cash on hand, and our historical and forecasted performance and operating results;
- the lack of an active public market for our common stock and our redeemable convertible preferred stock;
- the likelihood of achieving a liquidity event, such as an initial public offering (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 biopharmaceutical industry.

The assumptions underlying these valuations represented management’s best estimate, which involved inherent uncertainties and the application of management’s judgment. As a result, if we had used different assumptions or estimates, the fair value of our common stock and our stock-based compensation expense could have been materially different.

We estimated the valuations of our common stock, utilizing our enterprise value determined with assistance from a third-party valuation expert, as of the dates on which our board of directors granted equity awards. There are three main valuation approaches: market, income, and asset. The market approach involves the analysis of market data from comparable transactions to derive pricing indications. The income approach is based on the fundamental assumption that the value of a company today is the present value of all expected future income, appropriately adjusted for risk and time. In the asset approach each component of a company's assets and liabilities are valued separately and summed to conclude the value of the company. On September 15, 2017, March 29, 2019, September 16, 2019, January 11, 2021, and March 31, 2021, we used third-party valuations of our common stock prepared using the market, asset, and income approaches.

Once our value was estimated, it was allocated to our common shares. There are several allocation models which can be applied to value securities. The following models were used to allocate total equity value to our equity securities and total capital value to equity securities and debt:

- The option pricing method (OPM) which uses option pricing formulas to derive the value of each security class taking all economic rights of individual security class into account. The OPM analyzes a wide range of future equity values and assigns probabilities and equity values based on each security class's allocation of value in each value outcome.
- The probability weighted expected return method (PWERM) which 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.

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.

Once a public trading market for our common stock has been established in connection with the completion of this offering, it will no longer be necessary for our board of directors to estimate the fair value of our common stock in connection with our accounting for granted stock options and other such awards we may grant, as the fair value of our common stock will be determined based on the quoted market price of our common stock.

Quantitative and qualitative disclosures about market risk

Interest rate risk

Our cash and cash equivalents as of December 31, 2020 and March 31, 2021 consisted of readily available checking and money market funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of US interest rates. However, because of the nature of the instruments in our portfolio, a sudden change in market interest rates would not be expected to have a material impact on our financial condition or results of operations. We believe that our exposure to interest rate risks is not significant and that a hypothetical 10% movement in market interest rates would not have a significant impact on the total value of our portfolio or our interest income. In addition, we do not believe that our cash and cash equivalents have significant risk of default or illiquidity.

Financial institution risk

Substantially all of our cash is held with a single financial institution. Due to its size, this financial institution represents a minimal credit risk. Cash amounts held at financial institutions are insured by the Federal Deposit Insurance Corporation up to $250,000.

Foreign currency exchange risk

We have foreign currency risks related to some of our expenses denominated in Euros, British pound sterling, and Chinese yuan, which are subject to fluctuations due to changes in foreign currency exchange rates. Additionally, fluctuations in foreign currency exchange rates may cause us to recognize transaction gains and losses in our statements of operations. We have not engaged in foreign currency hedging transactions to minimize those fluctuations. To date, foreign currency transaction gains and losses have not been material to our financial statements.

Effects of inflation

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

Emerging growth company status

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act (the JOBS Act). Under the JOBS Act, emerging growth companies can delay the adoption of new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. Other exemptions and reduced reporting requirements under the JOBS Act for emerging growth companies include presentation of only two years of audited financial statements in a registration statement for IPO, an exemption from the requirement to provide an auditor's report on internal controls over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, as amended, an exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation and less extensive disclosure about our executive compensation arrangements. We have elected to use the 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 that (i) we are no longer an emerging growth company or (ii) we affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

We will remain an emerging growth company until the earliest of (i) the last day of our first fiscal year in which we have total annual gross revenues of $1.1 billion or more, (ii) the last day of our fiscal year following the fifth anniversary of the completion of this offering, (iii) the date on which we are deemed to be a large accelerated filer, under the rules of the SEC, which means the market value of equity securities that is held by non-affiliates exceeds $700.0 million as of the prior June 30th and (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

Recently adopted accounting pronouncements

See the section titled "Notes to Financial Statements—Note 2" included in our audited and unaudited financial statements elsewhere in this prospectus for more information.

BUSINESS

Overview

We are a clinical-stage biopharmaceutical company focused on developing a portfolio of internally-discovered, selective fatty acid synthase (FASN) inhibitors for the treatment of several diseases that result from the overproduction of the fatty acid, palmitate. Based on our clinical and preclinical data, we believe that our wholly-owned pipeline of oral FASN inhibitors has the potential to offer treatments for indications in several therapeutic areas of high unmet medical need including liver diseases and cancers. TVB-2640, an oral, once-daily pill, is our lead drug candidate that we selected from more than 1,200 compounds in our library of FASN inhibitors and has been studied in over 260 subjects, including healthy volunteers and patients with non-alcoholic steatohepatitis (NASH) or cancer. In our FASCINATE-1 Phase 2a clinical trial, TVB-2640 demonstrated statistically significant improvements across steatosis, inflammation/lipotoxicity, fibrosis and metabolic biomarkers important in NASH, and was well-tolerated. We believe that these attributes provide TVB-2640 the potential to treat a broad range of patients in this multifactorial disease. In the second quarter of 2021, we plan to initiate enrollment of our FASCINATE-2 Phase 2b clinical trial in NASH patients with moderate to advanced fibrosis to evaluate the impact of TB-2640 on disease improvement by assessing liver biopsies after 52 weeks of treatment. We also plan to conduct an interim analysis after a portion of the patients complete 26 weeks of treatment. Within oncology, in the second half of 2021, we plan to initiate a randomized, controlled Phase 2 clinical trial for glioblastoma multiforme (GBM) and a Phase 1b/2 basket clinical trial in several solid tumors where FASN inhibition may have promising utility. In addition, we plan to advance our second FASN inhibitor, TVB-3567, into a first-in-human clinical trial in the second half of 2021.

We are developing TVB-2640 as an oral, once-daily, selective FASN inhibitor for the treatment of NASH, an aggressive form of non-alcoholic fatty liver disease (NAFLD). In patients with NASH, increased FASN-mediated palmitate synthesis in the liver drives three key features of the disease: excess accumulation of liver fat, inflammation and fibrosis. In our FASCINATE-1 Phase 2a clinical trial, TVB-2640 demonstrated a statistically significant relative reduction of liver fat of 28.1% in patients treated with 50mg over 12 weeks, compared to a 4.5% relative increase observed with patients in the placebo group as measured by magnetic resonance imaging—proton density fat fraction (MRI-PDFF). A statistically significant 61% of patients treated with 50mg of TVB-2640 achieved a ≥30% relative reduction of liver fat. Additionally, TVB-2640 demonstrated statistically significant improvement across steatosis, inflammation/lipotoxicity, fibrosis and metabolic biomarkers important in NASH and was well-tolerated. In the second quarter of 2021, we plan to enroll an open-label cohort in the FASCINATE-1 Phase 2a clinical trial to assess the safety and efficacy of TVB-2640 in patients treated with 75mg for 12 weeks. We expect to report data from this cohort in the fourth quarter of 2021. In the second quarter of 2021, we also plan to initiate enrollment of our FASCINATE-2 Phase 2b trial in NASH patients with moderate to advanced fibrosis to evaluate disease improvement by assessing liver biopsies after 52 weeks of treatment. We will also measure liver fat, assessed using MRI-PDFF and other serum biomarkers will be measured in an interim analysis after a portion of patients complete 26 weeks of treatment.

The prevalence of NASH is increasing in the United States and globally, and is correlated with increasing rates of obesity, type 2 diabetes and metabolic syndrome. Metabolic syndrome is characterized by high blood sugar and lipid levels, insulin resistance and obesity. NASH is a significant unmet medical need for which no treatments have been approved in the United States or European Union. Approximately 5.7 million patients in the United States currently have NASH with moderate to advanced F2-F3 fibrosis (F2-F3 on a scale of F0-F4 by the NASH-CRN Scoring System) representing advanced liver disease, many of whom are currently undiagnosed. People with NAFLD have an increased risk of cardiovascular disease, liver failure, cancers of the liver and extrahepatic cancers. NASH is currently the leading cause of liver transplantation in women and second only to alcoholic liver disease in men and is expected to become the leading indication for liver transplantation. According to a study published in Hepatology in 2016, the direct healthcare costs associated with NAFLD and NASH in the United States in 2016 were estimated to be as high as $100 billion.

In addition to NASH, dysregulation of fatty acid metabolism is a hallmark of certain cancers. We have conducted a Phase 1 trial with high doses of TVB-2640 in cancer patients that showed manageable

tolerability results with prolonged stable disease in certain patients when the drug was used alone and in combination with a taxane and confirmed partial responses (PRs) when combined with a taxane, even in patients who had been previously treated with a taxane. In August 2020, positive data were also shared in an oral presentation at ESMO from a Phase 2 clinical trial with TVB-2640 and bevacizumab in GBM demonstrating an encouraging 65% objective response rate and 47% progression-free survival at six months. This investigator-sponsored trial was conducted at the University of Texas Health San Antonio. In the second half of 2021, we plan to initiate a randomized, controlled Phase 2 clinical trial evaluating TVB-2640 in patients with GBM and a Phase 1b/2 basket clinical trial evaluating TVB-2640 in several solid tumors where FASN inhibition may have promising utility.

Additionally, we expect to advance our second selective FASN inhibitor drug candidate, TVB-3567, into the clinic in the second half of 2021 with a Phase 1 clinical trial evaluating the safety and dosing profiles for development in an indication to be determined.

Our team

We assembled a team with extensive experience in drug discovery and development in the fields of hepatology, metabolic disease and oncology. Collectively, our team has been directly involved in a broad spectrum of research and development and commercial activities leading to successful outcomes, including FDA approvals and marketed drugs. Our president and chief executive officer, George Kemble, Ph.D., has broad experience in the biopharmaceutical industry and brings over 20 years of drug discovery and development experience. Before becoming our chief executive officer in October 2015, Dr. Kemble served as our chief scientific officer since August 2011. Prior to Sagimet, Dr. Kemble was senior vice president and head of research at MedImmune, LLC (now a subsidiary of AstraZeneca PLC, (MedImmune)), where he was responsible for a large group of scientists dedicated to the research and development of programs across a number of therapeutic areas, including launch of the intranasal vaccine FluMist, the first innovation in influenza vaccines in over 60 years. Our chief medical officer, Eduardo Bruno Martins, M.D., D.Phil., has deep expertise in clinical development with leadership positions at AbbVie Inc., Allergan, Inc., Eiger BioPharmaceuticals, Inc., Gilead Sciences, Inc., Genentech, Inc., Dynavax Technologies Corporation, Intermune, Inc., and SciClone Pharmaceuticals, Inc. where he led clinical development and medical affairs activities from translational research to Phase IV trials in various therapeutic areas, including in hepatology, vaccines, and oncology. Our chief financial officer and head of corporate development, Dennis Hom, has been instrumental to a variety of financing events and corporate transactions at leading pharmaceutical and biotechnology companies including Achaogen, Inc., Amgen Inc. and Novartis AG, and was previously an investment banker at J.P. Morgan Chase & Co. and predecessor firm Hambrecht & Quist. In addition, we are backed by a group of renowned and leading investors including Altium Capital Management, the Invus Group, LLC, Kleiner Perkins Caufield & Byers, LLC, New Enterprise Associates Inc. (NEA), PFM Health Sciences, LP, Rock Springs Capital LP, other undisclosed investors, and Ascletis, our strategic partner in Greater China.

Our FASN inhibitor pipeline

We believe FASN inhibition holds promise in several diseases, including certain liver diseases, cancers, skin diseases, fibrotic diseases and viral infections. We are advancing a portfolio of small molecule FASN inhibitors, selected from our library of over 1,200 internally-discovered and wholly-owned compounds, designed for convenient oral administration and high selectivity for the FASN enzyme, with the goal of limiting off-target activity and unwanted side effects. Additionally, our drug candidates are designed to overcome limitations of early generation FASN inhibitors, developed by others, including poor potency, off-target activity, or suboptimal physiochemical or pharmacokinetic properties.

The following table summarizes our wholly-owned drug candidates in development for multiple diseases with high unmet need:

TEAE classification	Placebo n=31	25mg cohort n=33	50mg cohort n=35
Any TEAE	Gr. 1: 11 (35.5%) Gr. 2: 8 (25.8%)	Gr. 1: 18 (54.5%) Gr. 2: 7 (21.2%)	Gr. 1: 11 (31.4%) Gr. 2: 7 (20.0%)
TEAE leading to drug withdrawal	0	2 (6.1%)	0
Treatment Emergent Serious Adverse	0	0	0
Drug related TEAE	Gr. 1: 3 (9.7%) Gr. 2: 1 (3.2%)	Gr. 1: 10 (30.3%) Gr. 2: 2 (6.1%)	Gr. 1: 9 (25.7%) Gr. 2: 1 (2.9%)
TEAE leading to death	0	0	0

Although we believe our product candidates have the potential to address several diseases, we will need to complete additional preclinical studies and clinical trials to determine the safety and efficacy of our product candidates. The results of these future studies and trials may be different than the results of our earlier studies and trials. We have not received regulatory approval for any of our product candidates, and in order to obtain regulatory approval and commercialize our product candidates, the FDA or foreign regulatory agencies will need to determine that our product candidates are safe and effective for their intended uses.

TVB-2640 for NASH

In healthy adults, FASN is a key enzyme involved in the production of saturated fatty acids in the liver and other organs, and is the only enzyme in the human body capable of converting metabolized sugars into palmitate. Palmitate is a saturated fatty acid that serves as a building block for longer chain, polyunsaturated fatty acids and can directly interact with other proteins to sustain normal cell signaling and metabolic function. In patients with NASH, FASN-mediated palmitate synthesis is increased in the liver leading to excess accumulation of liver fat and stimulation of inflammation and fibrosis resulting in poor liver function. Our lead candidate, TVB-2640, is designed to bind to FASN and specifically inhibit one of the enzymatic subdomains (the ß-ketoacyl reductase), thereby reducing the body's overproduction of palmitate. We believe that this reduction can lead to meaningful clinical benefits to NASH patients. TVB-2640 is designed to reduce the dysfunctional, high level of lipid synthesis and directly blunt inflammatory and fibrotic pathways that are activated in the diseased liver.

TVB-2640 is an oral, once-daily pill that has been studied in over 260 subjects in clinical trials, including healthy volunteers and patients with NASH or cancer. In June 2020, we announced top-line results from our FASCINATE-1 Phase 2a clinical trial in NASH patients where TVB-2640 demonstrated a statistically significant 28.1% relative reduction of liver fat in patients treated with 50mg over 12 weeks, compared to the 4.5% relative increase of liver fat observed with patients in the placebo group as measured by MRI-PDFF. A statistically significant 61% of patients treated with 50mg of TVB-2640 achieved a ≥30% relative reduction of liver fat, who we refer to as MRI-PDFF responders. An independent meta-analysis of several studies demonstrated that MRI-PDFF responders had a 7-fold higher likelihood of a ≥2 point improvement in NAS and a 5-fold higher rate of NASH resolution, both measured by liver biopsy, compared with nonresponders. A completed clinical trial for another drug candidate also demonstrated a predictive, positive correlation between MRI-PDFF response and improvement of fibrosis that was higher compared to nonresponse. Additionally, TVB-2640 demonstrated statistically significant improvements across steatosis, inflammation/lipotoxicity, fibrosis and metabolic biomarkers important in NASH and was well-tolerated. In the second quarter of 2021, we plan to enroll an open-label cohort in the FASCINATE-1 Phase 2a clinical trial to assess the safety and efficacy in patients treated with 75mg of TVB-2640 for 12 weeks. We expect to report data from this cohort in the fourth quarter of 2021.

We plan to initiate enrollment of our FASCINATE-2 Phase 2b clinical trial in the second quarter of 2021 in NASH patients with moderate to advanced fibrosis to evaluate the potential impact of TVB-2640, as assessed by biopsy. We plan to enroll 330 patients and administer oral, daily doses of placebo, 50mg of TVB-2640 or 75mg of TVB-2640 for 52 weeks. Biopsies will be evaluated to determine the effect of TVB-2640 on liver fat, inflammation, and fibrosis. The co-primary endpoints will be: (1) subjects achieving at least a ≥2 point improvement in NAS that results from reduction of necro-inflammation (inflammation or ballooning), or (2) improvement in fibrosis. These two endpoints are accepted by the FDA for Phase 2b studies in NASH. Liver biopsy data will also be evaluated to assess NASH resolution without worsening of fibrosis and/or improvement in fibrosis without worsening of NASH, both of which are endpoints accepted by the FDA for accelerated approval. We will also measure liver fat, assessed using MRI-PDFF, and other serum biomarkers in a portion of patients at 26 weeks of treatment in an interim analysis. We expect to initiate dosing of the 75mg dose cohort in FASCINATE-2 following results from the planned 75mg, open-label cohort in our FASCINATE-1 Phase 2a clinical trial. If results from this open-label cohort do not support use of 75mg in our FASCINATE-2 trial, we expect to complete the trial with the 50mg and placebo arms. We expect to report interim results in the second half of 2022 and top-line liver biopsy results in 2023.

We believe TVB-2640, if successfully developed and approved, has the potential to become a backbone therapy for NASH with the potential to combine with a broad set of other mechanisms. We also intend to conduct exploratory clinical trials with relatively short treatment duration of ≤12 weeks. These trials will allow us to evaluate potential improvements in noninvasive biomarkers directly in NASH patients, and select combinations for further development.

TVB-2640 for oncology

Dysregulation of fatty acid metabolism is also a hallmark of cancer. Most normal cells get their palmitate from dietary sources and do not rely on FASN for palmitate production. However, cancer cells have a rapid proliferation rate and a high lipid requirement for cell signaling and membrane synthesis, and rely upon de novo lipogenesis (DNL) as an internal source of fatty acids, a process known as neoplastic lipogenesis. FASN is overexpressed in many cancer cell types including lung, breast, ovarian, prostate, hepatocellular, colorectal and malignant melanoma with increased expression of FASN associated with poor prognosis and reduced survival in several tumor cell types.

In our Phase 1 clinical trial, high doses of TVB-2640 demonstrated activity and showed manageable tolerability results in cancer patients with solid tumors. Administration of TVB-2640 led to prolonged stable disease in certain patients when the drug was used alone and in combination with a taxane. TVB-2640 also demonstrated confirmed PRs when combined with a taxane, even in patients who had been previously treated with a taxane.

In August 2020, positive data were also shared in an oral presentation at ESMO from an investigator-sponsored Phase 2 clinical trial in GBM. This open-label study enrolled a total of 25 patients who were treated with TVB-2640 at a dose of 100 mg/m2 and bevacizumab. The primary objective was to evaluate efficacy, as measured by brain MRI imaging according to the Response Assessment in Neuro-Oncology (RANO) criteria. TVB-2640 plus bevacizumab demonstrated an encouraging 65% objective response rate and 47% progression free survival at six months. The secondary outcome was to evaluate safety, and the study results showed the combination of TVB-2640 and bevacizumab was generally well-tolerated. This investigator-sponsored clinical trial was conducted at the University of Texas Health San Antonio. In the second half of 2021, we plan to evaluate TVB-2640 in a randomized, controlled Phase 2 clinical trial in patients with GBM and in a Phase 1b/2 basket clinical trial in several solid tumors where we believe FASN inhibition may have promising utility.

TVB-3567

We have shown that our FASN inhibitors demonstrate activity in preclinical models of NASH, skin and lung fibrosis, multiple solid tumors, hepatitis C virus infection and respiratory syncytial virus infection. In addition to our lead drug candidate, we are developing a second selective FASN inhibitor designated as TVB-3567. This compound also showed potent FASN inhibitory activity in certain preclinical models including modulation of diacylglycerol metabolism and protein kinase C signaling in cancer models. We have completed preclinical safety studies with TVB-3567 that we believe support an IND submission, including

safety pharmacology, genotoxicity and general toxicology studies in rats and dogs. We plan to submit an IND for TVB-3567 and initiate a Phase 1 clinical trial in the second half of 2021 in an indication to be determined.

Our strategy

Our goal is to develop and commercialize our selective FASN inhibitors in therapeutic areas where FASN plays a central role in the development or progression of disease. We intend to achieve this goal by pursuing the following key strategic objectives:

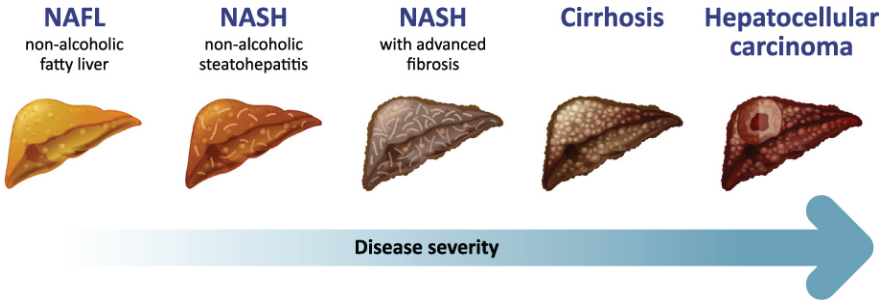
- ***Advance TVB-2640 through clinical development for the treatment of NASH.*** In a recent Phase 2a clinical trial, TVB-2640 reduced liver fat with statistical significance as assessed by MRI-PDFF, improved biomarkers of metabolic health, inflammation and fibrosis, and was well-tolerated. In the second quarter of 2021, we plan to initiate a Phase 2b clinical trial of TVB-2640 in NASH patients with moderate to advanced fibrosis in order to evaluate the impact of TVB-2640 on NASH assessed by biopsy following 52 weeks of treatment.
- ***Establish TVB-2640 as a backbone therapy for the treatment of NASH.*** Given the disease complexity, as well as the heterogeneity and large size of the NASH patient population, we believe combination therapies will have a meaningful role in the treatment paradigm of NASH in order to effectively address all patient segments. We intend to assess combinations of TVB-2640, as an oral small molecule agent, with other complementary mechanisms in order to maximize TVB-2640's full commercial potential in NASH.
- ***Progress our FASN inhibitors in clinical development for the treatment of solid tumors***. TVB-2640 showed antitumor activity in several solid tumor types in a Phase 1 clinical trial conducted by us and in GBM in a Phase 2 clinical trial conducted under an investigator sponsored IND at the University of Texas Health Science Center at San Antonio. In the second half of 2021, we plan to initiate a randomized, controlled Phase 2 clinical trial for TVB-2640 in GBM and in a Phase 1b/2 basket clinical trial in several tumor types where we believe FASN inhibition may have promising utility.
- ***Bring additional FASN inhibitors, such as TVB-3567, into clinical development.*** We have evaluated a second FASN inhibitor, TVB-3567, in preclinical cancer models and have completed IND-enabling toxicology and safety pharmacology studies. We plan to submit an IND for TVB-3567 and initiate a Phase 1 clinical trial in the second half of 2021. In addition to NASH and oncology, FASN is implicated to play a key role in several different diseases, such as acne, drug-induced fatty liver diseases and fibrotic diseases outside of the liver. We will continue to evaluate application of our FASN inhibitors in a number of diseases through internal research and development or partnerships.
- ***Independently develop and commercialize our drug candidates in indications and geographies where we believe we can maximize the value and benefit to patients.*** Because we believe our FASN platform and drug candidates have the potential to treat a wide range of diseases, we will independently develop those drug candidates in indications and geographies where we believe we can ultimately commercialize successfully on our own if they are approved. We will 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. Our license agreement with Ascletis for the development, manufacturing and commercialization of TVB-2640 in Greater China is an example of us prosecuting this strategy.

TVB-2640 in NASH

Overview of NASH

NASH is an aggressive form of NAFLD, a process by which an abnormal retention of excess fat (known as steatosis) occurs in the liver unrelated to the consumption of alcohol and for which no treatments have been approved in the United States or European Union. NAFLD encompasses a progressive and

histologically-defined range of liver diseases from simple steatosis (the presence of excess liver fat without inflammation or fibrosis) to NASH without fibrosis (excess liver fat with inflammation), to NASH with fibrosis and ultimately to cirrhosis or cancer of the liver.



NASH is initiated and propagated through several processes driven by excess fat in liver cells. Excess intracellular fat damages hepatocytes, the predominant cell type in the liver, leading to apoptosis, or cell death, of hepatocytes. Hepatocyte apoptosis triggers the stimulation of specialized immune cells and the increased activity of these cells drives inflammation in the liver. Additionally, as more hepatocyte tissue is destroyed and inflammation increases, hepatic stellate cells, another cell type found in the liver, are stimulated and induce fibrotic scarring. As this progressive cycle continues, the functions of the liver itself become compromised.

The diagnosis and severity of the disease can be assessed by histological analyses of liver tissue taken by biopsy which examine the degree of steatosis, inflammation and fibrosis using a microscope. For example, the NAS is a compilation of scores measuring steatosis, ballooning and inflammation. Additionally, the severity of fibrosis is scored on a 5-level scale of F0 (no fibrosis) to F4 (cirrhosis). NAS, along with the fibrosis stage, indicate the degree of progression of an individual's disease.

NASH is currently the leading cause of liver transplantation in women and second only to alcoholic liver disease in men. It is expected to become the leading cause of liver transplantation in the general population. In the United States, the prevalence of NASH was estimated to total about 17.3 million people in 2016, of which about 5.7 million have NASH with advanced fibrosis (F2-F3) and continues to be a vast and growing global healthcare problem.

NASH treatments in development

NASH is characterized by the build-up of fat in the liver and various degrees of inflammation and fibrosis along with systemic metabolic changes including dyslipidemia (increased fat levels in blood) and insulin resistance, among others. These parameters provide a framework to classify the various treatments under development and their mechanisms of action, many of which have significant limitations or address only a subset of NASH patients. Treatments that primarily address the build-up of fat in the liver and systemic metabolic changes include enzyme-specific inhibitors, gene expression activators, and growth factor analogs, while other approaches attempt to directly target only inflammation and fibrosis.

Enzyme-specific inhibitors in the lipid synthesis pathway target an enzyme in the DNL pathway to return lipid synthesis to a normal level and is expected to reduce liver fat and blunt the ongoing inflammation and fibrosis in NAFLD and NASH patients, ultimately allowing the liver tissue to regain its normal cellular structure and function. FASN and acetyl-CoA carboxylase (ACC) are examples of enzymes being targeted, both of which have shown significant clinical improvements in fat reduction, and improvements in biomarkers of liver enzymes, inflammation and fibrosis. However, ACC inhibitors have also been shown to increase plasma triglyceride levels in NASH patients, which is particularly problematic for NASH patients who have an elevated risk for cardiovascular disease.

Nuclear receptor modulators alter the gene expression pattern and affect multiple biochemical pathways in cells which can lead to unintended changes beyond the intended target pathway. Examples of nuclear receptor modulators include farnesoid X receptor (FXR) agonists, peroxisome proliferator-activated receptor (PPAR), agonists, and thyroid hormone receptor beta (THRß) agonists. FXR agonists can affect

pathways leading to excess bile acids, which have long been shown to be toxic, and causing pruritus, or itching of the skin. THRß agonists need to be highly selective for the beta isoform of this receptor and avoid binding the alpha isoform, which exists in the heart and kidneys and can result in significant, potentially life-threatening, side-effects.

Growth factor analogs attempt to mimic natural proteins, such as FGF21 and FGF19, to bring several disordered systems back to normal levels and have shown promise in early studies. Because of the large size of proteins, the mode of delivery is typically limited to injection and more expensive to manufacture compared to small molecules. In addition to the difficulty of frequent injections for a chronic disease considered asymptomatic by most patients, these drugs often require significant development effort to address potential downsides. In addition, based on the tumor-inducing nature of the FGF19 protein, the drug form of the molecule has undergone significant alteration to attempt to alleviate this concern. While animal studies have shown that it is not tumor-promoting, human studies await sufficiently sized clinical trials to determine the risk. Treatment of patients with this modified form of FGF19 also leads to significant increases in LDL-cholesterol levels.

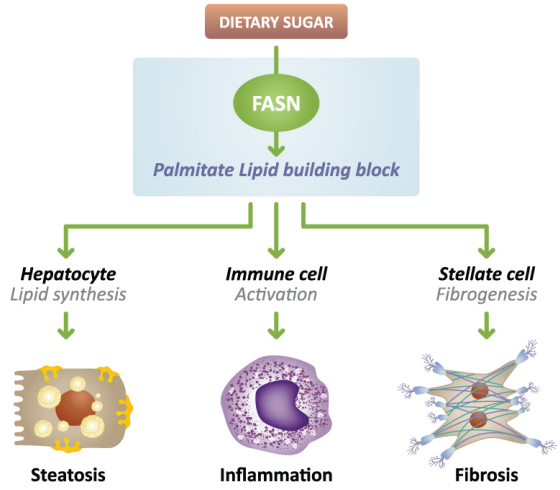
Anti-inflammatory and anti-fibrotics target the inflammation and fibrosis resulting from the build-up of fat in the liver. Despite promising preclinical and early clinical data, drugs targeting fibrosis have often failed to produce meaningful results in mid- to late- stage clinical studies, suggesting that drugs that only impact liver fibrosis may not be sufficient to impact NASH in a meaningful way. For instance, a Phase 3 study of a drug candidate targeting the CCR2/5 receptor on inflammatory cells to stop fibrosis has been terminated early due to lack of efficacy. If successful, anti-inflammatory and anti-fibrotic drug candidates can help treat elements of NASH, but they are not expected to target and reduce the liver fat synthesis that drives the disease.

Our lead drug candidate—TVB-2640 in NASH

TVB-2640, an oral, once-daily pill, is our selective FASN inhibitor currently being developed for the treatment of NASH. TVB-2640 has been administered to over 260 subjects including healthy volunteers, cancer patients and patients with NASH. We have reported results from a Phase 1 clinical trial that showed TVB-2640 inhibited FASN in adults, as measured by up to a 90% reduction of liver fat synthesis. We recently completed the FASCINATE-1 Phase 2a trial, a randomized, placebo-controlled clinical trial in 99 patients with NASH. A single oral tablet of 25mg or 50mg once a day for 12 weeks reduced liver fat measured by MRI-PDFF and improved biomarkers of NASH in a dose-dependent manner. These doses were well-tolerated and, in the second quarter of 2021, we plan to enroll an open-label cohort of patients who will receive 75mg once-daily for 12 weeks. We also plan to initiate a Phase 2b clinical trial in the second quarter of 2021 to evaluate the potential impact of TVB-2640 treatment on liver tissue, as assessed by biopsy. We received Fast-Track designation for TVB-2640 for the treatment of NASH in March 2021. See “Government Regulation and Product Approval—Expedited Development and Review Programs.”

Potential mechanism of action in NASH

FASN is the key enzyme in the DNL pathway that converts metabolites of dietary sugars such as fructose into palmitate, a saturated fatty acid. Excess DNL activity and palmitate drive the hallmarks of NASH through accumulation of triglyceride in hepatocytes, and induction of inflammatory responses. The amount of FASN expressed and the DNL pathway activity are increased in the livers of patients with metabolic syndrome or NAFLD compared to healthy individuals. Increased DNL activity in hepatocytes leads to the accumulation of excess fat (steatosis) in the liver. This initiating event drives NASH, and is necessary for liver inflammation, tissue damage, and fibrosis. In addition, inflammatory cells require DNL for pro-inflammatory function, and hepatic stellate cells, which generate fibrotic scar tissue in the liver, require DNL to express profibrotic genes including procollagen. Furthermore, palmitate, the product of FASN, is used to synthesize pro-inflammatory and pro-fibrotic molecules called lipotoxins which contribute to the mechanisms driving the progressive nature of NASH. This places FASN at the nexus of three major drivers of liver damage in NASH: excess intracellular fat synthesis, inflammation and fibrosis.

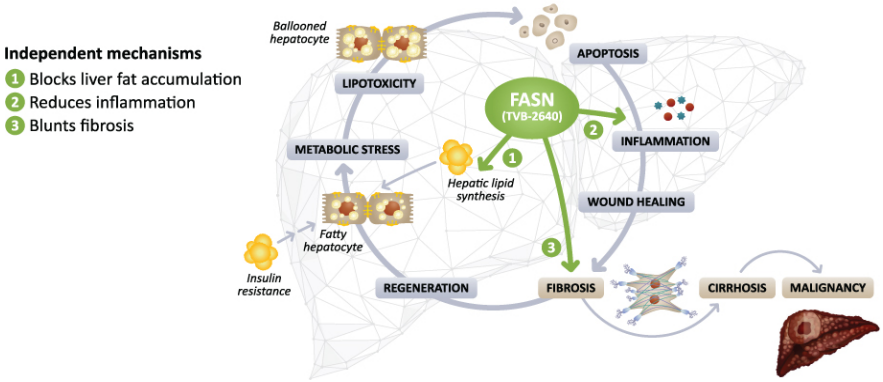


We believe that TVB-2640 has the potential to alleviate NASH by inhibiting FASN and thereby impacting key drivers of NASH as follows:

1) Potential to block liver fat accumulation (steatosis) by reducing liver fat synthesis in hepatocytes;

2) Potential to reduce inflammation by blocking the activation and cytokine secretion by inflammatory cells; and

3) Potential to reduce fibrosis by blocking the activation and fibrogenic activity of stellate cells.



This diagram above of the cycle of NASH pathogenesis shows how the excess dietary sugar, especially in someone with decreased sensitivity to insulin, produces excess palmitate in hepatocytes (hepatic lipid synthesis) leading to fatty hepatocytes. The high level of palmitate, a lipotoxin, creates metabolic stress in these cells leading to ballooned hepatocytes, which is evidence of cellular damage. These damaged hepatocytes undergo programmed cell death, known as apoptosis. The cellular debris resulting from apoptosis stimulates inflammatory cells in the liver eliciting an inflammatory response. This damage and inflammation in the liver stimulates hepatic stellate cells which elicit fibrotic responses to repair the wound. As more sugars come in via the diet, this process is continued, leading to build up of fibrotic scar tissue. If the damaging environment is removed, the liver has the potential to regenerate healthy tissue over time. However, if the damaging environment continues, some patients will progress to cirrhosis and may also develop hepatocellular carcinoma.

Recent studies, including evidence presented at the European Association for the Study of Liver in Paris, France in 2018, have shown that the liver also continues to produce fat in the later stages of NAFLD,

including patients with early stages of cirrhosis, broadening the number of patients who could see benefit from FASN inhibition. These late-stage patients can progress to liver cirrhosis that can lead to significant complications including acute liver decompensation events which can be life threatening, require hospitalization and in the case of decompensated cirrhosis, liver transplant. We believe the three-pronged potential mechanism of action of TVB-2640 (reduction of liver fat synthesis, inflammation and fibrosis) could address these patients, preventing further liver damage.

Preclinical studies in NASH models

We used several model systems to measure the impact of FASN inhibition on different components of NASH pathogenesis. *In vitro* and *in vivo* data collectively showed that TVB-2640 reduced all three hallmarks of NASH.

Key mechanistic result observed in preclinical studies with Sagimet's FASN inhibitors:	Details
• *Reduced* ***steatosis in human liver microtissue (LMT) model***	Primary human liver cells stimulated with sugar and fatty acids to mimic NASH. • Reduced cellular triglyceride levels (steatosis) • Reduced production of pro-inflammatory chemokine
• *Decreased* ***pro-inflammatory*** *activity of immune cells*	Primary human blood cells (direct) • Reduced pro-inflammatory cytokines in human blood cells, and in mice fed a high fat high sugar diet • Blocked production of pro-inflammatory T cells and increased T regulatory cells
• *Decreased activation and* ***fibrogenic activity*** of human stellate cells	Fibrosis assays in human liver stellate cells (direct) • Reduced DNL pathway output • Decreased levels of fibrotic genes such as collagen

We evaluated the effect of FASN inhibitors in mouse models of NASH, and the results showed that FASN inhibition alleviated established hallmarks of NASH. While TVB-2640 showed a favorable half-life in clinical studies, mice rapidly cleared the drug from their system in preclinical studies; therefore, we used a surrogate FASN inhibitor TVB-3664 for these experiments due to its improved PK in mice. TVB-3664 has a chemical structure highly related to TVB-2640 and inhibited FASN in a similar fashion.

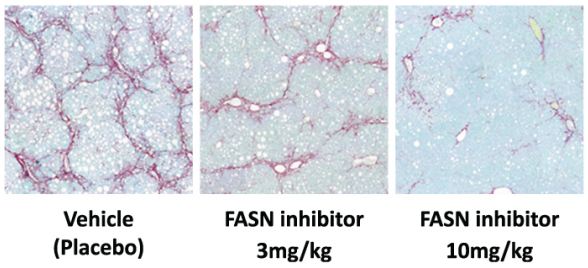
FASN inhibition treats diet induced NASH in mouse models

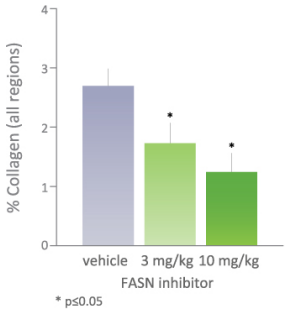
After 44 weeks on a high-fat/fructose/cholesterol diet, mice developed obesity, steatohepatitis and liver fibrosis before FASN inhibitor treatment was initiated and the mice continued the same diet for eight additional weeks. After treatment with our FASN inhibitor, livers showed reduced steatosis and NAS score, despite being fed a diet high in fat, fructose and cholesterol. FASN inhibition also improved biomarkers of liver inflammation, diminished liver triglyceride and cholesterol, and reduced expression of fibrosis biomarkers and fibrosis severity.

FASN inhibition has shown clinical activity in NASH model with established fibrosis and liver cancer

In a study performed by our collaborator Professor Scott Friedman at the Icahn School of Medicine at Mt. Sinai Hospital in New York, mice were fed a high-fat, high-sugar diet and given a once weekly injection of carbon tetrachloride, for six months. This toxic chemical causes liver fibrosis in rodent models of NASH. Mice received either placebo or FASN inhibitor for the last three months. After six months, mice in the placebo group had extensive fibrosis evidenced by scar tissue and collagen deposition in their livers as well as liver tumors. In contrast, mice that received the FASN inhibitor had statistically significantly less scar tissue and collagen deposition in their livers and, in most cases, less than observed before the drug was started, indicating that FASN inhibition reversed fibrosis despite continued insult to the liver as shown in the figure below. Additionally, animals receiving the FASN inhibitor had overall 85% fewer liver tumors than

those receiving placebo and several drug-treated animals had no tumors in their livers at the end of the study. These results were consistent with the documented role of FASN and the DNL pathway in liver fat accumulation, inflammation and fibrogenesis.



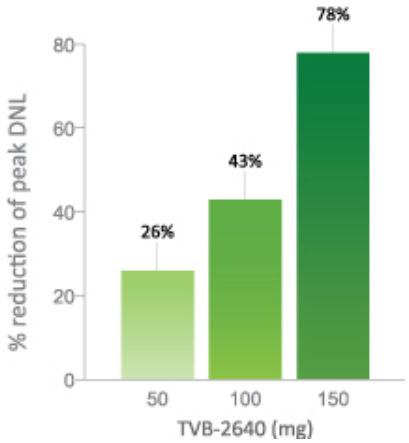


NASH clinical program

Phase 1 clinical trial in healthy male adults with characteristics of metabolic syndrome

We collaborated with Dr. Elizabeth Parks at the University of Missouri to evaluate the impact of TVB-2640 on liver fat synthesis in 12 healthy adults with characteristics of metabolic syndrome. Liver fat synthesis was quantified by measuring the conversion of acetate into the product of FASN, palmitate. This measurement was done in each subject once before they received TVB-2640 and again after ten days of taking a once-daily oral dose of either 50mg, 100mg or 150mg of TVB-2640. This second measurement was taken approximately 10 hours after the last dose so that we could measure the impact of steady-state drug levels on liver fat synthesis. This study showed there was a significant reduction of liver fat synthesis at all doses and such reduction occurred in a dose-dependent manner. The 50mg dose reduced peak liver fat synthesis by approximately 26% and the 150mg dose inhibited liver fat synthesis by 78%, as shown in the graphic below. The drug was well-tolerated; one of the four subjects given 100mg and one of the two subjects given 150mg of the drug experienced some hair thinning that returned to normal after the drug was stopped. These changes correlated with significant reduction of their skin sebum while on treatment, which returned to normal after drug was stopped.

TVB-2640 inhibits DNL



We believe the results from this clinical trial established the clinical proof of mechanism for TVB-2640. The results showed that an oral dose of TVB-2640 reached the liver of adults who were overweight, and by inhibiting FASN, reduced fat synthesis in the liver.

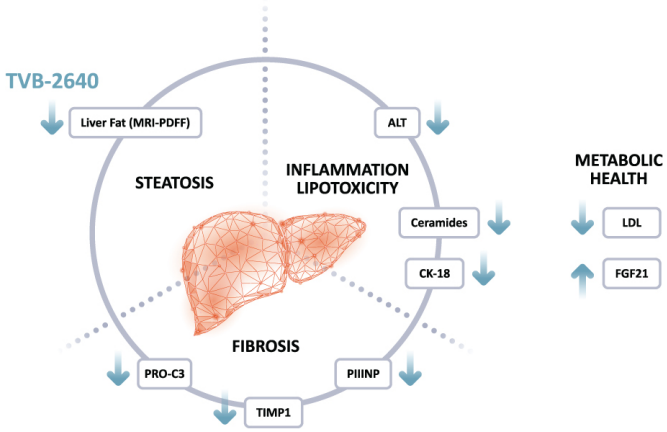
FASCINATE-1 Phase 2a clinical trial in NASH patients

The FASCINATE-1 Phase 2a clinical trial was a randomized, placebo-controlled, single-blind clinical trial that showed a once-daily, oral dose of TVB-2640 for 12 weeks was well-tolerated and significantly reduced excess liver fat in patients with NASH in a dose-dependent manner. In this clinical trial, TVB-2640 demonstrated improvements in biomarkers across three hallmarks of NASH:

- Liver fat (steatosis): MRI-PDFF
- Inflammation/lipotoxicity: alanine transaminase (ALT), ceramides, CK-18
- Fibrosis: PRO-C3, TIMP1, PIIINP

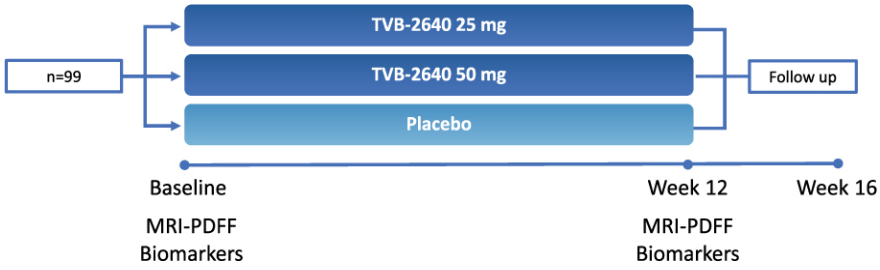
TVB-2640 also improved multiple biomarkers of metabolic health, including LDL-cholesterol and FGF21. We believe the concordance of improvements observed across multiple parameters in this relatively short time frame supports the potential of TVB-2640 to treat NASH patients.

TVB-2640 effect in NASH patients consistent across multiple biomarkers



Adults with ≥8% liver fat (assessed by MRI-PDFF) and evidence of liver fibrosis by either magnetic resonance elastography (MRE) or recent biopsy were eligible. Subjects (n=99) were enrolled at 10 sites across the United States and given either placebo, 25mg or 50mg of TVB-2640 orally once-daily for 12 weeks. Liver fat was measured by MRI-PDFF at baseline and after 12 weeks of treatment. The median age of patients in this clinical trial was 55 years, 46% were female, and most were white with 72% identifying as Hispanic or Latino. As expected for a NASH population, the median liver fat was 15-16%, the majority of patients had type 2 diabetes and the median body mass index (BMI) was 32.6 kg/m^2. The safety data were reported for all 99 patients enrolled in the clinical trial. The primary analysis of clinical activity was performed on 85 of the 99 patients. Nine of the of the 99 patients were excluded from the analysis because they did not receive the minimum of eight weeks of treatment and five were excluded because their end-of-treatment MRI-PDFF was extended beyond the 12-week timepoint primarily due to COVID-related delays.

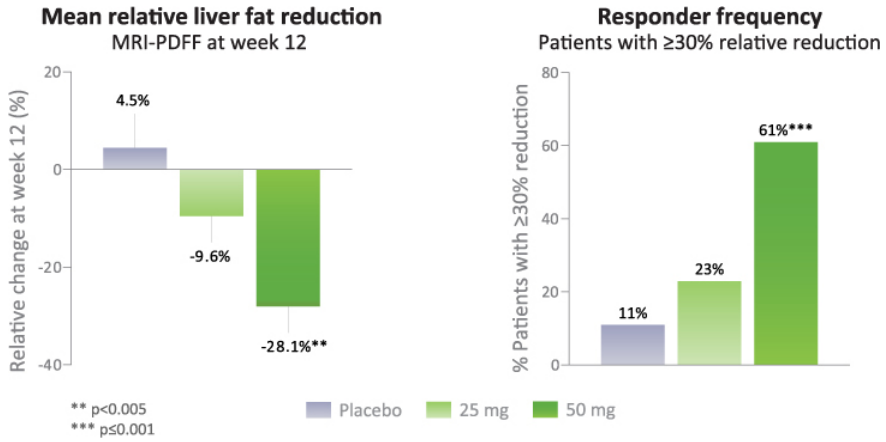
FASCINATE-1 Phase 2a clinical trial design



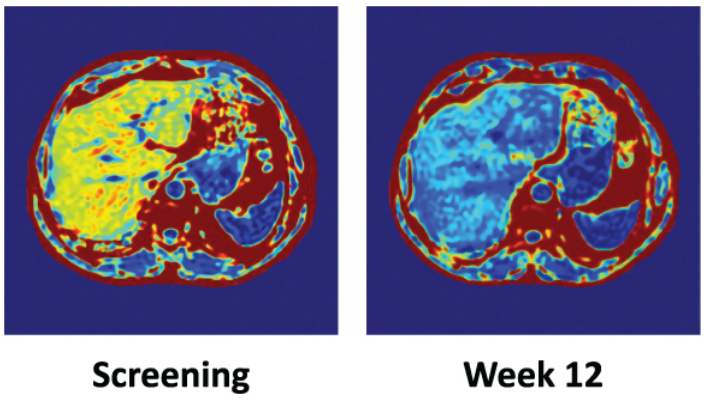
Liver fat biomarker: MRI-PDFF imaging

The primary endpoint of this clinical trial was the percent change in relative liver fat following 12 weeks of treatment. The patients in the placebo group, on average, had a 4.5% relative increase in relative liver fat over 12 weeks. In contrast, there was a dose-dependent relative reduction of liver fat of 9.6% (p=0.053) in patients treated with 25mg of TVB-2640 and 28.1% (p=0.001) in patients treated with 50mg. The p-value is a measure that states the probability that a comparable or better result would be produced purely by chance. Differences with a p-value of ≤0.05 are generally considered statistically significant, indicating a high degree of confidence that the measured result was due to administration of the drug and not due to chance.

