As filed with the Securities and Exchange Commission on January 24, 2024.

Registration No. 333-276664

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549
Amendment No. 1
to

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)

David Happel
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:

Rachael Bushey **Jennifer Porter** **Goodwin Procter LLP** **2005 Market Street, 32nd Floor** **Philadelphia, Pennsylvania 19103** **(445) 207-7800**	**Elizabeth Rozek, Esq.** **General Counsel and** **Chief Compliance Officer** **155 Bovet Road, Suite 303** **San Mateo, California 94402** **(650) 561-8600**	**John T. McKenna** **Natalie Y. Karam** **Denny Won** **Cooley LLP** **3175 Hanover Street** **Palo Alto, California 94304** **(650) 843-5000**

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, DATED JANUARY 24, 2024

9,000,000 Shares

Series A Common Stock

We are offering 9,000,000 shares of our Series A common stock in this offering.

Our Series A common stock is listed on the Nasdaq Global Market under the symbol "SGMT." On January 22, 2024, the last reported sale price of our Series A common stock on the Nasdaq Global Market was $18.42 per share.

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

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

Investing in our Series A common stock involves a high degree of risk. See the section titled "Risk Factors" beginning on page 12.

	Per Share	Total
Public offering price	$	$
Underwriting discounts and commissions[(1)]	$	$
Proceeds, before expenses, to us	$	$

(1) See "Underwriting" for a description of the compensation payable to the underwriters.

The underwriters may also exercise their option to purchase up to an additional 1,350,000 shares of Series A common stock from us, at the public offering price, less underwriting discounts and commissions, for 30 days after the date of this prospectus.

The underwriters expect to deliver the shares of Series A common stock on or about , 2024.

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.

Goldman Sachs & Co. LLC **TD Cowen** **Leerink Partners**

JMP Securities
A CITIZENS COMPANY

, 2024

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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 Series 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 Series 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 Series A common stock. You should read this entire prospectus carefully, including the sections of this prospectus titled "Risk Factors," "Special Note Regarding Forward-Looking Statements," "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 developing novel therapeutics called fatty acid synthase (FASN) inhibitors that target dysfunctional metabolic pathways in diseases resulting from the overproduction of the fatty acid, palmitate. Our lead drug candidate, denifanstat, is an oral, once-daily pill and selective FASN inhibitor in development for the treatment of nonalcoholic steatohepatitis (NASH), for which there are no treatments currently approved in the United States or Europe. Denifanstat has been studied in over 740 people to date in our clinical trials, including our FASCINATE-1 and -2 clinical trials, and we are currently designing a pivotal Phase 3 program for denifanstat in NASH. In January 2024, we announced positive topline results at week 52 from our FASCINATE-2 Phase 2b clinical trial. The FASCINATE-2 Phase 2b clinical trial achieved statistically significant results on primary and multiple secondary endpoints at week 52 in 168 NASH patients, including statistically significant improvements in NASH resolution without worsening of fibrosis with ≥2-point reduction in NAFLD Activity Score (NAS) (denifanstat 36% vs. placebo 13%, p=0.0022), and ≥2-point reduction in NAS without worsening of fibrosis (denifanstat 52% vs. placebo 20%, p=0.0001). Denifanstat-treated patients also showed statistically significant fibrosis improvement by ≥ 1 stage with no worsening of NASH (denifanstat 41% vs. placebo 18%, p=0.0051), and also showed statistical significance in fibrosis improvement by an independent approach of artificial intelligence (AI) digital pathology-based qfibrosis assessment. Analyses of liver fat showed a greater proportion of MRI-derived proton density fat fraction (MRI-PDFF) ≥30% responders relative to placebo (denifanstat 65% vs. placebo 21%, p<0.0001). MRI-PDFF responders are patients with ≥8% liver fat content at baseline who achieve a ≥30% relative reduction of liver fat at the end of treatment.

These results are consistent with earlier findings from our FASCINATE-1 Phase 2 trial, which achieved its primary endpoint (relative change from baseline in liver fat at 12 weeks) and key secondary endpoint (percentage of subjects with at least a 30% reduction in liver fat at 12 weeks) at the once-daily 50mg dose. Improvements in liver fat were also observed at the 25mg dose (not statistically significant) and at the 75mg dose (not placebo controlled).

However, Phase 1 and 2 and interim clinical trial results may not be indicative of future results. Additionally, our precision medicine approach is core to our development strategy in NASH, and includes the application of pharmacodynamic and predictive biomarkers to confirm target engagement and clinical response in patients treated with denifanstat. We are also evaluating the promise of FASN inhibition, beyond NASH, in additional disease areas in which dysregulation of fatty acid metabolism also plays a key role, including in acne and certain forms of cancer.

We believe that denifanstat is differentiated among treatments in development for NASH:

- ***Integral role of FASN in three key drivers of NASH.*** FASN is a key enzyme in de novo lipogenesis (DNL), the biochemical pathway responsible for production of palmitate resulting in excess liver fat buildup in NASH. It is also directly involved in inflammation and fibrosis.
- ***Demonstrated improvement in both NASH resolution and fibrosis assessed by liver histology.*** Denifanstat has demonstrated statistically significant improvements relative to placebo in NASH resolution without worsening of fibrosis with ≥2-point reduction in NAS, and ≥2-point reduction in NAS without worsening of fibrosis in its FASCINATE-2 Phase 2b clinical trial.
- ***Comprehensive improvements across biomarkers.*** Our clinical trial data to date have shown that denifanstat at the 50mg once daily dose level improves non-invasive biomarkers of NASH across liver fat, inflammation, and fibrosis—three major drivers of disease—and biomarkers of cardiometabolic

health. In our FASCINATE-2 Phase 2b clinical trial, we demonstrated improvements in MRI-PDFF, alanine aminotransferase (ALT), and FibroScan AST (FAST) score.

- ***Rigorous development strategy.*** Our denifanstat program began with in-house discovery of a proprietary portfolio of FASN inhibitors, followed by a comprehensive demonstration of activity in preclinical models, FASN inhibition in human clinical trials and improvement of critical biomarkers of NASH and has been generally well tolerated in the FASCINATE-1 trial at 25mg and 50mg dose levels once daily and the FASCINATE-2 Phase 2b clinical trial of biopsy-confirmed NASH patients.

Introduction to NASH

NASH is an aggressive form of nonalcoholic fatty liver disease (NAFLD), a condition where an abnormal buildup of excess fat (known as steatosis) occurs in the liver unrelated to the consumption of alcohol. According to a study published in 2023, NASH is a growing epidemic that affected more than 265 million people worldwide in 2019 and for which there are currently no approved treatments in the United States or Europe. It is often associated with insulin resistance, type 2 diabetes, cardiovascular disease, and an increase in overall mortality. Left untreated, damage to the liver can lead to cirrhosis or liver cancer, potentially making liver transplantation necessary.

Our lead drug candidate—denifanstat

Denifanstat, formerly known as TVB-2640, an oral, once-daily pill, is our selective FASN inhibitor currently being developed for the treatment of NASH. Denifanstat was selected from our library of over 1,200 internally-discovered and wholly owned FASN inhibitors that were identified through a rigorous medicinal chemistry and preclinical development effort. Denifanstat was advanced into clinical development based on its convenient oral administration, high selectivity for FASN, and excellent pharmacokinetic and pharmaceutical properties, including restricted penetration of the blood-brain barrier. Following a robust translational research program that demonstrated FASN inhibition reduced liver fat and decreased inflammation and fibrosis in multiple preclinical models, as well as a proof-of-mechanism clinical trial that demonstrated denifanstat's ability to inhibit hepatic DNL in humans, we embarked on two Phase 2 clinical trials in patients with NASH: FASCINATE-1 and FASCINATE-2. Across indications, denifanstat has been studied in over 740 people to date.

The FASCINATE-1 trial examined multiple doses of denifanstat, ranging from 25mg to 75mg daily, administered for 12 weeks compared to placebo in 142 patients in the United States and China. Denifanstat caused a rapid and robust reduction in liver fat that was statistically significant in the 50mg cohort, as well as improvements in inflammatory, fibrotic and cardiometabolic components of the disease. Denifanstat at dose levels of 25mg or 50mg once daily was generally well tolerated in these diverse populations. Based on the totality of the data, we selected the 50mg dose for further study.

The FASCINATE-2 trial evaluated 168 subjects with biopsy confirmed NASH with moderate to advanced fibrosis (F2-F3) at baseline. These patients were dosed with 50mg of denifanstat or placebo for one year. In November 2022, we announced results from a planned interim analysis of non-invasive tests (NITs) from a subset of patients and tolerability as of the data cut-off date of the interim analysis. At the end of dosing, a follow-up biopsy was used to evaluate the direct impact of the drug on disease at week 52. In January 2024, we announced topline results from our FASCINATE-2 trial, which achieved statistically significant results on primary and multiple secondary endpoints, and demonstrated improvement on additional endpoints, at week 52 in 168 NASH patients.

In November 2022, we presented interim analysis results from NITs, also known as biomarkers, from 52 of the earliest patients enrolled in the FASCINATE-2 trial after they completed 26 weeks of dosing. These interim results were consistent with the conclusions of the FASCINATE-1 trial in this more advanced population of NASH patients. Published studies have shown that NASH patients qualifying as responders are much more likely to have improved liver histology than patients who do not achieve this goal. Denifanstat also showed a statistically significant decrease of 16.5 U/L ($p<0.05$), or a 25% decrease, in levels of ALT, which is a marker of hepatic inflammation and damage, and a statistically significant decrease of 0.34 ($p<0.05$) in enhanced liver fibrosis (ELF) score (Figure A.2). Decreases in ELF score suggest reduced levels

of fibrosis. In addition to decreases in LDL-cholesterol, these improvements across biomarkers of liver fat, inflammation and fibrosis are consistent with those seen in the earlier FASCINATE-1 trial.

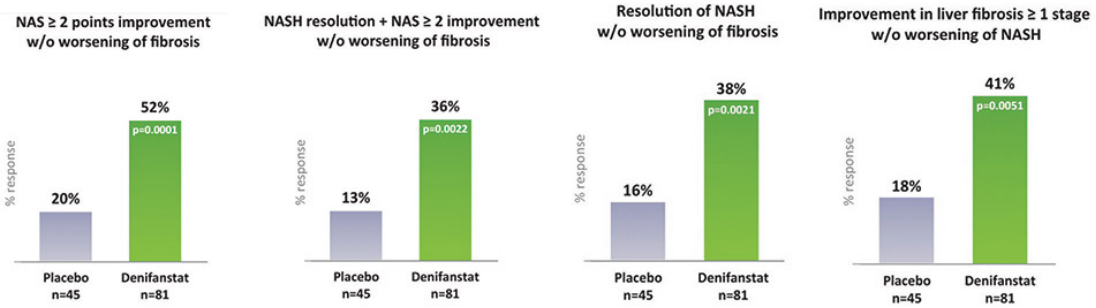

Figure A.1 : FASCINATE-2 liver biopsy analysis at Week 52, primary and secondary endpoints.

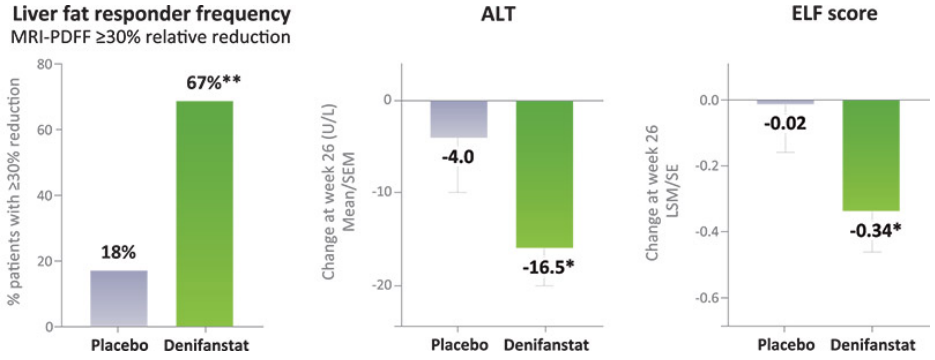

Figure A.2. FASCINATE-2 interim analysis at 26 weeks of dosing. *p<0.05 **p<0.01

Results from FASCINATE-1 and -2 will enable us to design the pivotal Phase 3 program for denifanstat in NASH. In March 2021, we received fast track designation for denifanstat for the treatment of NASH. This allows us to work expeditiously with the U.S. Food and Drug Administration (FDA) to align on the design of this program.

NASH remains an under-diagnosed and under-served disease, often due to lack of access to sophisticated or specialized equipment. Our precision medicine approach is central to our development strategy for denifanstat in NASH. This includes the development of blood-based pharmacodynamic drug response biomarkers, such as tripalmitin, to confirm FASN inhibition and pathway engagement by denifanstat. We are also developing blood-based predictive biomarker tests using metabolomics and single nucleotide polymorphisms (SNPs) to more easily identify patients at risk and likely to benefit from treatment. We anticipate developing complementary diagnostic tools to benefit patients, clinicians and payors.

Our FASN inhibitor pipeline

In addition to NASH, we are exploring the use of our FASN inhibitors, which include denifanstat and our pipeline product candidate, TVB-3567, in acne and in select forms of cancer, disease areas in which dysregulation of fatty acid metabolism also plays a key role. Denifanstat is currently being tested in a Phase 3 clinical trial for moderate to severe acne vulgaris, and a Phase 3 trial in recurrent glioblastoma multiforme (GBM) in combination with bevacizumab. Both trials are being conducted in China by our license partner Ascletis Bioscience Co. Ltd. (Ascletis), a subsidiary of Ascletis Pharma Inc. (Ascletis Pharma). In September 2023, Ascletis Pharma announced the enrollment of 120 recurrent GBM patients in its Phase 3 GBM trial, which it expects will provide a sufficient basis for its planned interim analysis of the Phase 3 trial. These results will inform our development strategy in these indications. Ascletis Pharma announced in May 2023 that it achieved primary and key secondary endpoints in the acne trial including a statistically significant 61.3% reduction in total lesion count in patients treated with 50mg of denifanstat compared with

a 34.2% reduction with placebo. The incidence rates of treatment-related adverse events (AEs) were comparable among the denifanstat groups and the placebo group. Furthermore, our compound library of FASN inhibitors provides us the ability to evaluate additional drug candidates for further development. For example, we have completed IND-enabling studies for TVB-3567 and intend to submit an IND for a Phase 1 clinical trial evaluating TVB-3567 in acne.

The following table summarizes our development programs for multiple diseases with high unmet need:

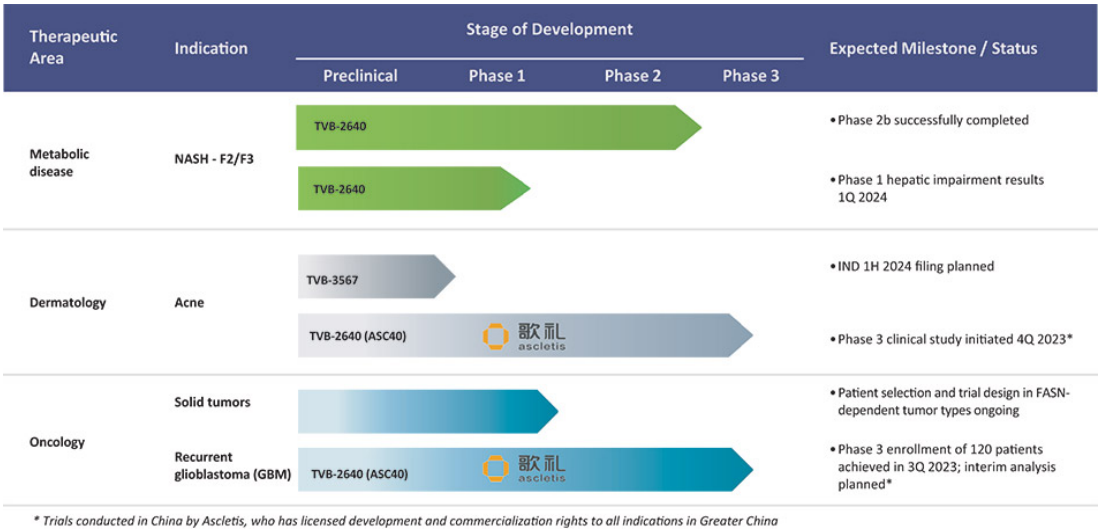

Figure B. Pipeline of denifanstat indications

Our strategy

Our goal is to develop and commercialize our selective FASN inhibitors in therapeutic areas where upregulation of 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:

- ***Progress denifanstat through clinical development for the treatment of NASH***
- ***Establish denifanstat as a backbone therapy for the treatment of NASH***
- ***Advance our precision medicine strategy to identify patients who will benefit from denifanstat***
- ***Expand pipeline development in indications beyond NASH where FASN plays a central role in disease pathogenesis***
- ***Develop and commercialize our drug candidates independently in indications and geographies where we believe we can maximize value and benefit to patients***

Our team

We have assembled a team with extensive experience in drug development and commercialization in the fields of hepatology, cardiometabolic 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. Members of our team bring experiences from multiple biotech and pharmaceutical companies including Cognoa Inc., Horizon Therapeutics PLC, Dynavax Technologies Corporation, Allergan, Inc., Gilead Sciences, Inc., AbbVie Inc., Adamas Pharmaceuticals, Inc. and a subsidiary of AstraZeneca PLC, among others.

Preliminary Unaudited Financial Results for the Year Ended December 31, 2023

As of December 31, 2023, we had approximately $94.9 million of cash, cash equivalents and short-term investments in marketable securities. This unaudited, preliminary amount has been prepared by and is the

responsibility of management. This amount is based upon information available to us as of the date of this prospectus and subject to completion of financial closing procedures that could result in changes to the amount. Furthermore, this amount does not present all information necessary for an understanding of our financial condition and liquidity as of December 31, 2023. Our independent registered public accounting firm, Deloitte & Touche LLP, has not audited, reviewed, compiled or performed any procedures with respect to this preliminary financial data and, accordingly, Deloitte & Touche LLP does not express an opinion or any other form of assurance with respect thereto.