A secondary analysis evaluated how many patients achieved an MRI-PDFF response, an important imaging-based biomarker in NASH. A meta-analysis of several clinical trials showed that patients who experience a ≥30% relative reduction of liver fat had a 7-fold higher likelihood that the biopsied liver tissue in these responders would show a ≥2 point improvement in NAS and a 5-fold higher rate of NASH resolution. A third-party ongoing clinical trial evaluating a different compound has also suggested a predictive, positive correlation between responders and improvement of fibrosis that was higher compared to patients who experienced less than a 30% relative reduction of liver fat. In our FASCINATE-1 Phase 2a clinical trial, 23% of patients in the 25mg cohort achieved a response (p=0.23) and 61% of subjects treated with 50mg of TVB-2640 achieved a response (p=0.001), compared with 11% of the placebo group, as depicted below.

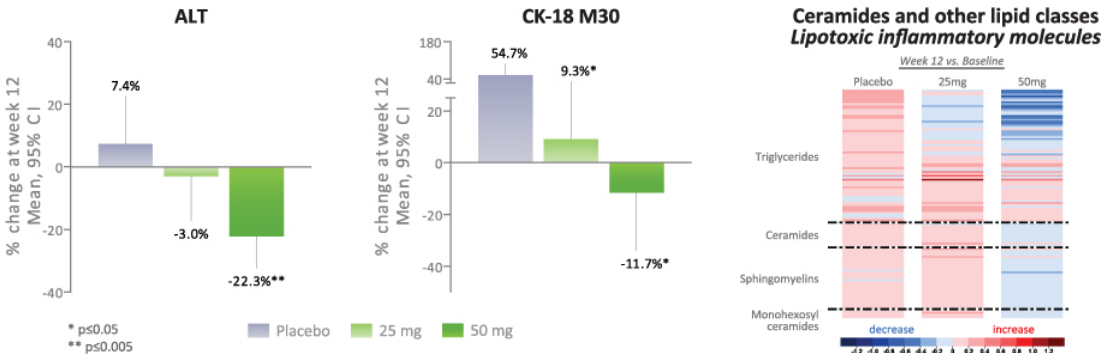


MRI-PDFF images for one patient treated with 50mg of TVB-2640 are shown below. The two images were taken 12 weeks apart from one another at the same horizontal position in the patient's body. The image on the left shows substantial liver fat deposits, represented by the yellow-green colored portion of the image. After 12 weeks of treatment this same area no longer had a substantial amount of liver fat, as shown by the lack of yellow-green coloration and presence of the blue background color.



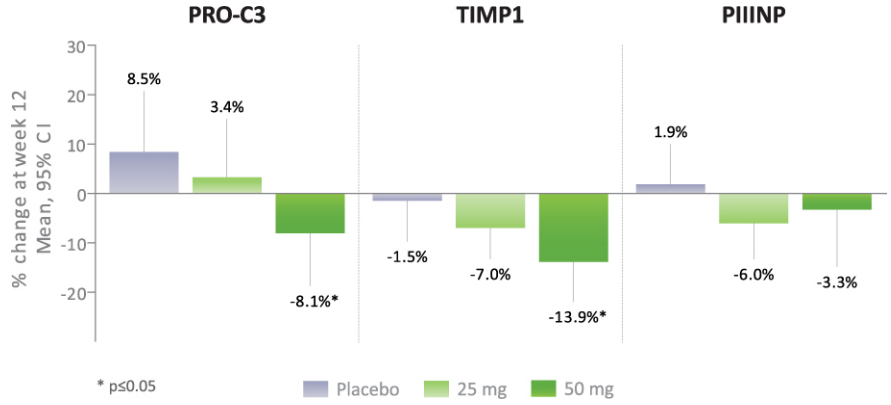
In addition to liver fat, a number of inflammation/lipotoxicity, fibrosis and metabolic health biomarkers that are important to NASH were assessed in this clinical trial.

Inflammation/lipotoxicity biomarkers



- ***ALT.*** TVB-2640 showed a statistically significant decrease of ALT up to 22.3% ($p<0.005$) in a dose-dependent manner. Additionally, of the ten patients in the 50mg cohort with elevated ALT at baseline, 60% achieved normalization versus 33% of placebo patients. ALT is a liver enzyme often elevated in NASH patients and indicative of hepatic inflammation and damage. Decreasing ALT levels in NASH patients has been shown to correlated with improvement of liver biopsy.
- ***CK-18(M30).*** TVB-2640 showed a statistically significant decrease of CK-18(M30) up to 11.7% ($p<0.05$) in a dose-dependent manner. Cytokeratin 18 (CK-18) is a major cytoskeleton protein in hepatocytes that is released into the bloodstream when the cell is damaged. CK-18(M30), a major fragment of CK-18, is often elevated in NASH patients. Decreasing CK-18 levels is indicative of improved liver tissue.
- ***Ceramides.*** TVB-2640 showed a statistically significant decrease in multiple ceramides. Excess accumulation of ceramides, a type of fat often increased in NASH patients, are toxic and lead to inflammation and fibrosis. Decreasing ceramide levels likely reflects the reduction of excess palmitate and suggests an improved inflammatory environment.

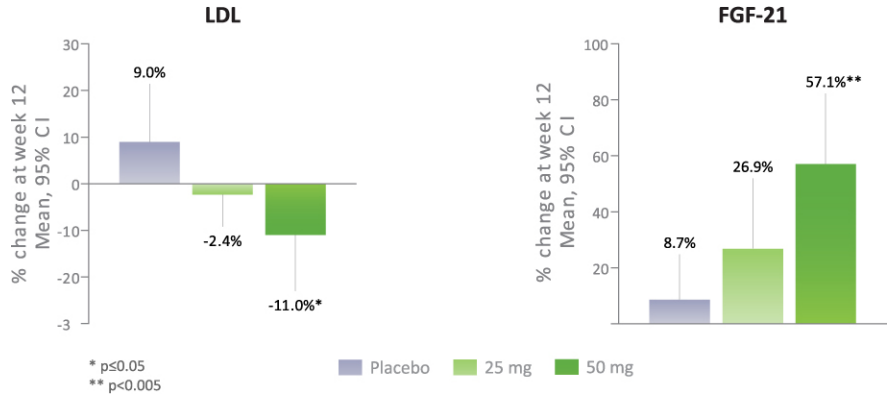
Fibrosis biomarkers



- ***PRO-C3.*** TVB-2640 showed a statistically significant decrease in PRO-C3 levels up to 8.1% ($p<0.05$) in a dose-dependent manner. PRO-C3 is a protein fragment of procollagen and indicative of active hepatic fibrogenesis when found in the blood. Decreases of PRO-C3 suggest reduced levels of fibrosis in the liver.

- ***TIMP-1***. TVB-2640 showed a statistically significant decrease in TIMP-1 levels up to 14% ($p<0.05$) in a dose-dependent manner. TIMP-1 is secreted by activated hepatic stellate cells, the predominant cell type responsible for fibrogenesis. Decreases of TIMP-1 suggest reduced levels of fibrosis in the liver.
- ***PIIINP.*** TVB-2640 decreased PIIINP levels, though these reductions were not significant. PIIINP detects both complete and partially degraded procollagen in the blood. Reduction of PIIINP is indicative of improved fibrosis in the liver.

Metabolic/lipid biomarkers



- ***LDL-cholesterol***. TVB-2640 showed a statistically significant decrease in LDL-cholesterol levels up to 11% ($p=0.01$) in a dose- dependent manner. Elevated LDL-cholesterol levels are associated with increased risk of cardiovascular disease and often elevated in NASH patients.
- ***FGF-21.*** TVB-2640 showed a statistically significant increase in FGF-21 levels up to 57% ($p<0.005$) in a dose-dependent manner. Elevated FGF-21 levels are indicative of a protective response to restore insulin sensitivity especially in obese subjects.

Over the course of the clinical trial, we also assessed other laboratory values in the patients as described below:

- ***Tripalmitin.*** TVB-2640 decreased tripalmitin levels up to 40% ($p<0.001$) in a dose-dependent manner. Tripalmitin is a triglyceride in which all three fatty acid chains are palmitate. We believe this reduction reflects the reduction of excess palmitate resulting from the inhibition of FASN.
- ***Total plasma triglycerides***. There were minor elevations of triglyceride levels of 22mg/dL ($p=0.93$) and 13mg/dL ($p=0.77$) in the 25mg and 50mg cohorts, respectively. We believe the lack of dose-dependence suggests that these small, statistically nonsignificant increases were not due to the action of TVB-2640.
- ***Total- and HDL-cholesterol***. TVB-2640 decreased total cholesterol levels up to 5.1% ($p=0.01$) and HDL-cholesterol up to 4.4% ($p<0.005$) in a dose dependent manner. The ratio of total-cholesterol and HDL-cholesterol (4.4-4.6) did not change in any cohort in the clinical trial during 12 weeks of treatment suggesting that the reduction of HDL-cholesterol was indicative of lowered total-cholesterol levels in the blood.

Safety results

TVB-2640 was well-tolerated in the FASCINATE-1 Phase 2a trial, with adverse events that were mostly mild and similar among the cohorts. Safety data were collected from all 99 patients, of whom 68 were treated with TVB-2640. Overall, 62 (63%) patients experienced at least one treatment-emergent adverse event (TEAE), all of which were assessed by the investigator as Grade 1 or mild except one incidence of Grade 2 urinary tract infection and one incidence of increased appetite at 25mg, and one shortness of

breath at 50mg; all three resolved without dose adjustment. No TVB-2640-related serious adverse events occurred in any dose group. Overall, the most common TEAEs, regardless of drug-relatedness, among TVB-2640-treated patients included headache (6 patients; 9%), peripheral edema, rash, and upper respiratory tract infection (four patients; 6%); bronchitis, diarrhea, nausea, and urinary tract infection (three patients; 4%); and hypertriglyceridemia (noted as unrelated to treatment; two patients; 5.7%). Two (3%) patients discontinued TVB-2640 due to a TEAE: (1) mild eye allergy on day two of the clinical trial and (2) mild conjunctivitis; both of these events occurred at the 25mg dose and resolved following discontinuation; no discontinuations for a TEAE were observed in the 50mg dose cohort. These safety results are summarized in the table below:

TEAE classification	Placebo n=31	25mg cohort n=33	50mg cohort n=35
Any TEAE	Gr. 1: 11 (35.5%) Gr. 2: 8 (25.8%)	Gr. 1: 18 (54.5%) Gr. 2: 7 (21.2%)	Gr. 1: 11 (31.4%) Gr. 2: 7 (20.0%)
TEAE leading to drug withdrawal	0	2 (6.1%)	0
Treatment Emergent Serious Adverse	0	0	0
Drug related TEAE	Gr. 1: 3 (9.7%) Gr. 2: 1 (3.2%)	Gr. 1: 10 (30.3%) Gr. 2: 2 (6.1%)	Gr. 1: 9 (25.7%) Gr. 2: 1 (2.9%)
TEAE leading to death	0	0	0

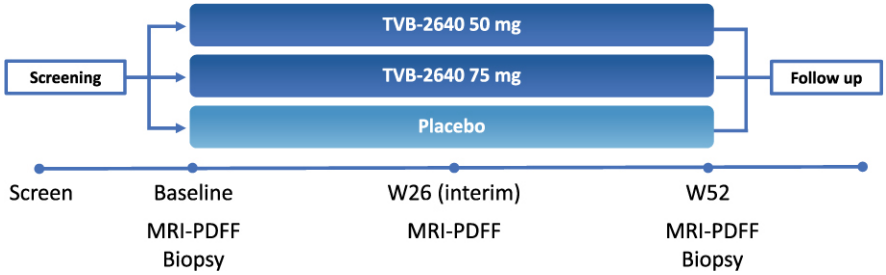
The results from the FASCINATE-1 Phase 2a clinical trial showed that a once-daily, oral dose of TVB-2640 for 12 weeks was well-tolerated and significantly reduced excess liver fat in patients with NASH in a dose-dependent manner. Additionally, these data showed improvements across steatosis, inflammation/ lipotoxicity and fibrosis biomarkers associated with NASH and multiple biomarkers of metabolic health. We believe these results merit further development as a potential treatment for NASH. In the second quarter of 2021, we plan to enroll an open-label cohort in the FASCINATE-1 Phase 2a clinical trial to assess the safety and efficacy in patients treated with 75mg of TVB-2640 for 12 weeks.

Under our license agreement with Ascletis, we are evaluating the profile of TVB-2640 (designated ASC-40 in China) in a small cohort of NASH patients under our FASCINATE-1 protocol in China. We enrolled 30 NASH patients who received either 50mg of ASC-40 or placebo once-daily for 12 weeks. Together with Ascletis, we announced in March 2021 preliminary results showing ASC40 markedly reduced liver fat with a 50% responder rate in patients treated with TVB-2640. ASC40 also demonstrated a statistically significant decrease of ALT by 29.8% (p=0.0499) (mean decrease of 33 U/L at week 12), and in 63% of patients had at least at 17U decrease in ALT. ASC40 was well tolerated with a benign adverse event profile with no serious adverse events, all treatment emergent adverse events Grade 1/2 and no statistically significant changes in serum triglycerides. These results will inform Ascletis' further development of ASC-40 in China, including dosing regimen.

Planned FASCINATE-2 Phase 2b clinical trial in NASH patients

In the second quarter of 2021, we plan to initiate a randomized, placebo-controlled, double-blind Phase 2b clinical trial, designated FASCINATE-2, which is designed to evaluate the impact of TVB-2640 on the liver assessed by biopsy following one year of daily oral treatment. Non- cirrhotic NASH patients with F2-F3 fibrosis, the majority of whom will have a biopsy-confirmed diagnosis, are expected to begin enrolling in FASCINATE-2 in the second quarter of 2021. We plan to enroll approximately 330 NASH patients who will be randomized overall 1:2:2 to receive placebo, 50mg of TVB-2640 or 75mg of TVB-2640 daily for 52 weeks. We expect to initiate dosing of the 75mg dose cohort in FASCINATE-2 following results from the planned 75mg, open-label cohort in our FASCINATE-1 Phase 2a clinical trial. If results from this open-label cohort do not support use of 75mg in our FASCINATE-2 trial, we expect to complete the trial with the 50mg and placebo arms.

FASCINATE-2 Phase 2b clinical trial design



We plan to conduct a formal interim analysis of noninvasive biomarkers and safety once enrollment is completed and a portion of patients have completed 26 weeks of treatment. We expect that the interim analysis will include an assessment of the interim clinical activity. Changes in liver fat between baseline and 26 weeks by MRI-PDFF measurements and MRI-PDFF responder rate will be compared between both dose groups and placebo. We expect that other select serum biomarkers of lipotoxicity/inflammation and fibrosis will be included in this assessment depending on availability at that time.

Following twelve months of therapy, a second liver biopsy will be obtained. A central pathologist who will be unaware of the patients' assignment to TVB-2640 or placebo cohorts will evaluate these biopsies. The results will determine the effect of TVB-2640 on liver fat, inflammation, and fibrosis. Improvement will be measured by the reduction in NAS, targeting a reduction in NAS of at least two points that results from reduction of inflammation/ballooning or improvement in fibrosis. In addition, two other co-primary endpoints will be assessed: (1) ≥2 point improvement in NAS that results from reduction of necro-inflammation (inflammation or ballooning) and (2) improvement in fibrosis. In addition, liver biopsy data will also be evaluated to assess NASH resolution without worsening of fibrosis, and/or improvement in fibrosis without worsening of NASH, both of which are endpoints accepted by the FDA for accelerated approval. Throughout the clinical trial, an Independent Data Monitoring Committee (IDMC) will review the data, to monitor patient safety. We plan to enroll the first patient in FASCINATE-2 in the second quarter of 2021, announce interim results in the second half of 2022 and announce top-line biopsy results in 2023. The results of the FASCINATE-2 clinical trial are intended to inform the design, dose, duration, and size of a pivotal Phase 3 clinical trial of TVB-2640 for the treatment of NASH.

Combination strategy in NASH patients

NASH is a complex, progressive disease influenced by dietary, genetic and environmental factors. The large number of patients combined with disease complexity support the concept that multiple combinations of drugs targeting different mechanisms will be required to effectively manage this large, diverse population. We believe TVB-2640, if successfully developed and approved, has the potential to be a backbone therapy in combination with a broad set of other mechanisms given the design of TVB-2640.

We have explored combinations in preclinical models that we will use to inform the agents to potentially combine with TVB-2640. We have experience with models of human liver microtissues and murine models; these models and others continue to be refined in order to provide information that guides identification of mechanisms and drugs that would exhibit a significant benefit for combination therapy.

We also intend to conduct exploratory clinical trials with relatively short durations to evaluate combinations of TVB-2640 and other complementary mechanisms. These trials will allow us to evaluate potential improvements in noninvasive biomarkers directly in NASH patients and select combinations for further development.

For example, early combination data in humans from a third-party Phase 2 clinical trial evaluating an ACC inhibitor, a mechanism in the DNL pathway related to the potential mechanism of action of TVB-2640, and an FXR agonist, showed improved histology in NASH patients with F4 fibrosis better than either drug on its own. Consistent with earlier studies, these patients also experienced a significant side effect of elevated triglycerides due to the ACC inhibitor. However, we believe these data support exploration

of a combination TVB-2640 with an FXR agonist because TVB-2640 has not been observed to significantly elevate triglycerides in clinical studies.

TVB-2640 in oncology

In addition to NASH, dysregulation of fatty acid metabolism is a hallmark of certain cancers. In our Phase 1 clinical trial, high doses of TVB-2640 achieved human proof-of-concept and a manageable tolerability profile in cancer patients with solid tumors. TVB-2640 demonstrated prolonged stable disease in patients when the drug was used alone and in combination with a taxane. TVB-2640 also demonstrated confirmed partial responses when combined with a taxane, even in patients who had been previously treated with a taxane. In August 2020, positive data were shared in an oral presentation at ESMO from a Phase 2 clinical trial with TVB-2640 and bevacizumab in relapsed GBM, the most aggressive form of astrocytoma, demonstrating an encouraging 65% objective response rate and 47% progression free survival at six months, exceeding those reported for bevacizumab alone. In the second half of 2021, we plan to initiate a randomized, controlled Phase 2 clinical trial for TVB-2640 in GBM and a Phase 1b/2 basket clinical trial in several tumor types that are expected to be sensitive to FASN inhibition.

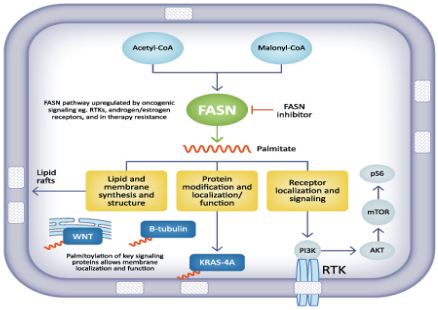
Potential mechanism of action in oncology

Dysregulation of lipid metabolism is a hallmark of cancer. In order to meet the demands of high proliferation in a cellular environment that is often associated with nutrient limitations, many cancer cell oncogenes change cellular metabolism to allow sustained proliferation and growth (referred to as onco-metabolism). Altered lipid metabolism, whereby cancer cells depend on neoplastic DNL, is one such approach and is a hallmark of some cancer types including prostate and breast cancer. Examples of onco-metabolism drugs include ivosidenib and enasidenib that target cells with isocitrate dehydrogenase 1 (IDH1) mutations. We believe that the reliance of some cancer types on DNL for proliferation and/or for resistance to targeted therapies, provides a vulnerability that can be exploited with FASN inhibitors. We are developing FASN inhibitors as an onco-metabolism drug for the treatment of specific subsets of solid tumors either alone or in combination with other classes of oncology drugs.

Most normal cells get their palmitate from dietary sources and do not rely on FASN for palmitate production. Cancer cells however have a rapid proliferation rate and a high requirement of lipids for signaling and membrane synthesis. Many types of cancer cells therefore exploit and rely on DNL as an internal source of fatty acids. Increased expression of FASN has been associated with poor prognosis and reduced survival in several tumor cell types. Several molecular mechanisms by which FASN plays a role in cancer cells have been defined, including the following:

- ***Structural role in membrane lipid synthesis.*** Tumor cells become dependent on FASN and use palmitate to make membrane lipids which are enriched for saturated or mono-unsaturated triglycerides. These membranes are more robust and resistant to oxygen free radicals, which supports proliferation.
- ***Palmitoylation of signaling molecules.*** Palmitate covalently modifies critical oncogenes to allow them to localize in membranes and function properly. This includes oncogenes, such as KRAS4A and Wnt, and essential proteins such as tubulin.
- ***Oncogenic signaling by tyrosine kinase receptors and hormone receptors.*** Multiple oncogenic drivers such as receptor tyrosine kinases and hormone receptors upregulate FASN and stimulate lipogenesis as part of their oncogenic activity. This includes tyrosine kinases such as HER2, androgen receptor and estrogen receptor.
- ***Resistance to cancer therapies.*** The emergence of resistance to cancer therapies is an enormous challenge in the field. It has been recently shown that one strategy cancer cells use for resistance is to upregulate FASN which re-wires lipid metabolism and changes the nature of the tumor cell membrane making these cells resistant to traditional cancer drugs. Use of a FASN inhibitor to normalize metabolism and tumor cell membranes is an appealing strategy to confer susceptibility in combination with a second agent.

We believe this illustrates strong potential for application of FASN inhibitors in cancer therapy. The following diagram depicts the role of FASN in the molecular mechanisms associated with cancer:



Preclinical studies in oncology models

We believe the data from our preclinical studies suggest that our FASN inhibitors have the potential to treat human tumors. The results of these studies are summarized in the following table:

Model	Key Result Observed with Sagimet's FASN Inhibitors
Human banked tumor samples • ***FASN was highly expressed in several tumor types***	• High expression of FASN was observed in human tumor samples
In vitro cell proliferation • ***Broad anti-tumor activity observed*** • ***KRAS mutant lung cancers were more sensitive***	• FASN inhibition induced cell death in over 90 cell lines including lung, breast, prostate and ovarian, but not in normal cells • Non-small cell lung cancer (NSCLC) cell lines with KRAS mutations were more sensitive than KRAS wild-type lines (7/9 and 7/21 showed >50% inhibition of viability respectively)
In vivo mouse xenograft models • ***Decreased tumor cell growth observed with monotherapy*** • ***Increased activity observed in combination with taxanes and bevacizumab***	• Reduced tumor growth in pancreatic cancer (PANC-1) model • Reduced tumor growth in colon adenocarcinoma (COLO-205) • Enhanced anti-tumor activity of taxanes (paclitaxel or docetaxel) in lung, ovarian, prostate, and pancreatic tumor xenografts • Enhanced anti-tumor activity of bevacizumab in rat COLO-205 tumor xenograft model

Our oncology clinical program

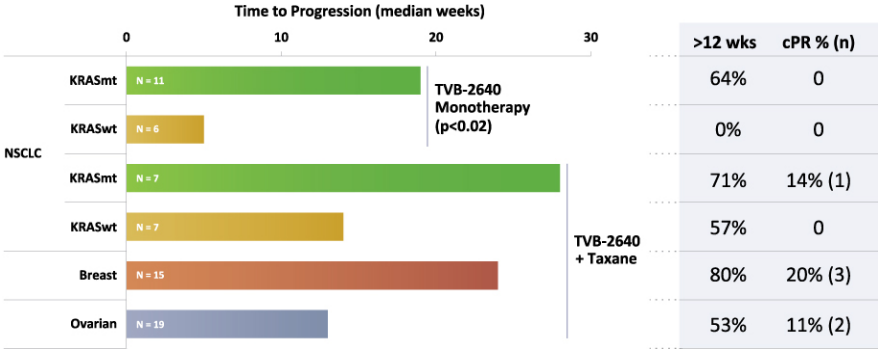
Phase 1 in multiple solid tumors

Based on the potential mechanism of action of TVB-2640 and nonclinical pharmacology results observed in oncology models, we conducted a Phase 1 clinical trial of TVB-2640 in patients with solid tumors. Overall, 136 patients were treated with TVB-2640, 76 treated with TVB-2640 only (monotherapy) and 60 treated in combination with a taxane, a commonly used anti-cancer drugs. In the initial stage of the clinical trial, a typical "3+3" design was used to establish the MTD in patients; this portion of the clinical trial

identified the MTD as 100mg per square meter of body surface area (100mg/m^2) whether TVB-2640 was used alone or in combination. As examples, at this dose level, the average body surface area of 1.7m^2 for adult females and 1.9m^2 for adult males would correspond to daily doses of 150mg and 200mg, respectively, because doses were rounded to the nearest 50mg.

The patients enrolled in this clinical trial had advanced cancers: 90% had Stage IV disease at baseline, 97% had known metastatic disease and the majority (75%) had received three or more prior treatments with other cytotoxic agents. TVB-2640 was dosed daily until disease progression was noted or the patient withdrew for another reason including an adverse event. On average, patients treated with TVB-2640 monotherapy were dosed for 62 days and in combination with paclitaxel for 129 days. TVB-2640 monotherapy treatment resulted in 42% of patients (29/69 evaluable patients) experiencing stable disease, making the disease control rate (DCR) 42%. With TVB-2640+paclitaxel, the confirmed objective partial response (PR) rate was 11% (6/53 evaluable patients), and the DCR was 70% (37/53 evaluable patients). Disease control was observed across multiple tumor types, including breast (100%), NSCLC (82%), and gynecological (ovarian and cervical) (53%). We believe these results are promising in these heavily pretreated, advanced stage patients.

In patients treated with TVB-2640 monotherapy, evaluation of time-to-progression (TTP) among patients with NSCLC revealed notably longer TTP for patients with a mutation in the KRAS gene ($KRAS^{MUT}$) (N=11) compared to those with a normal, or wild-type, KRAS gene ($KRAS^{WT}$) (N=6) (22 weeks versus five weeks; p<0·02). With the combination, median TTP also was longer among NSCLC patients with $KRAS^{MUT}$ disease compared to $KRAS^{WT}$ disease (28 weeks versus 14 weeks, respectively), although this difference was not statistically significant.



In this trial, we established the recommended Phase 2 dose (RP2D) for TVB-2640 in cancer patients was determined to be at 100mg/m^2 of body surface area once a day. The results from this Phase 1 clinical trial identified several other tumor types for that may merit further development, including $KRAS^{MUT}$ non-small cell lung cancer (NSCLC), breast cancer, and ovarian cancer. In addition, we are supporting four investigator-sponsored clinical trials of TVB-2640 in certain cancer patients with the objective to provide early proof-of-concept data that could help guide further development in specific cancer types. Three investigator sponsored clinical trials are ongoing (breast cancer in Phase 2, non-small cell lung cancer with a KRAS mutation in Phase 2, and colorectal cancer in Phase 1b), and a fourth recently presented top-line results at the European Society of Medical Oncology (ESMO) in September 2020. is described below.

As anticipated, based on prior nonclinical toxicology clinical trial findings, the principal toxicities associated with TVB-2640 monotherapy were skin and ocular effects, with most being Grade 1 or 2. Common (i.e., incidence >10%) skin effects included PPE syndrome (46%), dry skin (22%), skin exfoliation (12%), and rash (11%). Ocular effects included dry eye (17%) and increased lacrimation increased (13%). ECG and Holter monitoring data revealed no clinically relevant QTc prolongation effect associated with TVB-2640.

As monotherapy, the most common individual TEAEs were alopecia (61%), PPE syndrome (46%), fatigue (37%), decreased appetite (26%), and dry skin (22%). At the MTD, no >Grade 2 skin or eye toxicities were observed. With TVB-2640 administered in combination with paclitaxel, skin and ocular effects also were common. Most skin events were Grade 1 or 2 in intensity, and all but one skin event were non-serious.

Two dose-limiting toxicities were observed with this combination, including Grade 3 PPE syndrome (n=1) and Grade 2 uveitis (n=1). The most common TEAEs were fatigue (53%), alopecia (46%), PPE syndrome (46%), nausea (40%), and peripheral neuropathy (36%). At the MTD, no >Grade 2 skin or eye toxicities were observed. Six episodes of serious pneumonitis were experienced by 5 patients receiving TVB-2640 and paclitaxel, one of which was fatal, all assessed by the investigator as at least possibly related to both TVB-2640 and paclitaxel. Pneumonitis was not observed in patients treated with TVB-2640 monotherapy. ECG and Holter monitoring data revealed no clinically relevant QTc prolonging effect with TVB-2640.

We believe the skin and ocular side effects observed at relatively high dose levels in this oncology clinical trial (the MTD corresponded to an average dose of 150mg) were due to the inhibition of FASN in sebocytes located in the skin and the meibomian glands of the eye. FASN is a key enzyme in the production of sebum; an analysis of skin sebum in patients in this oncology clinical trial showed that, at these relatively high doses of TVB-2640, sebum production was significantly inhibited, and analysis in several patients showed that sebum production recovered after TVB-2640 treatment was stopped. We believe reducing sebum production led to dry-skin and dry-eye conditions that ultimately resulted in the skin and eye adverse events noted above.

Phase 2 in glioblastoma

The Phase 2 clinical trial in glioblastoma patients (Grade 4 astrocytoma) was recently completed by the sponsor and principal investigator, Dr. Andrew Brenner from the University of Texas, San Antonio. Twenty-five bevacizumab naïve patients in their first relapse were treated with either bevacizumab or TVB-2640 plus bevacizumab for one month. Following this initial safety assessment, all patients continued on the combination therapy until disease progression. 65% of the patients experienced an objective tumor response by Revised Assessment of Neuro-Oncology criteria with 20% achieving a complete response. 47% of the patients had not progressed at month six which was reported by the investigators as significantly better than reported for bevacizumab alone in other studies (p=0.01). Most adverse events observed in this trial were Grade 1 or Grade 2, with PPE as the most frequent. There were four Grade 3 PPE adverse events, and no treatment-related Grade 4-5 adverse events. Four treatment-related serious adverse events were observed — a single occurrence each of deep vein thrombosis, peri-rectal abscess, vomiting and aphasia. These data suggest the potential for TVB-2640 combined with bevacizumab to have a positive impact in GBM patients, a disease of high unmet need.

In the second half of 2021, we plan to evaluate TVB-2640 in a randomized, controlled Phase 2 clinical trial in patients with GBM and in a Phase 1b/2 basket clinical trial in several solid tumors where we believe FASN inhibition may have promising utility. We believe the results of this Phase 1b/2 basket clinical trial will help identify additional tumor types we will pursue for further clinical development.

TVB-3567

We have shown that our FASN inhibitors demonstrated activity in preclinical models of NASH, skin and lung fibrosis, multiple solid tumors, hepatitis C virus infection and respiratory syncytial virus infection. In addition to our lead drug candidate, we are developing a second selective FASN inhibitor designated as TVB-3567. This compound also showed potent FASN inhibitory activity in certain preclinical models including modulation of diacylglycerol metabolism and protein kinase C signaling in cancer models. We have completed preclinical safety studies with TVB-3567 that we believe support an IND submission, including safety pharmacology, genotoxicity and general toxicology studies in rats and dogs. We plan to submit an IND for TVB-3567 and initiate a Phase 1 clinical trial in the second half of 2021 in an indication to be determined.

FASN inhibitors in other diseases

We have also explored other diseases in preclinical models that we believe may respond to FASN inhibitor therapy.

Acne. Acne is another disease area of interest for FASN inhibitors. Excess sebum, produced from lipid synthesis in the skin, is a pro-inflammatory stimulus leading to exacerbation of acne lesions. In two separate Phase 1 clinical trials, we observed that TVB-2640 inhibited FASN in the skin of subjects and

reduced the amount of sebum produced. Sebum reduction is one of the major mechanisms of isotretinoin (formerly branded as Accutane or Roaccutane), which is widely prescribed for acne. However, isotretinoin has significant side-effects including spontaneous abortion, birth defects and depression. We believe this makes acne a viable and potentially addressable market for FASN inhibitors.

Fibrosis diseases. Due to the anti-fibrotic properties resulting from FASN inhibition, we assessed treatment of skin fibrosis in mouse models. The skin of mice was exposed to a damaging chemical agent and then treated with placebo or a FASN inhibitor. Drug-treated mice had significantly less fibrotic scar tissue in the skin than untreated (placebo) mice. We believe these data suggest that the anti-fibrotic mechanism of FASN inhibition can provide benefit even when the fibrosis is not in the liver and not caused by high-fat, high-sugar diets.

Liver diseases. We believe a number of other liver diseases are candidates for further development of a FASN inhibitor. Diseases that may be evaluated either clinically or in preclinical models include liver cirrhosis and steatosis caused by certain chronic therapies. For example, some prospective studies have shown that up to one third of women experienced steatosis during 1 to 3 years of tamoxifen therapy as a maintenance regimen for breast cancer experience steatosis, which we believe can lead to discontinuation of their life-sustaining tamoxifen therapy. One alternative to discontinuing the drug may be to reduce their excess liver fat with a FASN inhibitor.

Viral infections. We believe the results from our preclinical studies suggest that our FASN inhibitors have the potential to treat certain viral infections including hepatitis C, rhinovirus and respiratory syncytial virus.

Discovery—FASN inhibitors

We recognized that the over-activity of FASN may be involved in a number of different human diseases and have discovered and developed specific inhibitors of this enzyme for the express purpose of treating human diseases. The goal of our program was to develop small molecule inhibitors of the enzyme that could be delivered orally for ease of use, requiring no more than two doses daily, and were highly selective for the FASN enzyme in order to avoid unexpected side-effects. Early generation FASN inhibitors developed by others suffered poor potency, off target activity, or suboptimal physiochemical or pharmacokinetic properties; none of these entered clinical development. While early FASN inhibitors functioned as substrate competitors, our inhibitors are designed to target co-factor binding sites and avoid these liabilities. Hundreds of molecules were ultimately designed, synthesized, tested through iterative cycles and several emerged as leading candidates based on their laboratory properties. A few were selected for further characterization leading to the identification of TVB-2640 as the leading candidate for human clinical trials. Our library of FASN inhibitors provides us with the possibility of selecting other compounds for additional indications. For example, we can select a compound from our library with preferred physio-chemical properties for a topical formulation that may be attractive for certain dermatology indications. We selected TVB-2640 out of more than 1,200 compounds within our library of FASN inhibitors.

TVB-2640 is designed to bind to FASN and specifically inhibits one of the enzymatic subdomains (the ß-ketoacyl reductase), ultimately blocking the ability of FASN to make palmitate. TVB-2640 is designed as a reversible inhibitor, meaning that; the compound is designed to be displaced and for FASN to regain its ability to make palmitate. Our preclinical studies have not identified other cellular proteins that bound well to TVB-2640, supporting our belief that this compound is may be highly selective for FASN and is unlikely to interact with unintended proteins or pathways.

Competition

The biopharmaceutical industry is characterized by intense competition and rapid innovation. Accordingly, our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results than our drug candidates. Our competitors include multinational pharmaceutical companies, specialized biotechnology companies and universities and other research institutions, including Akero Therapeutics, Inc., Bristol-Myers Squibb Company, CymaBay Therapeutics, Inc., Enanta Pharmaceuticals, Inc., Galmed Pharmaceuticals Ltd., Gilead Sciences, Inc., Intercept Pharmaceuticals, Inc., Inventiva S.A., Madrigal Pharmaceuticals, Inc., Metacrine, Inc., NGM Biopharmaceuticals, Inc., Novartis

AG, Pfizer Inc., Terns Pharmaceuticals, Inc. and Viking Therapeutics, Inc. Smaller or earlier-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. We believe that the key competitive factors that will affect the development and commercial success of our drug candidates are efficacy, safety and tolerability profile, convenience of dosing, price, the level of generic competition and reimbursement.

TVB-2640 could face competition from other classes individually or in combination, pursuing mechanisms including enzyme-specific inhibitors, gene expression activators, growth factor analogs, and anti-inflammation/anti-fibrotics. Given TVB-2640's potential mechanism of action, and its potential complementary mechanism to other therapies, we believe that TVB-2640 can be used alone or in combination with some of these potential NASH products in development.

License agreement with Ascletis

In January 2019, we entered into an Exclusive License and Development Agreement (the License Agreement) with Ascletis BioScience Co. Ltd. (Ascletis), a subsidiary of Ascletis Pharma Inc., a biotechnology company based in Hangzhou and Shaoxing, China. The License Agreement became effective in February 2019 in connection with the first closing of our Series E financing, which was led by Ascletis through a subsidiary. Under the License Agreement, we granted Ascletis an exclusive, royalty-bearing, sub-licensable license under our know-how and patents to develop, manufacture, and commercialize TVB-2640 and products containing related compounds in the People's Republic of China, Hong Kong, Macau and Taiwan, each referred to as a Region, or collectively as the Territory. We retained certain manufacturing rights and the right to practice our intellectual property in the Territory as necessary to perform our obligations under the License Agreement.

Under the License Agreement, we are solely responsible for conducting all development activities in connection with the Phase 2 global multi-center clinical trial in the United States and the Territory at our sole expense, except for certain in-kind contributions by Ascletis in the Territory. Ascletis is solely responsible at its sole expense for conducting development activities in connection with obtaining and maintaining regulatory approvals for TVB-2640 in the Territory, except we have the right to elect to take responsibility for conducting a Phase 1(c) clinical trial in China and Taiwan in exchange for issuing warrants for shares of our common stock to Ascletis. Ascletis will solely own all regulatory filings and approvals in the Territory other than those regulatory filings jointly applied for in connection with the Phase 2 global multi-center clinical trial. Further, during the term of the License Agreement, each party agreed not to develop, manufacture or commercialize any FASN inhibitors outside the scope of the License Agreement in the Territory.

We are eligible to receive development and commercial milestone payments from Ascletis in aggregate of up to $122 million. We are also eligible to receive from Ascletis tiered royalty payments ranging from high single digit to mid-teen percentages on annual net sales of TVB-2640 and other products containing licensed compounds in the Territory, subject to customary reductions. Ascletis's obligation to pay royalties expires on a product-by-product and region-by-region basis upon the earlier of the expiration of all valid claims covering a product in a region and 10 years following the first commercial sale of a product in a region.

Unless terminated earlier, the License Agreement will continue until the expiration of the last to expire royalty payment obligation. Ascletis has the right to terminate the License Agreement for any reason or no reason upon 90 days' written notice. In addition, either party may terminate the License Agreement upon the other party's uncured material breach, insolvency, or bankruptcy. In the event of early termination for any reason other than by Ascletis for our material breach, Ascletis will transfer all rights to us relating to the products, intellectual property, and regulatory approvals in the Territory, subject to our obligation to pay Ascletis royalties in the low single digit percentages on net sales of any reverted products in the Territory.

In October 2019, we entered into a Patent Assignment Agreement with Ascletis's subsidiary Gannex Pharma Co., Ltd., (Gannex), whereby we assigned to Gannex all our rights, title, and interest in and to all patents and patent applications in China that we previously licensed to Ascletis pursuant to the License Agreement. This assignment did not alter the economic terms under the License Agreement with respect to the assigned patents and patent applications, and we retained such rights under the assigned patents

and patent applications that we had previously retained under the License Agreement. Upon early termination of the License Agreement for any reason other than by Ascletis for our material breach, Gannex will reassign all assigned patents and patent applications in China back to us.

Sales and marketing

We are focused on the discovery and development of our drug candidates. We currently have no sales, marketing or distribution capabilities to commercialize any approved drug candidates. If our drug candidates are approved, we intend either to establish a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our products, or to outsource this function to a third party.

Manufacturing

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We currently rely, and expect to rely, upon third-party contract manufacturing organizations (CMOs) for the manufacture of any drug candidates that we may develop for larger-scale preclinical and clinical testing, as well as for commercial quantities of any drug candidates that are approved. Our contracted CMOs have manufactured several lots, each one yielding several kilograms of drug, and have manufactured the clinical trial materials in both capsule and tablet form.

Intellectual property

We strive to protect the proprietary technologies that we believe are important to our business, including pursuing and maintaining patent protection intended to cover the composition of matter of our drug candidates, for example, TVB-2640 and TVB-3567, their methods of use, related technologies and other inventions that are important to our business. In addition to patent protection, we also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

Our commercial success depends in part upon our ability to obtain and maintain patent and other proprietary protection for our drug candidates and other commercially important technologies, inventions and know-how related to our business, defend and enforce our intellectual property rights, in particular, our patent rights, preserve the confidentiality of our trade secrets and operate without infringing valid and enforceable intellectual property rights of others.

The patent positions for biotechnology and pharmaceutical companies like us are generally uncertain and can involve complex legal, scientific and factual issues. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. In addition, the coverage claimed in a patent application can be significantly reduced before a patent is issued, and its scope can be reinterpreted and even challenged after issuance. As a result, we cannot guarantee that any of our drug candidates will be protected or remain protectable by enforceable patents. Moreover, any patents that we hold may be challenged, circumvented or invalidated by third parties. For more information regarding the risks related to our intellectual property please see “Risk Factors—Risks Related to Our Intellectual Property.”

As of March 5, 2021, we owned ten US patents, 101 issued foreign patents, two pending US patent applications, and 41 pending foreign patent applications.

With regard to TVB-2640, as of March 5, 2021, we owned one issued US patent with composition of matter and pharmaceutical composition claims directed to TVB-2640. The issued US patent is expected to expire in 2032, without taking a potential patent term extension into account. In addition, we have patents that have been granted in various jurisdictions including Australia, Europe, Japan, China, South Korea, and Israel, which are expected to expire in 2032, without taking potential patent term extensions into account, and at least four pending patent applications in various other countries, namely Argentina, Brazil, India, and Venezuela, which, if issued, are expected to expire in 2032, without taking potential patent term extensions into account. We also own two issued US patents with method of use claims directed to TVB-2640 and

combinations of TVB-2640 with additional agents. The issued US patents are expected to expire in 2035 and 2036, without taking a potential patent term extension into account. In addition we have patents with claims directed to methods of using TVB-2640, and methods of using combinations of TVB-2640 with additional agents, in China, Japan, and various countries across Europe, which are expected to expire in 2035 and 2036. We also have at least six pending applications in jurisdictions including China, Canada, Russia, and Korea, which, if issued, are expected to expire in 2035 and 2036, without taking potential patent term extensions into account

With regard to TVB-3567, as of March 5, 2021, we owned one issued US patent with composition of matter and method of use claims directed to TVB-3567. The issued US patent is expected to expire in 2035, without taking a potential patent term extension into account. In addition, we have patents that have been granted in Australia, South Africa, Japan, China, Macau, and Singapore, which are expected to expire in 2035, without taking potential term extensions into account. We also have at least 11 pending patent applications in New Zealand and various countries and regions in North America, Europe, South America, and Asia, which, if issued, are expected to expire in 2035, without taking potential patent term extensions into account.

With respect to claims specifically directed to the treatment of NASH, as of March 5, 2021, we have applications pending in the US, New Zealand, Australia, and various countries and regions in North America, Europe, and Africa, that disclose chemical genera encompassing TVB-2640 and TVB-3567 for the treatment of NASH. Any patents issuing from these applications are expected to expire in 2037, without taking potential patent term extensions into account.

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, the patent term is 20 years from the earliest date of filing a non-provisional patent application.

In the United States, the term of a patent covering an FDA-approved drug may, in certain cases, be eligible for a patent term extension under the Hatch-Waxman Act as compensation for the loss of patent term during the FDA regulatory review process. The period of extension may be up to five years, but 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 and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in Europe and in certain other jurisdictions to extend the term of a patent that covers an approved drug. It is possible that issued US patents covering TVB-2640 and TVB-3567 may be entitled to patent term extensions. If our drug candidates receive FDA approval, we intend to apply for patent term extensions, if available, to extend the term of patents that cover the approved drug candidates. We also intend to seek patent term extensions in any jurisdictions where they are available, however, there is no guarantee that the applicable authorities, including the FDA, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions.

In addition to patent protection, we also rely on trade secret protection for our proprietary information that is not amenable to, or that we do not consider appropriate for, patent protection. However, trade secrets can be difficult to protect. Although we take steps to protect our proprietary information, including restricting access to our premises and our confidential information, as well as entering into agreements with our employees, consultants, advisors and potential collaborators, such individuals may breach such 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, third parties may independently develop the same or similar proprietary information or may otherwise gain access to our proprietary information. As a result, we may be unable to meaningfully protect our trade secrets and proprietary information. For more information regarding the risks related to our intellectual property please see “Risk Factors— Risks Related to Our Intellectual Property.”

Government Regulation and Product Approval

As a pharmaceutical company that operates in the United States, we are subject to extensive regulation. Government authorities in the United States (at the federal, state, and local level) and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, quality

control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing, and export and import of drug products such as those we are developing. 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 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 are addressed in a centralized way, but country-specific regulation remains essential in many respects.

US Drug Development Process

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

- completion of extensive preclinical laboratory tests, preclinical animal studies and formulation studies in accordance with applicable regulations, including the FDA's Good Laboratory Practices (GLP) regulations, and other applicable regulations;
- submission to the FDA of an investigational new drug application (IND), which must become effective before human clinical trials may begin;
- approval by an independent institutional review board (IRB) or ethics committee at each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with applicable regulations, including the FDA's good clinical practices (GCP) regulations to establish the safety and efficacy of the proposed drug for its proposed indication;
- preparation and submission to the FDA of a new drug application (NDA) for a new drug 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 pre-approval inspection of the manufacturing facility or facilities where the drug is produced to assess compliance with the FDA's current cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality, and purity;
- potential FDA audit of the preclinical and/or clinical trial sites that generated the data in support of the NDA to assess compliance with GCP;
- satisfactory completion of an FDA advisory committee review, if applicable; and
- FDA review and approval of the NDA prior to any commercial marketing or sale of the drug in the United States.

Before testing any drug candidate in humans, the drug candidate enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity, and formulation, as well as animal studies, to assess the potential safety and activity of the drug candidate. The conduct of the preclinical tests must comply with federal regulations and requirements, including GLPs. The sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human trials. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the IND on clinical hold within that 30-day time period. In such a case, the

IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a drug candidate at any time before or during clinical trials due to safety concerns or non-compliance.

Clinical trials involve the administration of the drug candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Further, each clinical trial must be reviewed and approved by an IRB or ethics committee, at or servicing each institution at which the clinical trial will be conducted. 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. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial. There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries.

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

- *Phase 1.* The drug candidate is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution, and excretion, the side effects associated with increasing doses and if possible, to gain early evidence of effectiveness. In the case of some products for severe or life-threatening diseases, 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 drug candidate is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases or conditions and to determine dosage tolerance, optimal dosage, and dosing schedule.
- *Phase 3.* The drug candidate is administered to an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall benefit/risk ratio of the product and 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.

In some cases, FDA may require, or sponsors may voluntarily pursue, post-approval studies, or Phase 4 clinical trials, that are 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.

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 as well as 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 drug candidate and, among other things, must develop methods for testing the identity, strength, quality, and purity of the final drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

While the IND is active and before approval, progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events or any finding from tests in laboratory animals that suggests a significant risk for human subjects. The FDA, the IRB, or the sponsor may suspend or terminate 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.

US Review and Approval Processes

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, preclinical 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.

The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. The FDA must make a decision on accepting an NDA for filing within 60 days of receipt. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA.

After the NDA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality, and purity. Under the Prescription Drug User Fee Act (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 does not always meet its PDUFA goal dates for standard and priority NDAs, and the review process is often significantly extended by FDA requests for additional information or clarification.

The FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation, and 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 and typically follows the advisory committee's recommendations.

Before approving an NDA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical sites to assure compliance with GCP requirements. 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 the application, manufacturing process, and manufacturing facilities, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific 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 all of the specific deficiencies in the NDA identified by the FDA. The Complete Response Letter may require additional clinical data and/or (an) additional clinical trial(s), and/or other significant and time-consuming requirements related to clinical trials, preclinical studies, or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings, or precautions be included in the product labeling or may condition the approval of the NDA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post-market studies or clinical trials. For example, the FDA may require Phase 4 testing, which involves clinical trials designed to further assess a drug safety and effectiveness, and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. The FDA may also determine that a REMS is necessary to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without an approved REMS, if required. A REMS 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.

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

Expedited Development and Review Programs

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

A drug candidate intended to treat a serious or life-threatening disease or condition may also be eligible for Breakthrough Therapy designation to expedite its development and review. A drug candidate can receive Breakthrough Therapy designation if preliminary clinical evidence indicates that the drug candidate, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the Fast-Track

program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the drug candidate, including involvement of senior managers.

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

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

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

Accelerated Approval Program

Any NDA submitted to the FDA for approval may be eligible for FDA programs intended to expedite the FDA review and approval process, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition compared to marketed products. For products containing new molecular entities, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (compared with ten months under standard review).

Additionally, products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval (Subpart H and E regulations) upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. In addition, the FDA currently requires, as a condition for accelerated approval, pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

Orphan Drug Designation

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

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug or biological product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity or inability to manufacture the product in sufficient quantities. The designation of such drug also entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan exclusivity also could block the approval of a drug candidate for seven years if a competitor obtains approval of the same drug as defined by the FDA or if such drug candidate is determined to be contained within the competitor's product for the same indication or disease.

A designated orphan drug many not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or, as noted above, if a second applicant demonstrates that its product is clinically superior to the approved product with orphan exclusivity or the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Post-Approval Requirements

Any drug products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things, requirements related to manufacturing, record-keeping, reporting of adverse experiences periodic reporting, product sampling and distribution, and complying with FDA promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting drugs for uses or in patient populations that are not described in the drug's approved labeling (known as "off-label use"), limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the long-term stability of the drug product. We rely, and expect to continue to rely, on third parties for the production of clinical and, if approved, commercial quantities of our drug candidates in accordance with cGMP regulations. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP requirements. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs 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 and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP 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 trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters, or untitled letters;
- clinical holds on clinical trials;
- 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 Healthcare Provider letters, press releases, and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

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

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act (the 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 under the FDCA can also 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 (ANDA) or a 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 also 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 accepting ANDAs or 505(b)(2) NDAs for drugs referencing the approved application for review. 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 all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Orphan drug exclusivity, as described above, may offer a seven-year period of marketing exclusivity, except in certain circumstances. Pediatric exclusivity is another type of non-patent market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

Other US Healthcare Laws and Compliance Requirements

Although we currently do not have any products on the market, we are and, upon approval and commercialization, will be subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. In the United States, such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, price reporting, and healthcare provider sunshine laws and regulations.

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

The federal False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the US government. Several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus non-covered, uses.

In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act.

HIPAA also created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items, or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Additionally, the federal Physician Payments Sunshine Act and its implementing regulations require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program (with certain exceptions) annually report information related to certain payments or other transfers of value made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, certain ownership and investment interests held by such physicians and their immediate family members. Beginning in 2022, such reporting 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, anesthesiologist assistants, and certified nurse midwives.

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

If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any drug candidates for which we or our collaborators obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we or our collaborators receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage, and establish adequate reimbursement levels for such drug products.

In the United States, third-party payors include federal and state healthcare programs, government authorities, private managed care providers, private health insurers, and other organizations. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical drug products and medical services, in addition to questioning their safety and efficacy. Such payors may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the FDA-approved drugs for a particular indication. We or our collaborators may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Nonetheless, our drug candidates may not be considered medically necessary or cost-effective. Moreover, the process for determining whether a third-party payor will provide coverage for a drug product may be separate from the process for setting the price of a drug product or for establishing the reimbursement rate that such a payor will pay for the drug product. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

If we elect to participate in certain governmental programs, we may be required to participate in discount and rebate programs, which may result in prices for our future products that will likely be lower than the prices we might otherwise obtain. For example, drug manufacturers participating under the Medicaid Drug Rebate Program must pay rebates on prescription drugs to state Medicaid programs. Under the Veterans Health Care Act (VHCA) drug companies are required to offer certain drugs at a reduced price to a number of federal agencies, including the US Department of Veterans Affairs and Department of Defense, the Public Health Service and certain private Public Health Service designated entities in order to participate in other federal funding programs, including Medicare and Medicaid. Recent legislative changes require that discounted prices be offered for certain US Department of Defense purchases for its TRICARE program via a rebate system. Participation under the VHCA also requires submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations. If our products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply.

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

The marketability of any drug candidates for which we or our collaborators receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we or our collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare Reform

A primary trend in the US healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products and services, implementing reductions in Medicare

and other healthcare funding and applying new payment methodologies. For example, in March 2010, the Patient Protection and Affordable Care Act (the Affordable Care Act) was enacted, which affected existing government healthcare programs and resulted in the development of new programs.

Among the Affordable Care Act's provisions of importance to the pharmaceutical industry, in addition to those otherwise described above, are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively, and a cap on the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price (AMP);
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals, including individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the Affordable Care Act. For example, the Tax Cuts and Jobs Act of 2017 (the Tax Act) was enacted, which included a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act 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." In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the "Cadillac" tax on high-cost employer-sponsored health coverage and, effective January 1, 2021, also eliminated the health insurer tax. On December 14, 2018, a US District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseverable feature of the Affordable Care Act, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the Affordable Care Act are invalid as well. Additionally, on December 18, 2019, the US Court of Appeals for the 5th Circuit ruled that that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. The US Supreme Court is currently reviewing the case, although it is unknown when a decision will be made. On February 10, 2021, the Biden administration withdrew the federal government's support for overturning the Affordable Care Act. Further, although the US Supreme Court has not yet ruled on the constitutionality of the Affordable Care Act, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. It is unclear how the Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration will impact the Affordable Care Act.

Other legislative changes have also been proposed and adopted in the United States since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and due to subsequent legislative amendments to the statute will remain in effect through 2030, except for a temporary suspension from May 1, 2020 through December 31, 2021, unless additional congressional action is taken. In addition, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several 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.

There has also been heightened governmental scrutiny recently over the manner in which pharmaceutical companies set prices for their marketed products, which has resulted in several Congressional inquiries and proposed federal legislation, as well as state efforts, designed to, among other things, bring more transparency to product pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. As a result, the FDA released a final rule on September 24, 2020, effective November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the US Department of Health & Human Services (HHS) finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which has been delayed until January 1, 2023. On November 20, 2020, the Centers for Medicare & Medicaid Services (CMS) issued an interim final rule implementing the Trump administration's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the US District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Further, it is also possible that additional governmental action is taken in response to the COVID-19 pandemic.

Data Privacy and Security Laws

We may also be subject to federal, state and foreign data privacy and security laws and regulations. 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 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. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, impose requirements relating to the privacy, security and transmission of individually identifiable health information on certain health care providers, health plans and health care clearinghouses, known as covered entities and their business associates that perform certain services that involve creating, receiving, maintaining or transmitting individually identifiable health information for or on behalf of such covered entities as well as their covered subcontractors. Entities that are found to be in violation of HIPAA as the result of, for example, a breach of unsecured protected health information, a

complaint about privacy practices or an audit by 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. Further, entities that knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA may be subject to criminal penalties.

Even when HIPAA does not apply, according to the 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 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, state laws govern the privacy and security of health- related and other personal information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. By way of example, California recently enacted the CPPA, which went into effect on January 1, 2020, and creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling certain personal data of consumers or households. The CCPA requires covered companies to provide new disclosure to consumers about such companies' data collection, use and sharing practices, provide such consumers new ways to opt-out of certain sales or transfers of personal information, and provide consumers with additional causes of action. The CCPA 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 and became enforceable by the California Attorney General as of July 1, 2020. It may increase our compliance costs and potential liability, and many similar laws have been proposed at the federal level and in other states. As currently written, the CCPA may impact our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information. Further, the CPRA recently passed in California. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

We also are or will become subject to privacy laws in the jurisdictions in which we are established or in which we sell or market our products or run clinical trials. In particular, the GDPR will apply where we process personal data in relation to participants in our clinical trials in the European Economic Area (EEA) including the health and medical data of these participants. As noted above, the GDPR, which is directly applicable in EEA Member States, applies to any processing operations carried out in the context of an establishment in the EEA, as well as certain other processing relating to the offering of goods or services to individuals in the EEA and/or the monitoring of their behavior in the EEA. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EU and the United States remains uncertain. For example, in 2016, the EU and United States agreed to a transfer framework for data transferred from the EU to the United States, called the Privacy Shield, but the Privacy Shield was invalidated in July 2020 by the Court of Justice of the European Union.

The introduction of the GDPR creates significant and complex compliance burdens for companies such as (i) limiting permitted processing of personal data to only that which is necessary for specified, explicit and legitimate purposes; (ii) requiring the establishment a legal basis for processing personal data; (iii) expressly confirming that 'pseudonymized' or key-coded data constitutes personal data to which the GDPR applies; (iv) creating obligations for controllers and processors to appoint data protection officers in certain circumstances; (v) increasing transparency obligations to data subjects for controllers (including presentation of certain information in a concise, intelligible and easily accessible form about how their personal data is used and their rights vis-à-vis that data and its use); (vi) introducing the obligation to carry out so-called data protection impact assessments in certain circumstances; (vii) establishing limitations on collection and retention of personal data through 'data minimization' and 'storage limitation' principles;

(viii) establishing obligations to implement 'privacy by design'; (ix) introducing obligations to honor increased rights for data subjects (such as rights for individuals to be 'forgotten,' rights to data portability, rights to object etc. in certain circumstances); (x) formalizing a heightened and codified standard of data subject consent; (xi) establishing obligations to implement certain technical and organizational safeguards to protect the security and confidentiality of personal data; (xii) introducing obligations to agree to certain specific contractual terms and to take certain measures when engaging third-party processors and joint controllers; (xiii) introducing the obligation to provide notice of certain significant personal data breaches to the relevant supervisory authorities and affected individuals; and (xiv) mandating the appointment of representatives in the UK and/or EU and EEA in certain circumstances. The processing of "special category personal data" may also impose heightened compliance burdens under the GDPR and is a topic of active interest among relevant regulators.

The UK GDPR mirrors the fines under the GDPR, i.e., fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, and it is unclear how United Kingdom data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the United Kingdom will be regulated in the long term. These changes will lead to additional costs and increase our overall risk exposure. Currently there is a four to six-month grace period agreed in the EU and United Kingdom Trade and Cooperation Agreement, ending June 30, 2021 at the latest, whilst the parties discuss an adequacy decision. The European Commission published a draft adequacy decision on February 19, 2021. If adopted, the decision will enable data transfers from EU member states to the United Kingdom for a four-year period, subject to subsequent extensions. The GDPR also provides that EEA Member States may make their own further laws and regulations to introduce specific requirements related to the processing of "special categories of personal data", including personal data related to health, biometric data used for unique identification purposes and genetic information; as well as personal data related to criminal offences or convictions—in the UK, the Data Protection Act 2018 complements the UK GDPR in this regard. This fact may lead to greater divergence on the law that applies to the processing of such data types across the EEA and/or UK, compliance with which, as and where applicable, may increase our costs and could increase our overall compliance risk. Such country-specific regulations could also limit our ability to collect, use and share data in the context of our EEA and/or UK operations, and/or could cause our compliance costs to increase, ultimately having an adverse impact on our business and harming our business and financial condition.

The US Foreign Corrupt Practices Act

The US Foreign Corrupt Practices Act of 1977 (FCPA) prohibits any US individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Europe / Rest of World Government Regulation

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. Whether or not we or our potential collaborators obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the EU, for example, a CTA must be submitted to the national health authority and an independent ethics committee in each country in which we intend to conduct clinical trials, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed in that country. Under the new Regulation on Clinical Trials, which is expected to take effect in 2021, there will be a centralized

application procedure in respect of clinical trials to be conducted in the EU where one national authority takes the lead in reviewing the application and the other national authorities have more limited involvement. Any substantial changes to the trial protocol or other information submitted with the clinical trial applications must be notified to or approved by the relevant competent authorities and ethics committees.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of an investigational drug or biological product in the EU, we must submit a marketing authorization application either under the so-called centralized or national authorization procedures.

Centralized procedure. The Centralized Procedure provides for the grant of a single marketing authorization, which is issued by the European Commission based on the opinion of the Committee for Medicinal Products for Human Use (the CHMP) of the EMA and that is valid in all EU member states, as well as Iceland, Liechtenstein and Norway. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicines that contain a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU. Under the Centralized Procedure the maximum timeframe for the evaluation of an MAA is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP). Accelerated evaluation might be granted by the CHMP in exceptional cases, when the authorization of a medicinal product is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. Under the accelerated procedure the standard 210-day review period is reduced to 150 days.

- *National authorization procedures*. There are also two other possible routes to authorize medicinal products in several EU countries, which are available for investigational medicinal products that fall outside the scope of the centralized procedure:
- *Decentralized procedure*. Using the decentralized procedure, an applicant may apply for simultaneous authorizations in more than one EU country of medicinal products that have not yet been authorized in any EU Member State and that do not fall within the mandatory scope of the centralized procedure.
- *Mutual recognition procedure*. In the mutual recognition procedure, a medicine is first authorized in one EU Member State, in accordance with the national procedures of that country. Following this, further marketing authorizations can be sought from other EU countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

In the EEA, upon receiving marketing authorization, new chemical entities generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents regulatory authorities in the EU from referencing the innovator's data to assess a generic application. During the additional two-year period of market exclusivity, a generic marketing authorization can be submitted, and the innovator's data may be referenced, but no generic product can be marketed until the expiration of the market exclusivity. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical entity and qualify for data exclusivity.

The EMA grants orphan drug designation to promote the development of products that may offer therapeutic benefits for life-threatening or chronically debilitating conditions affecting not more than five in 10,000 people in the EU. In addition, orphan drug designation can be granted if the drug is intended for a life threatening, seriously debilitating or serious and chronic condition in the EU and without incentives it is unlikely that sales of the drug in the EU would be sufficient to justify developing the drug. Orphan drug designation is only available if there is no other satisfactory method approved in the EU of diagnosing,

preventing or treating the condition, or if such a method exists, the proposed orphan drug will be of significant benefit to patients. Orphan drug designation provides opportunities for free protocol assistance, fee reductions for access to the centralized regulatory procedures and ten years of market exclusivity following drug approval, which can be extended to 12 years if trials are conducted in accordance with an agreed-upon pediatric investigational plan. The exclusivity period may be reduced to six years if the designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Great Britain (GB) is no longer covered by the EEA's procedures outlined above (Northern Ireland will be covered by the centralized authorization procedure and can be covered under the decentralized or mutual recognition procedures). A separate GB marketing authorization will be required to market drugs in GB. However, for two years from January 1, 2021, the MHRA may adopt decisions taken by the European Commission on the approval of new marketing authorizations through the centralized procedure, and the MHRA will have regard to marketing authorizations approved in a country in the EEA (although in both cases a marketing authorization will only be granted if any GB-specific requirements are met). Various national procedures are now available to place a drug on the market in the UK, GB, or Northern Ireland, with the main national procedure having a maximum timeframe of 150 days (excluding time taken to provide any further information or data required). The data exclusivity periods in the UK are currently in line with those in the EU, but the Trade and Cooperation Agreement provides that the periods for both data and market exclusivity are to be determined by domestic law, so there could be divergence in the future.

Orphan designation in GB following Brexit is essentially identical to the position in the EU but is based on the prevalence of the condition in GB. It is therefore possible that conditions that are currently designated as orphan conditions in GB will no longer be and that conditions that are not currently designated as orphan conditions in the EU will be designated as such in GB.

For other countries outside of the EU, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we or our potential collaborators fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Employees and Human Capital Resources

We have a total of six employees, one of which works on a part-time basis. We have in the past, and may in the future, retain additional expert consultants if required in connection with our plans. We are not a party to any collective bargaining agreements.

We recognize that our continued ability to attract, retain and motivate exceptional employees is vital to ensuring our long-term competitive advantage. Our employees are critical to our long-term success and are essential to helping us meet our goals. Among other things, we support and incentivize our employees in the following ways:

- Talent development, compensation and retention—We strive to provide our employees with a rewarding work environment, including the opportunity for success and a platform for personal and professional development. We provide a competitive benefits package designed to attract and retain a skilled and diverse workforce. We also offer employees a 401(k) plan.
- Health and safety—Employee health and safety in the workplace is one of our core values. One of the ways in which we support the health and safety of our employees includes a generous health insurance program.
- Inclusion and diversity—We are committed to efforts to increase diversity and foster an inclusive work environment that supports our workforce.

Our top priority during the ongoing COVID-19 pandemic remains protecting the health and well-being of our employees, customers, partners and communities. Since the onset of the COVID-19 pandemic, we have maintained a work-from-home policy for all our employees.

Facilities

Our headquarters is currently located in San Mateo, California and consists of approximately 3,000 square feet of office space under a lease that expires June 2022. We believe that our facilities are adequate to meet our current needs.

We are operating virtually to align with local COVID-19 guidelines—which we believe meets our operational needs for the time being as a clinical-stage organization. We plan to reassess our facilities needs on a quarterly basis and anticipate a future lease or flexible arrangement for office-only space.

Legal Proceedings

From time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. However, litigation is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm our business.

We are currently not aware of any legal proceedings to which we are a party or of which any of our property is the subject, nor are we aware of any such proceedings that are contemplated by a government authority.

Regardless of 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.

MANAGEMENT

Executive Officers and Directors

The following table sets forth information regarding our executive officers and directors as of May 10, 2021.

Name	Age	Position
Executive Officers:		
George Kemble, Ph.D.	60	President, Chief Executive Officer and Director
Dennis Hom	45	Chief Financial Officer
Eduardo Bruno Martins, M.D., D.Phil.	58	Chief Medical Officer
Non-Employee Directors:		
Beth Seidenberg, M.D.(1)	64	Chair of the Board of Directors
Elizabeth Grammer, Esq.(3)	57	Director
Merdad Parsey, M.D., Ph.D.(1)	58	Director
Gordon Ringold, Ph.D.(1)	70	Director
Richard Rodgers(1)(2)(3)	54	Director
Jinzi J. Wu, Ph.D.(2)	57	Director
James F. Young, Ph.D.(3)	68	Director

(1) Member of the compensation committee.

(2) Member of the nominating and corporate governance committee.

(3) Member of the audit committee.

Executive officers

George Kemble, Ph.D. has been our chief executive officer and a director since October 2015, in addition to serving as chief scientific officer from August 2011. From 2001 through 2011, he held various leadership positions at MedImmune, a biologics company, including vice president of research & development for vaccines, senior vice president of research for biologics and general manager of the California operations. Early in his career he was a research scientist at Aviron Ltd from 1993 until 2001, focusing on viral vaccine technologies. He received his B.S. in biology from Santa Clara University, a Ph.D. from Stanford University from the department of microbiology & immunology and held a postdoctoral research fellowship at University of California, San Francisco. We believe that Dr. Kemble's experience with scientific programs spanning stages from early research through licensure combined with his leadership of organizations integrating both scientific and business disciplines is important for leadership of this company.

Dennis Hom has been our chief financial officer and head of corporate development since October 2017. From April 2014 until joining us, Mr. Hom was self-employed as a consultant, providing financial advisory services to a number of biotechnology companies, including to us beginning in April 2015. From January 2013 to March 2014, Mr. Hom was vice president, finance and corporate development at Achaogen, Inc., a biopharmaceutical company. From 2011 to 2012, Mr. Hom was executive director, corporate development at Amgen Inc., a biotechnology company. From 2005 to 2011, Mr. Hom held various positions in mergers and acquisitions, business development and licensing and sales at Novartis AG, a pharmaceutical and healthcare products company. Prior to Novartis AG, Mr. Hom worked in investment banking at a number of firms, including at J.P. Morgan Chase & Co. and predecessor firm Hambrecht & Quist. Mr. Hom holds a B.S. in biology from the Massachusetts Institute of Technology.

Eduardo Bruno Martins, M.D., D.Phil. was appointed our chief medical officer in February 2021. In September 2015, Dr. Martins co-founded Bruno Martins Consulting LLC, a boutique consulting firm

that provides scientific advice and services to biotechnology and pharmaceutical companies. Prior to joining us, he served as Vice President of Clinical Development at AbbVie Inc., a biopharmaceutical company, from May 2020 to December 2020. Prior to that, from August 2018 to May 2020, he served as Vice President of Clinical Development—Liver Disease for Allergan, Inc., a biopharmaceutical company. From November 2015 to August 2017, Dr. Martins served as Senior Vice President of Liver and Infectious Disease Drug Development at Eiger BioPharmaceuticals, Inc., a biopharmaceutical company. He also served as Senior Director of Medical Affairs for Hepatitis at Gilead Sciences, Inc., a biopharmaceutical company, from December 2010 to October 2015. Dr. Martins received his medical degree from the Universidade Federal do Rio de Janeiro in Rio de Janeiro, Brazil and his doctor of philosophy (D.Phil.) from the University of Oxford in Oxford, England.

Non-employee directors

Beth Seidenberg, M.D. has served as a member of our board of directors since April 2007. Dr. Seidenberg has been a managing director of Westlake Village BioPartners, a venture capital firm she founded in September 2018, and a general partner at Kleiner Perkins Caufield & Byers, LLC, a venture capital firm, since May 2005, where she has primarily focused on life science investing. Dr. Seidenberg was previously the senior vice president, head of global development and chief medical officer at Amgen Inc., a biotechnology company. In addition, Dr. Seidenberg was a senior executive in research and development at Bristol Myers Squibb Company, a biopharmaceutical company, and Merck & Co., Inc., a healthcare company. Dr. Seidenberg received a B.S. in biology and anthropology from Barnard College and an M.D. from the University of Miami School of Medicine and completed her post-graduate training at Johns Hopkins University, George Washington University and the National Institutes of Health. Dr. Seidenberg serves on the boards of directors of Atara Biotherapeutics, Inc. (Nasdaq: ATRA) and Progyny, Inc. (Nasdaq: PGNY), and several privately held life sciences companies. From February 2008 to September 2019, Dr. Seidenberg served as a director of Epizyme, Inc. (Nasdaq: EPZM). We believe that Dr. Seidenberg is qualified to serve on our board of directors due to her training as a physician and her experience in the life sciences industry as a senior executive and venture capitalist who has incubated and invested in twenty-five biotechnology ventures.

Elizabeth Grammer, Esq., has served as a member of our board of directors since April 2021. Ms. Grammer has served as the Chief Legal and Administrative Officer of Ardelyx, Inc. (Nasdaq: ARDX) since January 2020; the General Counsel since May 2014; and the vice president of legal affairs from December 2012 until May 2014. From 2006 to December 2012, Ms. Grammer served as an independent outside corporate counsel for public and private biotechnology companies. From 2001 to 2006, Ms. Grammer served as Vice President and General Counsel of Trine Pharmaceuticals, Inc., a biopharmaceutical company. In addition, Ms. Grammer previously served as independent outside corporate counsel to GelTex Pharmaceuticals, a biopharmaceutical company. Ms. Grammer received a B.A. from Boston University and a J.D. from Stanford Law School. We believe that Ms. Grammer is qualified to serve on our board of directors due to her extensive experience in pharmaceuticals and law.

Merdad Parsey, M.D. Ph.D. has served as a member of our board of directors since September 2010 and served as chief executive officer of our company from 2015 to 2019. Dr. Parsey has served as executive vice president and Chief Medical Officer at Gilead Sciences, Inc. since 2019. Previously, Dr. Parsey joined Genentech, Inc. in 2006 initially leading the respiratory group and subsequently overseeing early clinical development for the immunology, tissue growth and repair portfolio in 2008. From 2015 to 2019, Dr. Parsey served as senior vice president of early clinical development at Genentech, Inc. Dr. Parsey received his B.S. in microbiology and immunology at the University of Maryland, his M.D. and Ph.D. in immunology at the University of Maryland at Baltimore. He completed his internal medicine residency at Stanford University and his pulmonary and critical care fellowship at the University of Colorado. He was director of critical care medicine at the NYU School of Medicine and has been in clinical development roles at Merck & Co., Inc., Regeneron and Sepracor. We believe Dr. Parsey is well-suited to serve on our board due to his years of experience in clinical drug development, medical practice and extensive scientific experience.

Gordon Ringold, Ph.D. has served as a member of our board of directors since March 2009. Dr. Ringold has served as the president and chief executive officer of Quadriga BioSciences, Inc., a biotechnology company, since January 2015. From March 2000 to December 2013, Dr. Ringold served as chairman and chief executive officer of Alavita, Inc., a biotechnology company. From June 2001 until

September 2016, Dr. Ringold served as a director of Alexza Pharmaceuticals, Inc. (Nasdaq: ALXA). From 1997 to 2013, Dr. Ringold served as a member of the board of directors of Maxygen, Inc., formerly a publicly-traded biopharmaceutical company. Dr. Ringold received a Ph.D. in microbiology from University of California, San Francisco, in the laboratory of Dr. Harold Varmus before joining the Stanford University School of Medicine, department of pharmacology. Dr. Ringold also received a B.S. in biology from the University of California, Santa Cruz. We believe that Dr. Ringold is qualified to serve on our board of directors due to his significant life science industry experience, including as a chief executive officer, and service on other boards of directors of publicly-traded life sciences companies.

Richard Rodgers has served as a member of our board of directors since March 2015. Mr. Rodgers cofounded Tesaro, Inc., a pharmaceutical company, and served as its executive vice president, chief financial officer, secretary and treasurer from March 2010 until August 2013. Mr. Rodgers previously served as the chief financial officer of Abraxis BioScience, Inc., a biotechnology company, from June 2009 to February 2010. Prior to that, Mr. Rodgers served as senior vice president, controller and chief accounting officer of MGI PHARMA, Inc., a biopharmaceutical company, from 2004 until its acquisition by Eisai Co. Ltd., a pharmaceutical company, in January 2008. Mr. Rodgers has held finance and accounting positions at several private and public companies, including Arthur Anderson & Co. Mr. Rodgers currently serves on the board of directors of Ardelyx, Inc. (Nasdaq: ARDX) and Ocuphire Pharma, Inc. (Nasdaq: OCUP). Mr. Rodgers received a B.S. in financial accounting from St. Cloud State University and his M.B.A. in finance from the University of Minnesota, Carlson School of Business. We believe that Mr. Rodgers is qualified to serve on our board of directors due to his financial background, significant industry experience, and service on other boards of directors of publicly-traded life sciences companies.

Jinzi J. Wu, Ph.D. has served as a member of our board of directors since February 2019. In 2013, Dr. Wu founded Ascletis BioScience Co., Ltd. a pharmaceutical company, where he has served as president and chief executive officer since founding. In 2011, he co-founded Ascletis Pharmaceuticals (Hangzhou) Co., Ltd. a pharmaceutical company, where he has served as chief executive officer since 2011. From June 2008 to February 2011, Dr. Wu served as a vice president of the HIV drug discovery performance unit in the United States of GlaxoSmithKline plc. From June 2004 to June 2008, Dr. Wu served as a vice president of pre-clinical and basic research at Ambrilia (formerly known as Procyon), a global biotech company headquartered in Montreal Canada, where he was mainly responsible for overseeing research and development in areas of anti-viral and anti-cancer drugs. From 2002 to 2004, Dr. Wu served at PhageTech Inc., an antibiotic discovery company, as a vice president of research and development. Dr. Wu also worked at Immunex Corporation as a group leader of small molecule drug discovery in 2002 prior to joining PhageTech Inc. Dr. Wu received his bachelor's degree in physiology from Nanjing University in the People's Republic of China, his master's degree in physiology from Nanjing University and his Ph.D. in cancer biology from University of Arizona. We believe that Dr. Wu is qualified to serve as a director due to his more than 17 years of experience in pharmaceutical research and development.

James F. Young, Ph.D. has served as a member of our board of directors since June 2010. Dr. Young has been chairman of the board of Novavax, Inc. (Nasdaq: NVAX) since April 2011 and a director since April 2010. Dr. Young has served as the chairman of the board and chief executive officer of Targeted Microwave Solutions, Inc. (TSXV: TMS) from 2013 until 2016 and chief executive officer from 2016 until 2018. Dr. Young held the position of president, research and development, at MedImmune, a biopharmaceutical company, from 2000 until 2008 and previously served as executive vice president, research and development from 1999 to 2000, Senior Vice President from 1995 to 1999, and as vice president, research and development from 1989 to 1995. Dr. Young received B.S. degrees in general science and biology from Villanova University, as well as a Ph.D. in microbiology and immunology from Baylor College of Medicine. We believe that Dr. Young is qualified to serve on our board of directors due to his years of experience in the fields of molecular genetics, microbiology, immunology, and pharmaceutical development.

Family relationships

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

Composition of our board of directors

Our business and affairs are managed under the direction of our board of directors, which currently consists of eight members. The primary responsibilities of our board of directors are to provide

oversight, strategic guidance, counseling and direction to our management. Our board of directors meets on a regular basis and additionally as required.

Certain members of our board of directors were elected under the provisions of our Amended and Restated Voting Agreement we entered into in December 2020 (the Voting Agreement) which will terminate upon the closing of this offering. Under the terms of our Voting Agreement, the stockholders who are party to the Voting Agreement have agreed to vote their respective shares to elect: (i) one director designated KPCB Holdings, Inc., currently Dr. Seidenberg; (ii) two directors designated New Enterprise Associates 13, Limited Partnership, currently vacant; (iii) one director designated by AP11 Limited, currently Dr. Jinzi Wu; (iv) one director designated by Baker Brothers Life Sciences, L.P. and 667, L.P., currently vacant; (v) one director designated by the holders of our common stock, who shall be our then-current Chief Executive Officer, currently Dr. Kemble; and (vi) three directors designated by a majority of the holders of preferred stock and common stock, voting together as a single class (on an as-converted to common stock basis), currently Dr. Ringold, Mr. Rodgers and Dr. Young. The Voting Agreement will terminate upon the closing of this offering, and upon the closing of the offering no stockholder will have any special rights regarding the election or designation of the members of our board of directors. Our current directors elected to our board of directors pursuant to the Voting Agreement will continue to serve as directors until their successors are duly elected and qualified by holders of our common stock.

On April 15, 2021, we entered into an amended and restated nominating agreement (the Baker Brothers Nominating Agreement), with Baker Brothers Life Sciences L.P. and 667, L.P. (together, Baker Brothers). Pursuant to the Baker Brothers Nominating Agreement, during the period beginning on the 91st day following the date of effectiveness of the registration statement of which this prospectus is a part, at any time at which Baker Brothers, together with its affiliates, collectively beneficially own (i) at least 115,207,373 shares of our Class A common stock and Class B common stock, and (ii) at least 4.9% of our then-outstanding voting common stock (such period, the Nominating Agreement Period), we will have the obligation to support the nomination of, and to cause our board of directors to include in the slate of nominees recommended to our stockholders for election, one individual designated by Baker Brothers (the Baker Designee) unless a majority of our disinterested directors reasonably and in good faith determines that a Baker Designee would not be qualified to serve as our director under law, rules of the stock exchange on which our shares are listed, or our amended and restated bylaws. If a Baker Designee resigns his or her seat on our board of directors or is removed or does not become a director for any reason, the vacancy will be filled by the election or appointment of another designee of Baker Brothers as soon as reasonably practicable, subject to compliance with applicable laws, rules and regulations. Furthermore, during the Nominating Agreement Period, if there is no Baker Designee on our board of directors, we will have the obligation to invite one board of directors observer designee of Baker Brothers (the Baker Observer) to attend all meetings of our board of directors and all meetings of the committees of our board of directors as a nonvoting observer, subject to the Baker Observer's agreement to hold in confidence the information they receive as observers of our board of directors and committee meetings, as well as subject to their exclusion from our board of directors meetings to preserve our attorney-client privilege, to avoid conflicts of interest, if Baker Brothers is determined by our board of directors to be a competitor, or other customary conditions. The Baker Brothers Nominating Agreement automatically terminates upon the earliest of (i) such time when Baker Brothers together with its affiliates no longer beneficially own at least 115,207,373 shares of our Class A common stock and Class B common stock, (ii) the third anniversary of this offering, or (iii) the consummation of a liquidation as such terms are defined in our amended and restated certificate of incorporation.

Our amended and restated certificate of incorporation and amended and restated bylaws to become effective upon the closing of this offering will permit our board of directors to establish the authorized number of directors from time to time by resolution. Each director serves until the expiration of the term for which such director was elected or appointed, or until such director's earlier death, resignation or removal. In accordance with our amended and restated certificate of incorporation that will be in effect upon the closing of this offering, our board of directors will be divided into three classes with staggered three-year terms. At each annual 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 will be divided among the three classes as follows:

- the Class I directors will be Gordon Ringold, Ph.D., Beth Seidenberg, M.D., and James Young, Ph.D., and their terms will expire at our first annual meeting of stockholders following this offering, to be held in 2022;
- the Class II directors will be Elizabeth Grammer, Esq., Merdad Parsey, M.D., Ph.D., and Jinzi Wu, Ph.D., and their terms will expire at our second annual meeting of stockholders following this offering, to be held in 2023; and
- the Class III directors will be George Kemble, Ph.D. and Richard Rodgers, and their terms will expire at our third annual meeting of stockholders following this offering, to be held in 2024.

We expect that any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one third of the directors. 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.

Director independence

Under the listing standards, requirements and rules of The Nasdaq Stock Market LLC (the Nasdaq Listing Rules) independent directors must comprise a majority of our board of directors as a listed company within one year of the listing date.

Our board of directors has undertaken a review of the independence of each director. Based on information provided by each director concerning her or his background, employment and affiliations, including family relationships, our board of directors has determined that Beth Seidenberg, M.D., Gordon Ringold, Ph.D., James Young, Ph.D., Jinzi Wu, Ph.D., Merdad Parsey, M.D., Ph.D., Elizabeth Grammer, Esq., and Richard Rodgers do not have relationships that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the Nasdaq Listing Rules. Our board of directors has determined that Dr. Kemble, by virtue of his position as our Chief Executive Officer, is not independent under applicable rules and regulations of the US Securities and Exchange Commission (the SEC) and the Nasdaq Listing Rules. In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our shares by each non-employee director and the transactions described in the section titled "Certain Relationships and Related Person Transactions."

Board leadership structure and board's role in risk oversight

Dr. Seidenberg is the current chair of our board of directors and Dr. Kemble is our current chief executive officer, hence the roles of chairman of our board of directors and chief executive officer are separated. We believe that separating these positions allows our chief executive officer to focus on our day-to-day business, while allowing the chair of our board to lead the board of directors in its fundamental role of providing advice to and independent oversight of management. Our board of directors recognizes the time, effort and energy that the chief executive officer is required to devote to his position in the current business environment, as well as the commitment required to serve as our chair of our board of directors, particularly as the board of directors' oversight responsibilities continue to grow. While our amended and restated bylaws and corporate governance guidelines do not require that our the chair of our board and chief executive officer positions be separate, our board of directors believes that having separate positions is the appropriate leadership structure for us at this time and demonstrates our commitment to good corporate governance.

Risk is inherent with every business, and how well a business manages risk can ultimately determine its success. We face a number of risks, including risks relating to our financial condition, development and commercialization activities, operations, strategic direction and intellectual property as more fully discussed in the section titled "Risk Factors" appearing elsewhere in this prospectus. Management is responsible for the day-to-day management of risks we face, while our board of directors, as a whole and through its committees, has responsibility for the oversight of risk management. In its risk oversight role, our board of

directors has the responsibility to satisfy itself that the risk management processes designed and implemented by management are adequate and functioning as designed.

The role of the board of directors in overseeing the management of our risks is conducted primarily through committees of the board of directors, as disclosed in the descriptions of each of the committees below and in the charters of each of the committees. The full board of directors (or the appropriate board committee in the case of risks that are under the purview of a particular committee) discusses with management our major risk exposures, their potential impact on us, and the steps we take to manage them. When a board committee is responsible for evaluating and overseeing the management of a particular risk or risks, the chairperson of the relevant committee reports on the discussion to the full board of directors during the committee reports portion of the next board meeting. This enables the board of directors and its committees to coordinate the risk oversight role, particularly with respect to risk interrelationships.

Committees of our board of directors

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee. The composition and responsibilities of each of the committees of our board of directors are described below. Members serve on these committees until their resignation or until otherwise determined by our board of directors. Each committee intends to adopt a written charter that satisfies the application rules and regulation of the SEC and the Nasdaq Listing Rules, which we will post to our website at sagimet.com upon the closing of this offering. Our board of directors may establish other committees as it deems necessary or appropriate from time to time.

Audit committee

Our audit committee currently consists of Richard Rodgers, Elizabeth Grammer, Esq, and James Young, Ph.D., each of whom our board of directors has determined satisfies the independence requirements under Nasdaq Listing Rules and Rule 10A-3(b)(1) of the Securities Exchange Act of 1934, as amended (the Exchange Act). We intend to comply with the listing requirement of Nasdaq regarding the composition of our audit committee within the transition period for newly public companies. The chair of our audit committee is Richard Rodgers, who our board of directors has determined is an “audit committee financial expert” within the meaning of SEC regulations. Each member of our audit committee can read and understand fundamental financial statements in accordance with applicable requirements. In arriving at these determinations, our board of directors has examined each audit committee member’s scope of experience and the nature of their employment in the corporate finance sector.

The primary purpose of the audit committee is to discharge the responsibilities of our board of directors with respect to our corporate accounting and financial reporting processes, systems of internal control and financial-statement audits, and to oversee our independent registered public accounting firm. Specific responsibilities of our audit committee include:

- helping our board of directors oversee our corporate accounting and financial reporting processes;
- managing the selection, engagement, qualifications, independence and performance of a qualified firm to serve as the independent registered public accounting firm to audit our financial statements;
- discussing the scope and results of the audit with the independent registered public accounting firm, and reviewing, with management and the independent accountants, our interim and year-end operating results;
- developing procedures for employees to submit concerns anonymously about questionable accounting or audit matters;
- reviewing related person transactions;
- establishing insurance coverage for the company’s officers and directors;

- overseeing the preparation of the company's annual proxy statement, reviewing with management the company's financial statements to be included the company's quarterly reports to be filed with the SEC, and reviewing with management the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosures in the company's periodic reports filed with the SEC;
- obtaining and reviewing a report by the independent registered public accounting firm at least annually, that describes our internal quality control procedures, any material issues with such procedures, and any steps taken to deal with such issues when required by applicable law; and
- approving, or, as permitted, pre-approving, audit and permissible non-audit services to be performed by the independent registered public accounting firm.

Our audit committee will operate under a written charter, which will be effective upon the completion of this offering, that satisfies the applicable Nasdaq Listing Rules.

Compensation committee

Our compensation committee currently consists of Beth Seidenberg, M.D., Gordon Ringold, Richard Rodgers and Merdad Parsey. The chair of our compensation committee is Beth Seidenberg, M.D. Our board of directors has determined that each member of the compensation committee is independent under the Nasdaq Listing Rules and as a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act.

The primary purpose of our compensation committee is to discharge the responsibilities of our board of directors in overseeing our compensation policies, plans and programs and to review and determine the compensation to be paid to our executive officers, directors and other senior management, as appropriate. Specific responsibilities of our compensation committee include:

- reviewing and approving the compensation of our chief executive officer, other executive officers and senior management;
- reviewing and recommending to our board of directors the compensation paid to our directors;
- reviewing and approving the compensation arrangements with our executive officers and other senior management;
- administering our equity incentive plans and other benefit programs;
- reviewing, adopting, amending and terminating, incentive compensation and equity plans, severance agreements, profit sharing plans, bonus plans, change-of-control protections and any other compensatory arrangements for our executive officers and other senior management;
- reviewing, evaluating and recommending to our board of directors succession plans for our executive officers; and
- reviewing and establishing general policies relating to compensation and benefits of our employees, including our overall compensation philosophy.

Our compensation committee will operate under a written charter, which will be effective upon the completion of this offering, that satisfies the applicable Nasdaq Listing Rules.

Nominating and corporate governance committee

Our nominating and corporate governance committee currently consists of Gordon Ringold, Ph.D. and Jinzi Wu, Ph.D.. The chair of our nominating and corporate governance committee is Gordon Ringold, Ph.D. Our board of directors has determined that each member of the nominating and corporate governance committee is independent under the Nasdaq Listing Rules, a non-employee director, and free from any relationship that would interfere with the exercise of his or her independent judgment.

Specific responsibilities of our nominating and corporate governance committee include:

- identifying and evaluating candidates, including the nomination of incumbent directors for reelection and nominees recommended by stockholders, to serve on our board of directors;
- considering and making recommendations to our board of directors regarding the composition and chairmanship of the committees of our board of directors;
- instituting plans or programs for the continuing education of our board of directors and orientation of new directors;
- developing and making recommendations to our board of directors regarding corporate governance guidelines and matters; and
- overseeing periodic evaluations of the board of directors' performance, including committees of the board of directors and management.

Our nominating and corporate governance committee will operate under a written charter, which will be effective upon the completion of this offering, that satisfies the applicable Nasdaq Listing Rules.

Code of business conduct and ethics

In connection with this offering, we intend to adopt a written Code of Business Conduct and Ethics that applies to all our employees, officers and directors. This includes our principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions. The full text of our Code of Business Conduct and Ethics will be posted on our website at sagimet.com. We intend to disclose on our website any future amendments of our Code of Business Conduct and Ethics or waivers that exempt any principal executive officer, principal financial officer, principal accounting officer or controller, persons performing similar functions or our directors from provisions in the Code of Business Conduct and Ethics. Information contained on, or accessible through, our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is only an inactive textual reference.

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 officers or employees. None of our officers currently serves, or has served during the last calendar 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 compensation committee.

Non-employee director compensation

The following table sets forth information regarding the compensation earned by or paid to our directors during the year ended December 31, 2020, other than George Kemble, our President and Chief Executive Officer, who is also a member of our board of directors but did not receive any additional compensation for service as a director. The compensation of Dr. Kemble as a named executive officer is set forth below in the subsection titled "Executive Compensation—Summary compensation table."

2020 Director Compensation

Name	Fees Earned or Paid in Cash ($)	Total ($)
Beth Seidenberg, M.D.	$ —	$ —
Xufang Duan, M.D., Ph.D.	—	—
Jason Fuller, Ph.D.	—	—
Merdad Parsey, M.D., Ph.D.	40,000	40,000
Gordon Ringold, Ph.D.	40,000	40,000

Name	Fees Earned or Paid in Cash ($)	Total ($)
Richard Rodgers	40,000	40,000
James F. Young, Ph.D.	40,000	40,000
Jinzi J. Wu, Ph.D.	—	—

In addition, we have reimbursed and will continue to reimburse all of our non-employee directors for their reasonable out-of-pocket expenses incurred in attending board of directors and committee meetings.

We intend to approve and implement a compensation policy for our non-employee directors, to be effective in connection with the consummation of this offering.