Recent Developments

In January 2024, we announced positive topline results at week 52 from our FASCINATE-2 Phase 2b clinical trial. The FASCINATE-2 Phase 2b clinical trial achieved statistically significant results on primary and multiple secondary endpoints at week 52 in 168 NASH patients, including statistically significant improvements in NASH resolution without worsening of fibrosis with ≥2-point reduction in NAS (denifanstat 36% vs. placebo 13%, p=0.0022), and ≥2-point reduction in NAS without worsening of fibrosis (denifanstat 52% vs. placebo 20%, p=0.0001). Denifanstat-treated patients also showed statistically significant fibrosis improvement by ≥ 1 stage with no worsening of NASH (denifanstat 41% vs. placebo 18%, p=0.0051), and also showed statistical significance in fibrosis improvement by an independent approach of AI digital pathology-based qfibrosis assessment. Analyses of liver fat showed a greater proportion of MRI-PDFF ≥30% responders relative to placebo (denifanstat 65% vs. placebo 21%, p<0.0001).

Risks related to our business

Investing in our Series A common stock involves substantial risk. The risks described under "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:

- 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 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 our lead drug candidate, denifanstat, which is still in clinical development. If we are unable to obtain regulatory approval for or successfully commercialize denifanstat, 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 seek regulatory approval for and commercialize our drug candidates on a timely basis, which would require us to incur additional costs and substantially harm our business.
- We may not be successful in our efforts to expand our pipeline, including by identifying additional indications for which to investigate denifanstat in the future. We may expend our limited resources to pursue a particular indication or formulation for denifanstat 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.
- 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 have licensed rights to denifanstat to Ascletis, a significant stockholder, for a territory that we refer to as "Greater China" throughout this prospectus. Under the license agreement, Ascletis controls certain product development efforts in its territory, including conduct of clinical trials, which could have an impact on our clinical development programs.

- We may attempt to seek approval from the FDA or comparable foreign regulatory authorities through the use of the accelerated approval pathway. 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 engage in strategic transactions that could increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, subject us to other risks, adversely affect our liquidity, increase our expenses and present significant distractions to our management.
- 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 rely on third parties to conduct our clinical trials of our drug candidates and expect to rely on third parties to conduct future clinical trials, as well as investigator-sponsored clinical trials of our drug candidates. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business could be substantially harmed.
- We have relied on, and we expect to continue to rely on, third-party manufacturers to produce our drug candidates. Our manufacturers may experience manufacturing difficulties due to the ongoing effects of inflationary pressures, resource constraints, labor disputes or unstable political environments, which could delay the completion of our clinical trials, increase the costs associated with maintaining clinical trial programs and, significantly impact our ability to develop, obtain regulatory approval for, or market denifanstat and any future drug candidates.
- 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 common stock and have the ability to exercise significant control over matters subject to stockholder approval.
- Unfavorable global political or economic conditions could adversely affect our business, financial condition or results of operations.

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 December 31, 2028, which is the last day of our fiscal year following the fifth anniversary of the date of our initial public offering (IPO). 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 Series A common stock and Series B common stock that is held by non-affiliates exceeds $700 million, our annual gross revenues exceed $1.235 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. 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
Series A common stock offered by us	9,000,000 shares.
Option to purchase additional shares of Series A common stock	1,350,000 shares.
Series A common stock to be outstanding immediately after this offering	30,375,402 shares (or 31,725,402 shares if the underwriters exercise their option to purchase additional shares of Series A common stock in full).
Series B common stock to be outstanding immediately after this offering	1,520,490 shares.
Total Series A and Series B common stock to be outstanding immediately after this offering	31,895,892 shares (or 33,245,892 shares if the underwriters exercise their option to purchase additional shares of Series A common stock in full).
Use of proceeds	We estimate that the net proceeds from the sale of our Series A common stock in this offering will be approximately $155.0 million (or approximately $178.4 million if the underwriters exercise their option to purchase additional shares of Series A common stock in full), assuming a public offering price of $18.42 per share, which was the last reported sale price of our common stock on the Nasdaq Global Market on January 22, 2024, and after deducting 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, cash equivalents and short-term investments in marketable securities, as follows: (i) approximately $130.0 million to advance the development of denifanstat and begin startup activities related to the pivotal Phase 3 program in NASH, including manufacturing of additional drug supply (ii) approximately $8.0 million to advance the development of TVB-3567 and submit IND for Phase 1 clinical trial for the treatment of acne, and (iii) the remainder for other general corporate purposes, including additional clinical development, working capital and operating expenses. See “Use of Proceeds” for additional information.
Voting rights	We have two series of common stock: Series A common stock and Series B common stock. The rights of the holders of Series A common stock and Series B common stock are identical, except with respect to voting and conversion. Each share of Series A common stock is entitled to one vote and shares of Series B common stock are non-voting, except as may be required by law. Each share of Series B common stock may be converted into one share of Series A common stock at the option of its holder, subject to the ownership limitations provided for in our amended and restated certificate of incorporation. See the section titled “Description of capital stock” for additional information.

Risk factors	See "Risk Factors" for a discussion of factors you should carefully consider before deciding whether to invest in our Series A common stock.
Nasdaq Global Market trading symbol	"SGMT."

The number of shares of our Series A common stock and Series B common stock to be outstanding after this offering is based on 21,375,402 shares of Series A common stock and 1,520,490 shares of Series B common stock outstanding as of September 30, 2023 and excludes:

- 63,529 shares of Series A common stock issuable upon exercise of outstanding options under our 2007 Equity Incentive Plan (2007 Plan) as of September 30, 2023, with a weighted-average exercise price of $19.61 per share;
- 3,702,976 shares of Series A common stock issuable upon exercise of outstanding options under our 2017 Equity Incentive Plan (2017 Plan) as of September 30, 2023, with a weighted-average exercise price of $7.80 per share;
- 2,585,968 shares of Series A common stock reserved for future issuance as of September 30, 2023 under our 2023 Stock Option and Incentive Plan (2023 Plan), as well as any future automatic annual increases in the number of shares of Series A common stock reserved for issuance under the 2023 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 "Executive Compensation—Equity benefit plans";
- 215,497 shares of Series A common stock reserved for issuance as of September 30, 2023 under our 2023 Employee Stock Purchase Plan (ESPP), and any future automatic annual increases in the number of shares of Series A common stock reserved for future issuance under the ESPP; and
- 1,000 shares of Series A common stock issuable upon exercise of an outstanding warrant to purchase 1,000 shares of Series A common stock as of September 30, 2023, with an exercise price of $69.94 per share.

Unless otherwise indicated, the information in this prospectus assumes:

- no exercise of the outstanding stock options or warrant described above; and
- no exercise of the underwriters' option to purchase up to an additional 1,350,000 shares of Series A common stock.

Summary Financial Data

The following tables set forth our summary statements of operations and comprehensive loss data for the years ended December 31, 2022 and 2021 and the nine months ended September 30, 2023 and 2022, and our summary balance sheet data as of September 30, 2023. The statements of operations and comprehensive loss data for the years ended December 31, 2022 and 2021 have been derived from our audited financial statements included elsewhere in this prospectus. We derived our summary statements of operations and comprehensive loss data for the nine months ended September 30, 2023 and 2022 and the summary balance sheet data as of September 30, 2023 from our unaudited condensed financial statements included elsewhere in this prospectus, which have been prepared on a basis consistent with our audited financial statements and, in the opinion of management, 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, and our interim results are not necessarily indicative of the results that may be expected for the full year or any other period. You should read the following summary financial data together with "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 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 and comprehensive loss data:

	Years Ended December 31,		Nine Months Ended September 30,	
(in thousands, except share and per share data)	**2022**	**2021**	**2023**	**2022**
			(unaudited)	
Revenue:				
License revenue	$ —	$ —	$ 2,000	$ —
Total revenue	—	—	2,000	—
Operating expenses:				
Research and development	24,919	19,340	14,121	19,072
General and administrative	6,136	4,379	9,153	4,595
Total operating expenses	31,055	23,719	23,274	23,667
Loss from operations	(31,055)	(23,719)	(21,274)	(23,667)
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 warrant liability	3	2	(1)	3
Change in fair value of Series A common stock warrant liability			4	—
Interest income and other	553	26	1,546	360
Total other income (expense), net	556	(723)	1,549	363
Net loss	$ (30,499)	$ (24,442)	$ (19,725)	$ (23,304)
Other comprehensive (loss) gain				
Net unrealized (loss) gain on investments in marketable securities .	(84)	—	84	(162)
Total other comprehensive (loss) gain	(84)	—	84	(162)
Comprehensive loss	$ (30,583)	$ (24,442)	$ (19,641)	$ (23,466)

(in thousands, except share and per share data)	Years Ended December 31, 2022	2021	Nine Months Ended September 30, 2023	2022
				(unaudited)
Net loss per share attributable to common stockholders, basic and diluted	$ (165.20)	$ (199.40)	—	$ (126.13)
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	184,619	122,579	—	184,756
Net loss per share attributable to Series A and Series B common stockholders, basic and diluted	—	—	$ (3.22)	—
Weighted-average shares outstanding used in computing net loss per share attributable to Series A and Series B common stockholders, basic and diluted	—	—	6,131,541	—

Balance sheet data:

(in thousands)	As of September 30, 2023 (unaudited) Actual	As Adjusted[1][2]
Cash and cash equivalents	$ 101,842	$ 256,848
Working capital[3]	97,767	252,773
Total assets	102,925	257,931
Total liabilities	5,050	5,050
Series A common stock warrant liability	1	1
Accumulated deficit	(241,593)	(241,593)
Total stockholders' equity	97,875	252,881

(1) The as adjusted column reflects our issuance and sale of shares of our Series A common stock in this offering at the assumed public offering price of $18.42 per share, which is the last reported sale price of our Series A common stock on the Nasdaq Global Market on January 22, 2024, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

(2) The as adjusted information is illustrative only and will depend on the actual public offering price and other terms of this offering determined at pricing. Each $1.00 increase or decrease in the assumed public offering price of $18.42 per share, which is the last reported sale price of our Series A common stock on the Nasdaq Global Market on January 22, 2024, would increase or decrease, as applicable, each of cash and cash equivalents, working capital, total assets and total stockholders' equity by $8.5 million, assuming that the number of shares of Series A common stock offered by us, as set forth on the cover page of this prospectus, remains the same, after deducting 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 Series A common stock offered by us would increase or decrease, as applicable, each of cash and cash equivalents, working capital, total assets, and total stockholders' equity by $17.3 million, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

(3) 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 Series 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 appearing elsewhere in this prospectus and "Management's Discussion and Analysis of Financial Condition and Results of Operations" before deciding whether to invest in our Series 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 Series 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

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 denifanstat and other future drug candidates. Our net losses were $30.5 million and $24.4 million for the years ended December 31, 2022 and 2021, respectively, and $19.7 million and $23.3 million for the nine months ended September 30, 2023 and 2022, respectively. We had cash, cash equivalents and short-term investments in marketable securities of $32.3 million for the year ended December 31, 2022 and cash and cash equivalents of $56.7 million for the year ended December 31, 2021. As of September 30, 2023, we had cash and cash equivalents of $101.8 million. In the future, we intend to continue to conduct research and development, preclinical and clinical testing, regulatory compliance and, if denifanstat 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 denifanstat 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 preclinical and clinical development of, and seek regulatory approvals for, denifanstat 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.

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 preclinical and clinical development of, and seek regulatory approval for, denifanstat and any future drug candidates.

Because the design and outcome of our planned and anticipated preclinical studies and clinical trials are highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of denifanstat or any other drug candidate we develop. If we are required by the U.S. Food and Drug Administration (FDA), or any comparable foreign regulatory authority to perform clinical trials or preclinical studies in addition to those that we currently anticipate, our expenses could increase. In addition, if we obtain regulatory approval to market denifanstat or any other drug candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Other unanticipated costs may also arise. Since our initial public offering of Series A common stock in July 2023 (IPO), we also have incurred, and expect to continue to incur, additional costs associated with operating as a public company. Accordingly, following this offering we will continue to need to obtain substantial additional funding in order to maintain our continuing operations.

To date, we have financed our operations primarily through private equity and debt financings and our IPO. We currently have no outstanding debt obligations. We have incurred net losses and negative cash flows from operations since inception, including net losses of $30.5 million and $24.4 million for the years ended December 31, 2022 and 2021, respectively, and $19.7 million and $23.3 million for the nine months ended September 30, 2023 and 2022, respectively. For the years ended December 31, 2022 and 2021, we had negative cash flows from operations of $24.5 million and $21.7 million, respectively. For the nine months ended September 30, 2023 and 2022, we had negative cash flows from operations of $16.7 and $17.0 million, respectively. We had cash, cash equivalents and short-term investments in marketable securities of $32.3 million for the year ended December 31, 2022 and cash and cash equivalents of $56.7 million for the year ended December 31, 2021. As of September 30, 2023, we had cash and cash equivalents of $101.8 million. We expect to incur additional losses and negative cash flows from operations for the next 12 months. Based on our current operating plan, we believe that the net proceeds received from this offering, together with our existing cash, cash equivalents and short-term investments in marketable securities will be sufficient for us to fund our operating expenses and capital expenditure requirements through .

Our estimate as to how long we expect our current cash, cash equivalents and short-term investments in marketable securities 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, global economic conditions and volatility in the credit and financial markets, inflationary pressures and effects of the COVID-19 pandemic, the Russian invasion of Ukraine and the recent conflict in Israel. Our current cash, cash equivalents and short-term investments in marketable securities and the net proceeds from this offering will not be sufficient to fund all of the activities that are necessary to complete the development and commercialization of our drug candidates.

Until 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. 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 our lead drug candidate, denifanstat, which is still in clinical development. If we are unable to obtain regulatory approval for or successfully commercialize denifanstat, our business will be materially harmed.

Currently, our product development is primarily focused on our lead drug candidate, denifanstat, for the potential treatment of nonalcoholic steatohepatitis (NASH). Successful continued development and

ultimate regulatory approval of denifanstat 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 preclinical and clinical development of denifanstat. We will need to raise sufficient funds to successfully complete the development program for denifanstat. The future regulatory and commercial success of denifanstat 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 denifanstat, including but not limited to Phase 2 clinical trials and, later, registrational clinical trials to obtain drug approval;
- the mechanism of action of denifanstat 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 AEs, if any, when denifanstat 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 denifanstat, and there may be more uncertainty regarding relatedness to denifanstat if we pursue clinical trials of denifanstat in combination with other drugs or drug candidates, and this 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 denifanstat in NASH, or any other indication;
- in our clinical programs for denifanstat, 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 authorities may change at any time;
- the FDA or comparable foreign regulatory authority 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 denifanstat will be accepted as a therapy by physicians, patients and third-party payors, even if approved;
- if approved for NASH, denifanstat 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 denifanstat; 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 denifanstat or that otherwise compete with denifanstat.

Of the large number of drugs in development in the pharmaceutical industry, only a small percentage result in the submission of a new drug application (NDA) to the FDA and even fewer are approved for commercialization. Furthermore, even if we receive regulatory approval to market denifanstat, any such approval may be subject to limitations on the indicated uses or patient populations for which we may market the drug. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development program for denifanstat, we may be unable to successfully develop or commercialize denifanstat. If we or any of our future development partners are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize denifanstat, 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 who remain in the trials until their conclusion. 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 denifanstat or any other future drug candidates if we are unable to locate, enroll and retain 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
- other factors outside of our control, such as the effects of any future pandemics, global economic conditions and volatility in the credit and financial markets, inflationary pressures, the Russian invasion of Ukraine and the recent conflict in Israel.

In certain of our proposed NASH clinical trials, patient willingness to undergo a liver biopsy, particularly for trials of a longer duration, may also impact patient enrollment and retention. Potential patients for denifanstat or any other future drug candidates may not be adequately diagnosed or identified with the indications 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. 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 trials 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 seek regulatory approval for and commercialize our drug candidates on a timely basis, which would require us to incur additional costs and substantially harm our business.

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 FASCINATE-1 Phase 2 and FASCINATE-2 Phase 2b clinical trials of denifanstat in patients with NASH may not be predictive of the results from any future Phase 3 trial of denifanstat for the treatment of NASH. 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. For example, carcinogenicity and reproductive toxicology studies may be required to support late-stage clinical trials and/or approval;
- 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;
- reaching or failing to reach agreement on acceptable terms with prospective CROs, contract manufacturing organizations (CMOs), and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly;
- 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;
- 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) approval or positive ethics committee opinions to conduct a clinical trial at a prospective site;
- 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 side effects related to the drug candidate being tested;
- lack of adequate funding to continue the clinical trial;
- 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;
- failure of our third-party vendors to perform 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.

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 any future pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting, or completing our planned and ongoing clinical trials. For example, we have previously experienced delays in enrollment and temporary closures of clinical trial sites due to COVID-19. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs or relevant 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 or informed consents, 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, relevant ethics committees or competent authorities for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Further, conducting clinical trials in foreign countries, as our licensee, Ascletis, and its affiliate Gannex Pharma Co., Ltd. (Gannex), to whom Ascletis has assigned the license, are doing for denifanstat in China, and we may do in the future 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 frameworks, 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.

We may not be successful in our efforts to expand our pipeline, including by identifying additional indications for which to investigate denifanstat in the future. We may expend our limited resources to pursue a particular indication or formulation for denifanstat 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 currently focused on developing denifanstat for NASH. In May 2023, Ascletis Pharma announced topline results from a Phase 2 clinical

trial of denifanstat in 179 patients with moderate to severe acne in China. In December 2023, Ascletis Pharma announced the initiation of a randomized, double-blind, placebo-controlled, multicenter Phase 3 clinical trial to evaluate the safety and efficacy of denifanstat for the treatment of moderate to severe acne vulgaris in 480 patients in China. We have also identified other potential indications where fatty acid synthase (FASN) inhibition could have clinical benefit, including oncology. However, we may fail to generate additional clinical development opportunities for denifanstat or the other molecules in our catalog of FASN inhibitors for a number of reasons, including because denifanstat 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 denifanstat in parallel over the next several years. If we make incorrect determinations regarding the viability or market potential of denifanstat or any of our other drug candidates or misread trends in NASH, acne 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. For example, 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 denifanstat. Furthermore, research programs to identify additional indications for denifanstat 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.