EXECUTIVE COMPENSATION

Our named executive officers for the year ended December 31, 2020, consisting of our principal executive officer and the next two most highly compensated executive officers, were:

- George Kemble, Ph.D., President, Chief Executive Officer and Director
- Dennis Hom, Chief Financial Officer
- William McCulloch, M.B., Ch.B., FRCP, FFPM, Former Chief Medical Officer

Summary compensation table

The following table presents all the compensation awarded to or earned by or paid to our named executive officers during the fiscal year ended December 31, 2020.

Name and Principal Position	Fiscal Year	Salary ($)	Bonus ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	All Other Compensation ($)	Total ($)
George Kemble, Ph.D. *President and Chief Executive Officer*	2020	435,000	185,963	—	—	678	621,641
Dennis Hom *Chief Financial Officer*	2020	330,000	109,725	—	—	678	440,403
William McCulloch, M.B., Ch.B., FRCP, FFPM[(1)] *Former Chief Medical Officer*	2020	185,000	61,513	—	—	678	247,191

(1) Dr. McCulloch retired from his position as Chief Medical Officer in February 2021.

Narrative to the summary compensation table

Our board of directors reviews compensation annually for all employees, including our named executive officers. In making compensation determinations, we consider compensation for comparable positions in the market, the historical compensation levels of our executives, individual performance as compared to our expectations and objectives, our desire to motivate our employees to achieve short- and long-term results that are in the best interests of our stockholders and a long-term commitment to our company.

Our board of directors has historically determined our executive officers' compensation and has typically reviewed and discussed management's proposed compensation with our chief executive officer for all executives other than our chief executive officer. Based on those discussions and its discretion, our board of directors then approved the compensation of each executive officer. Upon the closing of this offering, the compensation committee will determine our executive officers' compensation and follow this process, but generally the compensation committee itself, rather than our board of directors, will approve the compensation of each executive officer.

Annual base salary

Base salaries for our executive officers are initially established through arm's-length negotiations at the time of the executive officer's hiring, taking into account such executive officer's qualifications, experience, the scope of his or her responsibilities and competitive market compensation paid by other companies for similar positions within the industry and geography. Base salaries are reviewed periodically, typically in connection with our annual performance review process, and adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance and experience. In making decisions regarding salary increases, we may also draw upon the experience of members of our board of directors with executives at other companies. The 2020 annual base salaries for our named executive officers are set forth in the table below.

Name	2020 Base Salary
George Kemble, Ph.D.	$435,000
Dennis Hom	$330,000
William McCulloch, M.B., Ch.B., FRCP, FFPM[1]	$185,000

(1) Dr. McCulloch retired from his position as Chief Medical Officer in February 2021.

Outstanding equity awards as of December 31, 2020

The following table presents the outstanding equity incentive plan awards held by each named executive officer as of December 31, 2020.

	Option Awards(1)					Stock Awards	
Name	Grant Date	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price Per Share ($)[2]	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)[3]
George Kemble, Ph.D.	8/25/11[4]	86,133	—	1.70	8/24/21	—	—
	2/9/12[4]	530,669	—	0.15	2/8/22	—	—
	9/27/13[4]	447,477	—	0.01	9/26/23	—	—
	3/13/14[4]	252,714	—	0.14	3/12/24	—	—
	12/17/14[4]	568,063	—	0.29	12/16/24	—	—
	10/13/15[4]	2,094,507	—	0.25	10/12/25	—	—
	4/28/19[5]	24,970,795	4,263,307	0.08	4/27/29	—	—
	4/28/19[6]	922,602	2,767,805	0.08	4/27/29	—	—
Dennis Hom.	4/28/19[5]	7,565,335	1,291,642	0.08	4/27/29	—	—
	4/28/19[6]	184,520	553,561	0.08	4/27/29	—	—
William McCulloch, M.B., Ch.B., FRCP, FFPM[7]	12/4/13[4]	100,000	—	0.01	12/3/23[4]	—	—
	2/20/14[4]	20,000	—	0.14	2/19/24[4]	—	—
	12/17/14[4]	257,011	—	0.29	12/16/24[4]	—	—
	10/13/15[4]	146,256	—	0.25	10/12/25[4]	—	—
	11/5/15[4]	315,172	—	0.25	11/4/25[4]	—	—
	4/28/19[5]	2,751,279	469,730	0.08	4/27/29[5]	—	—
	4/28/19[6]	92,260	276,781	0.08	4/27/29[6]		

(1) All of the option and stock awards were granted under either the 2007 Plan or the 2017 Plan, the terms of which plan are described below under the sections titled “Executive Compensation—Equity benefit plans—2007 equity incentive plan” and “Executive Compensation—Equity benefit plans—2017 equity incentive plan.”

(2) All of the option awards were granted with a per share exercise price equal to the fair market value of one share of our Class A common stock on the date of grant, as determined in good faith by our board of directors or compensation committee.

(3) This column represents the fair market value of a share of our Class A common stock of $0.25 as of December 31, 2020 (the determination of the fair market value by our board of directors as of the most proximate date) multiplied by the amount shown in the column "Stock Awards—Number of Shares or Units of Stock That Have Not Vested (#)".

(4) 25% of the total shares subject to this option will vest one year after the vesting commencement date and 1/48th of the shares subject to this option will vest monthly thereafter subject to continued service to us through the applicable vesting date. If applicable, vesting accelerates as provided in, and subject to the terms and conditions of, that executive employment agreement, as may be amended from time to time.

(5) 50% of the total shares subject to this option will vest upon the vesting commencement date and 1/24th of the shares subject to this option will vest monthly thereafter subject to continued service to us through the applicable vesting date. If applicable, vesting accelerates as provided in, and subject to the terms and conditions of, that executive employment agreement, as may be amended from time to time.

(6) 1/24th of the shares subject to this option will vest monthly following the vesting commencement date, subject to continued service to us through the applicable vesting date. If applicable, vesting accelerates as provided in, and subject to the terms and conditions of, that executive employment agreement, as may be amended from time to time.

(7) Dr. McCulloch retired from his position as Chief Medical Officer in February 2021.

Options held by certain of our named executive officers are eligible for accelerated vesting under specified circumstances. Please see the subsection titled "Executive Compensation—Employment, severance and change in control agreements" below for a description of such potential acceleration.

Pension benefits

Our named executive officers did not participate in, or otherwise receive any benefits under, any pension or retirement plan sponsored by us during the fiscal year ended December 31, 2020.

Nonqualified deferred compensation

We do not maintain nonqualified defined contribution plans or other nonqualified deferred compensation plans. Our board of directors may elect to provide our officers and other employees with nonqualified defined contribution or other nonqualified deferred compensation benefits in the future if it determines that doing so is in our best interests.

Employment, severance and change in control agreements

Offer letters

Below are descriptions of our offer letters with our named executive officers. For a discussion of the severance pay and other benefits to be provided in connection with a termination of employment and/or a change in control under the arrangements with our named executive officers, please see the section titled "Executive Compensation—Potential Payments and Benefits Upon Termination or Change in Control" below.

Dr. Kemble. In June 2011, we entered into an offer letter with Dr. Kemble that governs the current terms of Dr. Kemble's employment with us. Pursuant to the agreement, Dr. Kemble is entitled to an initial annual base salary of $310,000, is eligible to receive an annual performance bonus with a target achievement of 30% of his base salary, as determined by our board of directors, and was granted an option to purchase 861,336 shares of our Class A common stock at an exercise price based on the fair market value on the date of grant. Dr. Kemble is also entitled to certain severance benefits, the terms of which are described below under the section titled "Potential payments and benefits upon termination or change of control." Dr. Kemble's employment is at-will.

Mr. Hom. In January 2019, we entered into an amended and restated offer letter with Mr. Hom that governs the current terms of Mr. Hom's employment with us. Pursuant to the agreement, Mr. Hom is entitled to an initial annual base salary of $315,000, is eligible to receive an annual performance bonus with a

target achievement of 30% of his base salary, as determined by our board of directors, and was granted an option to purchase 8,856,977 shares of our Class A common stock at an exercise price based on the fair market value on the date of grant. Mr. Hom is also entitled to certain severance benefits, the terms of which are described below under the section titled "Potential payments and benefits upon termination or change of control." Mr. Hom's employment is at-will.

Dr. McCulloch. In October 2013, we entered into an offer letter with Dr. McCulloch that governed the terms of Dr. McCulloch's prior employment with us. Dr. McCulloch retired in February 2021. Pursuant to the agreement, Dr. McCulloch was entitled to an initial annual base salary of $80,000 and was eligible to receive an annual performance bonus with a target achievement of 20% of his base salary, as determined by our board of directors. He was granted an option to purchase 100,000 shares of our Class A common stock at an exercise price based on the fair market value on the date of grant. Dr. McCulloch is also entitled to certain severance benefits, the terms of which are described below under the section titled "Potential payments and benefits upon termination or change of control." Dr. McCulloch's employment is at will.

Potential payments and benefits upon termination or change of control

Dr. Kemble. Pursuant to Dr. Kemble's offer letter, if his employment is terminated without cause (as defined below), and other than as a result of his death or disability, then in addition to any amounts accrued and payable under the terms of our benefit plans through the date of termination, Dr. Kemble will be entitled to receive severance in the form of six months of his then base salary, such amount to be paid in equal installments in accordance with our regular payroll practices, subject to applicable taxes and withholding, as well as up to six months of COBRA premium payments. These severance benefits are conditioned upon Dr. Kemble continuing to comply with his obligations under his proprietary information agreement and his delivery of a general release of claims in favor of the company. Further, if within the twelve-month period that immediately follows a change of control (as defined below) Dr. Kemble's employment is terminated without cause or he is constructively terminated (as defined below), then 100% of all of his outstanding stock options and equity awards shall accelerate and become fully vested as of the termination date.

Mr. Hom. Pursuant to Mr. Hom's amended and restated offer letter, if his employment is terminated without cause (as defined below), and other than as a result of his death or disability, then in addition to any amounts accrued and payable under the terms of our benefit plans through the date of termination, Mr. Hom will be entitled to receive severance in the form of six months of his then base salary, such amount to be paid in equal installments in accordance with our regular payroll practices, subject to applicable taxes and withholding, as well as up to six months of COBRA premium payments. These severance benefits are conditioned upon Mr. Hom continuing to comply with his obligations under his proprietary information agreement and his delivery of a general release of claims in favor of the company. Further, if within the twelve-month period that immediately follows a change of control (as defined below) Mr. Hom's employment is terminated without cause or he is constructively terminated (as defined below), then 100% of all of his outstanding stock options and equity awards shall accelerate and become fully vested as of the termination date.

For the purposes of Dr. Kemble's and Mr. Hom's severance benefits, the following definitions apply:

- "cause" means a determination by the Board that his employment be terminated for any of the following reasons: (i) failure or refusal to comply in any material respect with the terms of his letter agreement or with any lawful policies, standards or regulations of Company after having received written notice of such failure and at least fifteen (15) days to cure such failure; (ii) a violation by him or caused by him of a federal or state law or regulation applicable to the business of the company; (iii) conviction or plea of no contest to a felony under the laws of the United States or any State; (iv) fraud or misappropriation of property belonging to the company or its affiliates; (v) a breach in any material respect of the terms of any confidentiality, invention assignment or proprietary information agreement with the company or with a former employer; (vi) his failure to satisfactorily perform his duties after having received written notice of such failure and at least thirty (30) days to cure such failure; (vii) his gross negligence

in connection with the performance of your duties; or (viii) a material breach of his fiduciary duties as an officer or director of the company.

- "change of control" means (i) a merger, reorganization, consolidation or other acquisition (or series of related transactions of such nature) unless securities representing more than fifty percent (50%) of the total combined voting power of the voting securities of the successor corporation are immediately thereafter beneficially owned, directly or indirectly and in substantially the same proportion, by the persons who beneficially owned the company's outstanding voting securities immediately prior to such transaction; (ii) a sale of all or substantially all of the assets of the company; or (iii) any other transaction or series of transactions, in which the company's stockholders immediately prior to such transaction or transactions own immediately after such transaction less than fifty percent (50%) of the voting equity securities of the surviving corporation or its parent.
- "constructively terminated" means a resignation of his employment within thirty (30) days of the occurrence of any of the following events: (i) a significant reduction in your responsibilities; (ii) a reduction in his base salary of ten percent (10%) or greater; or (iii) a relocation of his principal office to a location more than fifty (50) miles from the location of the principal office immediately preceding a change of control.

In addition, Dr. Kemble, Mr. Hom and Dr. McCulloch are eligible to participate in our Change in Control Retention Plan, which is described below.

Other compensation and benefits

All of our current named executive officers are eligible to participate in our employee benefit plans, including our medical, dental and vision, in each case on the same basis as all of our other employees. We pay the premiums for the medical, disability, accidental death and dismemberment insurance for all of our employees, including our named executive officers. We generally do not provide perquisites or personal benefits to our named executive officers.

Change in Control Retention Plan. In June 2020, our board of directors adopted a Change in Control Retention Plan (the Retention Plan), to advance our interests by establishing a bonus pool payable upon the occurrence of a "corporate transaction" (as defined below) to selected key service providers, including Dr. Kemble, Mr. Hom and Dr. McCulloch. The Retention Plan will automatically terminate immediately prior to the closing of this offering.

Subject to the terms of the Retention Plan, upon the closing of a corporate transaction, a pool will be established equal to 7% of the total consideration payable to the company's security holders, up to a maximum pool of $13.0 million. The pool is allocated to individuals designated as participants by our board of directors under the Retention Plan, and each participant's allocable share of the pool is equal to the product of (x) the pool multiplied by (y) such participant's individual percentage as set forth in a participation agreement and the Retention Plan. If the conditions for distribution set forth in the Retention Plan are satisfied, each participant is entitled to receive such participant's allocable share at the closing of the corporate transaction.

The Retention Plan is interpreted and administered by our board of directors. The board may delegate some or all of its powers and responsibilities under the retention plan to a committee of the board. The board at any time, and from time to time, prior to the execution of a letter of intent with respect to a corporate transaction, may amend or terminate the Retention Plan. For purposes of the Retention Plan, a "corporate transaction" means the occurrence of a liquidation, as defined in the company's amended and restated certificate of incorporation.

Equity benefit plans

We believe that our ability to grant equity-based awards is a valuable and necessary compensation tool that aligns the long-term financial interests of our employees, consultants and directors with the financial interests of our stockholders. In addition, we believe that our ability to grant options and other equity-based awards helps us to attract, retain and motivate employees, consultants and directors, and

encourages them to devote their best efforts to our business and financial success. The principal features of our equity incentive plans and our 401(k) plan are summarized below. These summaries are qualified in their entirety by reference to the actual text of the plans, which, other than the 401(k) plan, are filed as exhibits to the registration statement of which this prospectus is a part.

2021 equity incentive plan

Prior to the closing of this offering, we expect that our board of directors will adopt, and our stockholders will approve, our 2021 Equity Incentive Plan (our 2021 Plan). We expect our 2021 Plan will become effective on the date of the underwriting agreement related to this offering. Our 2021 Plan will come into existence upon its adoption by our board of directors, but no grants will be made under our 2021 Plan prior to its effectiveness. Once our 2021 Plan becomes effective, no further grants will be made under our 2017 Equity Incentive Plan (our 2017 Plan).

Awards. Our 2021 Plan will provide for the grant of incentive stock options (ISOs) within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended (the Code), to our employees and our parent and subsidiary corporations' employees, and for the grant of nonstatutory stock options (NSOs) stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of awards to our employees, directors and consultants and any of our affiliates' employees and consultants.

Authorized Shares. Initially, the maximum number of shares of our Class A common stock that may be issued under the 2021 Plan after it becomes effective will not exceed shares of our Class A common stock, which is the sum of (i) new shares, plus (ii) an additional number of shares up to a maximum of shares, which number consists of shares of our Class A common stock subject to outstanding stock options or other stock awards granted under the 2017 Plan or the 2007 Plan that, on or after the 2021 Plan becomes effective, terminate or expire prior to exercise or settlement; are not issued because the award is settled in cash; are forfeited because of the failure to vest; or are reacquired or withheld (or not issued) to satisfy a tax withholding obligation or the purchase or exercise price. In addition, the number of shares of our Class A common stock reserved for issuance under our 2021 Plan will automatically increase on January 1st of each year for a period of 10 years, beginning on January 1, 2022 and continuing through January 1, 2031, in an amount equal to (1) % of the total number of (A) shares of all classes of our common stock plus (B) securities convertible or exercisable into a class of shares of our common stock, for this purpose excluding any awards issued under the 2021 Plan, that are outstanding on December 31st of the immediately preceding year, or (2) a lesser number of shares determined by our board of directors no later than the date of any such increase. The maximum number of shares of our Class A common stock that may be issued on the exercise of ISOs under our 2021 Plan will be shares.

Shares subject to stock awards granted under our 2021 Plan that expire or terminate without being exercised in full or that are paid out in cash rather than in shares will not reduce the number of shares available for issuance under our 2021 Plan. Shares withheld under a stock award to satisfy the exercise, strike or purchase price of a stock award or to satisfy a tax withholding obligation will not reduce the number of shares available for issuance under our 2021 Plan. If any shares of our Class A common stock issued pursuant to a stock award are forfeited back to or repurchased or reacquired by us (i) because of a failure to meet a contingency or condition required for the vesting of such shares; (ii) to satisfy the exercise, strike or purchase price of a stock award; or (iii) to satisfy a tax withholding obligation in connection with a stock award, the shares that are forfeited or repurchased or reacquired will revert to and again become available for issuance under our 2021 Plan.

Plan Administration. Our board of directors, or a duly authorized committee of our board of directors, will administer our 2021 Plan. Our board of directors may delegate to one or more of our officers the authority to (i) designate employees (other than officers) to receive specified stock awards; and (ii) determine the number of shares subject to such stock awards. Under our 2021 Plan, our board of directors will have the authority to determine stock award recipients, the types of stock awards to be granted, grant dates, the number of shares subject to each stock award, the fair market value of our Class A common stock, and the provisions of each stock award, including the period of exercisability and the vesting schedule applicable to a stock award.

Under our 2021 Plan, our board of directors also generally will have the authority to effect, with the consent of any materially adversely affected participant, (i) the reduction of the exercise, purchase, or strike price of any outstanding option or stock appreciation right; (ii) the cancellation of any outstanding option or stock appreciation right and the grant in substitution therefore of other awards, cash, or other consideration; or (iii) any other action that is treated as a repricing under generally accepted accounting principles.

Stock Options. ISOs and NSOs are granted under stock option agreements adopted by the administrator. The administrator will determine the exercise price for stock options, within the terms and conditions of our 2021 Plan, except the exercise price of a stock option generally will not be less than 100% of the fair market value of our Class A common stock on the date of grant. Options granted under our 2021 Plan will vest at the rate specified in the stock option agreement as will be determined by the administrator.

The administrator will determine the term of stock options granted under our 2021 Plan, up to a maximum of ten years. Unless the terms of an optionholder's stock option agreement, or other written agreement between us and the recipient, provide otherwise, if an optionholder's service relationship with us or any of our affiliates ceases for any reason other than disability, death, or cause, the optionholder may generally exercise any vested options for a period of three months following the cessation of service. This period may be extended in the event that exercise of the option is prohibited by applicable securities laws. If an optionholder's service relationship with us or any of our affiliates ceases due to death, or an optionholder dies within a certain period following cessation of service, the optionholder or a beneficiary may generally exercise any vested options for a period of eighteen months following the date of death. If an optionholder's service relationship with us or any of our affiliates ceases due to disability, the optionholder may generally exercise any vested options for a period of twelve months following the cessation of service. In the event of a termination for cause, options generally terminate upon the termination date. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of any class of common stock issued upon the exercise of a stock option will be determined by the administrator and may include (i) cash, check, bank draft or money order; (ii) a broker-assisted cashless exercise; (iii) the tender of shares of any class of our common stock previously owned by the optionholder; (iv) a net exercise of the option if it is an NSO; or (v) other legal consideration approved by the administrator.

Unless the administrator provides otherwise, options or stock appreciation rights generally are not transferable except by will or the laws of descent and distribution. Subject to approval of the administrator or a duly authorized officer, an option may be transferred pursuant to a domestic relations order, official marital settlement agreement, or other divorce or separation instrument.

Tax Limitations on ISOs. The aggregate fair market value, determined at the time of grant, of our Class A common stock with respect to ISOs that are exercisable for the first time by an award holder during any calendar year under all of our stock plans may not exceed $100,000. Options or portions thereof that exceed such limit will generally be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our parent or subsidiary corporations unless (i) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant; and (ii) the term of the ISO does not exceed five years from the date of grant.

Restricted Stock Unit Awards. Restricted stock unit awards are granted under restricted stock unit award agreements adopted by the administrator. Restricted stock unit awards may be granted in consideration for any form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. A restricted stock unit award may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the administrator, or in any other form of consideration set forth in the restricted stock unit award agreement. Additionally, dividend equivalents may be credited in respect of shares covered by a restricted stock unit award. Except as otherwise provided in the applicable award agreement, or other written agreement between us and the recipient, restricted stock unit awards that have not vested will be forfeited once the participant's continuous service ends for any reason.

Restricted Stock Awards. Restricted stock awards are granted under restricted stock award agreements adopted by the administrator. A restricted stock award may be awarded in consideration for cash, check, bank draft or money order, past or future services to us, or any other form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. The administrator will determine the terms and conditions of restricted stock awards, including vesting and forfeiture terms. If a participant's service relationship with us ends for any reason, we may receive any or all of the shares of Class A common stock held by the participant that have not vested as of the date the participant terminates service with us through a forfeiture condition or a repurchase right.

Stock Appreciation Rights. Stock appreciation rights are granted under stock appreciation right agreements adopted by the administrator. The administrator will determine the purchase price or strike price for a stock appreciation right, which generally will not be less than 100% of the fair market value of our Class A common stock on the date of grant. A stock appreciation right granted under our 2021 Plan will vest at the rate specified in the stock appreciation right agreement as will be determined by the administrator. Stock appreciation rights may be settled in cash or shares of our Class A common stock or in any other form of payment as determined by our board of directors and specified in the stock appreciation right agreement.

The administrator will determine the term of stock appreciation rights granted under our 2021 Plan, up to a maximum of 10 years. If a participant's service relationship with us or any of our affiliates ceases for any reason other than cause, disability, or death, the participant may generally exercise any vested stock appreciation right for a period of three months following the cessation of service. This period may be further extended in the event that exercise of the stock appreciation right following such a termination of service is prohibited by applicable securities laws. If a participant's service relationship with us, or any of our affiliates, ceases due to disability or death, or a participant dies within a certain period following cessation of service, the participant or a beneficiary may generally exercise any vested stock appreciation right for a period of twelve months in the event of disability and eighteen months in the event of death. In the event of a termination for cause, stock appreciation rights generally terminate upon the termination date. In no event may a stock appreciation right be exercised beyond the expiration of its term.

Performance Awards. Our 2021 Plan will permit the grant of performance awards that may be settled in stock, cash or other property. Performance awards may be structured so that the stock or cash will be issued or paid only following the achievement of certain pre-established performance goals during a designated performance period. Performance awards that are settled in cash or other property are not required to be valued in whole or in part by reference to, or otherwise based on, our Class A common stock.

The performance goals may be based on any measure of performance selected by our board of directors. The performance goals may be based on company-wide performance or performance of one or more business units, divisions, affiliates, or business segments, and may be either absolute or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise by our board of directors at the time the performance award is granted, our board will appropriately make adjustments in the method of calculating the attainment of performance goals as follows: (i) to exclude restructuring or other nonrecurring charges; (ii) to exclude exchange rate effects; (iii) to exclude the effects of changes to generally accepted accounting principles; (iv) to exclude the effects of any statutory adjustments to corporate tax rates; (v) to exclude the effects of items that are "unusual" in nature or occur "infrequently" as determined under generally accepted accounting principles; (vi) to exclude the dilutive effects of acquisitions or joint ventures; (vii) to assume that any business divested by us achieved performance objectives at targeted levels during the balance of a performance period following such divestiture; (viii) to exclude the effect of any change in the outstanding shares of any class of our common stock by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change, or any distributions to stockholders who hold shares of a class of our common stock other than regular cash dividends; (ix) to exclude the effects of stock based compensation and the award of bonuses under our bonus plans; (x) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to be expensed under generally accepted accounting principles; and (xi) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles.

Other Stock Awards. The administrator will be permitted to grant other awards based in whole or in part by reference to a class of our common stock. The administrator will set the number of shares under the stock award (or cash equivalent) and all other terms and conditions of such awards.

Non-Employee Director Compensation Limit. The aggregate value of all compensation granted or paid to any non-employee director with respect to any calendar year, including awards granted and cash fees paid by us to such non-employee director, will not exceed $ in total value, except such amount will increase to $ for the first year for newly appointed or elected non-employee directors.

Changes to Capital Structure. In the event there is a specified type of change in our capital structure, such as a stock split, reverse stock split, or recapitalization, appropriate adjustments will be made to (i) the class and maximum number of shares reserved for issuance under our 2021 Plan, (ii) the class and maximum number of shares by which the share reserve may increase automatically each year, (iii) the class and maximum number of shares that may be issued on the exercise of ISOs, and (iv) the class and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding stock awards.

Corporate Transactions. In the event of a corporate transaction (as defined below), unless otherwise provided in a participant's stock award agreement or other written agreement with us or one of our affiliates or unless otherwise expressly provided by the administrator at the time of grant, any stock awards outstanding under our 2021 Plan may be assumed, continued or substituted for by any surviving or acquiring corporation (or its parent company), and any reacquisition or repurchase rights held by us with respect to the stock award may be assigned to the successor (or its parent company). If the surviving or acquiring corporation (or its parent company) does not assume, continue or substitute for such stock awards, then (i) with respect to any such stock awards that are held by participants whose continuous service has not terminated prior to the effective time of the corporate transaction, or current participants, the vesting (and exercisability, if applicable) of such stock awards will be accelerated in full (or, in the case of performance awards with multiple vesting levels depending on the level of performance, vesting will accelerate at 100% of the target level if the award is not assumed) to a date prior to the effective time of the corporate transaction (contingent upon the effectiveness of the corporate transaction), and such stock awards will terminate if not exercised (if applicable) at or prior to the effective time of the corporate transaction, and any reacquisition or repurchase rights held by us with respect to such stock awards will lapse (contingent upon the effectiveness of the corporate transaction); and (ii) any such stock awards that are held by persons other than current participants will terminate if not exercised (if applicable) prior to the effective time of the corporate transaction, except that any reacquisition or repurchase rights held by us with respect to such stock awards will not terminate and may continue to be exercised notwithstanding the corporate transaction.

In the event a stock award will terminate if not exercised prior to the effective time of a corporate transaction, the administrator may provide, in its sole discretion, that the holder of such stock award may not exercise such stock award but instead will receive a payment equal in value to the excess (if any) of (i) the value of the property the participant would have received upon the exercise of the stock award, over (ii) any per share exercise price payable by such holder, if applicable. In addition, any escrow, holdback, earn out or similar provisions in the definitive agreement for the corporate transaction may apply to such payment to the same extent and in the same manner as such provisions apply to the holders of our Class A common stock.

Under our 2021 Plan, a "corporate transaction" is generally the consummation of (i) a sale or other disposition of all or substantially all of our consolidated assets; (ii) a sale or other disposition of at least 50% of our outstanding securities; (iii) a merger, consolidation or similar transaction following which we are not the surviving corporation; or (iv) a merger, consolidation or similar transaction following which we are the surviving corporation but the shares of our Class A common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction.

Change in Control. Stock awards granted under our 2021 Plan may be subject to acceleration of vesting and exercisability upon or after a change in control (as defined below) as may be provided in the applicable stock award agreement or in any other written agreement between us or any affiliate and the participant, but in the absence of such provision, no such acceleration will automatically occur.

Under our 2021 Plan, a "change in control" is generally (i) the acquisition by any person or company of more than 50% of the combined voting power of our then outstanding stock; (ii) a merger, consolidation or similar transaction in which our stockholders immediately before the transaction do not own, directly or indirectly, more than 50% of the combined voting power of the surviving entity (or the parent of the surviving entity) in substantially the same proportions as their ownership immediately prior to such transaction; (iii) a sale, lease, exclusive license or other disposition of all or substantially all of our assets other than to an entity more than 50% of the combined voting power of which is owned by our stockholders in substantially the same proportions as their ownership of our outstanding voting securities immediately prior to such transaction; or (iv) when a majority of our board of directors becomes comprised of individuals who were not serving on our board of directors on the date of the underwriting agreement related to this offering, or the incumbent board, or whose nomination, appointment, or election was not approved by a majority of the incumbent board still in office.

Plan Amendment or Termination. Our board of directors has the authority to amend, suspend, or terminate our 2021 Plan at any time, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. Certain material amendments also require the approval of our stockholders. No ISOs may be granted after the tenth anniversary of the date our board of directors adopts our 2021 Plan. No stock awards may be granted under our 2021 Plan while it is suspended or after it is terminated.

2017 equity incentive plan

Our board of directors adopted the 2017 Plan in September 2017 and our stockholders approved the 2017 Plan in October 2017. The 2017 Plan is the successor to and continuation of our 2007 Equity Incentive Plan. The 2017 Plan provides for the grant of ISOs, NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards and other awards to our employees, directors and consultants or our affiliates. ISOs may be granted only to our employees or employees of our affiliates.

The 2017 Plan will be terminated on the date the 2021 Plan becomes effective. However, any outstanding awards granted under the 2017 Plan will remain outstanding, subject to the terms of our 2017 Plan and award agreements, until such outstanding options are exercised or until any awards terminate or expire by their terms.

Authorized Shares. Upon the effective date of the 2021 Plan, we will no longer grant awards under our 2017 Plan. As of December 31, 2020, options to purchase 70,537,063 shares Class A common stock were outstanding, and 157,563,189 shares of common stock remained available for future issuance under our 2017 Plan. The options outstanding as of December 31, 2020 had a weighted-average exercise price of $0.09 per share.

Plan Administration. Our board or a duly authorized committee of our board administers our 2017 Plan and the awards granted under it. The administrator has the power to modify outstanding awards under our 2017 Plan. The administrator has the authority to reprice any outstanding option with the consent of any adversely affected participant.

Corporate Transactions. Our 2017 Plan provides that in the event of certain specified significant corporate transactions, as defined under our 2017 Plan, our board may (1) arrange for the assumption, continuation or substitution of an award by a successor corporation, or the acquiring corporation's parent company; (2) arrange for the assignment of any reacquisition or repurchase rights held by us to a successor corporation, or the acquiring corporation's parent company; (3) accelerate the vesting, in whole or in part, of the award and provide for its termination prior to the transaction if not exercised prior to the effective time of the corporate transaction; (4) arrange for the lapse, in whole or in part, of any reacquisition or repurchase rights held by us; (5) cancel or arrange for the cancellation of the award prior to the transaction in exchange for a cash payment, if any, determined by the board; or (6) make a payment in such form as determined by the board of directors equal to the excess, if any, of the value of the property the participant would have received upon exercise of the awards prior to the transaction over any exercise price payable by the participant in connection with the exercise. The administrator is not obligated to treat all awards or portions of awards, even those that are of the same type, in the same manner.

In the event of a change in control, as defined under our 2017 Plan, awards granted under our 2017 Plan will not receive automatic acceleration of vesting and exercisability, although this treatment may be provided for in an award agreement.

Transferability. Our board may impose limitations on the transferability of ISOs, NSOs and stock appreciation rights as the board will determine. Absent such limitations, a participant may not transfer awards under our 2017 Plan other than by will, the laws of descent and distribution or as otherwise provided under our 2017 Plan.

Plan Amendment or Termination. Our board has the authority to suspend or terminate our 2017 Plan at any time, provided that such action will not impair a participant's rights under such participant's outstanding award without his or her written consent. As described above, our 2017 Plan will be terminated upon the effective date of the 2021 Plan and no future awards will be granted under the 2017 Plan following such termination.

2007 equity incentive plan

Our board of directors adopted the 2007 Equity Incentive Plan (the 2007 Plan) in December 2006, and our stockholders adopted the 2007 Plan in April 2007. The 2007 Plan provided for the grant of ISOs, NSOs and stock purchase rights, or restricted stock awards. ISOs were only granted to our employees or employees of our affiliates.

The 2007 Plan was terminated in September 2017. However, any outstanding awards granted under the 2007 Plan remain outstanding, subject to the terms of our 2007 Plan and award agreements, until such outstanding options are exercised or until any awards terminate or expire by their terms.

Authorized Shares. As of March 31, 2021, options to purchase 8,108,225 shares of Class A common stock were outstanding under the 2007 Plan with a weighted-average exercise price of $0.08 per share.

Plan Administration. Our board or a duly authorized committee of our board administers our 2007 Plan and the awards granted under it. The administrator has the power to modify outstanding awards under our 2007 Plan. The administrator has the authority to determine whether to offer to buyout previously granted options and to determine the terms and conditions of such offer and buyout.

Acquisitions. Our 2007 Plan provides that in the event of certain specified acquisitions, as defined under our 2007 Plan, our board may arrange for the assumption or substitution of an award by a surviving corporation or entity, or the acquiring corporation or entity. In the event that an award is not assumed or substituted then awards for participants that did not terminate status as a service provider, the vesting for the award will be accelerated and the award will be made fully exercisable at least ten (10) days prior to the closing of the acquisition. Awards for all other participants shall be terminated if not exercised prior to the closing of the acquisition.

Transferability. A participant may not transfer awards under our 2007 Plan other than by will, the laws of descent and distribution or as otherwise provided under our 2007 Plan.

2021 employee stock purchase plan

Prior to the closing of this offering, our board of directors intends to adopt, and we expect our stockholders will approve, our 2021 Employee Stock Purchase Plan (the ESPP). Our ESPP will become effective immediately prior to and contingent upon the date of the underwriting agreement related to this offering. The purpose of our ESPP will be to secure the services of new employees, to retain the services of existing employees, and to provide incentives for such individuals to exert maximum efforts toward our success and that of our affiliates. Our ESPP will include two components. One component will be designed to allow eligible US employees to purchase our Class A common stock in a manner that may qualify for favorable tax treatment under Section 423 of the Code. The other component will permit the grant of purchase rights that do not qualify for such favorable tax treatment in order to allow deviations necessary to permit participation by eligible employees who are foreign nationals or employed outside of the US while complying with applicable foreign laws.

Share Reserve. Following this offering, our ESPP will authorize the issuance of shares of our Class A common stock under purchase rights granted to our employees or to employees of any of our designated affiliates. The number of shares of our Class A common stock reserved for issuance will automatically increase on January 1st of each year for a period of 10 years, beginning on January 1, 2022 and continuing through January 1, 2031, by the lesser of (i) % of the total number of (A) shares of all classes of our common stock plus (B) securities convertible or exercisable into shares of a class of our common stock, for this purpose excluding any awards issued under the 2021 Plan, that are outstanding on December 31st of the immediately preceding year; and (ii) shares, except before the date of any such increase, our board of directors may determine that such increase will be less than the amount set forth in clauses (i) and (ii).

Administration. Our board of directors will administer our ESPP and may delegate its authority to administer our ESPP to our compensation committee. Our ESPP will be implemented through a series of offerings under which eligible employees are granted purchase rights to purchase shares of our Class A common stock on specified dates during such offerings. Under our ESPP, our board of directors will be permitted to specify offerings with durations of not more than 27 months and to specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of our Class A common stock will be purchased for employees participating in the offering. Our ESPP will provide that an offering may be terminated under certain circumstances.

Payroll Deductions. Generally, all regular employees, including executive officers, employed by us or by any of our designated affiliates, will be eligible to participate in our ESPP and to contribute, normally through payroll deductions, up to % of their earnings (as defined in our ESPP) for the purchase of our Class A common stock under our ESPP. Unless otherwise determined by our board of directors, Class A common stock will be purchased for the accounts of employees participating in our ESPP at a price per share equal to the lesser of (i) 85% of the fair market value of a share of our Class A common stock on the first day of an offering; or (ii) 85% of the fair market value of a share of our Class A common stock on the date of purchase.

Limitations. Employees may have to satisfy one or more of the following service requirements before participating in our ESPP, as determined by our board of directors: (i) being customarily employed for more than 20 hours per week; (ii) being customarily employed for more than five months per calendar year; or (iii) continuous employment with us or one of our affiliates for a period of time (not to exceed two years). No employee will be permitted to purchase shares under our ESPP at a rate in excess of $25,000 worth of our Class A common stock (based on the fair market value per share of our Class A common stock at the beginning of an offering) for each calendar year such a purchase right is outstanding. Finally, no employee will be eligible for the grant of any purchase rights under our ESPP if immediately after such rights are granted, such employee has voting power over 5% or more of our outstanding capital stock measured by vote or value under Section 424(d) of the Code.

Changes to Capital Structure. Our ESPP will provide that in the event there occurs a change in our capital structure through such actions as a stock split, merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, liquidating dividend, combination of shares, exchange of shares, change in corporate structure, or similar transaction, our board of directors will make appropriate adjustments to: (i) the class(es) and maximum number of shares reserved under our ESPP; (ii) the class(es) and maximum number of shares by which the share reserve may increase automatically each year; (iii) the class(es) and number of shares subject to, and purchase price applicable to, outstanding offerings and purchase rights; and (iv) the class(es) and number of shares that are subject to purchase limits under ongoing offerings.

Corporate Transactions. Our ESPP will provide that in the event of a corporate transaction (as defined below), any then-outstanding rights to purchase our stock under our ESPP may be assumed, continued, or substituted for by any surviving or acquiring entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue, or substitute for such purchase rights, then the participants' accumulated payroll contributions will be used to purchase shares of a class of our common stock within 10 business days before such corporate transaction, and such purchase rights will terminate immediately after such purchase.

Under our ESPP, a "corporate transaction" is generally the consummation of (i) a sale or other disposition of all or substantially all of our consolidated assets; (ii) a sale or other disposition of at least 50% of our outstanding securities; (iii) a merger, consolidation or similar transaction following which we are not the surviving corporation; or (iv) a merger, consolidation or similar transaction following which we are the surviving corporation but the shares of our Class A common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction.

Amendment or Termination. Our board of directors will have the authority to amend or terminate our ESPP, except in certain circumstances such amendment or termination may not materially impair any outstanding purchase rights without the holder's consent. We will obtain stockholder approval of any amendment to our ESPP as required by applicable law or listing requirements.

401(k) plan

We maintain a defined contribution employee retirement plan (401(k) Plan) for our employees. The 401(k) Plan is intended to qualify as a tax-qualified plan under Section 401(k) of the Code. The 401(k) Plan covers all employees, including our named executive officers, who meet defined minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pretax basis. The 401(k) Plan provides that each eligible participant may contribute up to the lesser of 100% of his or her compensation or the statutory limit, which is $19,500 for calendar year 2021. Participants that are 50 years or older can also make "catch-up" contributions, which in calendar year 2021 may be up to an additional $6,500 above the statutory limit. Participant contributions are held and invested, pursuant to the participant's instructions, by the plan's trustee. As a tax-qualified retirement plan, contributions to the 401(k) Plan are deductible by us when made, and contributions and earnings on those amounts are not generally taxable to the employees until withdrawn or distributed from the 401(k) Plan. We have not made any employer contributions to the 401(k) Plan as of December 31, 2019 and 2020.

Limitations on liability and indemnification

Our amended and restated certificate of incorporation, which will become effective immediately prior to the closing of this offering, will contain provisions that limit the liability of our current and former directors for monetary damages to the fullest extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to the corporation or its stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions; or
- any transaction from which the director derived an improper personal benefit.

Such limitation of liability does not apply to liabilities arising under federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our amended and restated certificate of incorporation will authorize us to indemnify our directors, officers, employees and other agents to the fullest extent permitted by Delaware law. Our amended and restated bylaws will provide that we are required to indemnify our directors and officers to the fullest extent permitted by Delaware law and may indemnify our other employees and agents. Our amended and restated bylaws will also provide that, on satisfaction of certain conditions, we will advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee, or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under the provisions of Delaware law. We have entered and expect to continue to enter into agreements to indemnify our directors, executive officers and other employees as determined by the board of directors. With certain exceptions, these agreements provide for indemnification for related expenses including attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding.

We believe that these amended and restated certificate of incorporation and amended and restated bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain customary directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended (the Securities Act), may be permitted for directors, executive officers, or persons controlling us, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Rule 10b5-1 plans

Our directors, officers and key consultants may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our Class A common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades under parameters established by the director or officer when entering into the plan, without further direction from them. The director or officer may amend a Rule 10b5-1 plan in some circumstances and may terminate a plan at any time. Our directors and executive officers may also buy or sell additional shares outside of a Rule 10b5-1 plan when they do not possess of material nonpublic information, subject to compliance with the terms of our insider trading policy. During the first 180 days from this offering, the sale of any shares under such plan would be subject to the lock-up agreement that the director or officer has entered into with the underwriters.

CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

Other than compensation arrangements for our directors and executive officers, which are described elsewhere in this prospectus, below we describe transactions since January 1, 2018 and each currently proposed transaction in which:

- the amounts involved exceeded or will exceeds the lesser of $120,000 or 1% of our total assets at the year- end for the last two completed fiscal years; and
- any of our directors, executive officers or holders of more than 5% of our outstanding capital stock, or any immediate family member of, or person sharing the household with, any of these individuals or entities, had or will have a direct or indirect material interest.

Convertible note financings

From June 2016 through December 2018, we issued and sold secured convertible promissory notes having an aggregate principal amount of $18.1 million. In connection with the purchase of the secured convertible promissory notes through September 2018, we issued an aggregate of 51,331,148 shares of our Series D-1 redeemable convertible preferred stock as a liquidation preference step up along with additional shares of our redeemable convertible preferred stock to adjust each holder's aggregate liquidation preference, and correspondingly cancelled shares of redeemable convertible preferred stock that were held by such parties. The following table summarizes the secured convertible promissory notes issued to our related parties.

Participants[1]	Loan Amount
KPCB Holdings, Inc., as nominee[2]	$7,701,447
New Enterprise Associates 13, Limited Partnership[3]	$9,265,338
Merdad Parsey[4]	$ 14,000

(1) Additional details regarding these stockholders and their equity holdings are included in this prospectus under the caption "Principal Stockholders."

(2) KPCB Holdings, Inc. beneficially owns more than 5% of our outstanding capital stock. Dr. Seidenberg is a general partner of KPCB Holdings, Inc. and a member of our board of directors.

(3) NEA beneficially owns more than 5% of our outstanding capital stock. David Mott and Jason Fuller, former principals at NEA, are former members of our board of directors. Matthew McAviney is a principal at NEA and a former member of our board of directors.

(4) In connection with the purchase of the secured convertible promissory notes and the cancellation thereof, Dr. Parsey, a member of our board of directors.

Series E preferred stock financing

In February and July of 2019, we issued and sold an aggregate of 238,347,982 shares of Series E redeemable convertible preferred stock to 19 accredited investors, at a purchase price of $0.09219 per share for aggregate cash proceeds of approximately $22.0 million. In addition, 393,290,743 shares were issued upon the conversion of, approximately $18.1 million total of aggregate principal and accrued interest were converted into shares of our Series E redeemable convertible preferred stock.

The following table summarizes the shares of our Series E redeemable convertible preferred stock issued to our related parties.

Participants[1]	Shares of Series E Redeemable Convertible Preferred Stock from Conversion of Convertible Notes	Shares of Series E Redeemable Convertible Preferred Stock from Cash Investment	Cash Purchase Price
AP11 Limited[2]	—	108,471,634	$9,999,999.95
KPCB Holdings, Inc., as nominee[3]	166,711,316	31,028,659	$2,860,532.08
New Enterprise Associates 13, Limited Partnership[4]	200,564,477	37,329,481	$3,441,404.86

(1) Additional details regarding these stockholders and their equity holdings are included in this prospectus under the caption "Principal Stockholders."

(2) AP11 Limited is an affiliate of Ascletis. Jinzi Wu, Ph.D., a member of our board of directors, is the Chief Executive Officer of Ascletis.

(3) KPCB Holdings, Inc. beneficially owns more than 5% of out outstanding capital stock. Dr. Seidenberg is a general partner of KPCB Holdings, Inc. and a member of our board of directors.

(4) NEA beneficially owns more than 5% of our outstanding capital stock. David Mott and Jason Fuller, former principals at NEA, are former members of our board of directors. Matthew McAviney is a principal at NEA and a former member of our board of directors.

Series F preferred stock financing

In December 2020, we issued and sold an aggregate of 530,107,520 shares of Series F redeemable convertible preferred stock to 13 accredited investors and, in February 2021, we issued an additional 84,485,407 shares of Series F redeemable convertible preferred stock to an additional accredited investor, at a purchase price of $0.13020 per share for aggregate cash proceeds of approximately $80.0 million.

The following table summarizes the shares of our Series F redeemable convertible preferred stock issued to our related parties.

Participants[1]	Shares of Series F Redeemable Convertible Preferred Stock from Cash Investment	Total Cash Purchase Price
AP11 Limited[2]	23,041,474	$ 2,999,999.92
Entities affiliated with Baker Brothers Life Sciences, L.P.[3]	153,609,831	$20,000,000.00
KPCB Holdings, Inc., as nominee[4]	26,881,720	$ 3,499,999.95
New Enterprise Associates 13, Limited Partnership[5]	23,041,474	$ 2,999,999.92
SGMT Holdings Limited	115,207,373	$14,999,999.97
Suzhou Huimei Kangrui Management Consulting Partnership L.P.	84,485,407	$11,000,000.00

(1) Additional details regarding these stockholders and their equity holdings are included in this prospectus under the caption "Principal Stockholders."

(2) AP11 Limited, a subsidiary of Ascletis Pharma Inc., beneficially owns more than 5% of our outstanding capital stock. Dr. Wu is founder, chairman and chief executive officer of Ascletis Pharma Inc., and a member of our board of directors.

(3) Includes shares of preferred stock purchased by 667 L.P.