We have conducted, are currently conducting, and may in the future conduct clinical trials for our drug candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

We have conducted and may in the future conduct one or more clinical trials of our current or future drug candidates outside the United States. For example, we conducted a cohort of our FASCINATE-1 clinical trial in China. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such as inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical power, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, we would need to conduct additional trials, which could be costly and time-consuming.

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 Series A common stock.

Others, including regulatory authorities, 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 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 intend to develop certain of our drug candidates in combination with other approved and investigational therapies, which exposes us to additional risks.

We intend to develop certain of our drug candidates in combination with one or more other approved therapies. For example, we conducted a Phase 1 trial of denifanstat in patients with solid tumors, which included arms in combination with taxane-based chemotherapy.

Our ability to develop and ultimately commercialize our drug candidates in combination with other therapies will depend on our ability to access such therapies on commercially reasonable terms for the clinical trials and their availability for use with our drug candidate. We cannot be certain that current or potential future commercial relationships will provide us with a steady supply of such therapies on commercially reasonable terms or at all.

Any failure to maintain or enter into new successful commercial relationships or the expense of purchasing these therapies may delay our development timelines, increase our costs and jeopardize our ability to develop our current drug candidates. If any of these circumstances occur, our business, financial condition, operating results, stock price and prospects may be materially harmed.

Moreover, the development of drug candidates for use in combination with another therapy may present challenges that are not faced for single agent drug candidates. The FDA or comparable foreign regulatory authorities may require us to use more complex clinical trial designs in order to evaluate the contribution of each drug candidate or therapy to any observed effects. It is possible that the results of such trials could show that any positive trial results are attributable to the other therapy and not our current drug candidates.

Even if any drug candidate we develop were to receive regulatory approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or comparable foreign regulatory authorities outside of the United States could revoke or amend approval of the therapy used in combination with our product or that safety, efficacy, manufacturing or supply issues could arise with any of those existing therapies. If the therapies we use in combination with our drug candidates are replaced as the standard of care for the indications we choose for any of our drug candidates, the FDA or comparable foreign regulatory authorities may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our own products, if approved, being removed from the market or being less successful commercially.

We also may choose to evaluate our current drug candidates and any other future drug candidates in combination with one or more therapies that have not yet been approved for marketing by the FDA or

comparable foreign regulatory authorities. We will not be able to market and sell our current drug candidates or any drug candidate we develop in combination with any unapproved therapies for a combination indication if that unapproved therapy does not ultimately obtain marketing approval either alone or in combination with our product. In addition, unapproved therapies face the same risks described with respect to our drug candidates currently in development and clinical trials, including the potential for serious adverse effects, delay in their clinical trials and lack of FDA approval.

If the FDA or comparable foreign regulatory authorities do not approve these other products or revoke or amend their approval, or if safety, efficacy, quality, manufacturing or supply issues arise with the products we choose to evaluate in combination with our drug candidate, we may be unable to obtain approval of or market such combination therapy.

If we or third parties are unable to successfully develop technologies or establish tests for biomarkers that enable patient selection or monitoring for drug responses, or if we experience significant delays in doing so, we may not realize the full commercial potential of our drug candidates.

A key component of our strategy includes the use of biomarkers to inform patient selection for and/or to confirm responses to our drug candidates. In some cases, third parties provide this technology. It is not always the case, however, that the biomarker we have identified is on a standard panel offered by testing providers. If not already commercially available, we may collaborate with testing providers for the development of biomarker tests associated with our drug candidates. We may have difficulty in establishing or maintaining such development relationships, and we will face competition from other companies in establishing these collaborations.

There are also several risks associated with biomarker identification and validation. We, in collaboration with any testing providers, may not be able to identify predictive biomarkers or pharmacodynamic biomarkers for one or more of our programs. We may not be able to validate potential biomarkers or their functional relevance preclinically in relevant *in vitro* or *in vivo* models. Data analytics and information from databases that we rely on for identifying or validating some of our biomarker-target relationships may not accurately reflect potential patient populations. Potential biomarkers, even if validated preclinically, may not be functionally effective or validated in human clinical trials.

If testing providers experience any delays including the biomarkers we have identified for patient selection and/or drug response monitoring on their panels or tests, or if they do not include those biomarkers on their panels or tests, our clinical trials may be delayed or may not identify sufficient patients to complete the trial, and our drug candidates may not advance to approval or realize their full commercial potential.

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 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. The FDA and other regulatory authorities 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 authorities that denifanstat 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 authorities for approval;
- the FDA or other regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical trials;

- the FDA or other regulatory authorities may not find the data from preclinical studies and clinical trials sufficient to demonstrate that the benefits of denifanstat or any of our other future drug candidates outweigh their safety risks;
- the FDA or other regulatory authorities 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 denifanstat 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 or other regulatory authorities may require development of a risk evaluation and mitigation strategy (REMS), or risk management plan (RMP), as a condition of approval;
- the FDA or other regulatory authorities 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 authorities may change their approval policies or adopt new regulations; and
- the FDA or other regulatory authorities may require simultaneous approval for both adults and for children and adolescents, which may delay approval, or we may have successful clinical trial results for adults but not children and adolescents, or vice versa.

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 authorities may require that we conduct additional clinical, preclinical, 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 authorities for obtaining approval.

In addition, the FDA or other regulatory authorities may 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 or comparable foreign risk management approaches. The FDA or other regulatory authorities 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 denifanstat 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 denifanstat 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 denifanstat 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 may not be able to file INDs or IND amendments, or comparable foreign applications, to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA or comparable foreign regulatory authorities may not permit us to proceed.

We may not be able to file Investigational New Drug applications (INDs), or comparable foreign applications, for our drug candidates on the timelines we expect. For example, we may experience manufacturing delays or other delays with IND-enabling studies. Moreover, we cannot be sure that submission of an IND, or comparable foreign applications, will result in the FDA or other regulatory authorities allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND, or comparable foreign applications, we cannot guarantee that such regulatory authorities will not change their requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs or to a new IND or comparable foreign applications. Any failure to file INDs, or comparable foreign applications, or submit our clinical trial protocols to regulatory authorities for review on the timelines we expect may prevent us from completing our clinical trials or commercializing our products on a timely basis, if at all.

Use of denifanstat 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 (AEs) associated with the use of denifanstat 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. For example, in our oncology Phase 1 clinical trial, six episodes of serious pneumonitis were experienced by five patients, one of which was fatal, assessed by the investigator as at least possibly related to both denifanstat and paclitaxel. No serious adverse events (SAEs) assessed as drug-related were reported in our NASH trials to date. Undesirable side effects caused by denifanstat 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 (SAEs) 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 denifanstat 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, over 700 subjects have been treated with denifanstat in our clinical trials to date. It is possible that as we test our drug candidates in larger, longer and more extensive clinical trials, illnesses, injuries, discomforts and other AEs 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. In many cases, 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 denifanstat 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 from 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 limit access to that product;
- 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 and other elements to assure safe use, or comparable foreign risk management approaches;
- 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 denifanstat or any future drug candidates, if approved, and could significantly harm our business, results of operations, and prospects.

We have received fast track designation for denifanstat for NASH and may seek such designation for our other drug candidates or for other indications, 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 preclinical 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. In March 2021, we received fast track designation for denifanstat for the treatment of NASH and we may seek fast track designation for certain other indications for denifanstat 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. The European Medicines Agency (EMA) has a similar program called PRIority MEdicine (PRIME) designation. The purpose of this program is to enhance support for the development of medicinal products that target an unmet medical need. PRIME provides enhanced interaction and early dialogue between the EMA and developers of promising medicinal products to optimize generation of robust data on the benefits and risks of a medicinal product and enable accelerated assessment of medicines applications. Participation in PRIME does not, however, limit the obligations that must be fulfilled for grant of a related marketing authorization. We may seek PRIME designation for one or more of our drug candidates, but might not receive such designations. Even if we receive PRIME designation, there is no guarantee of grant of marketing authorization at all or within any specific timeframe.

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.

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 GCP for any clinical trials that we conduct post-approval. Further, the FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for their approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on companies' communications regarding off-label use, and if we market our products for uses beyond their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion of prescription drugs may lead to FDA enforcement actions and investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other domestic and foreign regulatory authorities for compliance with current good manufacturing practice (cGMP), regulations and standards. If we or a regulatory authority discover previously unknown problems with a product, such as AEs 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.

If we fail to comply with the regulatory requirements of the FDA and other applicable domestic and foreign regulatory authorities, or if 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 marketing or manufacturing of our products;
- revisions to the labeling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings;
- imposition of a REMS, or comparable foreign risk management approaches, which may include distribution or use restrictions;
- requirements to conduct additional post-marketing clinical trials to assess the safety of the product;
- civil or criminal penalties;
- fines, warning letters or holds on clinical trials;
- injunctions;
- product seizures or detentions;
- voluntary or mandatory product recalls;
- suspension, modification or withdrawal of regulatory approvals; and
- refusal by the FDA or other domestic or foreign regulatory authorities 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 CMOs 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.

Changes in the manufacturing process or formulation may result in additional costs or delay.

As drug candidates progress through preclinical studies and clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our drug candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our drug candidates and jeopardize our ability to commercialize our drug candidates, if approved, and generate revenue. If we or our CMOs are not able to successfully manufacture our drug candidates in sufficient quality and quantity, clinical development and timelines for our drug candidates and subsequent approval could be adversely impacted.

Changes in funding for the FDA and other domestic and foreign government authorities could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA and other domestic and foreign government authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel, accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government authorities that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other domestic and foreign authorities may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government authorities, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory authorities, such as the FDA, have had to furlough critical FDA employees and stop critical activities. Our business depends upon the ability of the FDA to accept and review our potential regulatory filings. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our ability to advance clinical development of our drug candidates. Further, future shutdowns of other government authorities, such as the U.S. Securities and Exchange Commission (SEC), may also impact our business through review of our public filings and our ability to access the public markets.

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 we have. 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 denifanstat 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 89bio, Inc., Akero Therapeutics, Inc., Altimmune, Inc., Bristol-Myers Squibb Company, Eli Lilly and Company, Galmed Pharmaceuticals Ltd., Gilead Sciences, Inc., Intercept Pharmaceuticals, Inc., Inventiva S.A., Madrigal Pharmaceuticals, Inc., NGM Biopharmaceuticals, Inc., NorthSea Therapeutics B.V., Novartis AG, Novo Nordisk A/S, Pfizer Inc., Terns Pharmaceuticals, Inc., Viking Therapeutics, Inc., and Zydus 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 denifanstat 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 legislative and executive initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare.

The Inflation Reduction Act of 2022 (IRA), for example, includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket cap for Medicare Part D beneficiaries to $2,000 starting in 2025; impose new manufacturer financial liability on certain drugs under Medicare Part D; allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than the rate of inflation; and delay until January 1, 2032 the implementation of the Department of Health and Human Services (HHS) rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. If a product receives multiple orphan designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. The effects of the IRA on our business and the healthcare industry in general is not yet known.

President Biden has also issued multiple executive orders that have sought to reduce prescription drug costs. In February 2023, HHS also issued a proposal in response to an October 2022 executive order from President Biden that includes a proposed prescription drug pricing model that will test whether targeted Medicare payment adjustments will sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through FDA's accelerated approval pathway. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the potential use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights that would be voluntary for federal government agencies to follow when deciding whether to exercise march-in rights and which for the first time includes the price of a product as a factor a federal government agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain whether the federal government will actually exercise such

march-in rights in connection with pharmaceutical products or whether any such exercise will be subject to judicial review or challenge. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new measures to control drug costs.

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 denifanstat, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition, and prospects. For more information regarding these and other healthcare reform initiatives, see "Business—Government regulation and product approval."

We cannot predict the likelihood, nature, or extent of healthcare reform initiatives that may arise from future legislation or administrative action. We expect that 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. 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 denifanstat or our other drug candidates, if approved.

We may attempt to seek approval from the FDA for one or more of our drug candidates through the use of the accelerated approval pathway. 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 pathway, 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 verify and describe the drug's clinical benefit and, under the Food and Drug Omnibus Reform Act of 2022 (FDORA), the FDA is permitted to require, as appropriate, that such studies be underway prior to approval or within a specified time period after the date accelerated approval is granted. FDORA also requires sponsors to send updates to the FDA every 180 days on the status of such studies, including progress toward enrollment targets, and the FDA must promptly post this information publicly. In addition, FDORA gives the FDA increased authority to withdraw accelerated approval on an expedited basis if, for example, the sponsor fails to conduct such studies in a timely manner, such studies fail to confirm the drug's clinical benefit, or the sponsor fails

to send the necessary updates to the FDA. The FDA is empowered to take action, such as issuing fines, against companies that fail to conduct with due diligence any post-approval confirmatory study or submit timely reports to the agency on their progress. In addition, the FDA generally requires, unless otherwise informed by the agency, pre-approval of promotional materials for products receiving accelerated approval, which could adversely impact the timing of the commercial launch of the product.

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.

In addition, the policies of the FDA, the competent authorities of the EU Member States, the EMA, the European Commission and other comparable regulatory authorities with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the European Union recently evolved. The EU Clinical Trials Regulation (CTR), which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each EU Member State, leading to a single decision for each EU Member State. The assessment procedure for the authorization of clinical trials has been harmonized as well, including a joint assessment by all EU Member States concerned, and a separate assessment by each EU Member State with respect to specific requirements related to its own territory, including ethics rules. Each EU Member State's decision is communicated to the sponsor via the centralized EU portal. Once the clinical trial has been approved, clinical study development may proceed. The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. For clinical trials in relation to which application for approval was made on the basis of the EU Clinical Trials Directive before January 31, 2022, the EU Clinical Trials Directive will continue to apply on a transitional basis for three years. Additionally, sponsors could choose to submit a clinical trial application under either the EU Clinical Trials Directive or the CTR until January 31, 2023, and, if authorized, those trials will be governed by the EU Clinical Trials Directive until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as CROs, may impact our development plans.

It is currently unclear to what extent the United Kingdom will seek to align its regulations with the European Union in the future. The UK regulatory framework in relation to clinical trials is derived from the EU Clinical Trials Directive. However, the Retained EU Law (Revocation and Reform) Bill published in late 2022 which is intended to remove all EU-derived legislation from the UK statute book by the end of 2023, may result in a divergence of approach between the European Union and the United Kingdom.

In January 2022, the UK Medicines and Healthcare products Regulatory Agency (MHRA), launched an eight-week consultation on reframing the UK legislation for clinical trials. The consultation closed in March 2022 and aims to streamline clinical trials approvals, enable innovation, enhance clinical trials transparency, enable greater risk proportionality, and promote patient and public involvement in clinical trials. The outcome of the consultation will be closely watched and will determine whether the United Kingdom chooses to align with the CTR or diverge from it to maintain regulatory flexibility. A decision by the United Kingdom not to closely align its regulations with the CTR in the EU may have an effect on the cost of conducting clinical trials in the United Kingdom as opposed to other countries and/or make it harder to

seek a marketing authorization in the European Union for our drug candidates on the basis of clinical trials conducted in the United Kingdom.

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

If any product liability lawsuits are 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.

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 or comparable foreign regulations, to provide accurate information to the FDA or comparable foreign authorities, to comply with federal, state or foreign healthcare fraud and abuse laws and regulations, to report financial information or data timely, completely or accurately, or to disclose unauthorized activities to us, or failure to comply with comparable foreign requirements. 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 or comparable foreign equivalents, 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 denifanstat 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 mediated by overproduction of palmitate, including acne and some forms of cancer. 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 be certain that any such products that are approved will be manufactured or produced economically, be successfully commercialized, be widely accepted in the marketplace, or be more effective than other commercially available alternatives.

If we are unable to successfully validate, develop and obtain regulatory approval for diagnostic tests for certain our drug candidates that would commercially benefit from such tests, or experience significant delays in doing so, we may not realize the full commercial potential of these drug candidates.

In connection with the clinical development of certain of our drug candidates for certain indications, we may engage third parties to develop or otherwise obtain access to in vitro complementary diagnostic tests to identify patients within a disease category who may derive meaningful benefit from our drug candidates. Such complementary diagnostics may be used during our clinical trials as well as in connection

with the commercialization of our products that receive regulatory approval. To be successful, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. The FDA and comparable foreign regulatory authorities regulate in vitro complementary diagnostics as medical devices and, under that regulatory framework, will likely require the conduct of clinical trials to demonstrate the safety and effectiveness of any diagnostics we or third parties may develop, which we expect will require separate regulatory clearance or approval prior to commercialization of such diagnostics.

We intend to rely on third parties for the design, development and manufacture of such complementary diagnostic tests for our drug candidates. If we enter into such collaborative agreements, we will be dependent on the sustained cooperation and effort of our future collaborators in developing and obtaining approval for these complementary diagnostics. It may be necessary to resolve issues such as selectivity/specificity, analytical validation, reproducibility, or clinical validation of complementary diagnostics during the development and regulatory approval processes. Moreover, even if data from preclinical studies and early clinical trials appear to support development of a complementary diagnostic for a drug candidate, data generated in later clinical trials may fail to support the analytical and clinical validation of the complementary diagnostic. We and our future collaborators may encounter difficulties in developing, obtaining regulatory clearance or approval for, manufacturing and commercializing complementary diagnostics similar to those we face with respect to our drug candidates themselves, including issues with achieving regulatory clearance or approval, production of sufficient quantities at commercial scale and with appropriate quality standards, and in gaining market acceptance. If we are unable to successfully develop complementary diagnostics for these drug candidates, or experience delays in doing so, the development and commercialization of these drug candidates may be adversely affected, these drug candidates may not obtain regulatory approval, and we may not realize the full commercial potential of any of these products that obtain regulatory approval. As a result, our business, results of operations and financial condition could be materially harmed. In addition, a diagnostic company with whom we contract may decide to discontinue selling or manufacturing the complementary diagnostic test that we anticipate using in connection with development and commercialization of our drug candidates or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our drug candidates or do so on commercially reasonable terms.

We may engage in strategic transactions that could increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, subject us to other risks, adversely affect our liquidity, increase our expenses and present significant distractions to our management.

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

Any pandemic, epidemic, or outbreak of an infectious disease may materially and adversely affect our business and our financial results and could cause a disruption to the development of our drug candidates.

Public health crises, such as pandemics or similar outbreaks, could adversely impact our business. For example, the impact of the COVID-19 pandemic and the efforts to mitigate it resulted in and may continue to result in disruptions to the global economy, as well as businesses and capital markets around the world. We experienced modest delays in our development activities as a result of the COVID-19 pandemic, primarily due to temporary closures of certain clinical sites that delayed patient enrollment in our FASCINATE-2 trial. Although the public health emergency declarations related to COVID-19 ended on May 11, 2023, the extent to which the COVID-19 pandemic will continue to impact our operations or those of our consultants and collaborators will depend on future developments, including the global macroeconomic effects of the virus. Any future pandemic, epidemic or outbreak of an infectious disease could have similar effects. Furthermore, economic recessions, increased inflation and/or interest rates, and any disruptions to our operations or workforce availability, including those brought on by the continued effects of the COVID-19 pandemic or a similar health epidemic may have a negative effect on our operating results. The foregoing and other continued disruptions to our business as a result of the COVID-19 pandemic or similar public health crisis could result in an adverse effect on our business, results of operations, financial condition and cash flows.

Risks related to 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 denifanstat, 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 may enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, including any 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 U.S. and foreign patents and 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 pre-issuance 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.

We may rely on more than one patent to provide multiple layers of patent protection for our drug candidates. If the latest-expiring patent is invalidated or held unenforceable, in whole or in part, the overall protection for the drug candidate may be adversely affected. For example, if the latest-expiring patent is invalidated, the overall patent term for our drug candidate could be adversely affected.

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 may find 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 U.S. 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 U.S. 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 (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 U.S. Supreme Court and the Court of Appeals for the Federal Circuit ("Federal Circuit") have 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. For example, with respect to patent term adjustment, the Federal Circuit's recent holding in *In re Cellect, LLC*, 81 F.4th 1216 (Fed. Cir. 2023), that obviousness-type double patenting analysis for a patent that has received patent term adjustment must be based on the expiration date of the patent after the patent term adjustment has been added, which may negatively impact the term of certain U.S. patents. 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 U.S. Congress, the U.S. 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. For a description of the intellectual property regulatory framework, see "Business—Intellectual property."

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 Series 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 several 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 authorities 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, particularly from our competitors currently developing products for the treatment of NASH, 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 our collaborators 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 U.S. patents may be eligible for limited patent term extension (PTE), under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments). We plan to seek PTE in the United States, 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. We also plan to see analogous forms of PTE in other countries where we are prosecuting

patents. However, the 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 "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, including denifanstat, 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 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, CMOs, 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, including our license agreement with Ascletis. 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 authorities 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 proprietary 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 proprietary product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties, and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. 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 denifanstat to Ascletis, a significant stockholder, for Greater China. Under the license agreement, Ascletis controls certain 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 certain clinical trials for the licensed drug candidate, denifanstat, 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 those trial designs nor control their interactions with respect to obtaining and maintaining regulatory approvals 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.

We may be exposed to reputational risk as a result of certain allegations against our license partners, which may require the attention of their management. For example, Ascletis, its affiliate Gannex, and certain of its other affiliates, and the chief executive officer of Ascletis and Gannex, Jinzi J. Wu (who is also a member of our board of directors), are the subject of legal complaints filed by another biopharmaceutical company in the U.S. District Court in the Southern District of California and the U.S. International Trade Commission with respect to intellectual property matters. We are not the subject of or party to such complaints, nor are they directed at the intellectual property under our license agreement with Ascletis. We do not believe that Ascletis' legal proceedings will have a material impact on our business, operations or financial condition.

We rely on third parties to conduct our clinical trials of our drug candidates and expect to rely on third parties to conduct future clinical trials, as well as investigator-sponsored clinical trials of our drug candidates. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business could be substantially harmed.

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 denifanstat 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, our investigators and CROs are required to comply with GCP, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for drug candidates in clinical development. Regulatory authorities enforce GCP 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 cGMP regulations and will require a large number of test subjects. Our failure or any failure by our investigators or 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 investigators or CROs violate federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws and foreign equivalents.

Our investigators and CROs are not our employees, and, except for remedies available to us under our agreements with such investigators and CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical, clinical and nonclinical programs. These investigators and 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 investigators and 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 denifanstat or any other future drug candidates. As a result, our financial results and the commercial prospects for denifanstat and any future drug candidates could be harmed, our costs could increase and our ability to generate revenues could be delayed.

Our investigators and CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our investigators and 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 parties terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. Switching or adding investigators or CROs involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new investigator or 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 investigators and 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.

We may also rely on individual investigators or academic and non-academic institutions to conduct investigator-sponsored clinical trials relating to our drug candidates. We will not control the design or conduct of these investigator-sponsored trials, and it is possible that the FDA or comparable foreign regulatory authorities will not view these investigator-sponsored trials as providing adequate support for future clinical trials, whether controlled by us or third parties, for any one or more reasons, including elements of the design or execution of the trials or safety concerns or other trial results. Such arrangements will likely provide us certain information rights with respect to the investigator-sponsored trials, including access to and the ability to use and reference the data, including for our own regulatory filings, resulting from the investigator-sponsored trials. However, we would not have control over the timing and reporting of the data from investigator-sponsored trials, nor would we own the data from the investigator-sponsored trials. If we are unable to confirm or replicate the results from the investigator-sponsored trials or if negative results are obtained, we would likely be further delayed or prevented from advancing further clinical development of our drug candidates. Further, if investigators or institutions breach their obligations with respect to the

clinical development of our drug candidates, or if the data proves to be inadequate compared to the first-hand knowledge we might have gained had the investigator-sponsored trials been sponsored and conducted by us, then our ability to design and conduct any future clinical trials ourselves may be adversely affected.

We have relied on, and we expect to continue to rely on, third-party manufacturers to produce our drug candidates. Our manufacturers may experience manufacturing difficulties due to the ongoing effects of inflationary pressures, resource constraints, labor disputes or unstable political environments, which could delay the completion of our clinical trials, increase the costs associated with maintaining clinical trial programs and, significantly impact our ability to develop, obtain regulatory approval for, or market denifanstat and any future 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;
- 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 drug candidates and substantially increase 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. In some cases, the technical skills required to manufacture our drug candidates may be unique or proprietary to the original manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate manufacturer, or we may be unable to transfer such skills at all. In addition, if we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and all applicable regulations, and there could be a substantial delay before new facilities could be qualified and registered with the FDA and other foreign regulatory authorities. We will also need to verify, such as through a comparability study, that any new manufacturer or new manufacturing process will produce our drug candidate according to the specifications previously submitted to the FDA or another domestic or foreign regulatory authority. The delays associated with the verification of a new manufacturer and demonstrating comparability of clinical trial drug product could negatively affect our ability to develop drug candidates or commercialize our products in a timely manner or within budget. To date, we have relied on three CMOs based in the United States and China to produce denifanstat drug substance and two CMOs in the United States and China to produce denifanstat

drug product. We will need to manufacture additional material to support late stage studies such as Phase 3 trials. Under the terms of our license agreement with Ascletis, we can source drug substance from and manufacture Product in Taiwan, but not from or in any other country in the territory of Greater China unless from Ascletis itself. There are no restrictions upon our manufacturing rights other than within Greater China (excluding Taiwan).

We currently rely on several manufacturers for the production of raw materials, APIs, and the finished products of denifanstat. Our reliance on third-party suppliers and CMOs could harm our ability to develop denifanstat 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 denifanstat 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 their manufacturing facilities. The FDA and corresponding foreign regulators also inspect these facilities to confirm compliance with cGMP and other applicable laws. We, our CMOs, any future collaborators and their CMOs could be subject to periodic unannounced inspections by the FDA or other comparable foreign regulatory authorities, to monitor and ensure compliance with cGMP. CMOs may face manufacturing or quality control problems causing production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP requirements. Despite our efforts to audit and verify regulatory compliance, one or more of our CMOs or third-party vendors may be found on regulatory inspection by the FDA or other comparable foreign regulatory authorities to be noncompliant with cGMP regulations. Any failure to comply with cGMP requirements or other FDA and foreign regulatory authority requirements may result in shutdown of the CMO or third-party vendor or invalidation of drug product lots or processes and could adversely affect our clinical research activities and our ability to develop our drug candidates and market our products following approval, if obtained. In some cases, a product recall may be warranted or required, which would materially affect our ability to supply and market our drug products, if approved.

We currently do not control the manufacturing process of denifanstat and are completely dependent on our CMOs for complying with the FDA's cGMP requirements for manufacture of both the active drug substances and finished drug product. If our CMOs cannot successfully manufacture material that conforms to our specifications and the FDA and comparable foreign regulatory authorities' strict regulatory requirements, we will not be able to secure or maintain FDA or comparable foreign regulatory approval for our drug candidates. 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 denifanstat or any future drug candidates, or if it withdraws any such approval in the future, or if our suppliers or CMOs 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 denifanstat 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 denifanstat 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 denifanstat or any future drug candidates may occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to the ongoing effects of the COVID-19 pandemic, inflationary pressures, resource constraints, 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, rights to receive milestones, royalties or other payments, the approach for regulatory approvals or commercialization strategy. Any disputes, delays 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.

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 denifanstat 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 denifanstat 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 denifanstat and any future drug candidates, if approved, 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 denifanstat or any of our other future drug candidates. To the extent we rely on third parties to commercialize denifanstat 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 denifanstat 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 denifanstat or any future drug candidates.

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

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.

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 authorities 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.

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.

Our commercial success 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. 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.

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.

Additionally, we may develop complementary diagnostic tests for use with our drug candidates. We, or our collaborators, may be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we seek for our drug candidates, once approved. While we have not yet developed any complementary diagnostic tests for our drug candidates, if we do, there is significant uncertainty regarding our ability to obtain coverage and adequate reimbursement for the same reasons applicable to our drug candidates.

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.

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. 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 authorities. Regulatory authorities 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. 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.

Many EU Member States periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. We expect that legislators, policymakers and healthcare insurance funds in the EU Member States will continue to propose and implement cost-containing measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative to branded products, and/or branded products available through parallel import to keep healthcare costs down. Moreover, in order to obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. Health Technology Assessment (HTA), of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States.

In December 2021, Regulation No 2021/2282 on HTA, amending Directive 2011/24/EU, was adopted in the European Union. This Regulation, which entered into force in January 2022 and will apply as of January 2025, is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at European Union level for joint clinical assessments in these areas. The Regulation foresees a three-year transitional period and will permit EU Member States to use common HTA tools, methodologies, and procedures across the European Union, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for drug candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the European Union could be negatively affected.

Legislators, policymakers and healthcare insurance funds in the European Union may continue to propose and implement cost-containing measures to keep healthcare costs down; particularly due to the financial strain that the COVID-19 pandemic has placed on national healthcare systems of the EU Member States. These measures could include limitations on the prices we would be able to charge for drug candidates that we may successfully develop and for which we may obtain regulatory approval or the level of reimbursement available for these products from governmental authorities or third-party payors. Further, an increasing number of European Union and other foreign countries use prices for medicinal products established in other countries as “reference prices” to help determine the price of the product in their own

territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere.

Our relationships with customers, healthcare providers, and third-party payors may be subject, directly or indirectly, to federal, state and foreign healthcare fraud and abuse laws, transparency laws, and other healthcare laws and regulations, including analogous foreign laws. 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 or comparable foreign 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.

Outside the United States, interactions between pharmaceutical companies and health care professionals are also governed by strict laws, such as national anti-bribery laws of European countries, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment. For a description of the U.S. healthcare laws and regulations that may affect our ability to operate, see "Business—Government regulation and product approval."

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 or similar foreign 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 denifanstat 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 and we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions, litigation, fines and penalties, disruptions of our business operations, reputational harm, loss of revenue or profits, loss of customers or sales, and other adverse consequences.

We and the third parties upon which we rely face a variety of evolving threats, which could cause security incidents, such as cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources.

Despite the implementation of security and back-up measures designed to protect against security incidents, our internal computer, server, and other information technology systems as well as those of our third-party collaborators, consultants, contractors, suppliers, and service providers upon which we rely, may be vulnerable to various threats including, but not limited to, damage from physical or electronic break-ins, computer viruses, malware, ransomware, personnel misconduct or error, supply chain attacks, natural disasters, terrorism, war, telecommunication and electrical failure, denial of service, attacks enhanced or facilitated by artificial intelligence (AI), 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 data, and health-related information, and could subject us to significant liabilities and regulatory and enforcement actions, and reputational damage. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations.

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.

In addition, our reliance on third-party partners could introduce new cybersecurity risks and vulnerabilities. If we or our third-party collaborators, consultants, contractors, suppliers, or service providers upon which we rely were to suffer an attack or breach, for example, that resulted in the unauthorized access to or use or disclosure of personal data, we may have to notify consumers, partners, collaborators, government authorities, other stakeholders 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. Any such disclosures may involve inconsistent requirements and are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. 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. While we may be entitled to damages if these providers fail to satisfy their data privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

Our reliance on internet technology and the number of our employees, and those of our CROs, who continue to work remotely may create additional opportunities for cybercriminals to exploit vulnerabilities, as this has caused an increased usage of computers operated on home networks, while in transit, or in public locations. 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.

We take steps to detect and remediate vulnerabilities, but we may not be able to detect and remediate all vulnerabilities because the threats and techniques used to exploit the vulnerability change frequently and

are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a security incident has occurred. Unremediated high risk or critical vulnerabilities pose material risks to our business.

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, and/or sensitive data, we could incur liability and suffer reputational harm, and the development and commercialization of denifanstat, or future drug candidates could be delayed.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that any insurance coverage that we do or will obtain will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Furthermore, our sensitive information could be leaked, disclosed or revealed as a result of or in connection with our employees', personnel's or vendors' use of generative AI technologies.

Failure to comply with data privacy and security laws, regulations and other obligations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, negative publicity, and/or other adverse consequences that 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 data 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 (FTC), failing to take appropriate steps to keep consumers' personal data 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 data 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, the California Consumer Privacy Act, as amended by the California Privacy Rights Act (collectively, the "CCPA"), grants individual privacy rights for California consumers, business representatives, and employees who are California residents, including the right to access, correct, or delete certain personal data, and opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The CCPA provides for administrative fines of up to $7,500 per violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA increases compliance costs and potential liability with respect to other personal data we maintain about California residents. The CCPA also created a new California data protection agency authorized to implement and enforce the law. Additional compliance investment and potential business process changes may be required.

The CCPA marked the beginning of a trend toward more stringent privacy legislation in the United States, which could increase our potential liability and adversely affect our business. For example, new consumer privacy laws were passed in several other states including Connecticut, Colorado, Virginia and Utah. In addition, a number of other states have proposed and/or passed new privacy laws. Such legislation may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and/or changes in business practices and policies. The existence of comprehensive privacy laws in different states in the country could make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance.

Additionally, our employees and personnel may use generative AI technologies to perform their work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and consumer lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages.

For additional information, see "Business—Government regulation and product approval—Data privacy and security laws."

Foreign data protection laws, including the European Union's General Data Protection Regulation (the EU GDPR), and the UK equivalent of the same (the UK GDPR, together with the EU GDPR, the GDPR) 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 (EEA), or the United Kingdom. The GDPR applies to any company established in the EEA or United Kingdom as well as to those outside the EEA or United Kingdom if they collect and use personal data in connection with the offering of goods or services to individuals in the EEA or United Kingdom or the monitoring of their behavior. The GDPR, together with national legislation, regulations and guidelines of the EEA Member States and the United Kingdom 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 United Kingdom, 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 (£17.5 million) or 4% of the annual global revenues of the noncompliant company, whichever is greater. The EU GDPR also confers a private right of action on data subjects to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the EU GDPR. The UK Government has also now introduced a Data Protection and Digital Information Bill ("UK Bill") into the UK legislative process. The aim of the UK Bill is to reform the UK's data protection regime following Brexit. If passed, the final version of the UK Bill may have the effect of further altering the similarities between the UK and EU data protection regime. This may lead to additional compliance costs and could increase our overall risk. The respective provisions and enforcement of the EU's and UK's GDPR may further diverge in the future and create additional regulatory challenges and uncertainties. In addition, EU Member States have adopted implementing national laws to implement the GDPR which may partially deviate from the GDPR and the competent authorities in the EU Member States may interpret GDPR obligations slightly differently from country to country, so that we do not expect to operate in a uniform legal landscape in the EU.

The EU GDPR prohibits the transfer of personal data from the EEA to third countries that are not considered to provide adequate protections for personal data, including the U.S. With regard to transfers of personal data from the EEA, transfers to third countries that have not been approved as "adequate" are prohibited unless an appropriate safeguard specified by the EU GDPR is implemented, such as the Standard

Contractual Clauses, or SCCs, approved by the European Commission, certification to the EU-U.S. Data Privacy Framework (which allows for transfers for relevant U.S.-based organizations who self-certify compliance and participate in the framework), binding corporate rules, or a derogation applies. Where relying on the SCCs for data transfers, we may also be required to carry out transfer impact assessments to assess whether the recipient is subject to local laws which allow public authority access to personal data. Like the EU GDPR, the UK GDPR restricts personal data transfers outside the UK to countries not regarded by the UK as providing adequate protection. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing. The Information Commissioner's Office has recently introduced new mechanisms for international transfers of personal data originating from the UK (an International Data Transfer Agreement along with a separate addendum to the EU SCCs). The UK and U.S. have also agreed an extension to the EU-US Data Privacy Framework to cover transfers of personal data from the UK to the U.S. These mechanisms are subject to legal challenges, and therefore the circumstances where we can rely on these measures may change with time, such that there is no assurance that we can continue to satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the United Kingdom, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and United Kingdom to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activities groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the GDPR's cross-border data transfer rules.

Implementing mechanisms to endeavor to ensure compliance with the GDPR and relevant local legislation in EEA Member States and the United Kingdom 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 or enforcement notices. While we have taken steps to comply with the GDPR where applicable, our efforts to achieve and remain in compliance may not be fully successful.