(4) KPCB Holdings, Inc. beneficially owns more than 5% of our outstanding capital stock. Dr. Seidenberg is a general partner at KPCB Holdings, Inc. and a member of our board of directors.

(5) NEA beneficially owns more than 5% of our outstanding capital stock. David Mott and Jason Fuller, former principals at NEA, are former members of our board of directors. Matthew McAviney is a principal at NEA and a former member of our board of directors.

Baker Brothers nominating agreement

On April 15, 2021, we entered into an amended and restated nominating agreement with Baker Brothers Life Sciences L.P. and 667, L.P. (together, Baker Brothers). Pursuant to the Baker Brothers nominating agreement, during the period beginning on the 91st day following the date of effectiveness of the registration statement of which this prospectus is a part, at any time at which Baker Brothers, together with its affiliates, collectively beneficially own (i) at least 115,207,373 shares of our Class A common stock and Class B common stock, and (ii) at least 4.9% of our then-outstanding voting common stock (such period, the nominating agreement period), we will have the obligation to support the nomination of, and to cause our

board of directors to include in the slate of nominees recommended to our stockholders for election, one individual designated by Baker Brothers (the Baker designee), unless a majority of our disinterested directors reasonably and in good faith determines that a Baker designee would not be qualified to serve as our director under law, rules of the stock exchange on which our shares are listed, or our amended and restated bylaws. If a Baker designee resigns his or her seat on our board of directors or is removed or does not become a director for any reason, the vacancy will be filled by the election or appointment of another designee of Baker Brothers as soon as reasonably practicable, subject to compliance with applicable laws, rules and regulations. Furthermore, during the nominating agreement period, if there is no Baker designee on our board of directors, we will have the obligation to invite one board of directors observer designee of Baker Brothers (the Baker observer) to attend all meetings of our board of directors and all meetings of the committees of our board of directors as a nonvoting observer, subject to the Baker observer's agreement to hold in confidence the information they receive as observers of our board of directors and committee meetings, as well as subject to their exclusion from our board of directors meetings to preserve our attorney-client privilege, to avoid conflicts of interest, if Baker Brothers is determined by our board of directors to be a competitor, or other customary conditions. The Baker Brothers nominating agreement automatically terminates upon the earliest of (i) such time when Baker Brothers together with its affiliates no longer beneficially own at least 115,207,373 shares of our Class A common stock and Class B common stock, (ii) the third anniversary of this offering, or (iii) the consummation of a liquidation as such terms are defined in our amended and restated certificate of incorporation.

Employment agreements and stock option grants to directors and executive officers

We have entered into employment agreements with certain of our named executive officers, and granted stock options to our named executive officers and certain of our directors, as more fully described in the sections titled "Executive Compensation" and "Management—Non-Employee director compensation."

Ascletis license agreement

In February 2019, we entered into a license agreement with Ascletis, as more fully described in the section titled "Business—License agreement with Ascletis."

Investors' rights agreement

In December 2020, we entered into an amended and restated investors' rights agreement with certain holders of more than 5% of our outstanding capital stock, including Baker Brothers Life Sciences, L.P., SGMT Holdings Limited, New Enterprise Associates 13, Limited Partnership, KPCB Holdings, Inc., as nominee, and AP11 Limited and including certain affiliates of our directors.

This investors' rights agreement grants to the holders of our outstanding redeemable convertible preferred stock certain rights, including certain registration rights with respect to the registrable securities held by them. See the section titled "Description of Capital Stock—Registration Rights" for additional information. In addition, the investors' rights agreement imposes certain affirmative obligations on us, including our obligation to, among other things, (i) grant each holder who holds at least 20,000,000 shares of our redeemable convertible preferred stock (the major investors) a right of first offer with respect to future sales of our equity, excluding the shares to be offered and sold in this offering, and (ii) grant certain information and inspection rights to such major investors. Each of these obligations will terminate in connection with the closing of this offering.

Voting agreement

In December 2020, we entered into an amended and restated voting agreement with certain holders of more than 5% of our outstanding capital stock, including Baker Brothers Life Sciences, L.P., SGMT Holdings Limited, New Enterprise Associates 13, Limited Partnership, KPCB Holdings, Inc., as nominee, and AP11 Limited and including certain affiliates of our directors.

Pursuant to the voting agreement, each of Baker Brothers Life Sciences, L.P., SGMT Holdings Limited, New Enterprise Associates 13, Limited Partnership, KPCB Holdings, Inc., as nominee, and AP11 Limited has the right to designate one or more members to be elected to our board of directors. See the section

titled “Management—Composition of Our Board of Directors.” The voting agreement will terminate by its terms in connection with the closing of this offering and none of our stockholders will have any continuing rights regarding the election or designation of members of our board of directors following this offering.

Right of first refusal and co-sale agreement

In December 2020, we entered into an amended and restated right of first refusal and co-sale agreement with certain holders of more than 5% of our outstanding capital stock, including Baker Brothers Life Sciences, L.P., SGMT Holdings Limited, New Enterprise Associates 13, Limited Partnership, KPCB Holdings, Inc., as nominee, and AP11 Limited and including certain affiliates of our directors.

Pursuant to the right of first refusal and co-sale agreement, we have a right of first refusal in respect of certain sales of securities by certain holders of our common stock and redeemable convertible preferred stock. To the extent we do not exercise such right in full, the investors that are party to the right of first refusal and co-sale agreement are granted certain rights of first refusal and co-sale in respect of such sale. The right of first refusal and co-sale agreement will terminate in connection with the closing of this offering.

Indemnification agreements

Our amended and restated certificate of incorporation will contain provisions limiting the liability of directors, and our amended and restated bylaws will provide that we will indemnify each of our directors and officers to the fullest extent permitted under Delaware law. Our amended and restated certificate of incorporation and amended and restated bylaws will also provide our board of directors with discretion to indemnify our employees and other agents when determined appropriate by the board. In addition, we have entered into or intend to enter into an indemnification agreement with each of our directors and executive officers, which will require us to indemnify them. For more information regarding these agreements, see the section titled “Executive Compensation—Limitations on Liability and Indemnification.”

Policies and procedures for transactions with related persons

Prior to closing of this offering, we intend to adopt a written policy that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of any class of our common stock and any members of the immediate family of any of the foregoing persons are not permitted to enter into a related person transaction with us without the approval or ratification of our board of directors or our audit committee. Any request for us to enter into a transaction with an executive officer, director, nominee for election as a director, beneficial owner of more than 5% of any class of our common stock, or any member of the immediate family of any of the foregoing persons, in which the amount involved exceeds $120,000 (or, if less, 1% of the average of our total assets in a fiscal year) and such person would have a direct or indirect interest, must be presented to our board of directors or our audit committee for review, consideration and approval. In approving or rejecting any such proposal, our board of directors or our audit committee is to consider the material facts of the transaction, including whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person’s interest in the transaction.

PRINCIPAL STOCKHOLDERS

The following table sets forth information regarding beneficial ownership of our capital stock as of May 10, 2021 by:

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

We have determined beneficial ownership in accordance with the rules and regulations of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Except as indicated by the footnotes below, we believe, based on information furnished to us, that the persons and entities named in the table below have sole voting and sole investment power with respect to all shares that they beneficially own, subject to applicable community property laws.

Applicable percentage ownership before the offering is based on (i) shares of our Class A common stock and shares of our Class B common stock outstanding immediately upon the closing of this offering and (ii) the net exercise of (a) the outstanding warrant to purchase 79,545 shares of our Series D redeemable convertible preferred stock, resulting in the issuance of shares of our common stock and (b) the outstanding warrant to purchase 8,361,424 shares of our common stock, resulting in the issuance of shares of our Class A common stock.

Applicable percentage ownership after the offering is based on shares of Class A common stock and shares of Class B common stock outstanding immediately prior to the closing of this offering, after giving effect to the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into shares of our Class A common stock and shares of our Class B common stock in connection with the closing of this offering. In computing the number of shares beneficially owned by a person and the percentage ownership of such person, we deemed to be outstanding all shares subject to options held by the person that are currently exercisable, or exercisable within 60 days of April 16, 2021. However, except as described above, we did not deem such shares outstanding for the purpose of computing the percentage ownership of any other person.

Unless otherwise indicated, the address for each beneficial owner listed in the table below is c/o Sagimet Biosciences Inc., 155 Bovet Road, Suite 303, San Mateo, California 94402.

	Number of Shares Beneficially Owned		Percentage of Shares Beneficially Owned Before the Offering		Percentage of Shares Beneficially Owned After the Offering		
Name of Beneficial Owner	Class A Common Stock	Class B Common Stock	Class A Common Stock	Class B Common Stock	Class A Common Stock	Class B Common Stock	Percentage of Total Voting Power After the Offering
Greater than 5% Holders:							
AP11 Limited[1]							
Entities affiliated with Baker Brothers Life Sciences, L.P.[2]							
KPCB Holdings, Inc., as nominee[3]							
Entities affiliated with New Enterprise Associates 13, Limited Partnership[4]							
SGMT Holdings Limited[5]							

Name of Beneficial Owner	Number of Shares Beneficially Owned		Percentage of Shares Beneficially Owned Before the Offering		Percentage of Shares Beneficially Owned After the Offering		Percentage of Total Voting Power After the Offering
	Class A Common Stock	Class B Common Stock	Class A Common Stock	Class B Common Stock	Class A Common Stock	Class B Common Stock	
Suzhou Huimei Kangrui Management Consulting Partnership L.P.[6]							
Directors and Named Executive Officers:							
George Kemble, Ph.D.[7]							
Dennis Hom[8]							
William McCulloch, M.B., Ch.B, FRCP, FFPM[9]							
Beth Seidenberg, M.D.[10]							
Elizabeth Grammer, Esq.							
Merdad Parsey, M.D., Ph.D.[11]							
Gordon Ringold, Ph.D.[12]							
Richard Rodgers[13]							
James F. Young, Ph.D.[14]							
Jinzi J. Wu, Ph.D.[15]							
All directors and executive officers as a group (11 persons)[16]							

* Represents beneficial ownership of less than 1%.

(1) Consists of shares of Class A common stock issuable upon the deemed conversion of shares of the Company's redeemable convertible preferred stock held by AP11 Limited. AP11 Limited is an affiliate of Ascletis. The address for AP11 Limited is 12/F, Building D, No. 198 Qidi Road, HIPARK, Xiaoshan District, Hangzhou China, 311200. Dr. Jinzi Jason Wu, Judy Hejingdao Wu, Dr. Yizhen Wei, Jiong Gu and Lin Hua are the individual directors of Ascletis and share voting and dispositive power with regard to the Company's securities directly held by AP11 Limited.

(2) Consists of (i) shares of Class B common stock issuable upon the deemed conversion of the Company's redeemable convertible preferred stock held by Baker Brothers Life Sciences, L.P. and (ii) shares of Class B common stock issuable upon the deemed conversion of the Company's redeemable convertible preferred stock held by 667, L.P. (together with Baker Brothers Life Sciences, L.P., the BBA Funds). Baker Bros. Advisors LP (BBA) is the management company and investment adviser to the BBA Funds and has the sole voting and investment power with respect to the shares held by the BBA Funds. Baker Bros. Advisors (GP) LLC (BBA-GP) is the sole general partner of BBA. The managing members of BBA-GP are Julian C. Baker and Felix J. Baker. The address for the BBA Funds is 860 Washington St. 3rd Fl., New York, NY 10014.

(3) Consists of shares of Class A common stock issuable upon the deemed conversion of shares of the Company's redeemable convertible preferred stock held by KPCB Pandemic and Bio Defense Fund, LLC (KPCB PBD), shares of Class A common stock issuable upon the deemed conversion of shares of the Company's redeemable convertible preferred stock held by KPCB PBD Founders Fund, LLC (KPCB PBD FF), shares of Class A common stock issuable upon the deemed conversion of shares of the Company's redeemable convertible preferred stock held by KPCB PBD Investors, LLC (PBD Investors), shares of Class A common stock issuable upon the deemed conversion of shares of the Company's redeemable convertible preferred stock held by KPCB PBD Investors II, LLC (PBD Investors II), shares of Class A common stock issuable upon the deemed conversion of shares of the Company's redeemable convertible preferred stock

beneficially owned by individuals and entities associated with Kleiner Perkins Caufield & Byers (KPCB), including shares held directly by Beth Seidenberg, M.D., a director of the Company, warrants to purchase Class A common stock held by KPCB PBD, warrants to purchase Class A common stock held by KPCB PBD FF and warrants to purchase Class A common stock held by individuals and entities associated with KPCB and held for convenience in the name of “KPCB Holdings, Inc., as nominee” for the accounts of such individuals and entities each of whom exercise their own voting and dispositive control over such shares. All shares are held for convenience in the name of "KPCB Holdings, Inc., as nominee" for the accounts of such individuals and entities, KPCB PBD, KPCB PBD FF, PBD Investors and PBD Investors II. The managing member of KPCB PBD, KPCB PBD FF, PBD Investors and PBD Investors II is KPCB PBD Associates, LLC (KPCB PBD Associates). Brook H. Byers, L. John Doerr, Raymond J. Lane and Theodore E. Schlein, the managing members of KPCB PBD Associates, exercise shared voting and dispositive control over the shares held by KPCB PBD and KPCB PBD FF and none of whom has veto power. The principal business address for all entities and individuals affiliated with Kleiner Perkins Caufield & Byers is c/o Kleiner Perkins Caufield & Byers, LLC, 2750 Sand Hill Road, Menlo Park, CA 94025.

(4) Consists of (i) shares of Class A common stock issuable upon the deemed conversion of shares of the Company’s redeemable convertible preferred stock held by NEA Ventures 2009, L.P. (NEA Ventures) and shares of Class A common stock issuable upon the deemed conversion of shares of the Company’s redeemable convertible preferred stock held by New Enterprise Associates 13, L.P. (NEA 13) and (ii) shares of Class A common stock subject to warrants exercisable within 60 days of December 31, 2020 held by NEA 13. The securities directly held by NEA 13 are indirectly held by NEA Partners 13, L.P. (NEA Partners 13), the sole general partner of NEA 13, NEA 13 GP, LTD (NEA 13 LTD), the sole general partner of NEA Partners 13 and each of the individual directors of NEA 13 LTD. Forest Baskett, Patrick Kerins, and Scott D. Sandell are the individual directors of NEA 13 LTD and share voting and dispositive power with regard to the Company’s securities directly held by NEA 13. Karen P. Welsh is the general partner of NEA Ventures and has voting and dispositive power with regard to the Company’s securities directly held by NEA Ventures. All indirect owners of the above referenced shares disclaim beneficial ownership of all applicable shares except to the extent of their actual pecuniary interest in such shares. The address for the entities and individuals listed above is 1954 Greenspring Drive 600 Timonium, MD 21093.

(5) Consists of shares of Class A common stock issuable upon the deemed conversion of shares of the Issuer's preferred stock held by SGMT Holdings Limited. SGMT Holdings Limited is incorporated in the Cayman Islands and is wholly owned by Hillhouse Venture Fund V, L.P. Hillhouse Capital Management, Ltd. (HCM) acts as the sole management company of Hillhouse Venture Fund V, L.P. Mr. Lei Zhang may be deemed to have controlling power over HCM. Mr. Lei Zhang disclaims beneficial ownership of all of the shares held by SGMT Holdings Limited, except to the extent of his pecuniary interest therein. The registered address of SGMT Holdings Limited is 89 Nexus Way, Camana Bay, P.O. Box 31106, Grand Cayman KY1-1205, Cayman Islands.

(6) Consists of shares of Class A common stock issuable upon the deemed conversion of shares of the Issuer's preferred stock held by Suzhou Huimei Kangrui Management Consulting Partnership L.P. Rushu Luo, the Managing Partner of Suzhou Huimei Kangrui Management Consulting Partnership L.P., has voting and dispositive power over the shares held by Suzhou Huimei Kangrui Management Consulting Partnership L.P. The address for Suzhou Huimei Kangrui Management Consulting Partnership L.P. is Room 112-11, Wuliu Building, No.88 Xiandai Avenue, Suzhou Industrial Park, Suzhou, China 215021.

(7) Consists of shares of Class A common stock subject to options exercisable within 60 days of May 10, 2021.

(8) Consists of shares of Class A common stock subject to options exercisable within 60 days of May 10, 2021.

(9) Consists of shares of Class A common stock subject to options exercisable within 60 days of May 10, 2021.

(10) Consists of (i) shares of Class A common stock issuable upon the deemed conversion of

shares of the Company's redeemable convertible preferred stock held by KPCB Holdings, Inc., as nominee and (ii) shares of Class A common stock subject to options exercisable within 60 days of May 10, 2021.

(11) Consists of (i) shares of Class A common stock, (ii) 1,391,995 shares of Class A common stock issuable upon the deemed conversion of shares of the Company's redeemable convertible preferred stock, (iii) shares of Class A common stock subject to options exercisable within 60 days of May 10, 2021.

(12) Consists of shares of Class A common stock subject to options exercisable within 60 days of May 10, 2021.

(13) Consists of shares of Class A common stock subject to options exercisable within 60 days of May 10, 2021.

(14) Consists of shares of Class A common stock subject to options exercisable within 60 days of May 10, 2021.

(15) Consists of (i) shares of Class A common stock issuable upon the deemed conversion of shares of the Company's redeemable convertible preferred stock held by AP 11 Limited and (ii) shares of Class A common stock subject to options exercisable within 60 days of May 10, 2021.

(16) Consists of (i) shares of Class A common stock beneficially owned by our current executive officers and directors, and (ii) shares subject to options exercisable within 60 days of May 10, 2021, all of which are vested as of such date.

DESCRIPTION OF CAPITAL STOCK

General

The following description of our capital stock and certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws are summaries and are qualified by reference to the amended and restated certificate of incorporation, which will become effective immediately prior to the closing of this offering, and the amended and restated bylaws, which will become effective upon the closing of this offering. Copies of these documents have been filed with the SEC as exhibits to our registration statement, of which this prospectus forms a part. The descriptions of the common stock and preferred stock reflect changes to our capital structure that will be in effect on the closing of this offering.

Upon filing of our amended and restated certificate of incorporation and the closing of this offering, our authorized capital stock will consist of shares of Class A common stock, par value $0.0001 per share, shares of Class B common stock, par value $0.0001 per share, and shares of preferred stock, par value $0.0001 per share. All of our authorized shares of redeemable convertible preferred stock will be undesignated.

As of , 2021, after giving effect to the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into shares of our Class A common stock and shares of our Class B common stock in connection with the closing of this offering, and the net exercise of (a) the outstanding warrant to purchase 79,545 shares of our Series D redeemable convertible preferred stock, and conversion to Class A common stock resulting in the issuance of shares of our Class A common stock and (b) the outstanding warrant to purchase 8,361,424 shares of our Class A common stock, resulting in the issuance of shares of our Class A common stock, there were shares of Class A common stock outstanding and shares of Class B common stock outstanding held of record by stockholders.

Class A common stock and Class B common stock

Holders of our Class A common stock and our Class B common stock have identical rights, provided that, (i) except as otherwise expressly provided in our amended and restated certificate of incorporation or as required by applicable law, on any matter that is submitted to a vote by our stockholders, holders of our Class A common stock are entitled to one vote per share of Class A common stock, and holders of our Class B common stock are not entitled to any votes per share of Class B common stock, including for the election of directors, and (ii) holders of our Class A common stock have no conversion rights, while holders of our Class B common stock have the right to convert each share of our Class B common stock into one share of Class A common stock at such holder's election, provided that as a result of such conversion, such holder would not beneficially own in excess of 4.99% of any class of our securities registered under the Exchange Act, except as expressly provided for in our amended and restated certificate of incorporation. However, this ownership limitation may be increased or decreased to any other percentage designated by such holder of Class B common stock upon 61 days' notice to us. Our Class A common stock and Class B common stock do not have cumulative voting rights. Accordingly, the holders of a majority of the outstanding shares of Class A common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they so choose, other than any directors that holders of any preferred stock we may issue may be entitled to elect. Subject to preferences that may be applicable to any then outstanding preferred stock, holders of our Class A common stock and Class B common stock are entitled to receive ratably those dividends, if any, as may be declared by the board of directors out of legally available funds. In the event of our liquidation, dissolution or winding up, the holders of our Class A common stock and Class B common stock will be entitled to share ratably in the assets legally available for distribution to stockholders after the payment of or provision for all of our debts and other liabilities, subject to the prior rights of any preferred stock then outstanding. Holders of our Class A common stock and Class B common stock have no preemptive rights or other subscription rights and there are no redemption or sinking funds provisions applicable to our Class A common stock and Class B common stock. All outstanding shares of our Class A common stock and Class B common stock are, and the Class A common stock and Class B common stock to be outstanding immediately prior to the closing of this offering will be, duly authorized, validly issued, fully paid and nonassessable. The rights, preferences and privileges of

holders of our Class A common stock and Class B common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Preferred stock

Upon the closing of this offering, all of our currently outstanding shares of redeemable convertible preferred stock (including shares issued upon expected net exercise of warrants) will convert into Class A common stock or Class B common stock and we will not have any redeemable convertible preferred stock outstanding. Immediately prior to the closing of this offering, our certificate of incorporation will be amended and restated to delete all references to such shares of redeemable convertible preferred stock. Under the amended and restated certificate of incorporation, our board of directors will have the authority, without further action by the stockholders, to issue up to shares of redeemable convertible preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of redeemable convertible preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the Class A common stock or the Class B common stock. The issuance of redeemable convertible preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in our control that may otherwise benefit holders of our Class A common stock and may adversely affect the market price of the Class A common stock and the voting and other rights of the holders of Class A common stock. We have no current plans to issue any shares of redeemable convertible preferred stock.

Stock options

As of March 31, 2021, 8,108,225 shares of Class A common stock were issuable upon the exercise of outstanding stock options under the 2007 Plan, at a weighted-average exercise price of $ 0.22 per share, 153,615,632 shares of Class A common stock were issuable upon exercise of outstanding options under the 2017 Plan, with a weighted average exercise price of $0.08 per share and shares of our Class A common stock reserved for future issuance under the 2021 Plan, which will become effective once the registration statement of which this prospectus forms a part is declared effective, as well as any future automatic annual increases in the number of shares of Class A common stock reserved for issuance under the 2021 Plan and any shares underlying outstanding stock awards granted under (i) the 2007 Plan or (ii) the 2017 Plan, that expire or are repurchased, forfeited, cancelled or withheld. For additional information regarding terms of our equity incentive plans, see the section titled “Executive Compensation—Equity benefit plans.”

Registration rights

Upon the closing of this offering and subject to the lock-up agreements entered into in connection with this offering and federal securities laws, certain holders of shares of our Class A common stock and Class B common stock, including those shares of our common stock that will be issued upon the conversion of our convertible preferred stock in connection with this offering, will initially be entitled to certain rights with respect to registration of such shares under 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.

Generally, in an underwritten offering, the managing underwriter, if any, has the right, subject to specified conditions and limitations, to limit the number of shares the holders may include. The demand,

piggyback and Form S-3 registration rights described below will expire no later than three years after the closing of this offering.

Demand registration rights

Upon the closing of this offering, holders of an aggregate of shares of our Class A common stock, including shares issuable upon conversion of our Class B common stock, will be entitled to certain demand registration rights. At any time beginning 180 days after the closing of this offering, the holders of a majority of these shares may request that we register all or a portion of their shares. We are not required to effect more than two registration statements which are declared or ordered effective. Such request for registration must cover shares with an anticipated aggregate offering price of at least $5 million. With certain exceptions, we are not required to effect the filing of a registration statement during the period starting with the date of the filing of, and ending on a date 180 days following the effective date of the registration statement for this offering.

Piggyback registration rights

In connection with this offering, the holders of an aggregate of shares of our Class A common stock, including shares issuable upon conversion of our Class B common stock, were entitled to, and the necessary percentage of holders waived, their rights to notice of this offering and to include their shares of registrable securities in this offering. After this offering, 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, the holders of these shares will be entitled to certain piggyback registration rights allowing the holder to include their shares in such registration, subject to certain marketing and other limitations.

Form S-3 registration rights

Upon the closing of this offering, holders of an aggregate of shares of Class A common stock, including shares issuable upon conversion of our Class B common stock, will be entitled to certain Form S-3 registration rights. Holders of % of these shares can make a request that we register their shares on Form S-3 if we are qualified to file a registration statement on Form S-3 and if the reasonably anticipated aggregate net proceeds of the shares offered would equal or exceed $ million. We will not be required to effect more than registrations on Form S-3 within any twelve-month period.

Anti-takeover provisions

The provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws, which are summarized below, may have the effect of delaying, deferring or discouraging another person from acquiring control of our company. They are also designed, in part, to encourage persons seeking to acquire control of us to negotiate first with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us because negotiation of these proposals could result in an improvement of their terms.

Certificate of incorporation and bylaws to be in effect in connection with this offering

Because our stockholders do not have cumulative voting rights, stockholders holding a majority of the voting power of our shares of Class A common stock will be able to elect all of our directors. Our amended and restated certificate of incorporation, to be effective immediately prior to the closing of this offering, and our amended and restated bylaws, to be effective upon the closing of this offering, will provide for stockholder actions at a duly called meeting of stockholders or, before the date on which all shares of Class A common stock convert into a single class, by written consent. A special meeting of stockholders may be called by a majority of our board of directors, the chair of our board of directors, or our chief executive officer or president. Our amended and restated bylaws will establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors.

As described above in "Management—Composition of Our Board of Directors," in accordance with our amended and restated certificate of incorporation to be filed in connection with this offering, immediately after this offering, our board of directors will be divided into three classes with staggered three-year terms.

The foregoing provisions will make it more difficult for another party to obtain control of us by replacing our board of directors. Because our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated redeemable convertible preferred stock makes it possible for our board of directors to issue redeemable convertible preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of deterring hostile takeovers or delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts.

Section 203 of the Delaware General Corporation Law

When we have a class of voting stock that is either listed on a national securities exchange or held of record by more than 2,000 stockholders, we will be subject to Section 203 of the Delaware General Corporation Law (the DGCL) which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, subject to certain exceptions.

Choice of forum

Our amended and restated certificate of incorporation to be effective immediately prior to the closing of this offering will provide that the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) and any appellate court therefrom is the sole and exclusive forum for the following claims or causes of action under the Delaware statutory or common law: (i) any derivative claim or cause of action brought on our behalf; (ii) any claim or cause of action for a breach of fiduciary duty owed by any of our current or former directors, officers, or other employees to us or our stockholders; (iii) any claim or cause of action against us or any of our current or former directors, officers or other employees arising out of or pursuant to any provision of the DGCL, our amended and restated certificate of incorporation, or our bylaws (as each may be amended from time to time); (iv) any claim or cause of action seeking to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws (as each may be amended from time to time, including any right, obligation, or remedy thereunder); (v) any claim or cause of action as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; and (vi) any claim or cause of action against us or any of our current or former directors, officers, or other employees governed by the internal-affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants.

This choice of forum provision would not apply to claims or causes of action brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction, or the Securities Act.

In addition, our amended and restated certificate of incorporation to be effective immediately prior to the closing of this offering will provide that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause or causes of action arising under the Securities Act, including all causes of action asserted against any defendant to such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and

directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering.

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. We note that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Additionally, our amended and restated certificate of incorporation to be effective immediately prior to the closing of this offering will provide that any person or entity holding, owning or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions.

Limitations on liability and indemnification

See the section titled "Executive Compensation—Limitations on Liability and Indemnification."

Exchange listing

Our Class A common stock is currently not listed on any securities exchange. We intend to apply to have our Class A common stock approved for listing on The Nasdaq Global Market under the symbol " ."

Transfer agent and registrar

On the closing of this offering, the transfer agent and registrar for our Class A common stock and Class B common stock will be .

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our Class A common stock. Future sales of substantial amounts of our Class A common stock, including shares issued on the exercise of outstanding options, in the public market after this offering, or the possibility of these sales or issuances occurring, could adversely affect the prevailing market price for our Class A common stock or impair our ability to raise equity capital. Although we intend to apply to list our Class A common stock on The Nasdaq Global Market, we cannot assure you that there will be an active public market for our Class A common stock.

Following the closing of this offering, based on our shares outstanding as of December 31, 2020, a total of shares of Class A common stock and shares of Class B common stock will be outstanding, after giving effect to (i) the issuance of an additional 84,485,407 shares of our Series F redeemable convertible preferred stock in February 2021, (ii) the reclassification and renaming of all outstanding shares of common stock into shares of Class A common stock, (iii) the conversion of our outstanding shares of redeemable convertible preferred stock into shares of our Class A common stock and shares of our Class B common and (iv) the net exercise of (a) the outstanding warrant to purchase 79,545 shares of our Series D redeemable convertible preferred stock, resulting in the issuance of shares of our Class A common stock and (b) the outstanding warrant to purchase 8,361,424 shares of our Class A common stock, resulting in the issuance of shares of our Class A common stock.

Of these shares, all of the Class A common stock sold in this offering by us, plus any shares sold by us upon exercise of the underwriters' option to purchase additional Class A common stock, will be freely tradable in the public market without restriction or further registration under the Securities Act, unless these shares are held or purchased by "affiliates," as that term is defined in Rule 144 under the Securities Act (Rule 144). Shares purchased by our affiliates would be subject to the Rule 144 resale restrictions described below, other than the holding period requirement.

The remaining shares of our Class A common stock will be, and shares of Class A common stock subject to stock options or issuable upon conversion of Class B shares will be on issuance, "restricted securities," as that term is defined in Rule 144. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rules 144 or 701 under the Securities Act, which are summarized below. Restricted securities may also be sold outside of the United States to non-US persons in accordance with Rule 904 of Regulation S.

Subject to the lock-up agreements described below and the provisions of Rule 144 or Regulation S under the Securities Act, as well as our insider trading policy, these restricted securities will be available for sale in the public market after the date of this prospectus.

Rule 144

In general, under Rule 144 as currently in effect, once we have been subject to public company reporting requirements of Section 13 or Section 15(d) of the Exchange Act for at least 90 days, an eligible stockholder is entitled to sell such shares without complying with the manner of sale, volume limitation, or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. To be an eligible stockholder under Rule 144, such stockholder must not be deemed to have been one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and must have beneficially owned the shares proposed to be sold for at least six months, including the holding period of any prior owner other than our affiliates. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then such person is entitled to sell such shares without complying with any of the requirements of Rule 144, subject to the expiration of the lock-up agreements described below.

In general, under Rule 144, as currently in effect, our affiliates or persons selling shares on behalf of our affiliates are entitled to sell shares on expiration of the lock-up agreements described below. Beginning 90 days after the date of this prospectus, within any three-month period, such stockholders may sell a number of shares that does not exceed the greater of:

- 1% of the number of shares of Class A common stock then outstanding, which will equal approximately shares immediately after this offering, assuming no exercise of the underwriters' option to purchase additional shares of Class A common stock from us; or

- the average weekly trading volume of our Class A common stock on The Nasdaq Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us.

Rule 701

Rule 701 of the Securities Act (Rule 701) generally allows a stockholder who was issued shares under a written compensatory plan or contract and who is not deemed to have been an affiliate of our company during the immediately preceding 90 days, to sell these shares in reliance on Rule 144, but without being required to comply with the public information, holding period, volume limitation, or notice provisions of Rule 144. Rule 701 also permits affiliates of our company to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required by that rule to wait until 90 days after the date of this prospectus before selling those shares under Rule 701, subject to the expiration of the lock-up agreements described below.

Form S-8 registration statements

We intend to file one or more registration statements on Form S-8 under the Securities Act with the SEC to register the offer and sale of shares of our Class A common stock that are issuable under the 2007 Plan, the 2017 Plan, the 2021 Plan and the ESPP. These registration statements will become effective immediately upon filing. Shares covered by these registration statements will then be eligible for sale in the public markets, subject to vesting restrictions, any applicable lock-up agreements described below, and Rule 144 limitations applicable to affiliates.

Lock-up arrangements

We, and all of our directors, executive officers and the holders of substantially all of our Class A common stock and securities exercisable for or convertible into our Class A common stock outstanding immediately on the closing of this offering, have agreed with the underwriters that, until 180 days after the date of the underwriting agreement related to this offering, we and they will not, without the prior written consent of the representatives of the underwriters, subject to certain exceptions, directly or indirectly, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant for the sale of, lend or otherwise dispose of or transfer any of our shares of Class A common stock, or any securities convertible into or exercisable or exchangeable for shares of our Class A common stock, or enter into any hedging, swap or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of the securities, whether any such swap or transaction is to be settled by delivery of our Class A common stock or other securities, in cash or otherwise. These agreements are described in the section titled “Underwriting.” The representatives of the underwriters may, in their sole discretion, release any of the securities subject to these lock-up agreements at any time.

In addition to the restrictions contained in the lock-up agreements described above, we have entered into agreements with certain security holders, including the amended and restated investors’ rights agreement, our standard form of option agreement and our standard form of restricted stock agreement, that contain market stand-off provisions or incorporate market stand-off provisions from our equity incentive plan imposing restrictions on the ability of such security holders to offer, sell or transfer our equity securities for a period of 180 days following the date of this prospectus.

CERTAIN MATERIAL US FEDERAL INCOME TAX CONSEQUENCES TO NON-US HOLDERS

The following is a summary of certain material US federal income tax consequences to non-US holders (as defined below) of the purchase, ownership and disposition of our Class A common stock issued pursuant to this offering. This discussion is not a complete analysis of all potential US federal income tax consequences relating thereto, does not address the potential application of the Medicare contribution tax on net investment income, the alternative minimum tax, or the special tax accounting rules under Section 451(b) of the Code, and also does not address any US federal non-income tax consequences, such as estate or gift tax consequences, or any tax consequences arising under any state, local or foreign tax laws. This discussion is based on the Code, Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the Internal Revenue Service (IRS) all as in effect on the date of this prospectus. These authorities are subject to differing interpretations and may change, possibly retroactively, resulting in US federal income tax consequences different from those discussed below. We have not requested a ruling from the IRS with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS or a court will agree with such statements and conclusions.

This discussion is limited to non-US holders who purchase our Class A common stock pursuant to this offering and who hold our Class A common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all of the US federal income tax consequences that may be relevant to a non-US holder in light of such non-US holder's particular circumstances. This discussion also does not consider any specific facts or circumstances that may be relevant to non-US holders subject to special rules under the US federal income tax laws, including:

- certain former citizens or long-term residents of the United States;
- partnerships or other entities or arrangements treated as pass-through or disregarded entities for US federal income tax purposes (and investors therein);
- "controlled foreign corporations";
- "passive foreign investment companies";
- corporations that accumulate earnings to avoid US federal income tax;
- banks, financial institutions, investment funds, insurance companies, brokers, dealers or traders in securities;
- tax-exempt organizations and governmental organizations;
- tax-qualified retirement plans;
- persons who acquire our Class A common stock through the exercise of an option or otherwise as compensation;
- qualified foreign pension funds as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds;
- persons that elect to apply Section 1400Z-2 of the Code to gains recognized with respect to shares of our Class A common stock;
- persons that own or have owned, actually or constructively, more than 5% of our Class A common stock;
- persons who have elected to mark securities to market; and
- persons holding our Class A common stock as part of a hedging or conversion transaction or straddle, or synthetic security or a constructive sale, or other risk reduction strategy or integrated investment.

If an entity or arrangement that is classified as a partnership for US federal income tax purposes holds our Class A common stock, the US federal income tax treatment of a partner in the partnership will generally depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Partnerships holding our Class A common stock and the partners in such

partnerships are urged to consult their tax advisors about the particular US federal income tax consequences to them of holding and disposing of our Class A common stock.

THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. PROSPECTIVE INVESTORS SHOULD CONSULT THEIR TAX ADVISORS REGARDING THE PARTICULAR US FEDERAL INCOME TAX CONSEQUENCES TO THEM OF ACQUIRING, OWNING AND DISPOSING OF OUR CLASS A COMMON STOCK, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL OR FOREIGN TAX LAWS AND ANY OTHER US FEDERAL TAX LAWS.

Definition of Non-US Holder

For purposes of this discussion, a non-US holder is any beneficial owner of our Class A common stock that is not a "US holder" or a partnership (including any entity or arrangement treated as a partnership) for US federal income tax purposes. A US holder is any person that, for US federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is subject to US federal income tax regardless of its source; or
- a trust (1) whose administration is subject to the primary supervision of a US court and which has one or more US persons who have the authority to control all substantial decisions of the trust or (2) that has a valid election in effect under applicable Treasury Regulations to be treated as a US person.

Distributions on Our Class A Common Stock

As described under the section titled "Dividend Policy," we do not anticipate declaring or paying, in the foreseeable future, any cash distributions on our capital stock. However, if we distribute cash or other property on our Class A common stock, such distributions will constitute dividends for US federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under US federal income tax principles. Amounts not treated as dividends for US federal income tax purposes will constitute a return of capital and will first be applied against and reduce a holder's tax basis in our Class A common stock, but not below zero. Any excess will be treated as gain realized on the sale or other disposition of our Class A common stock and will be treated as described under the section titled "Certain Material US Federal Income Tax Consequences to Non-US Holders—Gain on Disposition of Our Class A Common Stock" below.

Subject to the discussion below regarding effectively connected income, backup withholding and FATCA (as defined below), dividends paid to a non-US holder of our Class A common stock generally will be subject to US federal withholding tax at a rate of 30% of the gross amount of the dividends or such lower rate specified by an applicable income tax treaty. To receive the benefit of a reduced treaty rate, a non-US holder must furnish us or our withholding agent with a valid IRS Form W-8BEN (in the case of individuals) or IRS Form W-8BEN-E (in the case of entities), or other appropriate form, certifying such holder's qualification for the reduced rate. This certification must be provided to us or our withholding agent before the payment of dividends and must be updated periodically. In the case of a non-US Holder that is an entity, Treasury Regulations and the relevant tax treaty provide rules to determine whether, for purposes of determining the applicability of the tax treaty, dividends will be treated as paid to the entity or to those holding an interest in the entity. If the non-US holder holds our Class A common stock through a financial institution or other agent acting on the non-US holder's behalf, the non-US holder will be required to provide appropriate documentation to the agent, which then will be required to provide certification to us or our withholding agent, either directly or through other intermediaries.

If a non-US holder holds our Class A common stock in connection with the conduct of a trade or business in the United States, and dividends paid on our Class A common stock are effectively connected with such holder's US trade or business (and are attributable to such holder's permanent establishment or

fixed base in the United States if required by an applicable tax treaty), the non-US holder will be exempt from US federal withholding tax. To claim the exemption, the non-US holder must generally furnish a valid IRS Form W-8ECI (or applicable successor form) to the applicable withholding agent.

However, any such effectively connected dividends paid on our Class A common stock generally will be subject to US federal income tax on a net income basis at the regular US federal income tax rates in the same manner as if such holder were a resident of the United States. A non-US holder that is a foreign corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items.

Non-US holders that do not provide the required certification on a timely basis, but that qualify for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-US holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

Gain on Disposition of Our Class A Common Stock

Subject to the discussion below regarding backup withholding and FATCA (as defined below), a non-US holder generally will not be subject to US federal income tax on any gain realized on the sale or other disposition of our Class A common stock, unless:

- the gain is effectively connected with the non-US holder's conduct of a trade or business in the United States and, if required by an applicable income tax treaty, is attributable to a permanent establishment or fixed base maintained by the non-US holder in the United States;
- the non-US holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition, and certain other requirements are met; or
- our Class A common stock constitutes a "United States real property interest" by reason of our status as a United States real property holding corporation (USRPHC) for US federal income tax purposes at any time within the shorter of the five-year period preceding the disposition or the non-US holder's holding period for our Class A common stock, and our Class A common stock is not "regularly traded" on an established securities market during the calendar year in which the sale or other disposition occurs.

Gain described in the first bullet point above generally will be subject to US federal income tax on a net income basis at the regular US federal income tax rates in the same manner as if such holder were a resident of the United States. A non-US holder that is a foreign corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items.

Gain described in the second bullet point above will be subject to US federal income tax at a flat 30% rate (or such lower rate specified by an applicable income tax treaty), but may be offset by certain .-US-source capital losses (even though the individual is not considered a resident of the United States), provided that the non-US holder has timely filed US federal income tax returns with respect to such losses.

Determining whether we are a USRPHC depends on the fair market value of our US real property interests relative to the fair market value of our other trade or business assets and our foreign real property interests. We believe that we are not currently and we do not anticipate becoming a USRPHC for US federal income tax purposes, although there can be no assurance we will not in the future become a USRPHC. Even if we are treated as a USRPHC, gain realized by a Non-US Holder on a disposition of our Class A common stock will not be subject to US federal income tax so long as (1) the Non-US Holder owned, directly, indirectly and constructively, no more than 5% of our Class A common stock at all times within the shorter of (a) the five-year period preceding the disposition or (b) the holder's holding period and (2) our Class A common stock is regularly traded on an established securities market within the meaning of applicable US Treasury regulations. There can be no assurance that our Class A common stock qualify as regularly traded on an established securities market. If any gain on a non-US holder's disposition of our Class A common stock is taxable because we are a USRPHC and such holder's ownership of our Class A common

stock exceeds 5%, such holder will be taxed on such disposition generally in the manner applicable to US persons and in addition, a purchaser of such holder's Class A common stock may be required to withhold tax with respect to that obligation.

Non-US holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

Annual reports are required to be filed with the IRS and provided to each non-US holder indicating the amount of distributions on our Class A common stock paid to such holder and the amount of any tax withheld with respect to those distributions. These information reporting requirements apply even if no withholding was required because the distributions were effectively connected with the holder's conduct of a US trade or business, or withholding was reduced or eliminated by an applicable income tax treaty. This information also may be made available under a specific treaty or agreement with the tax authorities in the country in which the non-US holder resides or is established. Backup withholding, currently at a 24% rate, generally will not apply to payments to a non-US holder of dividends on or the gross proceeds of a disposition of our Class A common stock provided the non-US holder furnishes the required certification for its non-US status, such as by providing a valid IRS Form W-8BEN, IRS Form W-8BEN-E or IRS Form W-8ECI, or certain other requirements are met, and if the payor does not have actual knowledge, or reason to know, that the holder is a US person who is not an exempt recipient.

Backup withholding is not an additional tax. If any amount is withheld under the backup withholding rules, the non-US holder should consult with a US tax advisor regarding the possibility of and procedure for obtaining a refund or a credit against the non-US holder's US federal income tax liability, if any.

Withholding on Foreign Entities

Sections 1471 through 1474 of the Code, which are commonly referred to as FATCA, impose a US federal withholding tax of 30% on certain payments made to a "foreign financial institution" (as specially defined under these rules) unless such institution enters into an agreement with the US government to withhold on certain payments and to collect and provide to the US tax authorities substantial information regarding certain US account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with US owners) or an exemption applies. FATCA also generally imposes a US federal withholding tax of 30% on certain payments made to a non-financial foreign entity unless such entity provides the withholding agent a certification identifying certain direct and indirect US owners of the entity or an exemption applies. An intergovernmental agreement between the United States and an applicable foreign country may modify these requirements. Under certain circumstances, a non-US holder might be eligible for refunds or credits of such taxes. FATCA currently applies to dividends paid on our Class A common stock and would have applied also to payments of gross proceeds from the sale or other disposition of our Class A common stock. However, the US Treasury Department has released proposed regulations under FATCA providing for the elimination of the federal withholding tax of 30% applicable to gross proceeds of a sale or other disposition of from property of a type that can produce US source dividends or interest. Under these proposed Treasury Regulations (which may be relied upon by taxpayers prior to finalization), FATCA will not apply to gross proceeds from sales or other dispositions of our Class A common stock.

Prospective investors are encouraged to consult with their own tax advisors regarding the possible implications of FATCA on their investment in our Class A common stock.

EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS OWN TAX ADVISOR REGARDING THE TAX CONSEQUENCES OF PURCHASING, HOLDING AND DISPOSING OF OUR CLASS A COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY RECENT AND PROPOSED CHANGE IN APPLICABLE LAW, AS WELL AS TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL, NON-US OR US FEDERAL NON-INCOME TAX LAWS.

UNDERWRITING

BofA Securities, Inc., Cowen and Company, LLC and Piper Sandler & Co. are acting as representatives of each of the underwriters named below. Subject to the terms and conditions set forth in an underwriting agreement among us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of shares of common stock set forth opposite its name below.

Underwriter	Number of Shares
BofA Securities, Inc.	
Cowen and Company, LLC	
Piper Sandler & Co.	
Oppenheimer & Co. Inc.	
Total	

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the shares, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officers' certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Commissions and discounts

The representatives have advised us that the underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of $ per share. After the initial offering, the public offering price, concession or any other term of the offering may be changed.

The following table shows the public offering price, underwriting discount and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional shares.

	Per Share	Without Option	With Option
Public offering price	$	$	$
Underwriting discount	$	$	$
Proceeds, before expenses, to us	$	$	$

The expenses of the offering, not including the underwriting discount, are estimated at $ and are payable by us. We have also agreed to reimburse the underwriters for certain of their expenses incurred in connection with, among others, the review and clearance by the Financial Industry Regulatory Authority, Inc. in an amount of up to $.

Option to purchase additional shares

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus, to purchase up to additional shares at the public offering price, less the underwriting

discount. If the underwriters exercise this option, each will be obligated, subject to conditions contained in the underwriting agreement, to purchase a number of additional shares proportionate to that underwriter's initial amount reflected in the above table.

No sales of similar securities

We, our executive officers and directors and our other existing security holders have agreed not to sell or transfer any common stock or securities convertible into, exchangeable for, exercisable for, or repayable with common stock, for 180 days after the date of this prospectus without first obtaining the written consent of BofA Securities, Inc., Cowen and Company, LLC and Piper Sandler & Co. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly:

- offer, pledge, sell or contract to sell any common stock,
- sell any option or contract to purchase any common stock,
- purchase any option or contract to sell any common stock,
- grant any option, right or warrant for the sale of any common stock,
- lend or otherwise dispose of or transfer any common stock,
- request or demand that we file or make a confidential submission of a registration statement related to the common stock, or
- enter into any swap or other agreement that transfers, in whole or in part, the economic consequence of ownership of any common stock whether any such swap or transaction is to be settled by delivery of shares or other securities, in cash or otherwise.