Compliance with U.S. 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 (or perceived failure) to comply with U.S. and foreign data protection laws and regulations could result in government investigations and enforcement actions which could include civil or criminal penalties (e.g., fines, penalties, audits, additional reporting requirements and/or oversight, bans on processing personal data, and orders to destroy or not use personal data), private litigation (including class-action claims) and mass arbitration demands, 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.

In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for significant statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; inability to process personal data or to operate in certain jurisdictions (including in relation to clinical trials); limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

For additional information, see "Business—Government regulation and product approval—Data privacy and security laws."

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 U.S. federal and state net operating loss carryforwards (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 U.S. federal NOLs arising in taxable years beginning before January 1, 2018, may be carried forward to the earlier of the next subsequent twenty tax years to offset future taxable income, if any. Under current federal tax law, U.S. federal NOLs incurred in taxable years beginning after December 31, 2017, can be carried forward indefinitely, but the ability to use such U.S. 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 current U.S. federal tax law.

As of December 31, 2022, we had U.S. federal NOLs of approximately $128.2 million which may be available to offset future U.S. federal income. Our U.S. federal NOLs incurred in taxable years beginning prior to January 1, 2018 of approximately $91.0 million expire beginning in 2029 while U.S. federal NOLs incurred in taxable years beginning after December 31, 2017 of approximately $37.2 million will have an indefinite carryforward period, subject to annual limitations. As of December 31, 2022, we also had state NOL carryforwards of approximately $25.5 million which may be available to offset future state income and expire at various years beginning with 2028. Our NOL carryforwards are subject to review and possible adjustment by the U.S. federal and state tax authorities.

As of December 31, 2022, we had U.S. federal research and development tax credit carryforwards of approximately $4.4 million available to reduce future tax liabilities which expire at various years beginning with 2028. As of December 31, 2022, we had state credit carryforwards of approximately $2.5 million available to reduce future tax liabilities which do not expire.

Our NOL carryforwards and research and development (R&D) credits are subject to review and possible adjustment by the U.S. federal and state tax authorities.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (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 by "5% shareholders" over a rolling three-year period, the corporation's ability to use its pre-change NOLs, 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 U.S. 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. 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.

Changes in tax law may adversely affect us or our investors.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service (IRS) and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our Series A common stock. For example, under Section 174 of the Code, in taxable years beginning after December 31, 2021, expenses that are incurred for research and development in the United States are capitalized and amortized, which may have an adverse effect on our cash flow. In recent years, many such changes have been made, and changes are likely to continue to occur in the future. It cannot be predicted whether, when, in what form or with what effective dates tax laws, regulations and rulings may be

enacted, promulgated or issued, which could result in an increase in our or our shareholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law.

We have incurred, and will continue to incur, significant increased costs as a result of operating as a public company, and our management is devoting substantial time and resources to new compliance initiatives.

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (Exchange Act), the Sarbanes-Oxley Act of 2002 (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 continue to increase, our legal and financial compliance costs and may 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 10 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.

As a result of becoming a public company, we are obligated to develop and maintain proper and effective internal controls over financial reporting and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in our company and, as a result, the value of our common shares.

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act to furnish a report by management on, among other things, the effectiveness of our internal controls over financial reporting for the fiscal year ending December 31, 2024. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal controls over financial reporting and 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. 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. Implementing any appropriate changes to our internal controls may distract our officers and employees, entail substantial costs to modify our existing processes, and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and harm our business.

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, our investors could lose confidence in our reported financial information, the market price of our stock could decline, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities.

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. The loss of the services of any of our executive officers, other key employees and other scientific and medical advisors, and an inability to find suitable replacements could result in delays in product development and harm our business. We are highly dependent on the management, research and development, clinical, financial, and business development expertise of David Happel, our Chief Executive Officer, Dr. Eduardo Martins, our Chief Medical Officer, Anthony Rimac, our Chief Financial Officer, and Elizabeth Rozek, our General Counsel and Chief Compliance Officer. On December 28, 2023, Mr. Rimac provided notice of his intent to step down as our Chief Financial Officer effective January 31, 2024. Contingent on the approval of our board of directors, we intend to appoint Joe Oriti, a director at Stout, a global advisory firm specializing in corporate finance, accounting and transaction advisory services, as our Interim Principal Financial Officer and Principal Accounting Officer following Mr. Rimac's departure to serve in such role while our board of directors conducts a search of potential candidates to replace Mr. Rimac. Mr. Oriti has served as a director at Stout since February 2023. Prior to joining Stout, he was a director at Riveron and SOLIC Capital serving clients in interim C-Suite roles. Mr. Oriti received his B.B.A. from Kent State University. Each of our other executive officers may currently terminate their employment with us at any time. We do not currently maintain "key person" insurance for any of our executives or employees.

Recruiting and retaining qualified scientific and clinical personnel and, if we progress the development of our product pipeline toward scaling up for commercialization, manufacturing and sales and marketing personnel, will also be critical to our success. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. If we fail to manage these transitions successfully, we could experience significant delays or difficulty in the achievement of our product development and our business, financial condition and results of operations could be materially and adversely affected. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our development and commercialization strategy. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

Risks related to our Series 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, many of which are beyond our control, including without limitation:

- 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 Series 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 has been and may continue to be volatile, and purchasers of our Series A common stock could incur substantial losses.

Our stock price has been and is likely to continue to be volatile. As a result of this volatility, investors in this offering may not be able to sell their Series A common stock at or above the public offering price. The market price for our Series A common stock may be influenced by various factors, many of which are beyond our control, including the other risks described in this "Risk Factors" section and many others, such as but not limited to:

- our ability to advance denifanstat or potential future drug candidates;
- results of preclinical studies and clinical trials of denifanstat or potential future drug candidates, or those of our competitors or potential collaborative 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 authorities 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 biopharmaceutical and biotechnology sectors;

- manufacturing, supply or distribution delays or shortages;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, financing efforts 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 Series 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;
- speculation in the press or investment community;
- trading volume of our Series A common stock;
- sales of our Series A common stock by us or our stockholders;
- the concentrated ownership of our common stock;
- changes in accounting principles;
- macroeconomic conditions, including volatility in the credit and financial markets, inflationary pressures and lingering effects of the COVID-19 pandemic on the global economy;
- terrorist acts, acts of war or periods of widespread civil unrest, including Russia's invasion of Ukraine and the recent conflict in Israel;
- natural disasters, including earthquakes, 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 Series A common stock, regardless of our operating performance.

The dual series structure of our common stock may limit our Series A common stockholders' ability to influence corporate matters and may limit visibility with respect to certain transactions.

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

Future sales and issuances of our Series A common stock, or rights to purchase our Series A common stock, could result in dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating as a public company. To the extent that additional capital is raised through the issuance of shares of Series A common stock or other securities convertible into shares of Series A common stock, our stockholders will be diluted. Future issuances of our Series A common stock or other equity securities, or the perception that such sales may occur, could adversely affect the trading price of our Series 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 Series A common stock or other equity securities or the availability of Series A common stock for future sales will have on the trading price of our Series A common stock.

Pursuant to our 2023 Plan, our management is authorized to grant stock options to our employees, directors and consultants. Initially, the aggregate number of shares of our Series A common stock that may be issued pursuant to stock awards under the 2023 Plan is 2,585,968 shares. Additionally, the number of shares of our Series A common stock reserved for issuance under the 2023 Plan automatically increases on January 1st of each year, beginning on January 1, 2024 and continuing through and including January 1, 2033, by 4% 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.

Our principal stockholders and management own a significant percentage of our common stock and have the ability to exercise significant control over matters subject to stockholder approval.

Our executive officers and directors, principal stockholders and their respective affiliates, beneficially own a significant amount of our Series A common stock. 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.

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

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

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act (JOBS 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 (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.

We will remain an emerging growth company until the earliest to occur of: (i) the last day of the fiscal year in which we have more than $1.235 billion in annual revenue; (ii) the date we qualify as a "large accelerated filer," with at least $700.0 million of equity securities held by non-affiliates; (iii) the date on which

we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period; and (iv) December 31, 2028. 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 Series A common stock less attractive because we may rely on these exemptions.

In addition, the JOBS Act provides that an emerging growth company can also take advantage of an extended transition period for complying with new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards, and therefore we will not be subject to the same requirements to adopt new or revised accounting standards as other public companies that are not emerging growth companies.

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

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

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 Series A common stock will the sole source of gain for our stockholders in the foreseeable future. In addition, the terms of any future debt agreements may preclude us from paying dividends. Any return to stockholders will therefore be limited to the appreciation of their stock. There is no guarantee our Series A common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares.

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 be called only by our board of 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 bylaws 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 bylaws 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.

However, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all claims brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Consequently, 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 U.S. federal courts have exclusive jurisdiction. Moreover, Section 22 of the Securities Act of 1933, as amended (the Securities Act), creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder.

In addition, our amended and restated bylaws 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 such 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 bylaws 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.

Risks related to this offering

If you purchase our Series A common stock in this offering, you will experience immediate and substantial dilution and may experience additional dilution in the future.

Investors purchasing our Series A common stock in this offering will pay a price per share that substantially exceeds the as adjusted net tangible book value per share. As a result, investors purchasing our Series A common stock in this offering will incur immediate dilution of $10.49 per share (or $10.11 per share if the underwriters exercise their option to purchase additional shares in full), representing the difference between the assumed public offering price of $18.42 per share, which is the last reported sale price of our Series A common stock on the Nasdaq Global Market on January 22, 2024, and our as adjusted net tangible book value as of September 30, 2023. To the extent outstanding options to purchase shares of our Series A common stock are exercised, new investors may incur further dilution. For more information on the dilution you may suffer as a result of investing in this offering, see "Dilution."

Additionally, 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 Series 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 Series 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 Series A common stock, including shares of Series A common stock sold in this offering.

We may allocate the net proceeds from this offering in ways that you and other stockholders may not approve.

Our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in the section titled "Use of Proceeds." Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our management might not apply our net proceeds in ways that ultimately increase the value of your investment, and the failure by our management to apply these funds effectively could harm our business. If we do not invest or apply the net proceeds from this offering in ways that enhance stockholder value, we may fail to achieve expected results, which could cause our Series A common stock price to decline.

Future sales of shares of our Series A common stock in the public market, or the perception that such sales could occur, could cause our stock price to fall.

Sales of a substantial number of shares of our Series A common stock or other equity-related securities in the public market, or the perception in the market that such sales could occur, could reduce the market price of our Series A common stock and impair our ability to raise capital through the sale of additional equity securities. We may sell large quantities of our Series A common stock at any time pursuant to this prospectus or in one or more separate offerings. In addition, third party sales of a substantial number of shares of our Series A common stock in the public market could occur at any time. As of January 1, 2024, we had 21,375,402 shares of Series A common stock outstanding, of which our executive officers and directors, principal stockholders and their respective affiliates beneficially owned approximately 79.5%. Following this offering, our executive officers and directors, principal stockholders and their respective affiliates will

beneficially own approximately % of our Series A common stock, assuming no exercise of the underwriters' option to purchase additional shares and assuming no exercise of outstanding options. If one or more of them were to sell a substantial portion of the shares they hold, it could cause our stock price to decline.

In connection with this offering, we and our directors, executive officers and certain of our stockholders have agreed that for a period of 90 days following the date of this prospectus, with respect to us, 75 days with respect to our executive officers and directors and 30 to 75 days with respect to certain of our stockholders affiliated with our directors, among other things and subject to certain exceptions, we or they will not sell, dispose of or hedge any shares of our Series A common stock or securities convertible into or exchangeable or exercisable for any shares of our Series A common stock without the prior written consent of Goldman Sachs & Co. LLC. See the section titled "Underwriting" for a more complete description of the lock-up agreements with the underwriters. Sales of a substantial number of such shares upon expiration of the lock-up agreements, the perception that such sales may occur, or early release of these agreements, could cause our market price to fall or make it more difficult for you to sell your Series A common stock at a time and price that you deem appropriate.

Moreover, certain holders of our Series A common stock have rights, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders, until such shares can otherwise be sold without restriction under Rule 144 under the Securities Act of 1933, as amended (the Securities Act) or until the rights terminate pursuant to the terms of the stockholders agreement between us and such holders. We have also registered all shares of Series A common stock subject to equity awards issued or reserved for future issuance under our equity compensation plans on a registration statement on Form S-8. These shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates under Rule 144 under the Securities Act and the market standoff provisions and lock-up agreements described above. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our Series A common stock could decline.

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 issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.

The trading market for our Series A common stock depends in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property rights or our Series A common stock performance, or if our target studies and operating results fail to meet the expectations of the analysts, our stock price could 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.

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The global credit and financial markets have experienced severe volatility and disruptions in the past several years. A severe or prolonged economic downturn, such as the global financial crisis, could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. There can be no assurance that further deterioration in credit

and financial markets and confidence in economic conditions will not occur. A weak or declining economy could also result in supply chain disruptions. In addition, the ongoing military conflict between Russia and Ukraine and in Israel could disrupt or otherwise adversely impact our operations and those of third parties upon which we rely. Related sanctions, export controls or other actions have been or may in the future be initiated by nations including the United States, the European Union or Russia, which could adversely affect our business and/or our supply chain, our CROs, CMOs and other third parties with whom we conduct business. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and financial condition and results of operations.

Events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. Even though we assess our banking relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our business, financial condition or results of operations.

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

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

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, cash equivalents and short-term investments in marketable securities 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 denifanstat or any other drug candidates we may develop, and conducting preclinical studies and clinical trials;
- the timing and costs involved in obtaining and maintaining regulatory approval of denifanstat 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 or accelerated approvals for our drug candidates for various indications;
- current and future agreements with third parties in connection with the development and commercialization of denifanstat or any other future drug candidate;
- our estimated number of patients in the United States who suffer from the diseases we target, including NASH, and the number of subjects that will enroll in our clinical trials;
- our ability to advance drug candidates into and successfully complete clinical trials;
- our relationship with Ascletis and its affiliate Gannex, and the success of its development efforts for denifanstat;
- the ability of our clinical trials to demonstrate the safety and efficacy of denifanstat and any other drug candidates we may develop, and other positive results;
- our plans relating to commercializing denifanstat 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 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 denifanstat and any other drug candidates we may develop, including additional indications that we may pursue for denifanstat or other drug candidates;
- existing regulations and regulatory developments in the United States and other jurisdictions;
- our potential and ability to successfully manufacture and supply denifanstat 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 denifanstat and any other drug candidates we may develop, as well as the pricing and reimbursement of denifanstat 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 denifanstat and for any other future drug candidate;
- our ability to realize the anticipated benefits of any strategic transactions;
- 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;
- the impact of macroeconomic conditions, geopolitical turmoil and the COVID-19 pandemic on our business and operations;
- 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, cash equivalents and short-term investments in marketable securities, 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 "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.

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 "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 the net proceeds from this offering will be approximately $155.0 million (or approximately $178.4 million if the underwriters exercise their option to purchase additional shares of our Series A common stock in full) based on an assumed public offering price of $18.42 per share, which is the last reported sale price of our Series A common stock on the Nasdaq Global Market on January 22, 2024 and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

Each $1.00 increase or decrease in the assumed public offering price of $18.42 per share, which is the last reported sale price of our Series A common stock on the Nasdaq Global Market on January 22, 2024, would increase or decrease, as applicable, the net proceeds to us from this offering by approximately $8.5 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 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 Series A common stock offered by us would increase or decrease, as applicable, the net proceeds to us from this offering by approximately $17.3 million, assuming the public offering price of $18.42 per share, which is the last reported sale price of our Series A common stock on the Nasdaq Global Market on January 22, 2024, remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

We currently intend to use the net proceeds from this offering, together with our existing cash, cash equivalents and short-term investments in marketable securities, as follows:

- approximately $130.0 million to advance the development of denifanstat and begin startup activities related to the pivotal Phase 3 program in NASH, including manufacturing of additional drug supply;
- approximately $8.0 million to advance the development of TVB-3567 and submit an IND for a Phase 1 clinical trial for the treatment of acne; and
- the remainder for other general corporate purposes, including additional clinical development, working capital and operating expenses.

We may also use a portion of the remaining net proceeds and our existing cash, cash equivalents and short-term investments in marketable securities 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, cash equivalents and short-term investments in marketable securities, will be sufficient to fund our operations through the first quarter of 2026. However, our expected use of proceeds from this offering described above represents our current intentions based on our present plans and business condition. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the actual amounts that we will spend on the uses set forth above. We expect that we will require additional funds in order to fully accomplish the specified uses of the proceeds of this offering. 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 “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 total capitalization as of September 30, 2023:

- on an actual basis; and
- on an as adjusted basis, giving effect to the issuance and sale of 9,000,000 shares of Series A common stock in this offering at the assumed public offering price of $18.42 per share, which is the last reported sale price of our Series A common stock on the Nasdaq Global Market on January 22, 2024, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The as adjusted information below is illustrative only, and our capitalization following the closing of this offering will be adjusted based on the actual 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 "Management's Discussion and Analysis of Financial Condition and Results of Operations."

	As of September 30, 2023	
(in thousands, except share and per share data)	**Actual**	**As Adjusted[1]**
	(unaudited)	
Cash and cash equivalents	$ 101,842	$ 256,848
Series A common stock warrant liability	$ 1	$ 1
Series A common stock, par value $0.0001 per share; 500,000,000 shares authorized, 21,375,402 shares issued and outstanding, actual; 500,000,000 shares authorized, 30,375,402 shares issued and outstanding, as adjusted	2	3
Series B common stock, par value $0.0001 per share; 15,000,000 shares authorized, 1,520,490 shares issued and outstanding, actual; 15,000,000 shares authorized, 15,000,000 shares authorized, 1,520,490 shares issued and outstanding, as adjusted	—	—
Additional paid-in capital	339,466	494,471
Accumulated deficit	(241,593)	(241,593)
Total stockholders' equity	97,875	252,881
Total capitalization	$ 97,876	$ 252,882

(1) Each $1.00 increase or decrease, as applicable, in the assumed public offering price of $18.42 per share, which is the last reported sale price of our common stock on the Nasdaq Global Select Market on January 22, 2024, would increase or decrease, as applicable, the as adjusted amount of each of cash and cash equivalents, additional paid-in capital, total stockholders' equity and total capitalization by $8.5 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 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 Series A common stock offered by us at the assumed public offering price per share, would increase or decrease, as applicable the as adjusted amount of each of cash and cash equivalents, additional paid-in capital, total stockholders' equity and total capitalization by $17.3 million.