This lock-up provision applies to common stock and to securities convertible into or exchangeable or exercisable for or repayable with common stock. It also applies to common stock owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition.

Nasdaq Global Market listing

We expect the shares to be approved for listing on The Nasdaq Global Market, subject to notice of issuance, under the symbol " ."

Before this offering, there has been no public market for our common stock. The initial public offering price will be determined through negotiations between us and the representatives. In addition to prevailing market conditions, the factors to be considered in determining the initial public offering price are:

- the valuation multiples of publicly traded companies that the representatives believe to be comparable to us,
- our financial information,
- the history of, and the prospects for, our company and the industry in which we compete,
- an assessment of our management, its past and present operations, and the prospects for, and timing of, our future revenues,
- the present state of our development,
- the likelihood of approval for our drug candidates, and
- the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for the shares may not develop. It is also possible that after the offering the shares will not trade in the public market at or above the initial public offering price.

The underwriters do not expect to sell more than 5% of the shares in the aggregate to accounts over which they exercise discretionary authority.

Price stabilization, short positions and penalty bids

Until the distribution of the shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing our common stock. However, the representatives may engage in transactions that stabilize the price of the common stock, such as bids or purchases to peg, fix or maintain that price.

In connection with the offering, the underwriters may purchase and sell our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering. "Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares described above. The underwriters may close out any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option granted to them. "Naked" short sales are sales in excess of such option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of shares of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. The underwriters may conduct these transactions on The Nasdaq Global Market, in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor any of the underwriters make any representation that the representatives will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

Electronic distribution

In connection with the offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail.

Other relationships

Some of the underwriters and their affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They have received, or may in the future receive, customary fees and commissions for these transactions.

In addition, in the ordinary course of their business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

European Economic Area

In relation to each Member State of the European Economic Area (each a "Relevant State"), no shares have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that offers of shares may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

a. to any legal entity which is a qualified investor as defined under the Prospectus Regulation;

b. to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or

c. in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares shall require us or any representative to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

Each person in a Relevant State who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with us and the representatives that it is a qualified investor within the meaning of the Prospectus Regulation.

In the case of any shares being offered to a financial intermediary as that term is used in Article 5(1) of the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer to the public other than their offer or resale in a Relevant State to qualified investors, in circumstances in which the prior consent of the representatives has been obtained to each such proposed offer or resale.

We, the representatives and our respective affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements and agreements.

For the purposes of this provision, the expression an "offer to the public" in relation to any shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

The above selling restriction is in addition to any other selling restrictions set out below.

In connection with the offering, the underwriters are not acting for anyone other than the issuer and will not be responsible to anyone other than the issuer for providing the protections afforded to their clients nor for providing advice in relation to the offering.

Notice to prospective investors in the United Kingdom

In relation to the United Kingdom (UK), no shares have been offered or will be offered pursuant to the offering to the public in the UK prior to the publication of a prospectus in relation to the shares which has been approved by the Financial Conduct Authority in the UK in accordance with the UK Prospectus Regulation and the FSMA, except that offers of shares may be made to the public in the UK at any time under the following exemptions under the UK Prospectus Regulation and the FSMA:

a. to any legal entity which is a qualified investor as defined under the UK Prospectus Regulation;

b. to fewer than 150 natural or legal persons (other than qualified investors as defined under the UK Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or

c. at any time in other circumstances falling within section 86 of the FSMA,

provided that no such offer of shares shall require us or any representative to publish a prospectus pursuant to Section 85 of the FSMA or Article 3 of the UK Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation.

Each person in the UK who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with us and the representatives that it is a qualified investor within the meaning of the UK Prospectus Regulation.

In the case of any shares being offered to a financial intermediary as that term is used in Article 5(1) of the UK Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer to the public other than their offer or resale in the UK to qualified investors, in circumstances in which the prior consent of the representatives has been obtained to each such proposed offer or resale.

We, the representatives and our respective affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements and agreements.

For the purposes of this provision, the expression an "offer to the public" in relation to any shares in the UK means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, the expression "UK Prospectus Regulation" means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018, and the expression "FSMA" means the Financial Services and Markets Act 2000.

In connection with the offering, the underwriters are not acting for anyone other than the issuer and will not be responsible to anyone other than the issuer for providing the protections afforded to their clients nor for providing advice in relation to the offering.

This document is for distribution only to persons who (i) have professional experience in matters relating to investments and who qualify as investment professionals within the meaning of Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (as amended, the Financial Promotion Order), (ii) are persons falling within Article 49(2)(a) to (d) ("high net worth companies, unincorporated associations etc.") of the Financial Promotion Order, (iii) are outside the United Kingdom, or (iv) are persons to whom an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000, as amended (FSMA)) in connection with the issue or sale of any securities may otherwise lawfully be communicated or caused to be communicated (all such persons together being referred to as "relevant persons"). This document is directed only at relevant persons and must not be acted on or relied on by persons who are not relevant persons. Any investment or investment activity to which this document relates is available only to relevant persons and will be engaged in only with relevant persons.

Notice to prospective investors in Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (SIX) or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, the company, the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority (FINMA), and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes (CISA). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

Notice to prospective investors in the Dubai International Financial Centre

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority (DFSA). This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

Notice to prospective investors in Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission, in relation to the offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001 (the Corporations Act), and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons (the Exempt Investors) who are "sophisticated investors" (within the meaning of section 708(8) of the Corporations Act), "professional investors" (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of twelve months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

Notice to prospective investors in Hong Kong

The shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or (b) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the shares has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong

(except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the Securities and Futures Ordinance and any rules made under that Ordinance.

Notice to prospective investors in Japan

The shares have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold, directly or indirectly, in Japan, or for the benefit of any Japanese Person or to others for re-offering or resale, directly or indirectly, in Japan or to any Japanese Person, except in compliance with all applicable laws, regulations and ministerial guidelines promulgated by relevant Japanese governmental or regulatory authorities in effect at the relevant time. For the purposes of this paragraph, "Japanese Person" shall mean any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

Notice to prospective investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, the shares were not offered or sold or caused to be made the subject of an invitation for subscription or purchase and will not be offered or sold or caused to be made the subject of an invitation for subscription or purchase, and this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares, has not been circulated or distributed, nor will it be circulated or distributed, whether directly or indirectly, to any person in Singapore other than (i) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time (the SFA)) pursuant to Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

(a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

(b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities or securities-based derivatives contracts (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

(a) to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;

(b) where no consideration is or will be given for the transfer;

(c) where the transfer is by operation of law; or

(d) as specified in Section 276(7) of the SFA.

Notice to prospective investors in Canada

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of

the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 *Underwriting Conflicts* (**NI 33-105**), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

LEGAL MATTERS

Cooley LLP is representing us in this offering. Certain legal matters in connection with this offering will be passed upon for the underwriters by Latham & Watkins LLP.

EXPERTS

The financial statements as of December 31, 2020 and 2019, and for each of the two years in the period ended December 31, 2020, included in this Prospectus have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report appearing herein. Such financial statements have been so included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of Class A common stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all the information set forth in the registration statement, some of which is contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and our Class A common stock, we refer you to the registration statement, including the exhibits filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. The SEC also maintains an internet website that contains reports and other information about issuers, like us, that file electronically with the SEC. The address of that website is www.sec.gov.

On the closing of this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for inspection and copying at the public reference room and website of the SEC referred to above.

We also maintain a website at sagimet.com. Information contained in, or accessible through, our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is only as an inactive textual reference.

SAGIMET BIOSCIENCES INC.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of Sagimet Biosciences Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Sagimet Biosciences Inc. (the "Company") as of December 31, 2020 and 2019, the related statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders' deficit, and cash flows, for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of 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 accounting principles generally accepted in the United States of America.

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/ DELOITTE & TOUCHE LLP

San Jose, California
March 10, 2021
We have served as the Company's auditor since 2015.

SAGIMET BIOSCIENCES INC.

BALANCE SHEETS
(in thousands, except for share and per share amounts)

	As of December 31, 2019	As of December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 10,212	$ 68,702
Prepaid expenses and other current assets	603	36
Total current assets	10,815	68,738
Operating lease right-of-use assets	318	194
Deposits	27	27
Total assets	$ 11,160	$ 68,959
Liabilities, redeemable convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 1,199	$ 513
Accrued expenses and other current liabilities	747	1,252
Operating lease liabilities	130	145
Total current liabilities	2,076	1,910
Long-term liabilities		
Operating lease liabilities, less current portion	211	65
Redeemable convertible preferred stock warrant liability	9	9
Total liabilities	2,296	1,984
Commitments and contingencies (Note 9)		
Redeemable convertible preferred stock: $0.0001 par value; 759,506,853 and 1,373,810,170 shares authorized at December 31, 2019 and 2020, respectively; 759,137,698 and 1,289,245,218 shares issued and outstanding at December 31, 2019 and 2020, respectively; liquidation value of $152,944 and $221,963 at December 31, 2019 and 2020, respectively.	134,179	202,885
Stockholders' deficit:		
Common stock, $0.0001 par value; 854,406,696 and 1,590,550,754 shares authorized at December 31, 2019 and 2020, respectively; 7,674,259 shares issued and outstanding at December 31, 2019 and 2020, respectively.	1	1
Additional paid-in capital	30,241	31,016
Accumulated deficit	(155,557)	(166,927)
Total stockholders' deficit	(125,315)	(135,910)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	$ 11,160	$ 68,959

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

SAGIMET BIOSCIENCES INC.

STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except for share and per share amounts)

	Year ended December 31, 2019	Year ended December 31, 2020
Operating expenses:		
Research and development	$ 8,391	$ 8,182
General and administrative	5,861	3,218
Total operating expenses	14,252	11,400
Loss from operations	(14,252)	(11,400)
Other income (expense), net:		
Interest expense	(64)	—
Change in fair value of related parties convertible notes	321	—
Change in fair value of redeemable convertible preferred stock tranche liability	(390)	—
Change in fair value of redeemable convertible preferred stock warrants	(4)	—
Interest income and other	128	30
Total other income (expense), net	(9)	30
Net loss and comprehensive loss	$ (14,261)	$ (11,370)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.86)	$ (1.48)
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	7,674,259	7,674,259

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

SAGIMET BIOSCIENCES INC.

STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(in thousands, except share amounts)

	Redeemable convertible preferred stock		Common stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at January 1, 2019	127,498,973	$ 75,683	7,674,259	$ 1	$ 27,253	$ (141,296)	$ (114,042)
Net loss	—	—	—	—	—	(14,261)	(14,261)
Issuance of Series E redeemable convertible preferred stock, net of issuance costs of $124, in conjunction with extinguishment and conversion of related parties convertible notes (Notes 8 and 10)	631,638,725	58,496	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	2,988	—	2,988
Balance at December 31, 2019	759,137,698	134,179	7,674,259	1	30,241	(155,557)	(125,315)
Net loss	—	—	—	—	—	(11,370)	(11,370)
Issuance of Series F redeemable convertible preferred stock, net of issuance costs of $314	530,107,520	68,706	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	775	—	775
Balance at December 31, 2020	1,289,245,218	$202,885	7,674,259	$ 1	$ 31,016	$ (166,927)	$ (135,910)

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

SAGIMET BIOSCIENCES INC.

STATEMENTS OF CASH FLOWS
(in thousands)

	Year ended December 31, 2019	Year ended December 31, 2020
Cash flows from operating activities		
Net loss	$(14,261)	$(11,370)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1	—
Gain on sale of property and equipment	—	(20)
Non-cash lease expense	87	124
Stock-based compensation expense	2,988	775
Debt discount and issuance cost amortization	8	—
Gain on debt extinguishment	(93)	—
Change in fair value of redeemable convertible preferred stock warrants	4	—
Change in fair value of related parties convertible notes	(321)	—
Change in fair value of redeemable convertible preferred stock tranche liability	390	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(569)	567
Accounts payable and accrued expenses	1,278	(361)
Operating lease liabilities	(64)	(131)
Net cash used in operating activities	(10,552)	(10,416)
Cash flows from investing activities		
Change in deposits	(27)	—
Proceeds from sale of property and equipment	—	20
Net cash provided by (used in) investing activities	(27)	20
Cash flows from financing activities		
Repayment of debt financing	(3,364)	—
Proceeds from issuance of redeemable convertible preferred stock, net	21,849	68,886
Net cash provided by financing activities	18,485	68,886
Net increase in cash	7,906	58,490
Cash and cash equivalents at the beginning of the period	2,306	10,212
Cash and cash equivalents at the end of the period	$ 10,212	$ 68,702
Supplemental cash flow information		
Series F financing costs in accrued liabilities	—	$ 180
Cash paid for interest	$ 136	—
Extinguishment and conversion of related parties convertible notes with issuance of Series E redeemable convertible preferred stock (Notes 8 and 10)	$ 36,257	—

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

SAGIMET BIOSCIENCES INC.

NOTES TO THE FINANCIAL STATEMENTS

1. Organization and description of business

Overview

Sagimet Biosciences Inc. (the Company) was incorporated in Delaware on December 19, 2006 as 3-V Biosciences, Inc. and is headquartered in San Mateo, California. The Company changed its name from 3-V Biosciences, Inc. to Sagimet Biosciences Inc. in August 2019. The Company is a clinical-stage biopharmaceutical company focused on developing a portfolio of in-house discovered, selective fatty acid synthase (FASN) inhibitors for the treatment of diseases that result from dysfunctional lipid metabolism pathways.

Liquidity

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry including, but not limited to, development by competitors of new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with governmental regulations and the need to obtain additional financing to fund operations. Drug candidates currently under development will require significant additional research and development efforts prior to commercialization. The Company's drug candidates are still in development and, to date, none of the Company's drug candidates have been approved for sale and, therefore, the Company has not generated any revenue from product sales.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The financial statements do not reflect any adjustments relating to the recoverability and reclassification of assets and liabilities that might be necessary if the Company is unable to continue as a going concern.

The Company has incurred operating losses and negative cash flows from operations since inception, including net losses of $14.3 million and $11.4 million for the years ended December 31, 2019 and 2020, respectively, and has relied on private equity and debt financings to fund its operations. As of December 31, 2020, the Company had an accumulated deficit of $166.9 million. For the years ended December 31, 2019 and 2020, the Company had net cash used in operations of $10.6 million and $10.4 million, respectively. To date, none of the Company's drug candidates have been approved for sale and therefore the Company has not generated any revenue from product sales. The Company expects to incur increased research and development expenses as it develops existing and future drug candidates. The Company expects operating losses to continue to increase for the foreseeable future. The Company's prospects are subject to risks, expenses and uncertainties frequently encountered by companies in the biotechnology industry as discussed above.

In December 2020, the Company received gross subscriptions for $80.0 million of Series F redeemable convertible preferred stock financings from new and existing investors. $68.7 million of net proceeds were received in December 2020 and $11.0 million of net proceeds were received in February 2021. The Company had cash and cash equivalents of $68.7 million as of December 31, 2020. Management believes that the Company's current cash and cash equivalents will be sufficient to fund its planned operations for at least 12 months from the issuance date of these financial statements.

Risks and Uncertainties

The Company is subject to certain risks and uncertainties, including, but not limited to changes in any of the following areas that the Company believes could have a material adverse effect on future financial position or results of operations: the availability of future financing; the ability to obtain regulatory approval and market acceptance of, and reimbursement for, the Company's drug candidates; the performance of third-party clinical research organizations and manufacturers; protection of the intellectual property; litigation or claims against the Company based on intellectual property, patent, product, regulatory or other

factors; and the Company's ability to attract and retain employees necessary to support commercial success. In addition, significant changes in the industry or customer requirements or the emergence of competitive products with new capabilities could adversely affect the Company's development and operating results.

The Company's general business strategy may be adversely affected by any such economic downturns, including the current downturn related to the ongoing COVID-19 pandemic, volatile business environments and continued unstable or unpredictable economic and market conditions.

Impact of the COVID-19 Pandemic

The COVID-19 pandemic, which began in December 2019 and has spread worldwide, has caused many governments to implement measures to slow the spread of the outbreak through quarantines, travel restrictions, heightened border security and other measures. The impact of this pandemic has been, and will likely continue to be, extensive in many aspects of society, which has resulted, and will likely continue to result, in significant disruptions to the global economy as well as businesses and capital markets around the world. The future progression of the pandemic and its effects on the Company's business and operations are uncertain. In response to public health directives and orders and to help minimize the risk of the virus to employees, the Company has taken precautionary measures, including implementing work-from-home policies for all employees. The impact of the virus, including work-from-home policies, may negatively impact productivity, disrupt the Company's business, and delay development program timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on the Company's ability to conduct its business in the ordinary course. Other impacts to the Company's business may include temporary closures of its suppliers and disruptions or restrictions on its employees' ability to travel. Any prolonged material disruption to the Company's employees or suppliers could adversely impact the Company's development activities, financial condition and results of operations, including its ability to obtain financing. The Company is monitoring the potential impact of the COVID-19 pandemic on its business and financial statements. To date, the Company has not experienced material business disruptions or incurred impairment losses in the carrying values of its assets as a result of the pandemic and it is not aware of any specific related event or circumstance that would require it to revise its estimates reflected in these financial statements.

2. Summary of significant accounting policies

Basis of Presentation

The financial statements and accompanying notes have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP).

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. On an ongoing basis, the Company evaluates its estimates and assumptions, including those related to the valuation of operating lease right-of-use assets, valuation of clinical trial accruals, related parties convertible notes, redeemable convertible preferred stock tranche liability, common and redeemable convertible preferred stock, stock-based compensation and income taxes. Management bases its estimates on historical experience and on various other assumptions that are believed to be 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. Actual results may differ materially from those estimates.

Cash and Cash equivalents

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. As of December 31, 2019 and 2020, cash and cash equivalents which are denominated in U.S. dollars consisted of bank deposits including deposits in a money market fund. All cash and cash equivalents were unrestricted as to withdrawal or use.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash and cash equivalents. Substantially all the Company's cash and cash equivalents were deposited in accounts at one financial institution, and account balances may at times exceed federally insured limits. Management believes that the Company is not exposed to significant credit risk due to the financial strength of the depository institution in which the cash is held.

Deferred Offering Costs

Deferred offering costs, consisting of legal, accounting and other fees and costs relating to the Company's planned Initial Public Offering (IPO) are capitalized and recorded on the balance sheets. The deferred offering costs will be offset against the proceeds received upon the closing of the planned IPO. In the event that the Company's plans for an IPO are terminated, all of the deferred offering costs will be written off within operating expenses in the Company's statements of operations and comprehensive loss. There were no deferred offering costs capitalized as of December 31, 2019 and 2020.

Property and Equipment

Property and equipment are recorded at cost, net of accumulated depreciation. Depreciation is recorded using the straight-line method over the estimated useful lives of the assets, generally three to five years. Major replacements and improvements are capitalized, while general repairs and maintenance are expensed as incurred.

	Estimated Useful Life
Computer equipment	3 years
Laboratory equipment	5 years
Office furniture	5 years
Leasehold improvements	Lesser of useful life or remaining lease term

Upon sale or retirement of assets, the cost and accumulated depreciation are removed from the balance sheet and any resulting gain or loss is reflected in the statement of operations and comprehensive loss in the period realized.

Impairment of Long-Lived Assets

The Company evaluates the carrying amount of its long-lived assets whenever events or changes in circumstances indicate that the assets may not be recoverable. An impairment loss is recognized when estimated future cash flows expected to result from the use of the asset and its eventual disposition are less than the carrying amount of the asset. To date, there have been no such impairment losses.

Leases

The Company enters into lease agreements for its office facility and accounts for its lease obligations under Accounting Standards Update (ASU) No. 2016-02, *Leases* (Topic 842) which the Company adopted in 2018.

The Company determines if an arrangement is or contains a lease and the classification of that lease at inception of a contract. The Company's operating lease asset is included in "operating lease right-of-use asset" (ROU asset), and the current and non-current portions of the operating lease liability are included in "operating lease liabilities", and "operating lease liabilities, less current portion", respectively, on the balance sheet. As of December 31, 2019 and 2020, the Company had no finance leases.

Operating lease ROU assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at the lease commencement date. Operating lease ROU assets are based on the corresponding lease liability adjusted for (i) payments made at or before the commencement date, (ii) initial direct costs incurred, and (iii) tenant incentives under the lease. The Company does not account for renewals or early terminations unless it is reasonably certain to exercise these options

at commencement. Operating lease expense is recognized on a straight-line basis over the lease term. The Company accounts for lease and non-lease components as a single lease component for operating leases. The Company does not record leases with terms of 12 months or less on the balance sheets.

As the implicit rate for the operating lease was not determinable, the Company used an incremental borrowing rate based on the information available at the lease commencement date in determining the present value of future payments. The Company's incremental borrowing rate was estimated to approximate the interest rate on a collateralized basis with similar terms and payments, in an economic environment where the leased asset is located. The Company determined the incremental borrowing rate by considering various factors, such as its credit rating, interest rates of similar debt instruments of entities with comparable credit ratings, the lease term and the currency in which the lease was denominated.

Accrued Research and Development Expense

Research and development costs are charged to expense as incurred. Research and development expenses include certain payroll and personnel expenses, consulting costs, external contract research and development expenses, and allocated overhead, including rent, equipment depreciation and utilities. Advance payments for goods or services for future research and development activities are deferred and expensed as the goods are delivered or the related services are performed.

The Company estimates preclinical study and clinical trial expenses based on the services performed pursuant to contracts with research institutions and clinical research organizations that conduct and manage preclinical studies and clinical trials on the Company's behalf. In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. These estimates are based on communications with the third-party service providers and the Company's estimates of accrued expenses and on information available at each balance sheet date. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly.

Revenue Recognition

The Company enters into or may enter into collaboration and licensing arrangements that generally contain multiple elements or deliverables, which may include (1) licenses to the Company's technology, (2) research and development activities performed for the collaboration partner, (3) participation on joint steering committees (JSCs), and (4) the manufacturing of clinical or preclinical material. Payments pursuant to these arrangements include milestone payments upon achieving significant development events, research and development reimbursements, sales milestones, and royalties on future drug sales. Variable consideration is constrained until it is probable that the revenue is not at a significant risk of reversal in a future period.

In determining the appropriate amount of revenue to be recognized for the components of the arrangements that are within the scope of Accounting Standards Codification, Topic 606, *Revenue from Contracts with Customers* (ASC 606), the Company performs the following steps: (i) identification of the promised goods or services in the contract within the scope of ASC 606; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. As part of the accounting for these arrangements, the Company must use significant judgment to determine: a) the number of performance obligations based on the determination under step (ii) above; b) the transaction price under step (iii) above; and c) the stand-alone selling price for each performance obligation identified in the contract for the allocation of transaction price in step (iv) above, and d) the measure of progress in step (v) above. The Company uses judgment to determine whether milestones or other variable consideration, except for royalties, should be included in the transaction price as described further below.

At the inception of each arrangement that includes milestone payments, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. 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 control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. At the end of each subsequent reporting period, the Company reevaluates the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings gin the period of adjustment.

For arrangements that include sales-based royalties or milestone payments, for which the license is deemed to be the predominant item, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

As of December 31, 2019 and 2020, no revenue has been recognized from any license agreement and no milestone is probable of being achieved for at least the next 12 months. For further discussion of accounting for revenues, see Note 8.

Segment Information

The Company operates and manages its business as a single operating and reporting segment for the purposes of assessing performance and making operating decisions. The Company's current focus is on developing and commercializing therapeutics for the treatment of a range of diseases including NASH and certain cancers.

Common Stock Valuation

Due to the absence of an active market for the Company's common stock, 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 exercise prices for options granted, 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 has been determined at each grant date based upon a variety of factors, including the illiquid nature of the common stock, arm's-length sales of the Company's capital stock (including redeemable convertible preferred stock), the effect of the rights and preferences of the redeemable convertible preferred stockholders, and the prospects of a liquidity event. Among other factors are the Company's financial position and historical financial performance, the status of technological developments within the Company's research, the composition and ability of the current research and management team, an evaluation or benchmark of the Company's competition, and the current business climate in the marketplace. Significant changes to the key assumptions underlying the factors used could result in different fair values of common stock at each valuation date.

Redeemable Convertible Preferred Stock

The Company records redeemable convertible preferred stock at fair value on the dates of issuance, net of issuance costs. The redeemable convertible preferred stock is recorded outside of stockholders' deficit because the shares contain liquidation features that are not solely within the Company's control. The Company has not adjusted the carrying values of the redeemable convertible preferred stock to the liquidation preferences of such shares because it is uncertain whether or when an event would occur that would obligate the Company to pay the liquidation preferences to holders of shares of redeemable convertible preferred stock. Subsequent adjustments to the carrying values to the liquidation preferences will be made only when it becomes probable that such a liquidation event will occur.

Redeemable Convertible Preferred Stock Tranche Liability

The Company determined the right of the investors to purchase shares of Series E redeemable convertible preferred stock at a future date met the definition of a freestanding instrument and was recognized as a liability at fair value upon the initial issuance of Series E redeemable convertible preferred stock in February 2019 (Redeemable Convertible Preferred Stock Tranche Liability). The liability was subject

to remeasurement at each balance sheet date, with changes in fair value recognized in other income (expense) in the statement of operations. Upon closing of the second tranche of Series E redeemable convertible preferred stock in July 2019, the Redeemable Convertible Preferred Stock Tranche Liability was extinguished and the marked-to-market fair value of the liability was included in the carrying value of redeemable convertible preferred stock issued.

Related Parties Convertible Notes

The Company has entered into convertible note agreements with certain investors of the Company (Related Parties Convertible Notes). The Company has elected to record certain Related Parties Convertible Notes at fair value on the date of issuance, with gains and losses arising from changes in fair value recognized in the statement of operations at each period end while such notes are outstanding. The fair value of the Related Parties Convertible Notes was determined using a probability weighted expected return model, a scenario-based valuation model in which discrete future outcome scenarios for the Company are projected and discounted to present value (see Note 3). Issuance costs are recognized in the statement of operations in the period in which they are incurred.

Common Stock Warrants

From time to time, the Company has issued warrants to investors and creditors together with the Company's debt and equity financings. When issued in connection with debt, the allocated value related to the warrants is generally recorded as additional interest cost on the related debt. When issued with redeemable convertible preferred stock, the allocated value related to the warrants is recorded as additional issuance costs of the redeemable convertible preferred stock. The Company values warrants using an option pricing model.

Stock-Based Compensation Expense

The Company accounts for all stock-based payment awards granted to employees and non-employees as stock-based compensation expense at fair value. The Company's stock-based payments include stock options and grants of common stock, including common stock subject to vesting. The measurement date for employee awards is the date of grant, and stock-based compensation costs are recognized as expense over the employees' requisite service period, which is the vesting period, on a straight-line basis. Prior to the adoption of ASU No. 2018-07, *Compensation-Stock Compensation* (Topic 718): *Improvements to Nonemployee Share-Based Payment Accounting (ASU 2018-07)* as discussed below under "Recently Adopted Accounting Pronouncements", the measurement date for non-employee awards was generally the date the services were completed, resulting in financial reporting period adjustments to stock-based compensation during the vesting terms for changes in the fair value of the awards. Since the adoption of ASU 2018-07, the measurement date for non-employee awards is the date of grant without changes in the fair value of the award. Stock-based compensation costs for non-employees are recognized as expense over the vesting period on a straight-line basis. Stock-based compensation expense is classified in the accompanying statement of operations based on the function to which the related services are provided. The Company recognizes stock-based compensation expense for the portion of awards that have vested. Forfeitures are recorded as they occur.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The Company has historically been a private company and lacks company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends on common stock and does not expect to pay any cash dividends in the foreseeable future.

For awards with service-based vesting conditions only, the Company recognizes share-based compensation expense on a straight-line basis over the requisite service or vesting period. For awards with

service- and performance-based vesting conditions, the Company recognizes stock-based compensation expense using the graded vesting method over the requisite service period beginning in the period in which the awards are deemed probable to vest, to the extent such awards are probable to vest. The Company recognizes the cumulative effect of changes in the probability outcomes in the period in which the changes occur.

Income Taxes

The Company accounts for income taxes using the asset and liability method. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse.

In evaluating the ability to recover its deferred income tax assets, the Company considers all available positive and negative evidence, including its operating results, ongoing tax planning and forecasts of future taxable income on a jurisdiction-by-jurisdiction basis. In the event the Company determines that it would be able to realize its deferred income tax assets in the future in excess of their net recorded amount, it would make an adjustment to the valuation allowance that would reduce the provision for income taxes. Conversely, in the event that all or part of the net deferred tax assets are determined not to be realizable in the future, an adjustment to the valuation allowance would be charged to earnings in the period when such determination is made. As of December 31, 2019 and 2020, the Company has recorded a full valuation allowance on its deferred tax assets.

Tax benefits related to uncertain tax positions are recognized when it is more likely than not that a tax position will be sustained during an audit. Interest and penalties related to unrecognized tax benefits are included within the provision for income tax.

Comprehensive Loss

Comprehensive loss includes all changes in stockholders' deficit during a period from non-owner sources. There have been no items qualifying as other comprehensive loss and, therefore, the Company's comprehensive loss was the same as its reported net loss.

Net Loss per Share Attributable to Common Stockholders

Basic net loss per common share attributable to common stockholders is calculated by dividing the net loss by the weighted-average number of common shares outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss by the weighted-average number of common shares and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share attributable to common stockholders calculation, the redeemable convertible preferred stock, common stock options and common and redeemable convertible preferred stock warrants are considered to be potentially dilutive securities. Basic and diluted net loss per share attributable to common stockholders is presented in conformity with the two-class method required for participating securities as the redeemable convertible preferred stock is considered a participating security. The Company's participating securities do not have a contractual obligation to share in the Company's losses. As such, the net loss was attributed entirely to common stockholders. As the Company has reported a net loss for the period presented, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders for this period.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (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 June 2018, the FASB issued ASU No. 2018-07 *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* (ASU 2018-07), which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. ASU 2018-07 is effective for fiscal years beginning after December 15, 2019 and applicable for interim periods in fiscal years beginning after December 15, 2020. Early adoption is permitted. The Company early adopted this standard on January 1, 2019. The adoption of this standard did not have a material impact on the Company's financial statements.

Effective January 1, 2019, the Company early adopted, for both annual and interim periods, ASC 606, *Revenue from Contracts with Customers* using the modified retrospective method. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity 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 entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and 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. ASC 606 is effective for periods beginning after December 15, 2018. The Company adopted ASC 606 on January 1, 2019. The adoption of this standard had no impact on the Company's financial statements as the Company does not currently have any revenue-generating arrangements.

In November 2018, the FASB issued ASU No. 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606* (ASU 2018-18). The primary focus of the standard is to clarify the interaction between Topic 808, *Collaborative Arrangements*, and Topic 606, *Revenue from Contracts with Customers*. The standard is effective for fiscal years beginning after December 15, 2020 and interim periods within fiscal years beginning after December 15, 2021. An entity is permitted to early adopt for periods for which financial statements have not yet been made available for issuance. An entity may not adopt the amendments earlier than its adoption date of Topic 606. The Company adopted this standard effective January 1, 2019 and the adoption did not have a material impact on the Company's financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement*, which modifies the disclosure requirements for fair value measurements (ASU 2018-13). ASU 2018-13 is effective for fiscal years, beginning after December 15, 2019. The Company adopted this standard on January 1, 2020. The adoption of ASU 2018-13 had no impact on the Company's financial statements.

New Accounting Pronouncements Not Yet Adopted

In December 2019, the FASB issued ASU No. 2019-12, *Simplifying Accounting for Income Taxes* (ASU 2019-12). The guidance simplifies the accounting for income taxes as part of the FASB's overall initiative to reduce complexity in accounting standards. Amendments include removal of certain exceptions to the general principles of ASC 740, *Income taxes*, and simplification in several other areas such as accounting for a franchise tax (or similar tax) that is partially based on income. This standard will be effective for fiscal years beginning after December 15, 2021. Early adoption is permitted for any financial

statements not yet issued to take advantage of the simplifications. The Company is still evaluating the impact of the ASU but does not expect the ASU to have a significant impact on the Company's financial statements when adopted.

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which address issues identified as a result of the complexity associated with applying generally accepted accounting principles for certain financial instruments with characteristics of liabilities and equity. This amendment is effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. The Company is currently evaluating the potential impact on its financial statements.

3. Fair value measurements and fair value of financial instruments

The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

Level 1—Quoted prices in active markets for identical assets or liabilities. The Company's deposits in a money market fund are Level 1 financial instruments.

Level 2—Observable inputs other than Level 1 prices, 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 and that are significant to the fair value of the assets or liabilities.

The Company's cash equivalents, which are funds held in a money market account, are measured at fair value on a recurring basis. The carrying amount of cash equivalents was $10.1 million and $68.7 million as of December 31, 2019 and 2020, respectively, which approximates the fair value and was determined based upon Level 1 inputs. The money market account is valued using quoted market prices with no valuation adjustments applied and is categorized as Level 1.

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.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability.

The Company's Level 3 liabilities that are measured at fair value on a recurring basis consist of the redeemable convertible preferred stock warrant liability, related parties convertible notes and redeemable convertible preferred stock tranche liability.

Assets and liabilities measured at fair value on a recurring basis are categorized in the tables below based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability.

The following table sets forth the Company's financial instruments that were measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

	December 31, 2019			
	Total fair value	Level 1	Level 2	Level 3
Assets:				
Cash and cash equivalents – money market funds	$10,066	$10,066	$—	$—
Liabilities:				
Redeemable convertible preferred stock warrant liability (Note 7)	$ 9	$ —	$—	$ 9

	December 31, 2020			
	Total fair value	Level 1	Level 2	Level 3
Assets:				
Cash and cash equivalents – money market funds	$68,672	$68,672	$ —	$ —
Liabilities:				
Redeemable convertible preferred stock warrant liability (Note 7)	$ 9	$ —	$ —	$ 9

During the periods presented, the Company has not changed the manner in which it values liabilities that are measured at estimated fair value using Level 3 inputs. There were no transfers within the hierarchy during the periods presented.

The following table provides a summary of changes in the estimated fair value of the financial instruments using significant Level 3 inputs (in thousands):

	Related parties convertible notes liability	Redeemable convertible preferred stock warrant liability	Redeemable convertible preferred stock tranche liability
Balance–January 1, 2019	$ 33,562	$ 5	$ —
Change in fair value of redeemable convertible preferred stock warrant liability	—	4	—
Change in fair value of related parties convertible notes	(321)	—	—
Change in fair value of redeemable convertible preferred stock tranche liability	—	—	390
Extinguishment and conversion of related parties convertible notes upon issuance of the first tranche of series E redeemable convertible preferred stock	(33,241)	—	—
Extinguishment of redeemable convertible stock tranche liability upon issuance of the second tranche of series E redeemable convertible preferred stock	—	—	(390)
Balance–December 31, 2019	$ —	$ 9	$ —
Change in fair value of redeemable convertible preferred stock warrant liability	—	—	—
Balance–December 31, 2020	$ —	$ 9	$ —

Redeemable Convertible Preferred Stock Warrant Liability

The Company estimates the fair value of the redeemable convertible preferred stock warrant liability (see Note 7) using an option pricing model and assumptions that are based on the individual characteristics of the warrants on the valuation date, as well as assumptions for fair value of the underlying redeemable convertible preferred stock, expected volatility, expected life, dividends, and risk-free interest rate. The Company will continue to adjust the liability for changes in fair value of these warrants until the earlier of: (i) exercise of warrants; (ii) expiration of warrants; (iii) a change of control of the Company; or (iv) the consummation of an initial public offering.

As of December 31, 2020, the fair value of the redeemable convertible preferred stock warrant liability was determined to be $9 thousand assuming a volatility rate of 92.6%, an expected term of 4.3 years, no dividends, and a risk-free interest rate of 0.29%. As of December 31, 2019, the fair value of the redeemable convertible preferred stock warrant liability was determined to be $9 thousand assuming a volatility rate of 92.8%, an expected term of 5.3 years, no dividends, and a risk-free interest rate of 1.71%.

Related Parties Convertible Notes

The fair value of the Related Parties Convertible Notes (see Note 8) was determined by using a probability weighted expected return model, a scenario-based valuation model in which discrete future

outcome scenarios for the Company are projected. At each outcome the future exit value is allocated to the security classes and the future allocations are discounted to present values to derive a value indication for a particular equity security. The fair value of the Related Parties Convertible Notes is remeasured at each reporting period and final conversion, with changes in fair value recognized in the Company's statement of operations.

2016 Related Parties Convertible Notes

The fair value of the first tranche of the Related Parties Convertible Notes was determined to be $8.8 million as of the issuance date in June 2016 using a discount rate of 45% to represent the required rate of return that an investor would demand to compensate for the risk of investment. The fair value of the second tranche of the Related Parties Convertible Notes was determined to be $11.4 million as of the issuance date in April 2017 using a discount rate of 40%.

2018 Related Parties Convertible Notes

The fair value of the February 2018 Related Parties Convertible Notes was determined to be $2.6 million as of the issuance date using a discount rate of 24% to represent the required rate of return that an investor would demand to be compensated for the risk of investment. The fair values of the first and second tranches of the June 2018 Related Parties Convertible Notes were each determined to be $0.7 million as of the issuance dates in June 2018 and July 2018 using a discount rate of 23%.

The Company recorded other income of $0.3 million and $0 for changes in the fair value of Related Parties Convertible Notes in its statement of operations for the years ended December 31, 2019 and 2020, respectively.

Redeemable Convertible Preferred Stock Tranche Liability

The fair value of the Redeemable Convertible Preferred Stock Tranche Liability was estimated using a Black Scholes Model to estimate the value of the second tranche as of issuance in February 2019 adjusting for probability considerations relating to different scenarios.

At the first close of the Series E redeemable convertible preferred stock in February 2019, the concluded value of the second tranche was determined to be nominal. The tranche was remeasured at each reporting period until the close of the second tranche in July 2019.

In July 2019, the Company issued the second tranche of the Series E redeemable convertible stock and the Redeemable Convertible Preferred Stock Tranche Liability was extinguished.

The Company recorded other expense of $0.4 million for the change in fair value of the Redeemable Convertible Preferred Stock Tranche Liability in its statement of operations for the year ended December 31, 2019. There was no impact in 2020.

4. Property and equipment, net

Property and equipment, net, as of December 31, 2019 consists of the following (in thousands):

	As of December 31, 2019
Laboratory equipment	$ 36
Office and computer equipment	—
Total property and equipment	$ 36
Less: accumulated depreciation	(36)
Total property and equipment, net	$ —

The Company had no property and equipment, net as of December 31, 2020.

Depreciation expense related to property and equipment was $1 thousand and $0 for the years ended December 31, 2019 and 2020, respectively.

5. Prepaid expenses and other current assets

Prepaid expenses and other current assets as of December 31, 2019 and 2020 consist of the following (in thousands):

	As of December 31, 2019	As of December 31, 2020
Prepaid research expenses	$130	$—
Prepaid clinical expenses	415	—
Other	58	36
Total	$603	$36

6. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities as of December 31, 2019 and 2020 consist of the following (in thousands):

	As of December 31, 2019	As of December 31, 2020
Accrued clinical costs	$671	$ 483
Accrued research costs	21	11
Employees' compensation	55	515
Other	—	243
Total	$747	$1,252

7. Note payable

In April 2015, the Company entered into a debt agreement with a financial institution to borrow up to $7.0 million. In June 2015, the Company borrowed an initial $5.0 million under the debt agreement. In June 2016, the Company borrowed the remaining $2.0 million. The Company was responsible for making interest only payments at an annual interest rate of 4.58% through January 2017. Following the interest only repayment period, on February 1, 2017, the Company was responsible for repaying the debt in equal monthly payments for 36 months thereafter. The Company could prepay the entire principal balance without penalty or premium. The debt agreement contains customary events of default, including bankruptcy or upon the occurrence of a material adverse change. The obligations under the debt agreement are collateralized by the Company's assets, excluding its intellectual property. In connection with the debt agreement, the Company issued to the lender 79,545 warrants to purchase Series D redeemable convertible preferred stock with an exercise price of $0.88 per share exercisable immediately with a contractual term of 10 years. As of December 31, 2019 and 2020, the fair value and carrying value of the redeemable convertible preferred stock warrant liability were $9 thousand (see Note 3).

On June 21, 2018, the Company entered into a forbearance agreement with the financial institution that allowed for the deferral until October 19, 2018 of five monthly principal payments upon certain events. Interest remained payable monthly during this period and the maturity date and principal payment schedule remained unchanged following the forbearance. Additionally, the Company's intellectual property was pledged as collateral. Following this forbearance period, the Company made a partial payment due under the forbearance agreement and, accordingly, the Company was in default.

On January 25, 2019 the Company entered into an amendment to the debt agreement with the financial institution. The amendment allowed for a waiver of certain events of default for periods prior to this amendment, modified certain financial and clinical trial covenants and modified the loan payments.

Upon closing of the Series E redeemable convertible preferred stock financing (see Note 10), the Company made all past due principal payments and on March 1, 2019 resumed monthly installments of principal and interest, which increased to prime plus 0.50% on both loan tranches. Upon certain additional financing milestones, the term of the loan was extended to 24 months and the interest rate increased to prime plus 2.50% for the remainder of the loan. This amendment was accounted for as a debt modification.

On May 15, 2019, the Company entered into a loan pay-off agreement with the financial institution, repaid all principal amounts due and settled all obligations under the debt agreement. Pursuant to the terms of the loan pay-off agreement, the Company realized a $0.1 million gain on the settlement which is included in interest income and other on the statement of operations.

8. Related parties

University of Zurich and ETH Zurich

In April 2007, the Company entered into a license agreement with the University of Zurich and ETH Zurich, both Company investors, for exclusive rights in the United States to certain know-how and patents related to antiviral drug testing. The license agreement remains in force until the last patent expires or the agreement is cancelled by either party. Upon execution of the agreement, the Company issued 153,000 shares of common stock to ETH Zurich and issued 76,500 shares of common stock to the University of Zurich.

Ascletis BioScience Co. Ltd

In January 2019, the Company entered into a license agreement that became effective in February 2019 with Ascletis, a biotechnology company based in Hangzhou and Shaoxing, China and a Company investor. The parties entered into this agreement with the intention to develop, manufacture, and commercialize the Company's proprietary fatty acid synthase (FASN) inhibitor, TVB-2640. Under the terms of the license agreement, the Company granted Ascletis an exclusive right and license under the Company's intellectual property to develop, manufacture, commercialize and otherwise exploit TVB-2640 and other FASN inhibitors in Greater China (People's Republic of China, Hong Kong, Macau and Taiwan, each referred to individually as a "Territory").

The Company will bear all expenses related to patients enrolled in Greater China as part of a global phase 2 trial, except for clinical operations and regulatory staff provided by Ascletis. The Company and Ascletwill jointly apply for an IND in Greater China. Except for this phase 2 trial and joint IND, Ascletis is solely responsible for all development activities and regulatory approvals for TVB-2640 in Greater China.

The Company is eligible to receive development and commercial milestone payments from Ascletis in aggregate of up to $122 million as well as tiered royalties ranging from percentages in the high single digits to mid-teens on future net sales of TVB-2640, which is referred to as ASC40 in Greater China. Ascletis also lead the Series E preferred stock financing in February 2019 (see Note 10).

This license and phase 2 research and development services components of this agreement are representative of a relationship with a customer and therefore are subject to ASC 606. As of December 31, 2019 and 2020, no revenue has been recognized from the license agreement with Ascletis and no milestone is probable of being achieved nor being included in the transaction price for at least the next 12 months.

Related Parties Convertible Notes

Since 2016, the Company has raised a total of $15.1 million through a series of note purchase agreements with certain investors (2016 and 2018 Notes Agreements).

The Company initially recorded the related parties convertible notes issued under the 2016 and 2018 Notes Agreements (collectively, the Related Parties Convertible Notes) at the fair value of $46.7 million. The Company recorded the subsequent change in the fair value of the Related Parties Convertible Notes in the statement of operations. The Company recorded other income of $0.3 million for the change in fair value

of Related Parties Convertible Notes in the statement of operations for the year ended December 31, 2019. In February 2019, the Related Parties Convertible Notes were converted and extinguished (see section immediately below).

December 2018 Related Parties Convertible Notes

On December 21, 2018 the Company entered into a convertible promissory note agreement (December 2018 Related Parties Convertible Notes) with related party investors raising $3.0 million from existing investors. The December 2018 Related Parties Convertible Notes bear interest at 8% per annum and mature on August 1, 2019, or upon request by the requisite holders after August 1, 2019. Upon a qualified financing of not less than $10.0 million or at the election of the noteholders, the December 2018 Related Parties Convertible Notes plus accrued interest will automatically convert into equity securities issued to the investors in the qualified financing at a conversion price equal to the cash price paid per share of the equity securities. In the event of default, the outstanding principal becomes immediately due and payable. The December 2018 Related Parties Convertible Notes were recorded at the amount of proceeds received of $3.0 million.

Conversion of All Convertible Notes

On February 12, 2019, the Company closed a financing through the issuance of Series E redeemable convertible preferred stock. In connection with such issuance, all Related Parties Convertible Notes and December 2018 Related Parties Convertible Notes plus accrued interest converted into shares of Series E at the applicable conversion rate (see Note 10).

9. Commitments and contingencies

Change in Control Retention Plan

In June 2020, the Company established a Change in Control Retention Plan (Retention Plan). The Retention Plan provides for incentive bonus payments to certain designated employees and other service providers of the Company in the event of a “Liquidation” as defined by the Company’s restated certificate of incorporation (Restated Certificate) which qualifies as a “change in ownership of a corporation” or a “change in ownership of a substantial portion of a corporation’s assets” as provided under Section 409A of the Internal Revenue Code. The Retention Plan provides for such incentive bonus payments as 7% of the total Liquidation consideration, up to a maximum of $13.0 million. The Retention Plan terminates on the earliest of (i) June 24, 2022; (ii) immediately prior to the Company’s consummation of an initial public offering; (iii) upon payment due to a Liquidation; or (iv) an earlier date decided by the Company’s board of directors in its sole discretion prior to the execution of a letter of intent for a Liquidation. The Company has not recognized compensation cost for the Retention Plan, as a Liquidation that qualifies as a change in ownership cannot be considered a probable occurrence until it is effective.

Facility Lease Agreement

Prior to 2019, the Company leased office space on a month-to-month basis which was terminated effective December 31, 2018. Deposits in the amount of approximately $2 thousand held by the lessor in connection with the Company’s expired facility lease agreement were repaid in February 2019. The Company rented temporary, as needed, office space until the commencement of the new facility operating lease on April 1, 2019.

On March 12, 2019, the Company executed a new 38-month non-cancelable operating lease agreement for 3,030 square feet of office space for its headquarters facility which commenced April 1, 2019. The lease provides for monthly lease payments of approximately $12 thousand with increases in the following two years. A security deposit of approximately $27 thousand is held by the lessor and is recorded as a long-term asset as of December 31, 2019 and 2020. The Company has accounted for the lease as an operating lease.

Operating lease cost for the years ended December 31, 2019 and 2020 was $0.1 million and $0.1 million, respectively.

The following is a schedule by year of future maturities of the Company's operating lease liabilities as of December 31, 2020 (in thousands):

2021	$157
2022	67
Total lease payments	224
Less: interest	(14)
Total	$210

Supplemental cash flow information related to leases was as follows for the year ended December 31, 2019 and 2020 (in thousands):

	Year ended December 31, 2019	Year ended December 31, 2020
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 87	$152
Right of use assets obtained in exchange for lease obligations (non-cash):		
Operating leases	$405	$ —

The weighted-average remaining lease term and discount rate related to the Company's lease liabilities as of December 31, 2019 and 2020 were 2.4 years and 8% and 1.4 years and 8%, respectively. The Company's lease discount rate is based on estimates of its incremental borrowing rate, as the discount rate implicit in the Company's lease cannot be readily determined. As the Company does not have any outstanding debt the Company estimates the incremental borrowing rate based on its estimated credit rating and available market information.

Guarantees and Indemnifications

In the normal course of business, the Company enters into agreements that contain a variety of representations and provide for general indemnification. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. As of December 31, 2019 and 2020, the Company does not have any material indemnification claims that were probable or reasonably possible and consequently has not recorded related liabilities.

Legal

The Company is not party to any material legal proceedings at this time. From time to time, the Company may become involved in various legal proceedings that arise in the ordinary course of its business.

10. Redeemable convertible preferred stock

Effective on February 11, 2019, the Company amended its Restated Certificate to increase the number of shares of redeemable convertible preferred stock that the Company is authorized to issue from 231,805,244 to 759,506,853, provide for a new series of redeemable convertible preferred stock, Series E, and decrease the authorized shares of all other series of redeemable convertible preferred stock. Effective December 21, 2020, the Company amended its Restated Certificate to increase the number of shares of redeemable convertible preferred stock that the Company is authorized to issue from 759,506,853 to 1,373,810,170 and provide for a new series of redeemable convertible preferred stock, series F.

The authorized, issued and outstanding shares of the redeemable convertible preferred stock, liquidation preferences and carrying values as of December 31, 2019 and 2020 were as follows (in thousands, except share numbers):

Series	As of December 31, 2019			
	Authorized Shares	Issued and Outstanding Shares	Liquidation Preference	Carrying Value
Series A	23,301	23,301	$ 233	$ 232
Series B	3,217	3,217	37	37
Series B-1	8,827,439	8,827,439	7,768	7,258
Series C	22,732,250	22,732,250	20,004	17,909
Series D	24,509,954	24,430,409	21,499	19,833
Series A’	720,199	720,199	—	—
Series B’	1,953,304	1,953,304	—	—
Series B-1’	14,001,243	14,001,243	—	2,781
Series C’	1,037	1,037	—	—
Series D’	3,475,426	3,475,426	—	739
Series D-1	51,331,148	51,331,148	45,172	26,894
Series E	631,928,335	631,638,725	58,231	58,496
Total	759,506,853	759,137,698	$152,944	$134,179

Series	As of December 31, 2020			
	Authorized Shares	Issued and Outstanding Shares	Liquidation Preference	Carrying Value
Series A	23,301	23,301	$ 233	$ 232
Series B	3,217	3,217	37	37
Series B-1	8,827,439	8,827,439	7,768	7,258
Series C	22,732,250	22,732,250	20,004	17,909
Series D	24,509,954	24,430,409	21,499	19,833
Series A’	720,199	720,199	—	—
Series B’	1,953,304	1,953,304	—	—
Series B-1’	14,001,243	14,001,243	—	2,780
Series C’	1,037	1,037	—	—
Series D’	3,475,426	3,475,426	—	739
Series D-1	51,331,148	51,331,148	45,171	26,894
Series E	631,638,725	631,638,725	58,231	58,496
Series F	614,592,927	530,107,520	69,020	68,707
Total	1,373,810,170	1,289,245,218	$221,963	$202,885

Issuance of Series Prime and Series D-1 Redeemable Convertible Preferred Stock

In June 2016, the Company entered into a 2016 note agreement to raise an amount of up to $12.0 million in two separate tranches with existing investors, which resulted in the Company increasing its authorized capital and the issuance of redeemable convertible series prime preferred stock (Series Prime) and Series D-1 redeemable convertible preferred stock.

The holders of the Series Prime are entitled to a number of votes equal to the number of shares of common stock to which the Series Prime can be converted at the time of the vote. In addition, shares of Series Prime have a liquidation preference equal to their issuance price increased by any declared and unpaid dividends, and follow other liquidation preference rules of corresponding redeemable convertible Series A, B, B-1, C and D preferred stock. The redeemable convertible Series D-1 preferred stock has senior liquidation preference to the other series of redeemable convertible preferred stock and no voting rights.

In connection with the issuance of the second tranche of the Related Parties Convertible Notes in April 2017, the Company cancelled shares of Junior Securities held by the investors and issued shares of redeemable convertible Series D-1 preferred stock and shares of Series Prime.

In February 2018 and June 2018, the Company entered into the 2018 Note Agreements to raise an amount of up to $4.5 million from existing investors. In connection with the issuance of the 2018 Related Parties Convertible Notes in February, June and July 2018, the Company exchanged, and cancelled shares of Junior Securities held by investors in the respective tranches of the Redeemable Convertible Related Parties Convertible Notes and issued shares of redeemable convertible Series D-1 preferred stock and shares of Series Prime.

Issuance of Series E Redeemable Convertible Preferred Stock

On February 12, 2019, the Company closed an $18.0 million Series E financing that consisted of the automatic conversion of the outstanding $3.0 million of December 2018 Related Parties Convertible Notes, plus accrued interest, and receipt of funds of $15.0 million in February 2019 from new and existing investors. Together, these transactions resulted in the issuance of 195,218,732 Series E redeemable convertible preferred shares (32,719,799 shares from the notes conversion and 162,498,933 shares purchased at a fair value of $0.09219 per share). In connection with this financing and at the election of the holders, all outstanding Related Parties Convertible Notes plus $2.2 million of accrued interest converted into 360,570,944 shares of Series E redeemable convertible preferred stock. In total, 555,789,676 shares of Series E redeemable convertible preferred stock were issued in February 2019.

In July 2019, the Company received proceeds from the second tranche of the Series E redeemable convertible preferred stock financing of $7.0 million, net of issuance costs, and issued 75,849,049 shares of Series E redeemable convertible preferred stock at a fair value of $0.09219 per share. Simultaneously with the issuance of the second tranche of the Series E redeemable convertible preferred stock, the Series E redeemable convertible preferred stock tranche liability was extinguished.

Issuance of Series F Redeemable Convertible Preferred Stock

On December 21, 2020, the Company received $68.7 million net of issuance costs from the first closing of its Series F financing from new and existing investors, resulting in the issuance of 530,107,520 Series F redeemable convertible preferred shares at $0.13020 per share (Series F Original Issue Price).

The rights, preferences and privileges of the redeemable convertible preferred stock as of December 31, 2020 were as follows:

Dividends. The holders of the Company's redeemable convertible preferred stock (excluding Series D-1) are entitled to receive noncumulative dividends of 8% per share (as adjusted for stock splits, combinations and reorganizations) per annum on each outstanding share of Series redeemable convertible preferred stock. Such dividends shall be payable only when and if declared by the Company's board of directors. Dividends on redeemable convertible preferred stock shall be payable in preference to and prior to any payments of any dividends on common stock. No dividends have been declared to date.

Conversion. Redeemable preferred stock is convertible, at the option of the holder, at any time, in fully paid, non-assessable shares of common stock at an initial conversion ratio of one-to-one (except Series D-1). Series D-1 does not have an elective conversion option.

All the redeemable convertible preferred stock will automatically convert into common stock, at the then-applicable conversion rate, in the event of either (i) the affirmative vote of the holders of a majority of the then-outstanding shares of series preferred, voting together as a single class on an as-converted to common stock basis, and the affirmative vote of the holders of a majority of the then-outstanding shares of Series F redeemable convertible preferred stock, or (ii) the closing of an underwritten initial public offering of the Company's common stock pursuant to a registration statement on Form S-1 under the Securities Act of 1933, as amended, at a price of at least 1.25 times the Series F Original Issue Price, with aggregate gross proceeds of not less than $50.0 million.

Voting rights. The holders of redeemable convertible preferred stock are entitled to that number of votes on all matters presented to stockholders equal to the number of shares of common stock then issuable upon conversion of such preferred stock, with the exception of the holders of the Series D-1 redeemable convertible preferred stock who do not have voting rights.

Liquidation. In the event of any sale of substantially all of the assets, a merger, or liquidation, dissolution or winding up of the Company, as defined in the Restated Certificate, the holders of Series A, B, B-1, C, D, D-1, E and F redeemable convertible preferred stock will be entitled to receive, on a pari passu basis and in preference to the holders of common stock, $10.00, $11.50, $0.88, $0.88, $0.88, $0.88, $0.09219 and $0.13020, respectively, per share (as adjusted for stock splits, combinations and reorganizations) plus declared and unpaid dividends, if any. In the event that the assets to be distributed among the holders of Series A, B, B-1, C, D, D-1, E and F redeemable convertible preferred stock are insufficient to permit full payment, the entire remaining assets of the Company legally available for distribution shall be distributed with equal priority and pro rata among these holders based on the aggregate liquidation preference of such holders. After distributing to all preferred stockholders, the remaining assets of the Company will be distributed ratably to the holders of the common stock on a pro rata basis. Each preferred stockholder may convert their shares to common stock shares and participate in the liquidation as a common stockholder. Such stockholder will not be entitled to receive any distribution that would otherwise be made to holders of shares of Series preferred that have not been converted (or have not been deemed to have converted) into shares of common stock. Series Prime do not have any liquidation preferences.

Deemed liquidation. A merger, acquisition, sale or lease of all of substantially all of the assets of the Company which will result in the Company's stockholders immediately prior to such transaction not holding at least 50% of the voting power of the surviving, continuing or purchasing entity, shall be deemed to be a liquidation, dissolution or winding up. Upon this event, holders of redeemable convertible preferred stock shall receive their liquidation preference including any accrued and unpaid dividends as of the liquidating date.

The holders of Series A, B, B-1, C, D, D-1, E and F redeemable 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, B, B-1, C, D, D-1, E and F redeemable convertible preferred stock. Therefore, the Series A, B, B-1, C, D, D-1, E and F redeemable convertible preferred stock are classified outside of stockholders' deficit on the balance sheets. The carrying value of the redeemable convertible preferred stock is not subsequently remeasured to the redemption value until the contingent redemption events are considered to be probable of occurring.

11. Stockholders' deficit

Common Stock

In connection with the Company's Tenth Amended and Restated Certificate filed December 21, 2020, the number of shares of common stock that the Company is authorized to issue increased from 854,406,696 to 1,590,550,754.

The Company's reserved shares of common stock for future issuance related to potential conversion of the redeemable convertible preferred stock, exercise of warrants and exercise of stock options as of December 31, 2019 and 2020 are as follows:

	As of December 31, 2019	As of December 31, 2020
Redeemable convertible preferred stock	707,806,550	1,237,914,070
Series D redeemable convertible preferred stock warrants	79,545	79,545
Options authorized and available for issuance	9,316,817	157,563,189
Options to purchase common stock	80,691,900	78,645,288
Warrants to purchase common stock (see Note 7)	8,361,424	8,361,424
Total	806,256,236	1,482,563,516

Redeemable Convertible Preferred Stock Warrant Liability

In connection with the note payable entered into on April 10, 2015 (see Note 7), the Company issued 79,545 Series D redeemable convertible preferred stock warrants with an exercise price of $0.88 per share. The warrants have a term of 10 years and are exercisable in whole or in part, at any time on or before the expiration date of April 10, 2025. At the time of issuance, the fair value of the redeemable convertible preferred stock warrant liability was determined using an option pricing model and assumptions that are based on the individual characteristics of the warrant on the valuation date, as well as assumptions for fair value of the underlying redeemable convertible preferred stock, expected volatility, expected life, dividends, and risk-free interest rate (see Note 3).

The Series D redeemable convertible preferred stock warrant has no voting rights, or other rights as a stockholder of the Company. The warrant is subject to adjustment in the event of any diluting dividends or distributions of the common stock, or any stock split, reverse stock split, recapitalization, reorganization or similar transaction. Upon any reclassification, exchange, substitution or other event, the number and or class of the securities and property that the holder would have received for the shares if this warrant had been issued immediately before such event will be adjusted.

If the Company completes an initial public offering within the three-year period immediately prior to the expiration date, the expiration date will automatically be extended until the third anniversary of the effective date of the Company's initial public offering. If the warrant has not been exercised prior to the expiration date, the warrant will be deemed to have been automatically exercised on the expiration date by cashless conversion.

As of December 31, 2019 and 2020, the following table summarizes the Company's outstanding common and redeemable convertible preferred stock warrants (in thousands, except share and per share data):

	As of December 31, 2019 and 2020					
Issuance Date	Number of Warrant Shares	Exercise Price Per Share	Expiration Date	Exercisable for	Fair Value on Issuance (in thousands)	Fair Value Recorded Against
November 2011	1,964,488	$0.01	November 2021	Common	$547	Redeemable convertible preferred stock
June 2013	4,264,624	0.01	June 2023	Common	678	Redeemable convertible preferred stock
January 2014	2,132,312	0.01	January 2024	Common	446	Redeemable convertible preferred stock
April 2015	79,545	0.88	April 2025	Series D	68	Debt

12. Stock-based compensation

In 2007, the Company adopted the 2007 Equity Incentive Plan, as amended, which allowed for the granting of incentive stock options (ISOs) and non-statutory stock options (NSOs) to the employees, members of the Company's board of directors, and consultants of the Company.

In 2017, the 2007 Equity Incentive Plan expired pursuant to its terms and the Company adopted the 2017 Equity Incentive Plan (the 2017 Plan) which allows for the granting of ISOs and NSOs as well as stock appreciation rights, restricted stock awards, restricted stock units, and other stock awards to employees, members of the Company's board of directors, and consultants. ISOs may be granted only to Company's employees, including officers and directors who are also employees. NSOs may be granted to employees,

directors and consultants. The Company has only granted ISOs and NSOs through December 31, 2020. As of December 31, 2019 and 2020, 9,316,817 and 157,563,189 shares are available for future grant under the 2017 Plan, respectively.

Options under the 2017 Plan may be granted for periods of up to 10 years and at prices no less than 100% of the estimated fair value of the shares on the date of grant as determined by the Company's board of directors, provided, however, that an ISO granted to a 10% stockholder shall not have an exercise price be less than 110% of the estimated fair value of the shares on the date of grant and shall not have a contractual term longer than five years.

The following table summarizes stock option transactions for the years ended December 31, 2019 and 2020 (in thousands, except share and per share data):

	Number of Shares Available For Grant	Number of Shares Underlying Outstanding Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value
Outstanding, January 1, 2019	4,132,608	8,379,633	$0.25	5.0	$63
Increase in authorized shares	77,496,476	—			
Options granted	(72,322,267)	72,322,267	0.08		
Options cancelled	10,000	(10,000)	1.00		
Outstanding, December 31, 2019	9,316,817	80,691,900	0.10	8.8	45
Increase in authorized shares	146,199,760	—			
Options cancelled	1,845,204	(1,845,204)	0.08		
Options expired	201,408	(201,408)	1.70		
Outstanding, December 31, 2020	157,563,189	78,645,288	0.09	7.8	45
Shares vested and exercisable as of December 31, 2020		63,216,888	0.10	7.7	45

The aggregate intrinsic value is calculated as the difference between the option exercise price and the estimated fair value of the underlying common stock.

Time-based options

The Company may award time-based options which vest and become exercisable, subject to the participant's continued employment or service through the applicable vesting date. Options granted have various vesting schedules including some that vest immediately and some that vest over four years.

The following table summarizes time-based stock option activity for the year ended December 31, 2019 and 2020 (in thousands, except share and per share data):

	Number of Shares Underlying Outstanding Options	Weighted-Average Exercise Price
Outstanding, January 1, 2019	8,319,633	$0.25
Options granted	24,999,569	0.08
Options cancelled	(10,000)	1.00
Outstanding, December 31, 2019	33,309,202	0.12
Options cancelled	(1,845,204)	0.08
Options expired	(201,408)	1.70
Outstanding, December 31, 2020	31,262,590	0.11
Vested as of December 31, 2020	26,248,077	

The weighted-average grant date fair value of options granted during 2019 was $0.06. There were no options granted in 2020. The total fair value of the time-based shares vested during the year ended December 31, 2020 was $0.2 million. As of the year ended December 31, 2020, there was $0.3 million of total unrecognized compensation cost related to the awards. The cost is being recognized over a remaining weighted-average period of 2.4 years.

Performance-based options

The Company may award grants of performance-based options to eligible individuals. Performance-based options are shares of common stock that vest based on performance measures against predetermined objectives that could include successful completion of qualified equity offerings, or announced topline results for clinical trials and positive clinical results over a specified performance period.

The following table summarizes performance-based stock option activity for the years ended December 31, 2019 and 2020 (in thousands, except share and per share data):

	Number of Shares Underlying Outstanding Options	Weighted-Average Exercise Price
Outstanding, January 1, 2019	60,000	$0.54
Options granted	47,322,698	0.08
Options cancelled	—	—
Outstanding, December 31, 2019	47,382,698	0.08
Options cancelled	—	
Options expired	—	
Outstanding, December 31, 2020	47,382,698	0.08
Vested as of December 31, 2020	36,968,811	

The weighted-average grant date fair value of options granted during 2019 was $0.05. There were no options granted in 2020. The total fair value of the performance-based shares vested during the year ended December 31, 2020 was $0.7 million. As of the year ended December 31, 2020, there was $0.2 million of total unrecognized compensation cost related to the awards. The cost is being recognized over a remaining weighted-average period of 0.7 years.

The Company has recorded aggregate stock-based compensation expense related to the issuance of stock option awards to employees and non-employees in the statements of operations and comprehensive loss as follows for the years ended December 31, 2019 and 2020 (in thousands):

	Year Ended December 31, 2019	Year Ended December 31, 2020
Research and development	$ 227	$179
General and administrative	2,761	596
Total stock-based compensation	$2,988	$775

The fair value of each award granted was estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions for the year ended December 31, 2019. There were no options granted in 2020.

	Year Ended December 31, 2019
Expected volatility	82% – 88%
Risk-free interest rate	1.6 – 2.3
Dividend yield	—
Expected term	5–6.1 years

The expected term of the stock options represents the average of the contractual term of the options and the weighted-average expected vesting period. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant. The expected volatility rate was based on the historical volatilities of comparable companies in the Company's industry. The Company has never declared or paid any cash dividends and does not presently plan to pay cash dividends in the foreseeable future. Consequently, the Company used an expected dividend yield of zero.

Prior period correction

Subsequent to the issuance of the financial statements for the year ended December 31, 2019, the Company identified an immaterial error related to the calculation and recording of stock-based compensation expense for the Company's performance-based stock option awards. The correction of this error resulted in an increase in additional paid-in capital and decrease in accumulated deficit as of December 31, 2019 of $0.4 million to $30.3 million and $155.6 million, respectively, and an increase in stock-based compensation expense of $0.4 million for the year ended December 31, 2019 to $3.0 million, of which $29,000 is recorded in research and development expenses and $0.4 million is recorded in general and administrative expenses. Stock-based compensation as presented in the statement of cash flows, statement of redeemable convertible preferred stock and stockholders' deficit and Note 12 has also been corrected.

Accordingly, management has corrected the aforementioned adjustment from amounts previously presented in the accompanying financial statements for the year ended December 31, 2019. Management evaluated the correction on a quantitative and qualitative basis and has determined that it is immaterial to the financial statements as of and for the year ended December 31, 2019.

13. 401(k) savings plan

The Company has a defined-contribution savings plan under Section 401(k) of the Internal Revenue Code of 1986, as amended. The 401(k) Plan covers all employees who meet defined minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pretax basis. The Company has not made any employer contributions to the 401(k) Plan as of December 31, 2019 and 2020.

14. Net loss per share attributable to common stockholders

The table below is the calculation of basic and diluted loss per share attributable to common stockholders for the years ended December 31, 2019 and 2020 (in thousands, except share and per share data):

	Year Ended December 31, 2019	Year Ended December 31, 2020
Numerator:		
Net loss attributable to common stockholders	$ (14,261)	$ (11,370)
Denominator:		
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	7,674,259	7,674,259
Net loss per share attributable to common stockholders, basic and diluted	$ (1.86)	$ (1.48)

The following outstanding shares of potentially dilutive securities were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods presented because including them would have been antidilutive:

	Year Ended December 31, 2019	Year Ended December 31, 2020
Redeemable convertible preferred stock	759,137,698	1,289,245,218
Options to purchase common stock	80,691,900	78,645,288
Warrants to purchase common stock	8,361,424	8,361,424
Warrants to purchase redeemable convertible preferred stock	79,545	79,545
Total	848,270,567	1,376,331,475

15. Income taxes

Loss before provision for income taxes consisted of the following (in thousands):

	Year Ended December 31, 2019	Year Ended December 31, 2020
United States	$(14,261)	$(11,370)
International	—	—
	$(14,261)	$(11,370)

A reconciliation of the provision for income taxes to the amount computed by applying the statutory income tax rate of 21% to the net loss is summarized for the years ended December 31, 2019 and 2020 is as follows:

	Year Ended December 31, 2019	Year Ended December 31, 2020
Federal income taxes at statutory rates	21.00%	21.00%
State income tax, net of federal benefit	1.29	1.69
Research and development credits	1.61	2.41
Stock-based compensation	(0.67)	(1.33)
Change in valuation allowance	(23.11)	(23.78)
Other permanent items	(0.12)	0.01
Effective income tax rate	—%	—%

For the years ended December 31, 2019 and 2020, the Company did not record a deferred income tax expense or benefit.

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. The following table presents significant components of the Company's net deferred tax assets as of December 31, 2019 and 2020 (in thousands):

	December 31, 2019	December 31, 2020
Deferred tax assets:		
Net operating loss carryforwards	$ 22,971	$ 24,518
Capitalized start-up costs	6,166	6,716
Research and development credits	2,440	2,912
Property and equipment	1	—
Accruals, reserves and other	606	801
Lease liabilities	72	43
Total gross deferred assets	32,256	34,990
Valuation allowance	(32,189)	(34,949)
Total deferred tax assets	67	41
Deferred tax liabilities:		
Right-of-use assets	(67)	(41)
Net deferred tax assets	$ —	$ —

The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. Based on the Company's history of operating losses, the Company has concluded that it is more likely than not that the benefit of its deferred tax assets will not be realized. Accordingly, the Company has provided a full valuation allowance for deferred tax assets as of December 31, 2019 and 2020. The valuation allowance increased $3.2 million and $2.7 million during the years ended December 31, 2019 and 2020, respectively.

As of December 31, 2020, the Company had U.S. federal net operating loss (NOL) carryforwards of approximately $108.2 million which may be available to offset future federal income. Federal NOLs incurred prior to January 1, 2018 of approximately $91.0 million expire beginning in 2026 while federal NOLs incurred after December 31, 2017 of approximately $17.2 million will have an indefinite carryforward period, subject to annual limitations. As of December 31, 2020, the Company also had state NOL carryforwards of approximately $26.6 million which may be available to offset future state income and expire at various years beginning with 2028.

As of December 31, 2020, the Company had federal research and development tax credit carryforwards of approximately $2.0 million available to reduce future tax liabilities which expire at various years beginning with 2028. As of December 31, 2020, the Company had state credit carryforwards of approximately $2.1 million available to reduce future tax liabilities which do not expire.

Under Section 382 of the Code, the ability to utilize NOL carryforwards or other tax attributes, such as research tax credits, in any taxable year may be limited if the Company has experienced an "ownership change." Generally, a Section 382 ownership change occurs if there is a cumulative increase of more than 50 percentage points in the stock ownership of one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock within a specified testing period. Similar rules may apply under state tax laws. As a result, the amount of NOL and research and credit carryforwards presented in our financial statements could be limited and may expire unutilized. The Company has not performed a Section 382 analysis through December 31, 2020, and as such, the Company is not able to determine the impact on the NOLs and tax credit carryforwards. To the extent that an assessment is completed in the future, the Company's ability to utilize tax attributes could be restricted on a year-by-year basis and certain attributes could expire before they are utilized.

The Company applies the two-step approach to recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates it is more likely than not that the position will be substantiated on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest

amount, which is more than 50% likely of being realized upon ultimate settlement. Income tax positions must meet a more likely than not recognition threshold at the effective date to be recognized upon the adoption of ASC 740 and in subsequent periods. This interpretation also provides guidance on measurement, de-recognition, classification, interest and penalties, accounting in interim periods and transition.

A reconciliation of the unrecognized tax benefits is as follows for the years ended December 31, 2019 and 2020 (in thousands):

	Year Ended December 31, 2019	Year Ended December 31, 2020
Unrecognized tax benefits as of the beginning of the year	$576	$689
Decrease related to prior year tax positions	—	—
Increase related to current year tax positions	113	128
Unrecognized tax benefits as of the end of the year	$689	$817

No amount of the unrecognized tax benefits, if recognized, would reduce the Company's annual effective tax rate because the benefits are in the form of deferred tax assets for which a full valuation allowance has been recorded. The Company does not anticipate a significant change to its unrecognized tax benefits over the next twelve months.

The Company recognizes interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2020, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company's statements of operations and comprehensive loss. There are no ongoing examinations by taxing authorities at this time.

The Company files the United States, and state income tax returns with varying statutes of limitations. The Company's tax years from inception in 2006 will remain open to examination due to the carryover of the unused NOLs and tax credits. The Company does not have any tax audits or other proceedings pending.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) was enacted in response to the COVID-19 pandemic. The CARES Act, among other things, permits NOL carryovers and carrybacks to offset 100% of taxable income for taxable years beginning before 2021. In addition, the CARES Act allows NOLs incurred in 2018, 2019, and 2020 to be carried back to each of the five preceding taxable years to generate a refund of previously paid income taxes. Due to the Company's history of NOLs, the CARES Act did not have a material impact on the Company's financial statements.

16. Subsequent events

The Company has evaluated subsequent events for financial statement purposes occurring through March 10, 2021, the date when these financial statements were issued.

Issuance of New Option Awards

On January 27, 2021, the Company granted to employees and directors 69,176,541 options under the 2017 Plan, to purchase the number of shares of the Company's common stock. The exercise price of each option granted is $0.08 per share, with monthly vesting over 4 years.

On February 19, 2021, the Company granted 15,747,232 options to a new executive employee under the 2017 Plan to purchase the number of shares of the Company's common stock. The exercise price of each option granted is $0.08 per share, with 25% of the vesting shares exercisable after the first year with the remaining vesting shares exercisable monthly thereafter, with all remaining shares fully vested and exercisable on the four-year anniversary.

February 2021 Closing of Series F Redeemable Convertible Preferred Stock Financing

On February 10, 2021, the Company issued and sold 84,485,407 shares of Series F redeemable convertible preferred stock at a price of $0.13020 per share, for total net proceeds of $11.0 million.

SAGIMET BIOSCIENCES INC.

CONDENSED BALANCE SHEETS
(Unaudited)
(in thousands, except for share and per share amounts)

	As of December 31, 2020	As of March 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 68,702	$ 74,944
Prepaid expenses and other current assets	36	2,068
Total current assets	68,738	77,012
Operating lease right-of-use assets	194	161
Deposits	27	27
Total assets	$ 68,959	$ 77,200
Liabilities, redeemable convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 513	$ 1,860
Accrued expenses and other current liabilities	1,252	1,116
Operating lease liabilities	145	149
Total current liabilities	1,910	3,125
Long-term liabilities		
Operating lease liabilities, less current portion	65	27
Redeemable convertible preferred stock warrant liability	9	9
Total liabilities	1,984	3,161
Commitments and contingencies (Note 8)		
Redeemable convertible preferred stock: $0.0001 par value; 1,373,810,170 shares authorized at December 31, 2020 and March 31, 2021; 1,289,245,218 and 1,373,730,625 shares issued and outstanding at December 31, 2020 and March 31, 2021, respectively; liquidation value of $221,963 and $232,963 at December 31, 2020 and March 31, 2021, respectively.	202,885	214,620
Stockholders' deficit:		
Common stock, $0.0001 par value; 1,590,550,754 shares authorized at December 31, 2020 and March 31, 2021; 7,674,259 and 9,519,463 shares issued and outstanding at December 31, 2020 and March 31, 2021, respectively.	1	1
Additional paid-in capital	31,016	31,893
Accumulated deficit	(166,927)	(172,475)
Total stockholders' deficit	(135,910)	(140,581)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	$ 68,959	$ 77,200

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

SAGIMET BIOSCIENCES INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)
(in thousands, except for share and per share amounts)

	Three months ended March 31, 2020	Three months ended March 31, 2021
Operating expenses:		
Research and development	$ 3,025	$ 3,354
General and administrative	982	1,449
Total operating expenses	4,007	4,803
Loss from operations	(4,007)	(4,803)
Other income (expense), net:		
Change in fair value of redeemable convertible preferred stock tranche liability	—	(751)
Change in fair value of redeemable convertible preferred stock warrants	(2)	—
Interest income	26	6
Total other income (expense), net	24	(745)
Net loss and comprehensive loss	$ (3,983)	$ (5,548)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.52)	$ (0.66)
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	7,674,259	8,350,834

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

SAGIMET BIOSCIENCES INC.

CONDENSED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(Unaudited)
(in thousands, except share amounts)

	Redeemable convertible preferred stock		Common stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at January 1, 2020	759,137,698	$134,179	7,674,259	$ 1	$ 30,241	$(155,557)	$(125,315)
Net loss	—	—	—	—	—	(3,983)	(3,983)
Stock-based compensation expense	—	—	—	—	332	—	332
Balance at March 31, 2020	759,137,698	$134,179	7,674,259	$ 1	$ 30,573	$(159,540)	$(128,966)

	Redeemable convertible preferred stock		Common stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at January 1, 2021	1,289,245,218	$202,885	7,674,259	$ 1	$ 31,016	$(166,927)	$(135,910)
Net loss	—	—	—	—	—	(5,548)	(5,548)
Issuance of Series F redeemable convertible preferred stock, net of issuance costs of $16	84,485,407	11,735	—	—	—	—	—
Exercise of stock options	—	—	1,845,204	—	148	—	148
Stock-based compensation expense	—	—	—	—	729	—	729
Balance at March 31, 2021	1,373,730,625	$214,620	9,519,463	$ 1	$ 31,893	$(172,475)	$(140,581)

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

SAGIMET BIOSCIENCES INC.

CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited)
(in thousands)

	Three months ended March 31, 2020	Three months ended March 31, 2021
Cash flows from operating activities		
Net loss	$ (3,983)	$ (5,548)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash lease expense	30	33
Stock-based compensation expense	332	729
Change in fair value of redeemable convertible preferred stock warrants	2	—
Change in fair value of redeemable convertible preferred stock tranche liability	—	751
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	156	(1,164)
Accounts payable and accrued expenses	896	330
Operating lease liabilities	(31)	(34)
Net cash used in operating activities	(2,598)	(4,903)
Cash flows from financing activities		
Proceeds from issuance of redeemable convertible preferred stock, net	—	10,997
Proceeds from exercise of stock options	—	148
Net cash provided by financing activities	—	11,145
Net (decrease) increase in cash	(2,598)	6,242
Cash and cash equivalents at the beginning of the period	10,212	68,702
Cash and cash equivalents at the end of the period	$ 7,614	$ 74,944
Supplemental cash flow information		
Series F financing costs included in accounts payable	$ —	$ 13
Unpaid deferred offering costs included in accounts payable and accrued expenses	$ —	$ 868

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

SAGIMET BIOSCIENCES INC.

NOTES TO THE UNAUDITED CONDENSED FINANCIAL STATEMENTS

1. Organization and description of business

Overview

Sagimet Biosciences Inc. (the Company) was incorporated in Delaware on December 19, 2006 as 3-V Biosciences, Inc. and is headquartered in San Mateo, California. The Company changed its name from 3-V Biosciences, Inc. to Sagimet Biosciences Inc. in August 2019. The Company is a clinical-stage biopharmaceutical company focused on developing a portfolio of in-house discovered, selective fatty acid synthase (FASN) inhibitors for the treatment of diseases that result from dysfunctional lipid metabolism pathways.

Liquidity

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry including, but not limited to, development by competitors of new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with governmental regulations and the need to obtain additional financing to fund operations. Drug candidates currently under development will require significant additional research and development efforts prior to commercialization. The Company's drug candidates are still in development and, to date, none of the Company's drug candidates have been approved for sale and, therefore, the Company has not generated any revenue from product sales.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The financial statements do not reflect any adjustments relating to the recoverability and reclassification of assets and liabilities that might be necessary if the Company is unable to continue as a going concern.

The Company has incurred operating losses and negative cash flows from operations since inception, including net losses of $4.0 million and $5.5 million for the three months ended March 31, 2020 and 2021, respectively, and has relied on private equity and debt financings to fund its operations. As of March 31, 2021, the Company had an accumulated deficit of $172.5 million. For the three months ended March 31, 2020 and 2021, the Company had net cash used in operations of $2.6 million and $4.9 million, respectively. To date, none of the Company's drug candidates have been approved for sale and therefore the Company has not generated any revenue from product sales. The Company expects to incur increased research and development expenses as it develops existing and future drug candidates. The Company expects operating losses to continue to increase for the foreseeable future. The Company's prospects are subject to risks, expenses and uncertainties frequently encountered by companies in the biotechnology industry as discussed above.

In February 2021, the Company received net proceeds of $11.0 million from a Series F redeemable convertible preferred stock financing from a new investor as part of its Series F preferred stock financing of approximately $80.0 million in aggregate. The Company had cash and cash equivalents of $74.9 million as of March 31, 2021. Management believes that the Company's current cash and cash equivalents will be sufficient to fund its planned operations for at least 12 months from the issuance date of these unaudited condensed financial statements.

Risks and Uncertainties

The Company is subject to certain risks and uncertainties, including, but not limited to changes in any of the following areas that the Company believes could have a material adverse effect on future financial position or results of operations: the availability of future financing; the ability to obtain regulatory approval and market acceptance of, and reimbursement for, the Company's drug candidates; the performance of third-party clinical research organizations and manufacturers; protection of the intellectual property;

litigation or claims against the Company based on intellectual property, patent, product, regulatory or other factors; and the Company's ability to attract and retain employees necessary to support commercial success. In addition, significant changes in the industry or customer requirements or the emergence of competitive products with new capabilities could adversely affect the Company's development and operating results.

The Company's general business strategy may be adversely affected by any such economic downturns, including the current downturn related to the ongoing COVID-19 pandemic, volatile business environments and continued unstable or unpredictable economic and market conditions.

Impact of the COVID-19 Pandemic

The COVID-19 pandemic, which began in December 2019 and has spread worldwide, has caused many governments to implement measures to slow the spread of the outbreak through quarantines, travel restrictions, heightened border security and other measures. The impact of this pandemic has been, and will likely continue to be, extensive in many aspects of society, which has resulted, and will likely continue to result, in significant disruptions to the global economy as well as businesses and capital markets around the world. The future progression of the pandemic and its effects on the Company's business and operations are uncertain. In response to public health directives and orders and to help minimize the risk of the virus to employees, the Company has taken precautionary measures, including implementing work-from-home policies for all employees. The impact of the virus, including work-from-home policies, may negatively impact productivity, disrupt the Company's business, and delay development program timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on the Company's ability to conduct its business in the ordinary course. Other impacts to the Company's business may include temporary closures of its suppliers and disruptions or restrictions on its employees' ability to travel. Any prolonged material disruption to the Company's employees or suppliers could adversely impact the Company's development activities, financial condition and results of operations, including its ability to obtain financing. The Company is monitoring the potential impact of the COVID-19 pandemic on its business and financial statements. To date, the Company has not experienced material business disruptions or incurred impairment losses in the carrying values of its assets as a result of the pandemic and it is not aware of any specific related event or circumstance that would require it to revise its estimates reflected in these financial statements (see Note 2).

Unaudited interim financial information

The accompanying condensed balance sheet as of March 30, 2021, the condensed statements of operations and comprehensive loss for the three months ended March 31, 2020 and 2021, the condensed statements of redeemable convertible preferred stock and stockholders' deficit for the three months ended March 31, 2020 and 2021, the condensed statements of cash flows for the three months ended March 31, 2020 and 2021, and the related disclosures are unaudited. These unaudited condensed financial statements include all adjustments necessary, consisting of only normal recurring adjustments, to fairly state the financial position and the results of the Company's operations and cash flows for interim periods in accordance with accounting principles generally accepted in the United States of America (GAAP). Interim period results are not necessarily indicative of results of operations or cash flows for a full year or any subsequent interim period. The condensed balance sheet as of December 31, 2020 has been derived from the audited consolidated financial statements of the Company, which are included elsewhere in this prospectus. The accompanying unaudited condensed financial statements should be read in conjunction with the Company's audited financial statements included elsewhere in this prospectus.

2. Summary of significant accounting policies

Basis of Presentation

The financial statements and accompanying notes have been prepared in accordance with GAAP.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the

financial statements and reported amounts of expenses during the reporting period. Such estimates include the determination of useful lives for equipment, accruals of research and development expenses, accrual of research contract costs, preferred and common stock and stock option valuations. On an ongoing basis, the Company evaluates its estimates and judgments, which are based on 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 and Cash equivalents

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. As of December 31, 2020 and March 31, 2021, cash and cash equivalents which are denominated in U.S. dollars consisted of bank deposits including deposits in a money market fund. All cash and cash equivalents were unrestricted as to withdrawal or use.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash and cash equivalents. Substantially all the Company's cash and cash equivalents were deposited in accounts at one financial institution, and account balances may at times exceed federally insured limits. Management believes that the Company is not exposed to significant credit risk due to the financial strength of the depository institution in which the cash is held.

Deferred Offering Costs

Deferred offering costs, consisting of legal, accounting and other fees and costs relating to the Company's planned Initial Public Offering (IPO) are capitalized and recorded on the balance sheets. The deferred offering costs will be offset against the proceeds received upon the closing of the planned IPO. In the event that the Company's plans for an IPO are terminated, all of the deferred offering costs will be written off within operating expenses in the Company's statements of operations and comprehensive loss. As of March 31, 2021, there were $0.9 million of deferred offering costs capitalized. There were no deferred offering costs capitalized as of December 31, 2020.

Impairment of Long-Lived Assets

The Company evaluates the carrying amount of its long-lived assets whenever events or changes in circumstances indicate that the assets may not be recoverable. An impairment loss is recognized when estimated future cash flows expected to result from the use of the asset and its eventual disposition are less than the carrying amount of the asset. To date, there have been no such impairment losses.

Leases

The Company enters into lease agreements for its office facility and accounts for its lease obligations under Accounting Standards Update (ASU) No. 2016-02, *Leases* (Topic 842) which the Company adopted in 2018.

The Company determines if an arrangement is or contains a lease and the classification of that lease at inception of a contract. The Company's operating lease asset is included in "operating lease right-of-use asset" (ROU asset), and the current and non-current portions of the operating lease liability are included in "operating lease liabilities", and "operating lease liabilities, less current portion", respectively, on the balance sheet. As of December 31, 2020 and March 31, 2021, the Company had no finance leases.

Operating lease ROU assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at the lease commencement date. Operating lease ROU assets are based on the corresponding lease liability adjusted for (i) payments made at or before the commencement date, (ii) initial direct costs incurred, and (iii) tenant incentives under the lease. The Company does not account for renewals or early terminations unless it is reasonably certain to exercise these options at commencement. Operating lease expense is recognized on a straight-line basis over the lease term. The

Company accounts for lease and non-lease components as a single lease component for operating leases. The Company does not record leases with terms of 12 months or less on the balance sheets.

As the implicit rate for the operating lease was not determinable, the Company used an incremental borrowing rate based on the information available at the lease commencement date in determining the present value of future payments. The Company's incremental borrowing rate was estimated to approximate the interest rate on a collateralized basis with similar terms and payments, in an economic environment where the leased asset is located. The Company determined the incremental borrowing rate by considering various factors, such as its credit rating, interest rates of similar debt instruments of entities with comparable credit ratings, the lease term and the currency in which the lease was denominated.

Accrued Research and Development Expense

Research and development costs are charged to expense as incurred. Research and development expenses include certain payroll and personnel expenses, consulting costs, external contract research and development expenses, and allocated overhead, including rent, equipment depreciation and utilities. Advance payments for goods or services for future research and development activities are deferred and expensed as the goods are delivered or the related services are performed.

The Company estimates preclinical study and clinical trial expenses based on the services performed pursuant to contracts with research institutions and clinical research organizations that conduct and manage preclinical studies and clinical trials on the Company's behalf. In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. These estimates are based on communications with the third-party service providers and the Company's estimates of accrued expenses and on information available at each balance sheet date. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly.

Revenue Recognition

The Company enters into or may enter into collaboration and licensing arrangements that generally contain multiple elements or deliverables, which may include (1) licenses to the Company's technology, (2) research and development activities performed for the collaboration partner, (3) participation on joint steering committees (JSCs), and (4) the manufacturing of clinical or preclinical material. Payments pursuant to these arrangements include milestone payments upon achieving significant development events, research and development reimbursements, sales milestones, and royalties on future drug sales. Variable consideration is constrained until it is probable that the revenue is not at a significant risk of reversal in a future period.

In determining the appropriate amount of revenue to be recognized for the components of the arrangements that are within the scope of Accounting Standards Codification, Topic 606, *Revenue from Contracts with Customers* (ASC 606), the Company performs the following steps: (i) identification of the promised goods or services in the contract within the scope of ASC 606; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. As part of the accounting for these arrangements, the Company must use significant judgment to determine: a) the number of performance obligations based on the determination under step (ii) above; b) the transaction price under step (iii) above; c) the stand-alone selling price for each performance obligation identified in the contract for the allocation of transaction price in step (iv) above; and d) the measure of progress in step (v) above. The Company uses judgment to determine whether milestones or other variable consideration, except for royalties, should be included in the transaction price as described further below.

At the inception of each arrangement that includes milestone payments, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. 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 control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. At the end of each subsequent reporting period, the Company reevaluates the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings gin the period of adjustment. For arrangements that include sales-based royalties or milestone payments, for which the license is deemed to be the predominant item, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

For the three months ended March 31, 2020 and March 31, 2021, no revenue has been recognized from any license agreement and no milestone is probable of being achieved for at least the next 12 months. For further discussion of accounting for revenues, see Note 7.

Segment Information

The Company operates and manages its business as a single operating and reporting segment for the purposes of assessing performance and making operating decisions. The Company's current focus is on developing and commercializing therapeutics for the treatment of a range of diseases including NASH and certain cancers.

Common Stock Valuation

Due to the absence of an active market for the Company's common stock, 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 exercise prices for options granted, 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 has been determined at each grant date based upon a variety of factors, including the illiquid nature of the common stock, arm's-length sales of the Company's capital stock (including redeemable convertible preferred stock), the effect of the rights and preferences of the redeemable convertible preferred stockholders, and the prospects of a liquidity event. Among other factors are the Company's financial position and historical financial performance, the status of technological developments within the Company's research, the composition and ability of the current research and management team, an evaluation or benchmark of the Company's competition, and the current business climate in the marketplace. Significant changes to the key assumptions underlying the factors used could result in different fair values of common stock at each valuation date.

Redeemable Convertible Preferred Stock

The Company records redeemable convertible preferred stock at fair value on the dates of issuance, net of issuance costs. The redeemable convertible preferred stock is recorded outside of stockholders' deficit because the shares contain liquidation features that are not solely within the Company's control. The Company has not adjusted the carrying values of the redeemable convertible preferred stock to the liquidation preferences of such shares because it is uncertain whether or when an event would occur that would obligate the Company to pay the liquidation preferences to holders of shares of redeemable convertible preferred stock. Subsequent adjustments to the carrying values to the liquidation preferences will be made only when it becomes probable that such a liquidation event will occur.

Redeemable Convertible Preferred Stock Tranche Liability

The Company determined the right of the investors to purchase shares of Series F redeemable convertible preferred stock at a future date met the definition of a freestanding instrument and was recognized as a liability at fair value upon the December 2020 issuance of Series F redeemable convertible preferred stock (Redeemable Convertible Preferred Stock Tranche Liability). The liability was subject to remeasurement at each balance sheet date, with changes in fair value recognized in other income (expense) in the consolidated statements of operations. Upon closing of the Series F redeemable convertible preferred

stock in February 2021, the Redeemable Convertible Preferred Stock Tranche Liability was extinguished and the marked-to-market fair value of the liability was included in the carrying value of redeemable convertible preferred stock issued.