The number of shares of Series A common stock and Series B common stock that will be outstanding after this offering on an as adjusted basis is based on 21,375,402 shares of Series A common stock and 1,520,490 shares of Series B common stock outstanding as of September 30, 2023 and excludes:

- 63,529 shares of Series A common stock issuable upon exercise of outstanding options under our 2007 Plan as of September 30, 2023, with a weighted-average exercise price of $19.61 per share;

- 3,702,976 shares of Series A common stock issuable upon exercise of outstanding options under our 2017 Plan as of September 30, 2023, with a weighted-average exercise price of $7.80 per share;
- 2,585,968 shares of Series A common stock reserved for future issuance as of September 30, 2023 under our 2023 Plan, as well as any future automatic annual increases in the number of shares of Series A common stock reserved for issuance under the 2023 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 "Executive Compensation—Equity benefit plans";
- 215,497 shares of Series A common stock reserved for issuance as of September 30, 2023 under our ESPP, and any future automatic annual increases in the number of shares of Series A common stock reserved for future issuance under the ESPP; and
- 1,000 shares of Series A common stock issuable upon exercise of an outstanding warrant to purchase 1,000 shares of Series A common stock as of September 30, 2023, with an exercise price of $69.94 per share.

DILUTION

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

Our historical net tangible book value as of September 30, 2023 was $97.9 million, or $4.27 per share of our common stock. Our historical net tangible book value represents the amount of our total tangible assets less our total liabilities. Historical net tangible book value per share represents historical net tangible book value divided by the number of shares of Series A and Series B common stock outstanding as of September 30, 2023.

After giving effect to the issuance and sale of 9,000,000 shares of Series A common stock in this offering at the assumed public offering price of $18.42 per share, which is the last reported sale price of our Series A common stock on the Nasdaq Global Market on January 22, 2024, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value as of September 30, 2023 would have been $252.9 million, or $7.93 per share. This amount represents an immediate increase in our net tangible book value of $3.66 per share to our existing stockholders and an immediate dilution in net tangible book value of $10.49 per share to new investors purchasing shares of Series A common stock in this offering. The following table illustrates this dilution (without giving effect to any exercise by the underwriters of their option to purchase additional shares):

Assumed public offering price per share		$18.42
Historical net tangible book value per share as of September 30, 2023	$4.27	
Increase in net tangible book value per share as of September 30, 2023 attributable to investors purchasing shares in this offering	3.66	
As adjusted net tangible book value per share after this offering		7.93
Dilution per share to new investors in this offering		$10.49

The dilution information discussed above is illustrative only and may change based on the actual public offering price and other terms of this offering. Each $1.00 increase or decrease, as applicable, in the assumed public offering price of $18.42 per share, which is the last reported sale price of our Series A common stock on the Nasdaq Global Market on January 22, 2024, would increase or decrease, as applicable, the as adjusted net tangible book value per share after this offering by $0.26, and dilution in net tangible book value per share to new investors by $0.74, assuming that the number of shares of Series A common stock offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting 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 Series A common stock offered by us would increase or decrease, as applicable, our as adjusted net tangible book value per share after this offering by $0.28 per share, in each case, and decrease or increase, as applicable, the dilution to investors participating in this offering by $0.28 per share, assuming that the assumed public offering price remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise their option to purchase up to 1,350,000 additional shares of our Series A common stock in full, the as adjusted net tangible book value after the offering would be $8.31 per share, the increase in net tangible book value per share to existing stockholders would be $4.04 per share and the dilution per share to new investors would be $10.11 per share, in each case assuming a public offering price of $18.42 per share.

The foregoing tables and calculations (other than the historical net tangible book value calculation) are based on 21,375,402 shares of Series A common stock and 1,520,490 shares of Series B common stock outstanding as of September 30, 2023 and exclude:

- 63,529 shares of Series A common stock issuable upon exercise of outstanding options under our 2007 Plan as of September 30, 2023, with a weighted-average exercise price of $19.61 per share;

- 3,702,976 shares of Series A common stock issuable upon exercise of outstanding options under our 2017 Plan as of September 30, 2023, with a weighted-average exercise price of $7.80 per share;
- 2,585,968 shares of Series A common stock reserved for future issuance as of September 30, 2023 under our 2023 Plan, as well as any future automatic annual increases in the number of shares of Series A common stock reserved for issuance under the 2023 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 "Executive Compensation—Equity benefit plans";
- 215,497 shares of Series A common stock reserved for issuance as of September 30, 2023 under our ESPP, and any future automatic annual increases in the number of shares of Series A common stock reserved for future issuance under the ESPP; and
- 1,000 shares of Series A common stock issuable upon exercise of an outstanding warrant to purchase 1,000 shares of Series A common stock as of September 30, 2023, with an exercise price of $69.94 per share.

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.

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

The following discussion should be read in conjunction with our financial statements and related notes thereto 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 "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 "Special Note Regarding Forward-Looking Statements."

Overview

We are a clinical-stage biopharmaceutical company developing novel therapeutics called fatty acid synthase (FASN) inhibitors that target dysfunctional metabolic pathways in diseases resulting from the overproduction of the fatty acid, palmitate. Our lead drug candidate, denifanstat, is an oral, once-daily pill and selective FASN inhibitor in development for the treatment of nonalcoholic steatohepatitis (NASH), for which there are no treatments currently approved in the United States or Europe. Denifanstat has been studied in over 740 people to date in our clinical trials, including our FASCINATE-1 and -2 clinical trials, and we are currently designing a pivotal Phase 3 program for denifanstat in NASH. In January 2024, we announced positive topline results at week 52 from our FASCINATE-2 Phase 2b clinical trial. The FASCINATE-2 Phase 2b clinical trial achieved statistically significant results on primary and multiple secondary endpoints at week 52 in 168 NASH patients, including statistically significant improvements in NASH resolution without worsening of fibrosis with ≥2-point reduction in NAFLD Activity Score (NAS) (denifanstat 36% vs. placebo 13%, p=0.0022), and ≥2-point reduction in NAS without worsening of fibrosis (denifanstat 52% vs. placebo 20%, p=0.0001). Denifanstat-treated patients also showed statistically significant fibrosis improvement by ≥ 1 stage with no worsening of NASH (denifanstat 41% vs. placebo 18%, p=0.0051), and also showed statistical significance in fibrosis improvement by an independent approach of artificial intelligence (AI) digital pathology-based qfibrosis assessment. Analyses of liver fat showed a greater proportion of MRI-derived proton density fat fraction (MRI-PDFF) ≥30% responders relative to placebo (denifanstat 65% vs. placebo 21%, p<0.0001). MRI-PDFF responders are patients with ≥8% liver fat content at baseline who achieve a ≥30% relative reduction of liver fat at the end of treatment. Additionally, our precision medicine approach is core to our development strategy in NASH and includes the identification of pharmacodynamic and predictive biomarkers to confirm target engagement and clinical response in patients treated with denifanstat.

We are also evaluating the promise of FASN inhibition, beyond NASH, in additional disease areas in which dysregulation of fatty acid metabolism also plays a key role, including in acne and certain forms of cancer.

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. Our revenues to date have been generated solely from the license agreement from Ascletis.

To date, we have financed our operations primarily through public and private equity and debt financings, including our initial public offering of Series A common stock (IPO). Prior to this, we raised $233.3 million in gross proceeds from the sale of our redeemable convertible preferred stock and convertible notes, and on July 18, 2023, we completed our IPO, in which we issued and sold 5,312,500 shares of Series A common stock, at a price to the public of $16.00 per share. The aggregate gross proceeds of the IPO were $96.4 million, inclusive of an additional 714,272 shares of Series A common stock sold upon the partial exercise of the underwriters' purchase option. We received approximately $86.2 million in net proceeds after deducting underwriting discounts, commissions and offering expenses. 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 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.

As of September 30, 2023, we had cash and cash equivalents of $101.8 million. 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;
- continue to 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 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.

Effects of COVID-19

We experienced modest delays in our development activities as a result of the COVID-19 pandemic, primarily due to temporary closures of certain clinical sites that delayed patient enrollment in our FASCINATE-2 trial. Although the public health emergency declarations related to COVID-19 in the United States ended on May 11, 2023, the extent to which the COVID-19 pandemic will continue to impact our operations or those of our consultants and collaborators, will depend on future developments, including the global macroeconomic effects of the virus. Economic recessions, increased inflation and/or interest rates, and any disruptions to our operations or workforce availability, including those brought on by the continued effects of the COVID-19 pandemic or a similar health epidemic may have a negative effect on our operating results.

License agreement with Ascletis

In January 2019, we entered into a license agreement that became effective in February 2019 with Ascletis, a subsidiary of Ascletis Pharma, a biotechnology company incorporated in the Cayman Islands and headquartered in Hangzhou, China and a significant stockholder. We entered into this agreement with the intention to develop, manufacture, and commercialize our FASN inhibitor denifanstat, which is referred to as ASC40 in the People's Republic of China, Hong Kong, Macau and Taiwan (referred to collectively in this prospectus as Greater China). Under the terms of the license agreement, we granted Ascletis and its affiliates an exclusive, royalty-bearing, sublicensable right and license under our intellectual property to develop, manufacture, commercialize and otherwise exploit denifanstat and other products

containing denifanstat-related compounds in Greater China. Under the license agreement, we conducted all development activities in connection with the FASCINATE-1 Phase 2 clinical trial in the United States and Greater China at our sole expense, except for certain in-kind contributions by Ascletis in Greater China. Ascletis is solely responsible at its sole expense for conducting development activities in connection with obtaining and maintaining regulatory approvals for denifanstat in Greater China. Ascletis will solely own all regulatory filings and approvals in Greater China other than those regulatory filings jointly applied for in connection with the FASCINATE-1 Phase 2 clinical trial. In July 2023, we entered into an Assignment and Assumption Agreement with Ascletis and Ascletis' affiliate Gannex under which Ascletis, while remaining responsible for performance under the license agreement, assigned all of its rights and obligations under the license agreement to Gannex and Gannex assumed such rights and obligations, effective as of October 2019.

We are eligible to receive development and commercial milestone payments from Ascletis in an aggregate of up to $122.0 million as well as tiered royalties ranging from percentages in the high single digits to mid-teens on future net sales of denifanstat in Greater China. The 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 discussed below, a $2.0 million development milestone payment was received in August 2023. In January 2022, Ascletis initiated dosing of a Phase 3 trial for recurrent GBM, potentially triggering a $2.0 million milestone payment, net of applicable taxes, under the license agreement. The parties were in discussions regarding the form and amount of consideration related to this milestone until July 2023, at which time we concluded that the risk of reversal was no longer present, resulting in revenue recognition of $2.0 million. In August 2023, we received a $1.7 million milestone payment (representing the $2.0 million development milestone payment, net of applicable taxes) from Ascletis.

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

We have not generated any revenue from product sales and do not expect to generate any revenue from product sales for the foreseeable future. Our revenues to date have been generated solely from the license agreement with Ascletis. We expect that our revenue for the next several years will be derived primarily from this agreement and any additional collaboration that we may enter into the 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 drug 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 U.S. Food and Drug Administration (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 clinical research organizations (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) approval, or positive ethics committee opinions 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 preclinical 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, finance and accounting and other administrative functions; legal services, including relating to intellectual property and corporate matters; accounting, auditing, consulting and tax services; insurance; information technology; 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 and tax-related services associated with maintaining compliance with Securities and Exchange Commission (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 primarily includes interest income earned and changes in the fair value of our Series A common stock and redeemable convertible preferred stock related instruments. Interest income consists of interest earned on our cash, cash equivalents and short-term investments in marketable securities.

Results of operations

Comparison of the years ended December 31, 2022 and 2021

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

	Years Ended			
	2022	2021	Change	% Change
Operating expenses:				
Research and development	$ 24,919	$ 19,340	$ 5,579	29%
General and administrative	6,136	4,379	1,757	40%
Total operating expenses	31,055	23,719	7,336	31%
Loss from operations	(31,055)	(23,719)	(7,336)	(31)%
Other income (expense), net:				
Change in fair value of redeemable convertible preferred stock tranche liability	—	(751)	751	100%
Change in fair value of redeemable convertible preferred stock warrant liability	3	2	1	50%
Interest income and other	553	26	527	nm
Total other income (expense), net	556	(723)	1,279	nm
Net loss	$(30,499)	$(24,442)	$(6,057)	(25)%

nm—not meaningful

Research and development expense. Our research and development expense increased by $5.6 million, or 29%, for the year ended December 31, 2022, compared to the year ended December 31, 2021. The increase in our research and development expense was primarily due to an increase of $6.2 million related to our FASCINATE-2 Phase 2b trial that commenced in mid-2021 and reached full enrollment in 2022, and a $0.8 million increase in salaries, wages and benefits due to increased headcount. These increases were offset by a decrease of $1.6 million related to the completion of a manufacturing campaign in 2021.

General and administrative expenses. Our general and administrative expenses increased by $1.8 million, or 40%, for the year ended December 31, 2022, compared to the year ended December 31, 2021 primarily due to $1.4 million in capitalized deferred financing costs expensed in 2022 and increases in headcount.

Other income (expense), net. Our other income (expense), net increased by $1.3 million for the year ended December 31, 2022, compared to the year ended December 31, 2021. Interest income increased $0.5 million offset by the loss of $0.8 million from the extinguishment of the redeemable convertible preferred stock liability with the completion of the Series F preferred stock financing in 2021.

Comparison of the three months ended September 30, 2023 and 2022

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

	Three Months Ended September 30,			
	2023	2022	Change	% Change
	(unaudited)			
Revenue:				
License revenue	$ 2,000	$ —	$ 2,000	nm
Total revenue	2,000	—	2,000	nm
Operating expenses:				
Research and development	4,958	6,838	(1,880)	(27)%
General and administrative	4,494	848	3,646	nm
Total operating expenses	9,452	7,686	1,766	23%
Loss from operations	(7,452)	(7,686)	234	(3)%
Other income, net:				
Change in fair value of redeemable convertible preferred stock warrant liability	—	1	(1)	nm
Change in fair value of Series A common stock warrant liability	4	—	4	nm
Interest income and other	1,095	218	877	nm
Total other income, net	1,099	219	880	nm
Net loss	$(6,353)	$(7,467)	$ 1,114	(15)%

nm—not meaningful

Revenue. Our revenue increased by $2.0 million for the three months ended September 30, 2023, compared to the three months ended September 30, 2022. The increase was due to the $2.0 million Ascletis milestone payment that was recognized in July 2023. There was no revenue in the three months ended September 30, 2022.

Research and development expense. Our research and development expense decreased by $1.9 million, or 27%, for the three months ended September 30, 2023, compared to the three months ended September 30, 2022. This decrease was primarily due to a $3.3 million decrease in clinical trial costs for our FASCINATE-2 Phase 2b trial as patients progressed through the trial. This decrease was offset by a $0.9 million increase in other clinical costs related to the conduct of clinical pharmacology trials of denifanstat, a $0.3 million increase in contract outside services research and preclinical activities, and a $0.2 million increase in salaries and benefits.

General and administrative expenses. Our general and administrative expenses increased by $3.6 million for the three months ended September 30, 2023, compared to the three months ended September 30, 2022 primarily due to a $1.4 million increase in stock-based compensation, a $1.1 million increase in salaries and benefits related to newly hired executives, an employee termination and corporate insurance costs, a $0.8 million increase in professional services related to the IPO, and a $0.3 million increase in taxes related to the Ascletis license revenue.

Other income, net. Our other income, net increased by $0.9 million for the three months ended September 30, 2023, compared to the three months ended September 30, 2022. Interest income increased primarily due to interest earned on the cash proceeds received from the IPO.

Comparison of the nine months ended September 30, 2023 and 2022

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

	Nine Months Ended September 30,			
	2023	2022	Change	% Change
	(unaudited)			
Revenue:				
License revenue	$ 2,000	$ —	$ 2,000	nm
Total revenue	2,000	—	2,000	nm
Operating expenses:				
Research and development	14,121	19,072	(4,951)	(26)%
General and administrative	9,153	4,595	4,558	99%
Total operating expenses	23,274	23,667	(393)	(2)%
Loss from operations	(21,274)	(23,667)	2,393	(10)%
Other income, net:				
Change in fair value of redeemable convertible preferred stock warrant liability	(1)	3	(4)	nm
Change in fair value of Series A common stock warrant liability	4	—	4	nm
Interest income and other	1,546	360	1,186	nm
Total other income, net	1,549	363	1,186	nm
Net loss	$(19,725)	$(23,304)	$ 3,579	(15)%

nm—not meaningful

Revenue. Our revenue increased by $2.0 million for the nine months ended September 30, 2023, compared to the nine months ended September 30, 2022. The increase was due to the $2.0 million Ascletis milestone payment that was recognized in July 2023. There was no revenue in the nine months ended September 30, 2022.

Research and development expense. Our research and development expense decreased by $5.0 million, or 26%, for the nine months ended September 30, 2023, compared to the nine months ended September 30, 2022. This decrease was primarily due to a $8.4 million decrease in clinical trial costs for our FASCINATE-2 Phase 2b trial as patients progressed through the trial, partially offset by a $2.3 million increase in other clinical costs related to the conduct of clinical pharmacology trials of denifanstat, a $0.5 million increase in contract outside services research and preclinical activities, and a $0.5 million increase in salaries, incentive compensation and benefits related to increased headcount in prior year.

General and administrative expenses. Our general and administrative expenses increased by $4.6 million, or 99%, for the nine months ended September 30, 2023, compared to the nine months ended September 30, 2022 primarily due to a $2.4 million increase in stock-based compensation, a $1.7 million increase in professional services related to the IPO, a $1.7 million increase in salaries and benefits related to newly hired executives, an employee termination and corporate insurance costs, and a $0.3 million increase in taxes related to the Ascletis license revenue. These increases were partially offset by $1.4 million of capitalized deferred financing costs related to our previous IPO activities in 2021 that were expensed during the nine months ended September 30, 2022, and a $0.2 million decrease in recruiting costs.