Common Stock Warrants

From time to time, the Company has issued warrants to investors and creditors together with the Company's debt and equity financings. When issued in connection with debt, the allocated value related to the warrants is generally recorded as additional interest cost on the related debt. When issued with redeemable convertible preferred stock, the allocated value related to the warrants is recorded as additional issuance costs of the redeemable convertible preferred stock. The Company values warrants using an option pricing model.

Stock-Based Compensation Expense

The Company accounts for all stock-based payment awards granted to employees and non-employees as stock-based compensation expense at fair value. The Company's stock-based payments include stock options and grants of common stock, including common stock subject to vesting. The measurement date for employee awards is the date of grant, and stock-based compensation costs are recognized as expense over the employees' requisite service period, which is the vesting period, on a straight-line basis. Prior to the adoption of ASU No. 2018-07, *Compensation-Stock Compensation* (Topic 718): *Improvements to Nonemployee Share-Based Payment Accounting (ASU 2018-07)* as discussed below under "Recently Adopted Accounting Pronouncements", the measurement date for non-employee awards was generally the date the services were completed, resulting in financial reporting period adjustments to stock-based compensation during the vesting terms for changes in the fair value of the awards. Since the adoption of ASU 2018-07, the measurement date for non-employee awards is the date of grant without changes in the fair value of the award. Stock-based compensation costs for non-employees are recognized as expense over the vesting period on a straight-line basis. Stock-based compensation expense is classified in the accompanying statements of operations based on the function to which the related services are provided. The Company recognizes stock-based compensation expense for the portion of awards that have vested. Forfeitures are recorded as they occur.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The Company has historically been a private company and lacks company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected erm of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends on common stock and does not expect to pay any cash dividends in the foreseeable future.

For awards with service-based vesting conditions only, the Company recognizes share-based compensation expense on a straight-line basis over the requisite service or vesting period. For awards with service- and performance-based vesting conditions, the Company recognizes stock-based compensation expense using the graded vesting method over the requisite service period beginning in the period in which the awards are deemed probable to vest, to the extent such awards are probable to vest. The Company recognizes the cumulative effect of changes in the probability outcomes in the period in which the changes occur.

Income Taxes

The Company accounts for income taxes using the asset and liability method. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse.

In evaluating the ability to recover its deferred income tax assets, the Company considers all available positive and negative evidence, including its operating results, ongoing tax planning and forecasts of future taxable income on a jurisdiction-by-jurisdiction basis. In the event the Company determines that it would be able to realize its deferred income tax assets in the future in excess of their net recorded amount, it would make an adjustment to the valuation allowance that would reduce the provision for income taxes. Conversely, in the event that all or part of the net deferred tax assets are determined not to be realizable in the future, an adjustment to the valuation allowance would be charged to earnings in the period when such determination is made. As of December 31, 2020 and March 31, 2021, the Company has recorded a full valuation allowance on its deferred tax assets.

Tax benefits related to uncertain tax positions are recognized when it is more likely than not that a tax position will be sustained during an audit. Interest and penalties related to unrecognized tax benefits are included within the provision for income tax.

Comprehensive Loss

Comprehensive loss includes all changes in stockholders' deficit during a period from non-owner sources. There have been no items qualifying as other comprehensive loss and, therefore, the Company's comprehensive loss was the same as its reported net loss.

Net Loss per Share Attributable to Common Stockholders

Basic net loss per common share attributable to common stockholders is calculated by dividing the net loss by the weighted-average number of common shares outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss by the weighted-average number of common shares and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share attributable to common stockholders calculation, the redeemable convertible preferred stock, common stock options and common and redeemable convertible preferred stock warrants are considered to be potentially dilutive securities. Basic and diluted net loss per share attributable to common stockholders is presented in conformity with the two-class method required for participating securities as the redeemable convertible preferred stock is considered a participating security. The Company's participating securities do not have a contractual obligation to share in the Company's losses. As such, the net loss was attributed entirely to common stockholders. As the Company has reported a net loss for the period presented, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders for this period.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (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 No. 2019-12, *Simplifying Accounting for Income Taxes*, (ASU 2019-12). The guidance simplifies the accounting for income taxes as part of the FASB's overall initiative to reduce complexity in accounting standards. Amendments include removal of certain exceptions to the general principles of ASC 740, *Income Taxes*, and simplification in several other areas such as accounting for a franchise tax (or similar tax) that is partially based on income. The Company has adopted this guidance effective January 1, 2021. The adoption of this new standard did not have a material impact on the Company's financial statements.

3. Fair value measurements and fair value of financial instruments

The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

Level 1 **—** Quoted prices in active markets for identical assets or liabilities. The Company's deposits in a money market fund are Level 1 financial instruments.

Level 2 **—** Observable inputs other than Level 1 prices, 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 and that are significant to the fair value of the assets or liabilities.

The Company's cash equivalents, which are funds held in a money market account, are measured at fair value on a recurring basis. The carrying amount of cash equivalents was $68.7 million and $74.8 million as of December 31, 2020 and March 31, 2021, respectively, which approximates the fair value and was determined based upon Level 1 inputs. The money market account is valued using quoted market prices with no valuation adjustments applied and is categorized as Level 1.

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.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability.

The Company's Level 3 liabilities that are measured at fair value on a recurring basis consist of the redeemable convertible preferred stock warrant liability and redeemable convertible preferred stock tranche liability.

Assets and liabilities measured at fair value on a recurring basis are categorized in the tables below based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability.

The following table sets forth the Company's financial instruments that were measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

	December 31, 2020			
	Total fair value	Level 1	Level 2	Level 3
Assets:				
Cash and cash equivalents – money market funds	$68,672	$68,672	$—	$—
Liabilities:				
Redeemable convertible preferred stock warrant liability	$ 9	$ —	$—	$ 9

	March 31, 2021			
	Total fair value	Level 1	Level 2	Level 3
Assets:				
Cash and cash equivalents – money market funds	$74,809	$74,809	$—	$—
Liabilities:				
Redeemable convertible preferred stock warrant liability	$ 9	$ —	$—	$ 9

During the periods presented, the Company has not changed the manner in which it values liabilities that are measured at estimated fair value using Level 3 inputs. There were no transfers within the hierarchy during the periods presented.

The following table provides a summary of changes in the estimated fair value of the financial instruments using significant Level 3 inputs (in thousands):

	Redeemable convertible preferred stock warrant liability	Redeemable convertible preferred stock tranche liability
Balance – January 1, 2020	$ 9	$ —
Change in fair value of redeemable convertible preferred stock warrant liability	2	—
Balance – March 31, 2020	$11	$ —
Balance – January 1, 2021	$ 9	$ —
Change in fair value of redeemable convertible preferred stock tranche liability	—	751
Extinguishment of redeemable convertible stock tranche liability upon subsequent issuance of series F redeemable convertible preferred stock	—	(751)
Balance – March 31, 2021	$ 9	$ —

Redeemable Convertible Preferred Stock Warrant Liability

In April 2015, the Company entered into a debt agreement with a financial institution which was repaid in full on May 15, 2019. In connection with the debt agreement, the Company issued to the lender 79,545 warrants to purchase Series D redeemable convertible preferred stock with an exercise price of $0.88 per share exercisable immediately with a contractual term of 10 years (Redeemable Convertible Preferred Stock Warrant Liability).

The Company estimates the fair value of the REDEEMABLE CONVERTIBLE PREFERRED STOCK WARRANT LIABILITY using an option pricing model and assumptions that are based on the individual characteristics of the warrants on the valuation date, as well as assumptions for fair value of the underlying redeemable convertible preferred stock, expected volatility, expected life, dividends, and risk-free interest rate. The Company will continue to adjust the liability for changes in fair value of these warrants until the earlier of: (i) exercise of warrants; (ii) expiration of warrants; (iii) a change of control of the Company; or (iv) the consummation of an initial public offering.

As of December 31, 2020, the fair value of the REDEEMABLE CONVERTIBLE PREFERRED STOCK WARRANT LIABILITY was determined to be $9 thousand assuming a volatility rate of 92.6%, an expected term of 4.3 years, no dividends, and a risk-free interest rate of 0.29%.

As of March 31, 2021, the fair value of the REDEEMABLE CONVERTIBLE PREFERRED STOCK WARRANT LIABILITY was determined to be $9 thousand assuming a volatility rate of 94.3%, an expected term of 4.0 years, no dividends, and a risk-free interest rate of 0.64%.

The Company recorded other income of $2 thousand for the change in fair value of the Redeemable Convertible Preferred Stock Warrant Liability in its condensed statement of operations for the three months ended March 31, 2020. There was no impact in 2021.

Redeemable Convertible Preferred Stock Tranche Liability

The Company determined the right of an investor to purchase shares of Series F redeemable convertible preferred stock in December 2020 met the definition of a freestanding instrument and was classified as a liability. The fair value in December 2020 was determined to be negligible. Upon the issuance and sale of Series F redeemable convertible preferred stock in February 2021, the Series F redeemable convertible preferred stock tranche liability was calculated to be $0.8 million. The fair value of the redeemable convertible preferred stock tranche liability was estimated using the intrinsic value of the Series F redeemable convertible preferred stock of $0.1391 per share. In February 2021, upon the issuance and sale of shares

of Series F redeemable convertible preferred stock, the redeemable convertible stock tranche liability was extinguished. The Company recorded other expense of $0.8 million for the change in fair value of the Series F redeemable convertible preferred stock tranche liability in its condensed statement of operations for the three months ended March 31, 2021. There was no impact in 2020.

4. Prepaid expenses and other current assets

Prepaid expenses and other current assets as of December 31, 2020 and March 31, 2021 consist of the following (in thousands):

	As of December 31, 2020	As of March 31, 2021
Prepaid clinical expenses	$—	$1,105
Deferred offering costs	—	926
Other	36	37
Total	$36	$2,068

5. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities as of December 31, 2020 and March 31, 2021 consist of the following (in thousands):

	As of December 31, 2020	As of March 31, 2021
Accrued clinical costs	$ 483	$ 590
Accrued research costs	11	115
Employees' compensation	515	62
Other	243	349
Total	$1,252	$1,116

6. Note payable

In April 2015, the Company entered into a debt agreement with a financial institution to borrow up to $7.0 million. In June 2015, the Company borrowed an initial $5.0 million under the debt agreement. In June 2016, the Company borrowed the remaining $2.0 million. The Company was responsible for making interest only payments at an annual interest rate of 4.58% through January 2017. Following the interest only repayment period, on February 1, 2017, the Company was responsible for repaying the debt in equal monthly payments for 36 months thereafter. The Company could prepay the entire principal balance without penalty or premium. The debt agreement contains customary events of default, including bankruptcy or upon the occurrence of a material adverse change. The obligations under the debt agreement are collateralized by the Company's assets, excluding its intellectual property. In connection with the debt agreement, the Company issued to the lender 79,545 warrants to purchase Series D redeemable convertible preferred stock with an exercise price of $0.88 per share exercisable immediately with a contractual term of 10 years. As of both December 31, 2020 and March 31, 2021, the fair value and carrying value of the redeemable convertible preferred stock warrant liability were $11 thousand and $9 thousand, respectively (see Note 3).

On June 21, 2018, the Company entered into a forbearance agreement with the financial institution that allowed for the deferral until October 19, 2018 of five monthly principal payments upon certain events. Interest remained payable monthly during this period and the maturity date and principal payment schedule remained unchanged following the forbearance. Additionally, the Company's intellectual property was pledged as collateral. Following this forbearance period, the Company made a partial payment due under the forbearance agreement and, accordingly, the Company was in default.

On January 25, 2019, the Company entered into an amendment to the debt agreement with the financial institution. The amendment allowed for a waiver of certain events of default for periods prior to

this amendment, modified certain financial and clinical trial covenants and modified the loan payments. Upon closing of the Series E redeemable convertible preferred stock financing (see Note 9), the Company made all past due principal payments and on March 1, 2019 resumed monthly installments of principal and interest, which increased to prime plus 0.50% on both loan tranches. Upon certain additional financing milestones, the term of the loan was extended to 24 months and the interest rate increased to prime plus 2.50% for the remainder of the loan.

On May 15, 2019, the Company entered into a loan pay-off agreement with the financial institution, repaid all principal amounts due and settled all obligations under the debt agreement.

7. Related parties

University of Zurich and ETH Zurich

In April 2007, the Company entered into a license agreement with the University of Zurich and ETH Zurich, both Company investors, for exclusive rights in the United States to certain know-how and patents related to antiviral drug testing. The license agreement remains in force until the last patent expires or the agreement is cancelled by either party. Upon execution of the agreement, the Company issued 153,000 shares of common stock to ETH Zurich and issued 76,500 shares of common stock to the University of Zurich.

Ascletis BioScience Co. Ltd

In January 2019, the Company entered into a license agreement that became effective in February 2019 with Ascletis, a biotechnology company based in Hangzhou and Shaoxing, China and a Company investor. The parties entered into this agreement with the intention to develop, manufacture, and commercialize the Company's proprietary fatty acid synthase (FASN) inhibitor, TVB-2640. Under the terms of the license agreement, the Company granted Ascletis an exclusive right and license under the Company's intellectual property to develop, manufacture, commercialize and otherwise exploit TVB-2640 and other FASN inhibitors in Greater China (People's Republic of China, Hong Kong, Macau and Taiwan, each referred to individually as a "Territory").

The Company will bear all expenses related to patients enrolled in Greater China as part of a global phase 2 trial, except for clinical operations and regulatory staff provided by Ascletis. The Company and Ascletis have jointly applied for an investigational new drug (IND) in Greater China. Except for this Phase 2 trial and joint IND, Ascletis is solely responsible for all development activities and regulatory approvals for TVB-2640 in Greater China. The Company received $0.1 million as reimbursement pursuant to the license agreement for Greater China patent protections costs during the three months ended March 31, 2021.

The Company is eligible to receive development and commercial milestone payments from Ascletis in aggregate of up to $122 million as well as tiered royalties ranging from percentages in the high single digits to mid-teens on future net sales of TVB-2640, which is referred to as ASC40 in Greater China. Ascletis also led the Series E preferred stock financing in February 2019 (see Note 9).

Under a separate manufacturing agreement with Ascletis, during the three months ended March 31, 2021, the Company paid $0.3 million for the manufacture of the drug tablets to be used in a planned Phase 2b trial. The Company recorded this payment as research and development expense in the condensed statement of operations for the three months ended March 31, 2021.

This license and phase 2 research and development services components of this agreement are representative of a relationship with a customer and therefore are subject to ASC 606. For the three months ended March 31, 2020 and 2021, no revenue has been recognized from the license agreement with Ascletis and no milestone is probable of being achieved nor being included in the transaction price for at least the next 12 months.

Related Parties Convertible Notes

Since 2016, the Company has raised a total of $15.1 million through a series of note purchase agreements with certain investors (2016 and 2018 Notes Agreements).

The Company initially recorded the related parties convertible notes issued under the 2016 and 2018 Notes Agreements (collectively, the Related Parties Convertible Notes) at the fair value of $46.7 million. In February 2019, the Related Parties Convertible Notes were converted and extinguished (see section immediately below).

December 2018 Related Parties Convertible Notes

On December 21, 2018, the Company entered into a convertible promissory note agreement (December 2018 Related Parties Convertible Notes) with related party investors raising $3.0 million from existing investors. The December 2018 Related Parties Convertible Notes bear interest at 8% per annum and mature on August 1, 2019, or upon request by the requisite holders after August 1, 2019. Upon a qualified financing of not less than $10.0 million or at the election of the noteholders, the December 2018 Related Parties Convertible Notes plus accrued interest will automatically convert into equity securities issued to the investors in the qualified financing at a conversion price equal to the cash price paid per share of the equity securities. In the event of default, the outstanding principal becomes immediately due and payable. The December 2018 Related Parties Convertible Notes were recorded at the amount of proceeds received of $3.0 million.

Conversion of All Convertible Notes

On February 12, 2019, the Company closed a financing through the issuance of Series E redeemable convertible preferred stock. In connection with such issuance, all Related Parties Convertible Notes and December 2018 Related Parties Convertible Notes plus accrued interest converted into shares of Series E redeemable convertible preferred stock at the applicable conversion rate (see Note 9).

8. Commitments and contingencies

Change in Control Retention Plan

In June 2020, the Company established a Change in Control Retention Plan (Retention Plan). The Retention Plan provides for incentive bonus payments to certain designated employees and other service providers of the Company in the event of a “Liquidation” as defined by the Company’s restated certificate of incorporation (Restated Certificate) which qualifies as a “change in ownership of a corporation” or a “change in ownership of a substantial portion of a corporation’s assets” as provided under Section 409A of the Internal Revenue Code. The Retention Plan provides for such incentive bonus payments as 7% of the total Liquidation consideration, up to a maximum of $13.0 million. The Retention Plan terminates on the earliest of (i) June 24, 2022; (ii) immediately prior to the Company’s consummation of an initial public offering; (iii) upon payment due to a Liquidation; or (iv) an earlier date decided by the Company’s board of directors in its sole discretion prior to the execution of a letter of intent for a Liquidation. The Company has not recognized compensation cost for the Retention Plan, as a Liquidation that qualifies as a change in ownership cannot be considered a probable occurrence until it is effective.

Guarantees and Indemnifications

In the normal course of business, the Company enters into agreements that contain a variety of representations and provide for general indemnification. The Company’s exposure under these agreements is unknown because it involves claims that may be made against the Company in the future. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. As of December 31, 2020, and March 31, 2021, the Company does not have any material indemnification claims that were probable or reasonably possible and consequently has not recorded related liabilities.

Legal

The Company is not party to any material legal proceedings at this time. From time to time, the Company may become involved in various legal proceedings that arise in the ordinary course of its business.

9. Redeemable convertible preferred stock

Effective on February 11, 2019, the Company amended its Restated Certificate to increase the number of shares of redeemable convertible preferred stock that the Company is authorized to issue from 231,805,244 to 759,506,853, provide for a new series of redeemable convertible preferred stock, Series E, and decrease the authorized shares of all other series of redeemable convertible preferred stock. Effective December 21, 2020, the Company amended its Restated Certificate to increase the number of shares of redeemable convertible preferred stock that the Company is authorized to issue from 759,506,853 to 1,373,810,170 and provide for a new series of redeemable convertible preferred stock, series F.

The authorized, issued and outstanding shares of the redeemable convertible preferred stock, liquidation preferences and carrying values as of December 31, 2020 and March 31, 2021 were as follows (in thousands, except share numbers):

	As of December 31, 2020			
Series	Authorized Shares	Issued and Outstanding Shares	Liquidation Preference	Carrying Value
Series A	23,301	23,301	$ 233	$ 232
Series B	3,217	3,217	37	37
Series B-1	8,827,439	8,827,439	7,768	7,258
Series C	22,732,250	22,732,250	20,004	17,909
Series D	24,509,954	24,430,409	21,499	19,833
Series A’	720,199	720,199	—	—
Series B’	1,953,304	1,953,304	—	—
Series B-1’	14,001,243	14,001,243	—	2,780
Series C’	1,037	1,037	—	—
Series D’	3,475,426	3,475,426	—	739
Series D-1	51,331,148	51,331,148	45,171	26,894
Series E	631,638,725	631,638,725	58,231	58,496
Series F	614,592,927	530,107,520	69,020	68,707
Total	1,373,810,170	1,289,245,218	$221,963	$202,885

	As of March 31, 2021			
Series	Authorized Shares	Issued and Outstanding Shares	Liquidation Preference	Carrying Value
Series A	23,301	23,301	$ 233	$ 232
Series B	3,217	3,217	37	37
Series B-1	8,827,439	8,827,439	7,768	7,258
Series C	22,732,250	22,732,250	20,004	17,909
Series D	24,509,954	24,430,409	21,499	19,833
Series A’	720,199	720,199	—	—
Series B’	1,953,304	1,953,304	—	—
Series B-1’	14,001,243	14,001,243	—	2,780
Series C’	1,037	1,037	—	—
Series D’	3,475,426	3,475,426	—	739
Series D-1	51,331,148	51,331,148	45,171	26,894
Series E	631,638,725	631,638,725	58,231	58,496
Series F	614,592,927	614,592,927	80,020	80,442
Total	1,373,810,170	1,373,730,625	$232,963	$214,620

Issuance of Series Prime and Series D-1 Redeemable Convertible Preferred Stock

In June 2016, the Company entered into a 2016 note agreement to raise an amount of up to $12.0 million in two separate tranches with existing investors, which resulted in the Company increasing its authorized capital and the issuance of redeemable convertible series prime preferred stock (Series Prime) and Series D-1 redeemable convertible preferred stock.

The holders of the Series Prime are entitled to a number of votes equal to the number of shares of common stock to which the Series Prime can be converted at the time of the vote. In addition, shares of Series Prime have a liquidation preference equal to their issuance price increased by any declared and unpaid dividend and follow other liquidation preference rules of corresponding redeemable convertible Series A, B, B-1, C and D preferred stock. The redeemable convertible Series D-1 preferred stock has senior liquidation preference to the other series of redeemable convertible preferred stock and no voting rights.

In connection with the issuance of the second tranche of the Related Parties Convertible Notes in April 2017, the Company cancelled shares of Junior Securities held by the investors and issued shares of redeemable convertible Series D-1 preferred stock and shares of Series Prime.

In February 2018 and June 2018, the Company entered into the 2018 Note Agreements to raise an amount of up to $4.5 million from existing investors. In connection with the issuance of the 2018 Related Parties Convertible Notes in February, June and July 2018, the Company exchanged, and cancelled shares of Junior Securities held by investors in the respective tranches of the Redeemable Convertible Related Parties Convertible Notes and issued shares of redeemable convertible Series D-1 preferred stock and shares of Series Prime.

Issuance of Series E Redeemable Convertible Preferred Stock

On February 12, 2019, the Company closed an $18.0 million Series E financing that consisted of the automatic conversion of the outstanding $3.0 million of December 2018 Related Parties Convertible Notes, plus accrued interest, and receipt of funds of $15.0 million in February 2019 from new and existing investors. Together, these transactions resulted in the issuance of 195,218,732 Series E redeemable convertible preferred shares (32,719,799 shares from the notes conversion and 162,498,933 shares purchased at a fair value of $0.09219 per share). In connection with this financing and at the election of the holders, all outstanding Related Parties Convertible Notes plus $2.2 million of accrued interest converted into 360,570,944 shares of Series E redeemable convertible preferred stock. In total, 555,789,676 shares of Series E redeemable convertible preferred stock were issued in February 2019.

In July 2019, the Company received proceeds from the second tranche of the Series E redeemable convertible preferred stock financing of $7.0 million, net of issuance costs, and issued 75,849,049 shares of Series E redeemable convertible preferred stock at a fair value of $0.09219 per share. Simultaneously with the issuance of the second tranche of the Series E redeemable convertible preferred stock, the Series E redeemable convertible preferred stock tranche liability was extinguished.

Issuance of Series F Redeemable Convertible Preferred Stock

On December 21, 2020, the Company received $68.7 million net of issuance costs from the first closing of its Series F financing from new and existing investors, resulting in the issuance of 530,107,520 Series F redeemable convertible preferred shares at $0.13020 per share (Series F Original Issue Price).

On February 10, 2021, the Company received $11.0 million net of issuance costs from a closing of its Series F financing from new and existing investors, resulting in the issuance of 84,485,407 shares of Series F redeemable convertible preferred stock at the Series F Original Issue Price.

The rights, preferences and privileges of the redeemable convertible preferred stock as of December 31, 2020 and March 31, 2021 were as follows:

Dividends. The holders of the Company's redeemable convertible preferred stock (excluding Series D-1) are entitled to receive noncumulative dividends of 8% per share (as adjusted for stock splits, combinations and reorganizations) per annum on each outstanding share of Series redeemable convertible

preferred stock. Such dividends shall be payable only when and if declared by the Company's board of directors. Dividends on redeemable convertible preferred stock shall be payable in preference to and prior to any payments of any dividends on common stock. No dividends have been declared to date.

Conversion. Redeemable preferred stock is convertible, at the option of the holder, at any time, in fully paid, non-assessable shares of common stock at an initial conversion ratio of one-to-one (except Series D-1). Series D-1 does not have an elective conversion option.

All the redeemable convertible preferred stock will automatically convert into common stock, at the then-applicable conversion rate, in the event of either (i) the affirmative vote of the holders of a majority of the then-outstanding shares of series preferred, voting together as a single class on an as-converted to common stock basis, and the affirmative vote of the holders of a majority of the then-outstanding shares of Series F redeemable convertible preferred stock, or (ii) the closing of an underwritten initial public offering of the Company's common stock pursuant to a registration statement on Form S-1 under the Securities Act of 1933, as amended, at a price of at least 1.25 times the Series F Original Issue Price, with aggregate gross proceeds of not less than $50.0 million.

Voting rights. The holders of redeemable convertible preferred stock are entitled to that number of votes on all matters presented to stockholders equal to the number of shares of common stock then issuable upon conversion of such preferred stock, with the exception of the holders of the Series D-1 redeemable convertible preferred stock who do not have voting rights.

Liquidation. In the event of any sale of substantially all of the assets, a merger, or liquidation, dissolution or winding up of the Company, as defined in the Restated Certificate, the holders of Series A, B, B-1, C, D, D-1, E and F redeemable convertible preferred stock will be entitled to receive, on a pari passu basis and in preference to the holders of common stock, $10.00, $11.50, $0.88, $0.88, $0.88, $0.88, $0.09219 and $0.13020, respectively, per share (as adjusted for stock splits, combinations and reorganizations) plus declared and unpaid dividends, if any. In the event that the assets to be distributed among the holders of Series A, B, B-1, C, D, D-1, E and F redeemable convertible preferred stock are insufficient to permit full payment, the entire remaining assets of the Company legally available for distribution shall be distributed with equal priority and pro rata among these holders based on the aggregate liquidation preference of such holders. After distributing to all preferred stockholders, the remaining assets of the Company will be distributed ratably to the holders of the common stock on a pro rata basis. Each preferred stockholder may convert their shares to common stock shares and participate in the liquidation as a common stockholder. Such stockholder will not be entitled to receive any distribution that would otherwise be made to holders of shares of Series preferred that have not been converted (or have not been deemed to have converted) into shares of common stock. Series Prime do not have any liquidation preferences.

Deemed liquidation. A merger, acquisition, sale or lease of all of substantially all of the assets of the Company which will result in the Company's stockholders immediately prior to such transaction not holding at least 50% of the voting power of the surviving, continuing or purchasing entity, shall be deemed to be a liquidation, dissolution or winding up. Upon this event, holders of redeemable convertible preferred stock shall receive their liquidation preference including any accrued and unpaid dividends as of the liquidating date.

The holders of Series A, B, B-1, C, D, D-1, E and F redeemable 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, B, B-1, C, D, D-1, E and F redeemable convertible preferred stock. Therefore, the Series A, B, B-1, C, D, D-1, E and F redeemable convertible preferred stock are classified outside of stockholders' deficit on the balance sheets. The carrying value of the redeemable convertible preferred stock is not subsequently remeasured to the redemption value until the contingent redemption events are considered to be probable of occurring.

10. Stockholders' deficit

Common Stock

In connection with the Company's Tenth Amended and Restated Certificate filed December 21, 2020, the number of shares of common stock that the Company is authorized to issue increased from 854,406,696 to 1,590,550,754.

The Company's reserved shares of common stock for future issuance related to potential conversion of the redeemable convertible preferred stock, exercise of warrants and exercise of stock options as of December 31, 2020 and March 31, 2021 are as follows:

	As of December 31, 2020	As of March 31, 2021
Redeemable convertible preferred stock	1,237,914,070	1,322,399,477
Series D redeemable convertible preferred stock warrants	79,545	79,545
Options authorized and available for issuance	157,563,189	72,639,416
Options to purchase common stock	78,645,288	161,723,857
Warrants to purchase common stock	8,361,424	8,361,424
Total	1,482,563,516	1,565,203,719

Redeemable Convertible Preferred Stock Warrant Liability

In connection with the note payable entered into on April 10, 2015 (see Note 6), the Company issued 79,545 Series D redeemable convertible preferred stock warrants with an exercise price of $0.88 per share. The warrants have a term of 10 years and are exercisable in whole or in part, at any time on or before the expiration date of April 10, 2025. At the time of issuance, the fair value of the redeemable convertible preferred stock warrant liability was determined using an option pricing model and assumptions that are based on the individual characteristics of the warrant on the valuation date, as well as assumptions for fair value of the underlying redeemable convertible preferred stock, expected volatility, expected life, dividends, and risk-free interest rate (see Note 3).

The Series D redeemable convertible preferred stock warrant has no voting rights, or other rights as a stockholder of the Company. The warrant is subject to adjustment in the event of any diluting dividends or distributions of the common stock, or any stock split, reverse stock split, recapitalization, reorganization, or similar transaction. Upon any reclassification, exchange, substitution or other event, the number and or class of the securities and property that the holder would have received for the shares if this warrant had been issued immediately before such event will be adjusted.

If the Company completes an initial public offering within the three-year period immediately prior to the expiration date, the expiration date will automatically be extended until the third anniversary of the effective date of the Company's initial public offering. If the warrant has not been exercised prior to the expiration date, the warrant will be deemed to have been automatically exercised on the expiration date by cashless conversion.

As of December 31, 2020 and March 31, 2021, the following table summarizes the Company's outstanding common and redeemable convertible preferred stock warrants:

	As of December 31, 2020 and March 31, 2021					
Issuance Date	Number of Warrant Shares	Exercise Price Per Share	Expiration Date	Exercisable for	Fair Value on Issuance (in thousands)	Fair Value Recorded Against
November 2011	1,964,488	$0.01	November 2021	Common	$547	Redeemable convertible preferred stock
June 2013	4,264,624	0.01	June 2023	Common	678	Redeemable convertible preferred stock
January 2014	2,132,312	0.01	January 2024	Common	446	Redeemable convertible preferred stock
April 2015	79,545	0.88	April 2025	Series D	68	Debt

11. Stock-based compensation

In 2007, the Company adopted the 2007 Equity Incentive Plan, as amended, which allowed for the granting of incentive stock options (ISOs) and non-statutory stock options (NSOs) to the employees, members of the Company's board of directors, and consultants of the Company.

In 2017, the 2007 Equity Incentive Plan expired pursuant to its terms and the Company adopted the 2017 Equity Incentive Plan (the 2017 Plan) which allows for the granting of ISOs and NSOs as well as stock appreciation rights, restricted stock awards, restricted stock units, and other stock awards to employees, members of the Company's board of directors, and consultants. ISOs may be granted only to Company's employees, including officers and directors who are also employees. NSOs may be granted to employees, directors, and consultants. The Company has only granted ISOs and NSOs through December 31, 2020. As of December 31, 2020 and March 31, 2021, 157,563,189 and 72,639,416 shares are available for future grant under the 2017 Plan, respectively.

Options under the 2017 Plan may be granted for periods of up to 10 years and at prices no less than 100% of the estimated fair value of the shares on the date of grant as determined by the Company's board of directors, provided, however, that an ISO granted to a 10% stockholder shall not have an exercise price be less than 110% of the estimated fair value of the shares on the date of grant and shall not have a contractual term longer than five years.

The following table summarizes stock option transactions for the three months ended March 31, 2021 (in thousands, except share and per share data):

	Number of Shares Available For Grant	Number of Shares Underlying Outstanding Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value
Outstanding, January 1, 2021	157,563,189	78,645,288	$0.09	7.8	$45
Options granted	(84,923,773)	84,923,773	0.08		
Options exercised	—	(1,845,204)	0.08		
Outstanding, March 31, 2021	72,639,416	161,723,857	0.09	8.8	45
Shares vested and exercisable as of March 31, 2021		75,300,075	0.09	7.8	45

The aggregate intrinsic value is calculated as the difference between the option exercise price and the estimated fair value of the underlying common stock.

Time-based options

The Company may award time-based options which vest and become exercisable, subject to the participant's continued employment or service through the applicable vesting date. Options granted have various vesting schedules including some that vest immediately and some that vest over four years.

The following table summarizes time-based stock option activity for the three months ended March 31, 2021:

	Number of Shares Underlying Outstanding Options	Weighted-Average Exercise Price
Outstanding, January 1, 2021	31,262,590	$0.11
Options granted	84,550,337	0.08
Options exercised	(1,845,204)	0.08
Outstanding, March 31, 2021	113,967,723	0.11
Vested as of March 31, 2021	35,057,307	

The weighted-average grant date fair value of time-based options granted during the three months ended March 31, 2021 was $0.06. The total fair value of the time-based shares vested during the three months ended March 31, 2021 was $0.6 million. As of March 31, 2021, there was $4.7 million of total unrecognized compensation cost related to the awards. The cost is being recognized over a remaining weighted-average period of 3.1 years.

Performance-based options

The Company may award grants of performance-based options to eligible individuals. Performance-based options are shares of common stock that vest based on performance measures against predetermined objectives that could include successful completion of qualified equity offerings or announced topline results for clinical trials and positive clinical results over a specified performance period.

The following table summarizes performance-based stock option activity for the three months ended March 31, 2021:

	Number of Shares Underlying Outstanding Options	Weighted-Average Exercise Price
Outstanding, January 1, 2021	47,382,698	$0.08
Options granted	373,436	0.08
Outstanding, March 31, 2021	47,756,134	0.08
Vested as of March 31, 2021	40,242,768	

The weighted-average grant date fair value of performance-based options granted during the three months ended March 31, 2021 was $0.06. The total fair value of the performance-based shares vested during the three months ended March 31, 2021 was $0.2 million. As of the three months ended March 31, 2021, there was $0.1 million of total unrecognized compensation cost related to the awards. The cost is being recognized over a remaining weighted-average period of 0.6 years.

The Company has recorded aggregate stock-based compensation expense related to the issuance of stock option awards to employees and non-employees in the statements of operations and comprehensive loss as follows for the three months ended March 31, 2020 and 2021 (in thousands):

	Three Months Ended March 31, 2020	Three Months Ended March 31, 2021
Research and development	$ 67	$110
General and administrative	265	619
Total stock-based compensation	$332	$729

The fair value of each award granted was estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions for the three months ended March 31, 2021. There were no options granted in the three months ended March 31, 2020.

	Three Months Ended March 31, 2021
Expected volatility	91% – 92%
Risk-free interest rate	0.4 – 0.8
Dividend yield	—
Expected term	5 – 6.1 years

The expected term of the stock options represents the average of the contractual term of the options and the weighted-average expected vesting period. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant. The expected volatility rate was based on the historical volatilities of comparable companies in the Company's industry. The Company has never declared or paid any cash dividends and does not presently plan to pay cash dividends in the foreseeable future. Consequently, the Company used an expected dividend yield of zero.

12. Net loss per share attributable to common stockholders

The table below is the calculation of basic and diluted loss per share attributable to common stockholders for the three months ended March 31, 2020 and 2021 (in thousands, except share and per share data):

	Three Months Ended March 31, 2020	Three Months Ended March 31, 2021
Numerator:		
Net loss attributable to common stockholders	$ (3,983)	$ (5,548)
Denominator:		
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	7,674,259	8,350,834
Net loss per share attributable to common stockholders, basic and diluted	$ (0.52)	$ (0.66)

The following outstanding shares of potentially dilutive securities were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods presented because including them would have been antidilutive:

	Three Months Ended March 31, 2020	Three Months Ended March 31, 2021
Redeemable convertible preferred stock	759,137,698	1,373,730,625
Options to purchase common stock	80,691,900	161,723,857
Warrants to purchase common stock	8,361,424	8,361,424
Warrants to purchase redeemable convertible preferred stock	79,545	79,545
Total	848,270,567	1,543,895,451

13. Income taxes

The provision for income taxes primarily relates to projected federal and state income taxes calculated on the projected taxable income for the period. To determine the quarterly provision for income taxes, the Company uses an estimated annual effective tax rate, which is generally based on expected annual income as well as statutory tax rates in the various jurisdictions in which the Company operates. In addition, the tax effects of certain significant or unusual items are recognized discretely in the quarter during which they occur and can be a source of variability in the effective tax rates from quarter to quarter.

As per ASC 740-270, the Company's interim tax provision is computed based on the estimated annual effective tax rate approach. The estimated annual effective tax rate approach is used to determine the tax related to ordinary income unless certain exceptions apply. The Company records a valuation allowance to reduce its deferred taxes to the amount it believes is more likely than not to be realized. In making such determination, the Company considers all available positive and negative evidence quarterly, including scheduled reversals of deferred tax liabilities, projected future taxable income, tax planning strategies, and recent financial performance. Forming a conclusion that a valuation allowance is not required is difficult when there is negative evidence such as cumulative losses in recent years. Based upon the Company's review of all positive and negative evidence, the Company continues to have a full valuation allowance on its deferred tax assets as of March 31, 2021.

The Company accounts for the uncertainty in income taxes by utilizing a comprehensive model for the recognition, measurement, presentation and disclosure in financial statements of any uncertain tax positions that have been taken or are expected to be taken on an income tax return. There have been no changes in the estimated uncertain positions or tax benefits recorded as of December 31, 2020.

14. Subsequent events

The Company has evaluated subsequent events for financial statement purposes occurring through May 10, 2021, the date when these financial statements were issued.

Issuance of New Option Awards

In April 2021, the Company granted to an employee, a consultant and a director 8,145,193 options under the 2017 Plan, to purchase the number of shares of the Company's common stock. The exercise price of each option granted is $0.11 per share. Non-employee shares vest monthly over 4 years. The employee shares vest 25% after the first year with the remaining shares exercisable monthly thereafter, with all remaining shares fully vested and exercisable on the four-year anniversary.

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Through and including , 2021, (the 25th day after the date of this prospectus), all dealers effecting transactions in the Class A common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

Shares

Class A Common Stock

PROSPECTUS

BofA Securities

Cowen

Piper Sandler

Oppenheimer & Co.

, 2021

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Unless otherwise indicated, all references to "Sagimet," the "company," "we," "our," "us" or similar terms refer to Sagimet Biosciences Inc.

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth all expenses to be paid by us, other than underwriting discounts and commissions, in connection with this offering. All amounts shown are estimates except for the Securities and Exchange Commission (SEC) registration fee, the Financial Industry Regulatory Authority, Inc. (FINRA), filing fee and The Nasdaq Global Market (Nasdaq) listing fee.

SEC registration fee	$	*
FINRA filing fee		*
Nasdaq listing fee		*
Printing and engraving expenses		*
Legal fees and expenses		*
Accounting fees and expenses		*
Custodian transfer agent and registrar fees		*
Miscellaneous expenses		*
Total	$	*

* To be provided by amendment.

Item 14. Indemnification of Directors and Officers.

Section 145 of the Delaware General Corporation Law (DGCL), authorizes a court to award, or a corporation's board of directors to grant, indemnity to directors and officers in terms sufficiently broad to permit such indemnification under certain circumstances for liabilities, including reimbursement for expenses incurred, arising under the Securities Act of 1933, as amended (the Securities Act). Our amended and restated certificate of incorporation that will be in effect immediately prior to the closing of this offering permits indemnification of our directors, officers, employees and other agents to the maximum extent permitted by the DGCL, and our amended and restated bylaws that will be in effect on the closing of this offering provide that we will indemnify our directors and officers and permit us to indemnify our employees and other agents, in each case to the maximum extent permitted by the DGCL.

We have entered into indemnification agreements with our directors and officers, whereby we have agreed to indemnify our directors and officers to the fullest extent permitted by law, including indemnification against expenses and liabilities incurred in legal proceedings to which the director or officer was, or is threatened to be made, a party by reason of the fact that such director or officer is or was a director, officer, employee, or agent of Sagimet Biosciences Inc., provided that such director or officer acted in good faith and in a manner that the director or officer reasonably believed to be in, or not opposed to, the best interest of Sagimet Biosciences Inc.

At present, there is no pending litigation or proceeding involving a director or officer of Sagimet Biosciences Inc. regarding which indemnification is sought, nor is the registrant aware of any threatened litigation that may result in claims for indemnification.

We maintain insurance policies that indemnify our directors and officers against various liabilities arising under the Securities Act and the Securities Exchange Act of 1934, as amended, that might be incurred by any director or officer in his capacity as such.

The underwriters are obligated, under certain circumstances, under the underwriting agreement to be filed as Exhibit 1.1 to this Registration Statement, to indemnify us and our officers and directors against liabilities under the Securities Act.

Item 15. Recent Sales of Unregistered Securities.

Set forth below is information regarding unregistered securities issued by us since January 1, 2018.

Equity Plan-Related Issuances

1. Since January 1, 2018, we have granted to certain of our directors, employees and consultants options to purchase 165,391,233 shares of our common stock with per share exercise prices ranging from $0.06 to $0.11 under the 2017 Plan.

Other Issuances of Capital Stock

2. In December 2020, we issued and sold an aggregate of 530,107,520 shares of Series F redeemable convertible preferred stock to 13 accredited investors and, in February 2021, we issued an additional 84,485,407 shares of Series F redeemable convertible preferred stock to an additional accredited investor, at a purchase price of $0.13020 per share for aggregate cash proceeds of approximately $80.0 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 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 paragraph (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, through employment, business or other relationships, to information about us. No underwriters were involved in these transactions.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits.

Exhibit Number	Description
1.1+	Form of Underwriting Agreement.
3.1†	Amended and Restated Certificate of Incorporation, as currently in effect.
3.2+	Form of Amended and Restated Certificate of Incorporation, to be in effect after the closing of the offering.
3.3†	Amended and Restated Bylaws, as currently in effect.
3.4+	Form of Amended and Restated Bylaws, to be in effect after the closing of the offering.
4.1+	Form of Common Stock Certificate.
4.2†	Amended and Restated Investors' Rights Agreement, by and among the Registrant and certain of its stockholders, dated December 21, 2020.
5.1+	Opinion of Cooley LLP.
10.1†	2007 Equity Incentive Plan.
10.2†	Forms of Grant Notice, Stock Option Agreement and Notice of Exercise under the 2007 Equity Incentive Plan.
10.3†	Sagimet Biosciences Inc. 2017 Equity Incentive Plan.
10.4†	Forms of Grant Notice, Stock Option Agreement and Notice of Exercise under the Sagimet Biosciences Inc. 2017 Equity Incentive Plan.
10.5+	Sagimet Biosciences Inc. 2021 Equity Incentive Plan.
10.6+	Forms of Stock Option Grant Notice, Stock Option Agreement and Notice of Exercise under the Sagimet Biosciences Inc. 2021 Equity Incentive Plan.
10.7+	Forms of Restricted Stock Unit Grant Notice and Award Agreement under the Sagimet Biosciences Inc. 2021 Equity Incentive Plan.
10.8+	Sagimet Biosciences Inc. 2021 Employee Stock Purchase Plan.
10.9+	Sagimet Biosciences Inc. 2021 Non-Employee Director Compensation Policy.
10.10†	Form of Indemnification Agreement by and between the Registrant and its directors and executive officers.
10.11+	Offer Letter with George Kemble, dated June 27, 2011, as amended.
10.12+	Amended and Restated Executive Employment Agreement with Dennis Hom, dated January 11, 2019
10.13+	Offer Letter with Eduardo Bruno Martins, M.D., D.Phil., dated February 9, 2021
10.14*†	Exclusive License and Development Agreement by and between the Registrant and Ascletis BioScience Co. Ltd., dated as of January 18, 2019.
10.15*†	Patent Assignment Agreement by and between the Registrant and Gannex Pharma Co., Ltd., dated as of October 25, 2019.
10.16†	Lease Agreement by and between the Registrant and Casiopea Bovet, LLC, dated as of March 1, 2019.
10.17†	Amended and Restated Nominating Agreement, dated as of April 15, 2021, by and among the Registrant, Baker Brothers Life Sciences, L.P. and 667, L.P.
23.1	Consent of independent registered public accounting firm.
23.2+	Consent of Cooley LLP (included in Exhibit 5.1).
24.1†	Power of Attorney (included on signature page).

+ To be filed by amendment.

† Previously filed.

* Portions of this exhibit (indicated by [***]) have been omitted because the registrant has determined that the information is both not material and is the type that the registrant treats as private and confidential.

(b) Financial Statement Schedules.

All financial statement schedules are omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or the notes thereto.

Item 17. Undertakings.

(a) The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

(b) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant under the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the US Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer, or controlling person of the registrant in the successful defense of any action, suit, or proceeding) is asserted by such director, officer, or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

(c) The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance on Rule 430A and contained in a form of prospectus filed by the registrant under Rule 424(b)(1) or (4) or 497(h) under the Securities Act will be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, as amended, each post-effective amendment that contains a form of prospectus will be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time will be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in San Mateo, State of California on May 10, 2021.

SAGIMET BIOSCIENCES INC.

By: /s/ George Kemble, Ph.D.

Name: George Kemble, Ph.D.
Title: President and Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ George Kemble, Ph.D. George Kemble, Ph.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	May 10, 2021
/s/ Dennis Hom Dennis Hom	Chief Financial Officer (Principal Financial and Accounting Officer)	May 10, 2021
* Beth Seidenberg, M.D.	Chair of the Board	May 10, 2021
* Elizabeth Grammer, Esq.	Director	May 10, 2021
* Merdad Parsey, M.D., Ph.D.	Director	May 10, 2021
* Gordon Ringold, Ph.D.	Director	May 10, 2021
* Richard Rodgers	Director	May 10, 2021
* James F. Young, Ph.D.	Director	May 10, 2021

Signature	Title	Date
*	Director	May 10, 2021
Jinzi J. Wu, Ph.D.		

*By /s/ George Kemble, Ph.D.
George Kemble, Ph.D.
Attorney-in-Fact

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the use in this Registration Statement No. 333-255304 on Form S-1 of our report dated March 10, 2021, relating to the financial statements of Sagimet Biosciences Inc. We also consent to the reference to us under the heading "Experts" in such Registration Statement.

/s/ Deloitte & Touche LLP

San Jose, California

May 10, 2021