Other income, net. Our other income, net increased by $1.2 million for the nine months ended September 30, 2023, compared to the nine months ended September 30, 2022. Interest income increased primarily due to interest earned on the cash proceeds received from the IPO.

Liquidity and capital resources

As of September 30, 2023, we have primarily relied on private equity and debt financings and our IPO, which we completed in July 2023, to fund our operations. We have incurred net losses and negative cash flows

from operations since inception, including net losses of $19.7 million and $23.3 million for the nine months ended September 30, 2023 and 2022, respectively. For the nine months ended September 30, 2023, and 2022 we had negative cash flows from operations of $16.7 million and $17.0 million, respectively. As of September 30, 2023, we had cash and cash equivalents of $101.8 million. We will require substantial additional capital to fund our research and development and ongoing operating expenses. On July 18, 2023, we completed our IPO, in which we issued and sold 5,312,500 shares of Series A common stock, at a price to the public of $16.00 per share. The aggregate gross proceeds of the IPO were $96.4 million, inclusive of an additional 714,272 shares of Series A common stock sold upon the partial exercise of the underwriters' option to purchase additional shares. We received approximately $86.2 million in net proceeds from the IPO, after deducting underwriting discounts, commissions and estimated offering expenses.

Based on our current business plans, we believe that the net proceeds received from this offering, together with our existing cash, cash equivalents and short-term investments in marketable securities will be sufficient for us to fund our operating expenses and capital expenditure requirements through . In the future, we may need to raise additional funds until we are able to generate sufficient revenues to fund our development activities. Our future operating activities, coupled with our plans to raise capital or issue debt financing, may provide additional liquidity in the future, however these actions are not solely within our control and we are unable to predict the outcome of these actions to generate the liquidity ultimately required.

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.

Until we can generate a sufficient amount of revenue from the commercialization of our drug candidates or additional revenue 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 macroeconomic conditions, disruptions to and volatility in the credit and financial markets, the effects of the COVID-19 pandemic and geopolitical turmoil. 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 preclinical 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,	
	2022	2021
Net cash (used in) provided by:		
Operating activities	$(24,490)	$(21,710)
Investing activities	(32,010)	—
Financing activities	(73)	9,739
Net decrease in cash and cash equivalents	$(56,573)	$(11,971)

Cash flows from operating activities. Our net cash used in operating activities was $24.5 million for the year ended December 31, 2022. Our cash used in operating activities resulted from a net loss of $30.5 million primarily driven by the use of funds in our operations to develop our drug candidates, partially offset by adjustments for non-cash items of $1.8 million related to stock-based compensation, non-cash lease expense

and accretion of discount on marketable securities. The net loss was also partially offset by a decrease in prepaid expenses and other assets of $1.4 million and an increase in accounts payable and accrued expenses of $2.9 million.

Our net cash used in operating activities was $21.7 million for the year ended December 31, 2021. Our cash used in operating activities resulted from a net loss of $24.4 million primarily driven by the use of funds in our operations to develop our drug candidates, partially offset by adjustments for non-cash based items of $2.8 million related to stock-based compensation, the change in fair value of redeemable convertible preferred stock tranche liability and non-cash lease expense, as well as a $0.6 million increase in accounts payable and accrued expenses. These were partially offset by an increase in prepaid expenses and other assets of $0.5 million.

Cash flows from investing activities. Our net cash used in investing activities was $32.0 million for the year ended December 31, 2022, which primarily related to purchases of marketable securities of $41.4 million, offset by sales of marketable securities of $9.4 million.

There was no cash used in investing activities for the year ended December 31, 2021.

Cash flows from financing activities. Our net cash used in financing activities was $73 thousand for the year ended December 31, 2022, which consisted primarily of the payment of deferred financing costs of $85 thousand offset by proceeds from the exercise of stock options of $12 thousand.

Our net cash provided by financing activities was $9.7 million for the year ended December 31, 2021, primarily consisting of net proceeds from the issuance of redeemable convertible preferred stock of $10.8 million, offset by the payment of deferred financing costs of $1.3 million.

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

	Nine Months Ended September 30,	
	2023	2022
	(unaudited)	
Net cash (used in) provided by:		
Operating activities	$ (16,683)	$(17,037)
Investing activities	32,200	(37,446)
Financing activities	86,167	(18)
Net increase (decrease) in cash and cash equivalents	$101,684	$(54,501)

Cash flows from operating activities. Our net cash used in operating activities was $16.7 million for the nine months ended September 30, 2023, consisting of a net loss of $19.7 million, partially offset by noncash adjustments of $3.7 million and net changes in our operating assets and liabilities of $0.7 million. Noncash adjustments primarily consisted of stock-based compensation expense.

Our net cash used in operating activities was $17.0 million for the nine months ended September 30, 2022, consisting of a net loss of $23.3 million, partially offset by noncash adjustments of $1.1 million and net changes in our operating assets and liabilities of $5.1 million. Noncash adjustments primarily consisted of stock-based compensation.

Cash flows from investing activities. Our net cash provided by investing activities was $32.2 million for the nine months ended September 30, 2023, which related entirely to sales of marketable securities.

Our net cash used by investing activities was $37.4 million for the nine months ended September 30, 2022, which related to purchases of marketable securities of $41.4 million, offset by sales of marketable securities of $4.0 million.

Cash flows from financing activities. Our net cash provided by financing activities was $86.2 million for the nine months ended September 30, 2023, which primarily related to $96.4 million in proceeds from our IPO, net of underwriters' commissions and discounts, partially offset by $10.3 million of payments of issuance costs for the IPO.

Our net cash used in financing activities was $18 thousand for the nine months ended September 30, 2022, which related to the $30 thousand payment of deferred financing costs, offset by $12 thousand in proceeds from the exercise of stock options.

Critical accounting policies and estimates

We prepare our financial statements in accordance with accounting principles generally accepted in the United States of America. The preparation of financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, costs and expenses and related disclosures. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results could differ significantly from the estimates made by our management.

There have been no material changes to our critical accounting policies and estimates during the relevant period.

Emerging growth company and smaller reporting 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 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 $1.235 billion or more, (ii) December 31, 2028, (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.

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

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 developing novel therapeutics called fatty acid synthase (FASN) inhibitors that target dysfunctional metabolic pathways in diseases resulting from the overproduction of the fatty acid, palmitate. Our lead drug candidate, denifanstat, is an oral, once-daily pill and selective FASN inhibitor in development for the treatment of nonalcoholic steatohepatitis (NASH), for which there are no treatments currently approved in the United States or Europe. Denifanstat has been studied in over 740 people to date in our clinical trials, including our FASCINATE-1 and -2 clinical trials, and we are currently designing a pivotal Phase 3 program for denifanstat in NASH. In January 2024, we announced positive topline results at week 52 from our FASCINATE-2 Phase 2b clinical trial. The FASCINATE-2 Phase 2b clinical trial achieved statistically significant results on primary and multiple secondary endpoints at week 52 in 168 NASH patients, including statistically significant improvements in NASH resolution without worsening of fibrosis with ≥2-point reduction in NAFLD Activity Score (NAS) (denifanstat 36% vs. placebo 13%, p=0.0022), and ≥2-point reduction in NAS without worsening of fibrosis (denifanstat 52% vs. placebo 20%, p=0.0001). Denifanstat-treated patients also showed statistically significant fibrosis improvement by ≥ 1 stage with no worsening of NASH (denifanstat 41% vs. placebo 18%, p=0.0051), and also showed statistical significance in fibrosis improvement by an independent approach of artificial intelligence (AI) digital pathology-based qfibrosis assessment. Analyses of liver fat showed a greater proportion of MRI-derived proton density fat fraction (MRI-PDFF) ≥30% responders relative to placebo (denifanstat 65% vs. placebo 21%, p<0.0001). MRI-PDFF responders are patients with ≥8% liver fat content at baseline who achieve a ≥30% relative reduction of liver fat at the end of treatment.

The topline results of the FASCINATE-2 Phase 2b clinical trial are consistent with interim results of the FASCINATE-2 Phase 2b clinical trial, which showed statistically significant improvements across key markers of disease in patients treated with denifanstat, including an approximately 34% reduction in liver fat and 67% responder rate (defined as reduction in liver fat by 30% or more) at 26 weeks as compared to baseline. These results are also consistent with earlier findings from our FASCINATE-1 Phase 2 trial, which achieved its primary endpoint (relative change from baseline in liver fat at 12 weeks) and key secondary endpoint (percentage of subjects with at least a 30% reduction in liver fat at 12 weeks) at the once-daily 50mg dose. Improvements in liver fat were also observed at the 25mg dose (not statistically significant) and at the 75mg dose (not placebo controlled). However, Phase 1 and 2 and interim clinical trial results may not be indicative of future results. Additionally, our precision medicine approach is core to our development strategy in NASH, and includes the identification of pharmacodynamic and predictive biomarkers to confirm target engagement and clinical response in patients treated with denifanstat. We are also evaluating the promise of FASN inhibition, beyond NASH, in additional disease areas in which dysregulation of fatty acid metabolism also plays a key role, including in acne and certain forms of cancer.

NASH is an aggressive form of nonalcoholic fatty liver disease (NAFLD), a condition where an abnormal buildup of excess fat, known as steatosis, occurs in the liver unrelated to the consumption of alcohol. According to a study published in 2023, NASH is a growing epidemic that affected more than 265 million people worldwide in 2019 and for which there are currently no approved treatments in the United States or Europe. It is often associated with insulin resistance, type 2 diabetes, cardiovascular disease, and an increase in overall mortality. Left untreated, damage to the liver can lead to cirrhosis or liver cancer, potentially making liver transplantation necessary. We believe denifanstat may offer a meaningful therapeutic solution for this unmet need. The therapeutic potential of denifanstat, as an oral, once-daily pill and FASN inhibitor, stems from its differentiated mechanism of action directly targeting the three key drivers of NASH pathogenesis: steatosis, inflammation, and fibrosis.

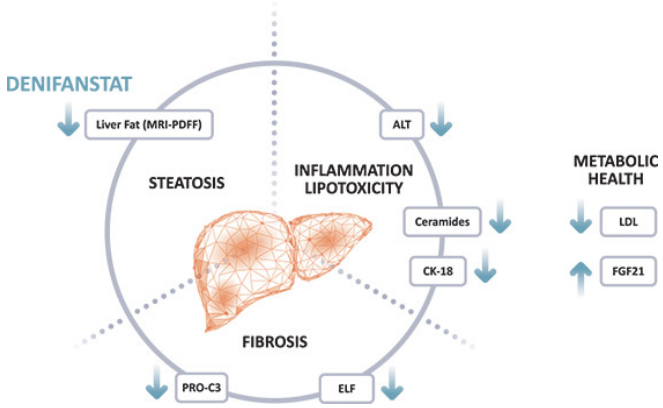

Figure 1. Comprehensive improvement across biomarkers

In January 2024, we announced positive topline results at week 52 from our FASCINATE-2 Phase 2b clinical trial. The FASCINATE-2 Phase 2b clinical trial achieved statistically significant results on primary and multiple secondary endpoints at week 52 in 168 NASH patients, including statistically significant improvements in NASH resolution without worsening of fibrosis with ≥2-point reduction in NAS (denifanstat 36% vs. placebo 13%, p=0.0022), and ≥2-point reduction in NAS without worsening of fibrosis (denifanstat 52% vs. placebo 20%, p=0.0001). Denifanstat-treated patients also showed statistically significant fibrosis improvement by ≥ 1 stage with no worsening of NASH (denifanstat 41% vs. placebo 18%, p=0.0051), and also showed statistical significance in fibrosis improvement by an independent approach of AI digital pathology-based qfibrosis assessment. Analyses of liver fat showed a greater proportion of MRI-PDFF ≥30% responders relative to placebo (denifanstat 65% vs. placebo 21%, p<0.0001). These results are consistent with the earlier interim analysis results which showed statistically significant improvements across key markers of disease in patients treated with denifanstat, including an approximately 34% reduction in liver fat and 67% responder rate. As in prior studies, no treatment-related serious adverse events (SAEs) were observed, and the majority of adverse events (AEs) were mild to moderate in nature (Grades 1 and 2). There were no Grade ≥3 treatment-related AEs. Overall, the FASCINATE-2 trial results confirmed significant activity of denifanstat across the three major drivers of liver damage in a biopsy-proven NASH population with advanced fibrosis. The results are also consistent with earlier results announced in June 2020 from our completed FASCINATE-1 Phase 2 clinical trial. The ability of denifanstat to directly target steatosis, inflammation, and fibrosis also underscores our plans to investigate the impact of denifanstat as a potential treatment of pediatric and cirrhotic NASH.

In addition to NASH, we are exploring the use of our FASN inhibitors in acne and in select forms of cancer, diseases in which dysregulation of fatty acid metabolism also play a key role. Denifanstat is currently being tested in a Phase 3 clinical trial for moderate to severe acne vulgaris, and a Phase 3 trial in recurrent glioblastoma multiforme (GBM) in combination with bevacizumab. Both trials are being conducted in China by our license partner, Ascletis, a subsidiary of Ascletis Pharma. In September 2023, Ascletis Pharma announced the enrollment of 120 recurrent GBM patients in its Phase 3 GBM trial, which it expects will provide a sufficient basis for its planned interim analysis of the Phase 3 trial. These results will inform our development strategy in these indications. Ascletis Pharma announced in May 2023 that it achieved primary and key secondary endpoints in the acne Phase 2 clinical trial including a statistically significant 61.3% reduction in total lesion count in patients treated with 50mg of denifanstat compared with a 34.2% reduction with placebo. The incidence rates of treatment-related AEs were comparable among the denifanstat groups and the placebo group. In December 2023, Ascletis Pharma announced the initiation of a randomized, double-blind, placebo-controlled, multicenter Phase 3 clinical trial to evaluate the safety and efficacy of denifanstat for the treatment of moderate to severe acne vulgaris in 480 patients in China. The co-primary efficacy endpoints of the Phase 3 clinical trial are: proportion of subjects achieving treatment success, percentage change from baseline in total lesion count, and percentage change from baseline in inflammatory lesion count (ILC). Our compound library of FASN inhibitors provides us the ability to evaluate additional drug candidates for further development. For example, we have completed IND-enabling studies for TVB-3567. We plan to initiate a TVB-3567 clinical development program in the U.S. for the treatment of acne. We expect

to file an IND with the FDA in the first half of 2024 to conduct a first-in-human Phase 1 clinical trial, as a basis for further clinical development in acne.

Given the inherent complexity of NASH and other diseases caused by dysregulated lipogenesis, our development strategy includes precision medicine approaches using non-invasive tests (NITs), which we also refer to as biomarkers, to identify indications that can be treated by denifanstat as well as patients who are most likely to respond to denifanstat. This includes the development of blood-based of pharmacodynamic biomarkers, such as tripalmitin, to confirm FASN inhibition and pathway engagement by denifanstat, as well as predictive biomarkers incorporating metabolomic and single nucleotide polymorphism (SNP) blood profiling to identify a biomarker signature that predicts improvements in markers of NASH disease in patients taking denifanstat. Furthermore, we may apply such predictive tests complementary to therapeutic intervention with denifanstat to better understand the patients who partially respond to denifanstat. Identifying these potential non-responders may help clinicians determine if, for instance, a combination of denifanstat and another non-FASN inhibitor therapeutic may optimize clinical outcomes. We anticipate developing complementary diagnostic tools to benefit patients, clinicians and payors. Ultimately, we intend to leverage these non-invasive biomarkers to ensure FASN biology is informing both the diseases we investigate and the patients who receive treatment.

Our management team brings extensive experience in research, clinical development and commercialization in the fields of hepatology, cardiovascular/metabolic disease, oncology and rare diseases. Members of our team have experience advancing drugs through FDA approval and subsequent commercialization.

Our FASN inhibitor pipeline

The critical role of FASN overactivity in NASH, acne and cancer has made it an attractive target for drug therapy. Early generations of FASN inhibitor compounds made by others were limited by their off-target activities, inappropriate localization to the brain and poor pharmaceutical properties. Most of these compounds never entered clinical development. The few that did failed in early-stage clinical trials due to these limitations. We selected denifanstat from our library of over 1,200 internally discovered and wholly owned FASN inhibitors after a rigorous medicinal chemistry and preclinical development effort. We advanced denifanstat into clinical development, based upon its oral administration, high selectivity for FASN, and excellent pharmacokinetic and pharmaceutical properties, including restricted penetration of the blood-brain barrier. FASN is a large protein with six different enzymatic domains. The selectivity of denifanstat is a consequence of binding to the protein in an area that is not an enzymatic active site and unique to the structure of FASN. This selectivity is critical for preventing off-target effects that plagued earlier generations of FASN inhibitor compounds.

The following table summarizes our development programs for multiple diseases with high unmet need:

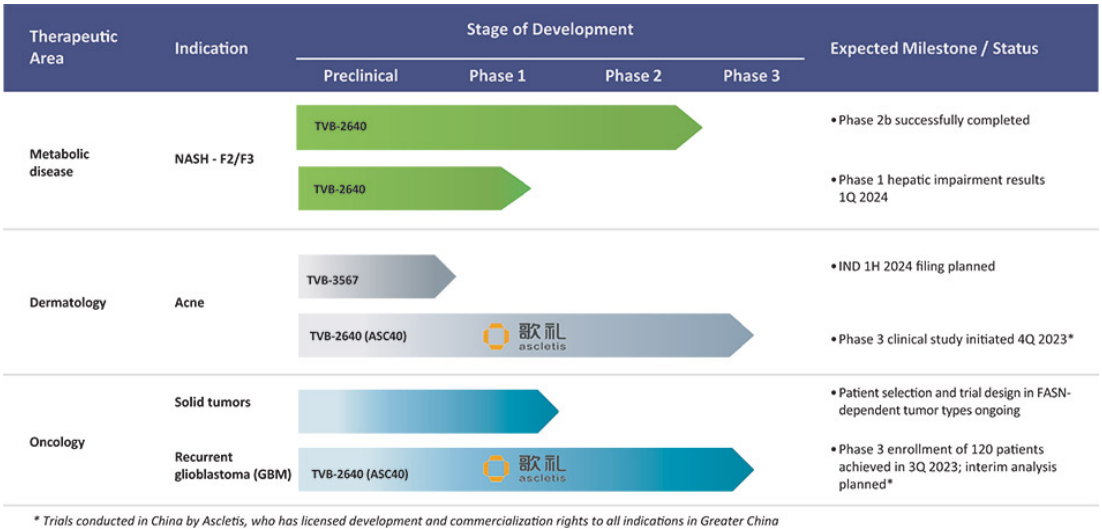

Figure 2. Pipeline of denifanstat indications

Although we believe our drug candidates have the potential to address several diseases, we need to complete additional preclinical studies and clinical trials to determine the safety and efficacy of our drug candidates. The results of future studies and trials may differ from the results of our earlier studies and trials.

We have not received regulatory approval for any of our drug candidates. To obtain regulatory approval and commercialize our drug candidates, the FDA or foreign regulatory authorities will need to determine that our drug candidates are safe and effective for their intended uses.

Our strategy

Our goal is to develop and commercialize our selective FASN inhibitors in therapeutic areas where upregulation of 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:

- ***Progress denifanstat through clinical development for the treatment of NASH.*** In our FASCINATE-2 Phase 2b clinical trial, denifanstat achieved statistically significant results on primary and multiple secondary endpoints at week 52 in 168 NASH patients , including statistically significant improvements relative to placebo in NASH resolution without worsening of fibrosis with ≥2-point reduction in NAS, and ≥2-point reduction in NAS without worsening of fibrosis. Denifanstat-treated patients also showed statistically significant fibrosis improvement by ≥ 1 stage with no worsening of NASH, and also showed statistical significance in fibrosis improvement by an independent approach of AI digital pathology-based fibrosis assessment. Analyses of liver fat showed a greater proportion of MRI-PDFF ≥30% responders relative to placebo. No treatment-related SAEs were observed, and the majority of AEs were mild to moderate in nature (Grades 1 and 2). We are currently designing a pivotal Phase 3 program for denifanstat in NASH.
- ***Establish denifanstat 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 denifanstat can address multiple NASH indications as a differentiated monotherapy and in combination with other agents. We intend to seek approval of denifanstat as monotherapy for the treatment of NASH patients with F2-F3 fibrosis and expand into additional NASH indications such as cirrhotic (F4) NASH and pediatric NASH to maximize denifanstat's full clinical and commercial potential. Combination therapy has the potential to play a meaningful role in the NASH treatment paradigm to effectively address all patient segments. We intend to assess combinations of denifanstat, as an oral small molecule agent, with other complementary mechanisms.
- ***Advance our precision medicine strategy to identify patients who will benefit from denifanstat***. Given that NASH is a complex, progressive disease with no approved treatments in the United States or Europe, our precision medicine strategy to develop non-invasive biomarkers complements our clinical development efforts for denifanstat. This includes the development and application of pharmacodynamic biomarkers to confirm drug response to denifanstat and predictive biomarkers to select the patients mostly likely to have a clinical response. We will continue to validate these biomarkers with results emerging from our ongoing clinical development, including our planned pivotal Phase 3 program for denifanstat in NASH.
- ***Expand pipeline in indications beyond NASH where FASN plays a central role in disease pathogenesis.*** Based on our seminal work around FASN biology and the broad potential of this mechanism in diseases beyond NASH, we have prioritized acne and oncology in our initial development pursuits for denifanstat beyond NASH. In acne, Ascletis Pharma announced in May 2023 that it achieved primary and key secondary endpoints in a Phase 2 clinical trial in patients with moderate to severe acne vulgaris in China, and in December 2023 announced the initiation of a randomized, double-blind, placebo-controlled, multicenter Phase 3 clinical trial in China to evaluate the safety and efficacy of denifanstat for the treatment of moderate to severe acne vulgaris. Based on Ascletis Pharma's reported Phase 2 results and initiation of Phase 3 clinical development of denifanstat in acne, we are evaluating options to move forward with our own acne program in the U.S., Europe and other markets. We expect to file an IND with the FDA in the first half of 2024 to conduct a first-in-human Phase 1 clinical trial of TVB-3567, as a basis for further clinical development in acne. In oncology, we are developing FASN inhibitors to treat specific subsets of solid tumors that are FASN-dependent. We are exploring the potential of denifanstat in combination with other classes of oncology

drugs. Our first-in-human Phase 1 clinical trial for denifanstat was conducted in patients with advanced solid tumors. Additionally, Ascletis Pharma has initiated a Phase 3 registrational trial for denifanstat in China in patients with recurrent GBM. In September 2023, Ascletis Pharma announced the enrollment of 120 recurrent GBM patients, which it expects will provide a sufficient basis for its planned interim analysis of the Phase 3 trial. We will maintain a focused and disciplined strategy in evaluating potential indications beyond NASH that may merit further advancement.

- ***Develop and commercialize our drug candidates independently in indications and geographies where we believe we can maximize value and benefit to patients***. Because we believe our FASN platform and drug candidates have the potential to treat a broad range of diseases, we will independently develop drug candidates in indications and geographies where we believe we can successfully commercialize 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 denifanstat in Greater China is an example of our prosecution of this strategy.

Our team

We have assembled a team with extensive experience in drug development and commercialization in the fields of hepatology, cardiometabolic 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. Prior to joining Sagimet in October 2022, our president and chief executive officer, David Happel, was chief executive officer at Cognoa Inc. and held leadership positions at Horizon Therapeutics plc, Raptor Pharmaceutical Corp., Dynavax Technologies Corporation, and Chiron Corporation. Our executive chairman, Dr. George Kemble, served as our chief executive officer from October 2015 to October 2022, and as our chief scientific officer from August 2011 to October 2015. Prior to Sagimet, Dr. Kemble was senior vice president and head of research at MedImmune, LLC (now a subsidiary of AstraZeneca PLC). Our chief medical officer, Dr. Eduardo Bruno Martins, M.D., D.Phil., has held 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 across various phases and therapeutic areas. Our chief financial officer, Anthony Rimac, was previously chief financial officer at Cognoa, Inc., ESCAPE Bio, Inc., Chrono Therapeutics Inc., Aldea Pharmaceuticals, Inc. and Adamas Pharmaceuticals, Inc. Our general counsel and chief compliance officer, Elizabeth Rozek, previously served as general counsel of Cognoa, Inc. and of Basilea Pharmaceutica International Ltd.

Denifanstat in NASH

Our lead drug candidate, denifanstat, is an oral, once-daily pill currently being developed for the treatment of NASH. In January 2024, we announced positive topline results at week 52 from our FASCINATE-2 Phase 2b clinical trial. The FASCINATE-2 Phase 2b clinical trial achieved statistically significant results on primary and multiple secondary endpoints at week 52 in 168 NASH patients, including statistically significant improvements in NASH resolution without worsening of fibrosis with ≥2-point reduction in NAS (denifanstat 36% vs. placebo 13%, p=0.0022), and ≥2-point reduction in NAS without worsening of fibrosis (denifanstat 52% vs. placebo 20%, p=0.0001). Denifanstat-treated patients also showed statistically significant fibrosis improvement by ≥ 1 stage with no worsening of NASH (denifanstat 41% vs. placebo 18%, p=0.0051), and also showed statistical significance in fibrosis improvement by an independent approach of AI digital pathology-based qfibrosis assessment. Analyses of liver fat showed a greater proportion of MRI-PDFF ≥30% responders relative to placebo (denifanstat 65% vs. placebo 21%, p<0.0001). These results were consistent with the interim results from this trial that showed denifanstat significantly improved markers of three major drivers of disease in patients. A 67% responder rate in liver fat reduction, 16.5 U/L decrease in ALT, and 0.34 decrease in ELF score were observed. These interim results are consistent with earlier positive findings from our FASCINATE-1 Phase 2 clinical trial, in which denifanstat demonstrated significant improvement across a comprehensive set of non-invasive biomarkers. However, Phase 1 and 2 and interim clinical trial results may not be indicative of future results. Denifanstat is differentiated among drug candidates in development for NASH due to its ability to directly target

hepatocytes, inflammatory cells and stellate cells in the liver. By targeting these cells, denifanstat leads to reductions in hepatic fat, inflammation, and fibrosis, which we believe will lead to meaningful clinical benefits to NASH patients. It is an inhibitor of FASN, the key enzyme in the de novo lipogenesis (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.

Overview of NASH

NASH is an aggressive form of NAFLD, a condition where an abnormal buildup of excess fat (known as steatosis) occurs in the liver unrelated to the consumption of alcohol. To date, no treatments have been approved in the United States or Europe. NAFLD encompasses a progressive and histologically-defined range of liver diseases including 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 may ultimately to cirrhosis or cancer of the liver.

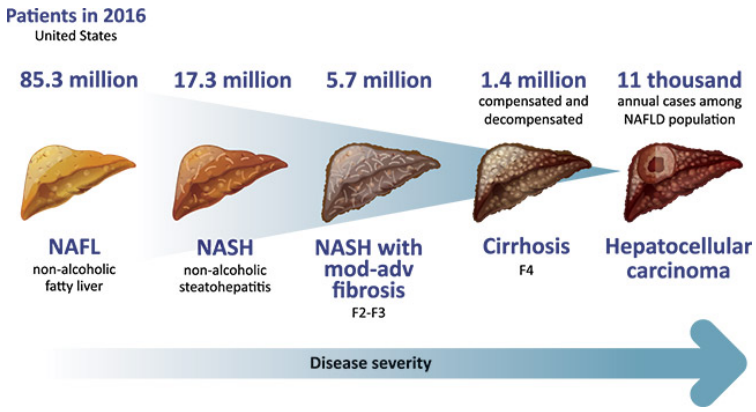

Figure 3. NAFLD disease progression and epidemiology

NASH is initiated and propagated through several processes driven by excess fat in liver cells.

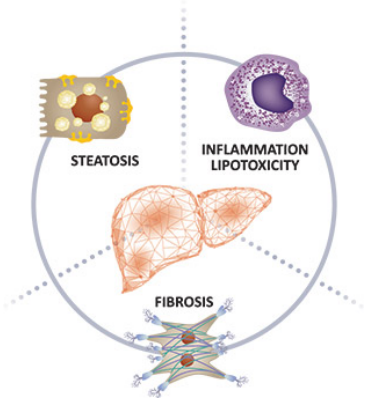

Figure 4. Excess liver fat drives three key diseases processes

Excess intracellular fat damages hepatocytes, the predominant cell type in the liver, leading to apoptosis, or cell death. Hepatocyte apoptosis triggers the stimulation of specialized immune cells. The increased activity of these cells drives inflammation in the liver. Additionally, as more hepatocytes are destroyed and inflammation increases, hepatic stellate cells, are stimulated and induce fibrotic scarring. As this progressive cycle continues, the functions of the liver become compromised, potentially necessitating transplantation.

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, NAS is the most widely used histological grading and staging score and 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. In addition to liver biopsy, non-invasive approaches for the diagnosis of NASH are becoming increasingly prevalent, and may eventually replace liver biopsy as further data becomes available. As part of its December 2018 NASH draft guidance, the FDA emphasized the importance of non-invasive biomarkers in accurately diagnosing and assessing various degrees of NASH. The FDA encouraged sponsors to include non-invasive biomarkers in clinical trials for NASH with the goal of ultimately supplanting liver biopsy.

NAFLD is a growing epidemic. According to a study published in 2023, NAFLD affected more than 1.6 billion people worldwide as of 2019, 265 million of whom had NASH. In a separate study published in 2018, the prevalence of NASH in the United States was estimated at 17.3 million in 2016 and expected to grow to 27.0 million by 2030. Of the NASH patients in the United States, 5.7 million had NASH with advanced fibrosis (F2-F3), which is our initial target patient population for denifanstat if approved. According to two studies published in 2021 and 2023, when left untreated, NASH can lead to liver cirrhosis, which is currently on par with alcohol as the leading indication for liver transplantation and is expected to surpass alcohol in the coming years. According to a study published in 2022, in the United States alone, the economic burden of NASH has been estimated to be over $222 billion.

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. 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. 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, reduce liver fat, and minimize 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 enzyme inhibitors, both of which have shown significant clinical improvements in fat reduction, and improvements in biomarkers of liver enzymes, inflammation and fibrosis. ACC inhibitors, unlike FASN inhibitors, have also been shown to increase plasma triglyceride levels in NASH patients. This is particularly problematic for NASH patients who typically have an elevated risk for cardiovascular disease.

Nuclear receptor modulators alter the gene expression pattern of cells, affecting multiple biochemical pathways, which can lead to unintended changes beyond the target pathway of interest. Examples of nuclear receptor modulators studied as therapeutic targets in NASH include farnesoid X receptor (FXR) agonists, peroxisome proliferator-activated receptor (PPAR) agonists, and thyroid hormone receptor beta (THRß) agonists. FXR is expressed in a number of tissues throughout the body, including the liver. It serves as a receptor for bile acids and participates in regulating their metabolism, including synthesis, conjugation, absorption, and secretion. The PPAR family of receptors modulate fatty acid metabolism and energy homeostasis. FXR and PPAR agonists have had mixed clinical results to date and are yet to be approved for the treatment of NASH in the United States or Europe. Recent data from a positive Phase 3 clinical trial with a THRß agonist represent a significant advancement in the NASH space. Activation of hepatic THRß is associated with systemic lipid lowering, increased bile acid synthesis, and fat oxidation. These results suggest that directly targeting liver fat metabolism can be a successful therapeutic strategy in NASH. However, it should be noted that therapeutic nuclear receptor modulation is not without safety risk. FXR agonists can affect pathways leading to excess bile acids, which have long been shown to be toxic. This can cause pruritus, or itching of the skin. PPAR agonists have been associated with weight gain. 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. If not highly selective they can result in significant, potentially life-threatening complications.

Growth factor analogs attempt to mimic natural proteins, such as FGF21, to bring several disordered systems back to normal levels. In a relatively small clinical trial in patients with F2-F3 fibrosis, an FGF21 analog showed evidence of NASH resolution and improvement in liver fibrosis after 24 weeks of treatment. Gastrointestinal side effects are common with injected FGF21, nausea and diarrhea being the most common. Because of the large size of proteins, the mode of delivery is typically limited to injection. Growth factor analogs are also more expensive to manufacture compared to small molecules. We believe there is a significant likelihood that patients will develop neutralizing antibodies against these therapeutics with chronic treatment.

Glucagon-like peptide 1 (GLP-1) analogs are approved to treat diabetes and obesity; they are under investigation for the treatment of NASH. In a recent Phase 2 trial, treatment with a GLP-1 analog reduced body weight, demonstrated significant histological NASH resolution, and reduced biomarkers associated with NASH. However, it did not achieve significant improvement in fibrosis compared to placebo. This is consistent with the GLP-1 peripheral mechanism of action via body weight loss, which reduces liver fat and inflammation. Gastrointestinal side effects are common with injected or oral GLP-1, with nausea being the most common.

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 trials. This suggests that drugs that only impact liver fibrosis may not be sufficient to impact NASH in a meaningful way. For instance, a Phase 3 clinical trial 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—denifanstat in NASH

Denifanstat, formerly known as TVB-2640, an oral, once-daily pill, is our selective FASN inhibitor currently being developed for the treatment of NASH. Following a robust translational research program in multiple preclinical models that demonstrated FASN inhibition reduced liver fat, decreased inflammatory cells and molecules and blunted fibrosis and a proof-of-mechanism Phase 1b clinical trial that demonstrated inhibition of hepatic DNL in humans, we initiated two Phase 2 clinical trials in patients with NASH: FASCINATE-1 and FASCINATE-2. The FASCINATE-1 Phase 2 clinical trial examined multiple doses of denifanstat, ranging from 25mg to 75mg daily, administered for 12 weeks compared to placebo in 142 patients in the United States and China. Denifanstat caused a rapid and robust reduction in liver fat that was statistically significant in the 50mg cohort, as well as improvements in inflammatory, fibrotic and cardiometabolic components of the disease in this short time period, and was generally well tolerated at dose levels of 25mg and 50mg once daily in these diverse populations. The 50mg dose was selected for further study.

Our FASCINATE-2 Phase 2b clinical trial examined the impact of 50mg denifanstat for one year on the liver of biopsy confirmed NASH patients with moderate to advanced fibrosis (F2-F3). In January 2024, we announced positive topline results at week 52 from our FASCINATE-2 Phase 2b clinical trial. The FASCINATE-2 Phase 2b clinical trial achieved statistically significant results on primary and multiple secondary endpoints at week 52 in 168 NASH patients, including statistically significant improvements in NASH resolution without worsening of fibrosis with ≥2-point reduction in NAS (denifanstat 36% vs. placebo 13%, p=0.0022), and ≥2-point reduction in NAS without worsening of fibrosis (denifanstat 52% vs. placebo 20%, p=0.0001). Denifanstat-treated patients also showed statistically significant fibrosis improvement by ≥ 1 stage with no worsening of NASH (denifanstat 41% vs. placebo 18%, p=0.0051), and also showed statistical significance in fibrosis improvement by an independent approach of AI digital pathology-based qfibrosis assessment. Analyses of liver fat showed a greater proportion of MRI-PDFF ≥30% responders relative to placebo (denifanstat 65% vs. placebo 21%, p<0.0001). In November 2022, we announced an interim analysis of non-invasive biomarkers from the earliest 52 patients enrolled in the trial after 26 weeks

of dosing. These results confirmed and extended the conclusions of the FASCINATE-1 trial in a more advanced population of NASH patients. In this interim cohort, 67% of patients treated with denifanstat reduced their liver fat by 30% or more, and 45% of these responders reduced their liver fat by 50% or more. Published studies have shown that NASH patients who reduce their liver fat by 30% or more, known as responders, are much more likely to have improved liver histology than those who do not achieve this goal. Denifanstat also showed a statistically significant decrease of 16.5 U/L ($p<0.05$), or 25%, in levels of ALT, a marker of hepatic inflammation and damage, and a statistically significant decrease of 0.34 ($p<0.05$) in ELF score. Decreases in ELF score suggest reduced levels of fibrosis. In addition to decreases in LDL-cholesterol, comprehensive improvements across biomarkers of liver fat, inflammation and fibrosis were consistent with those seen in the earlier FASCINATE-1 trial.

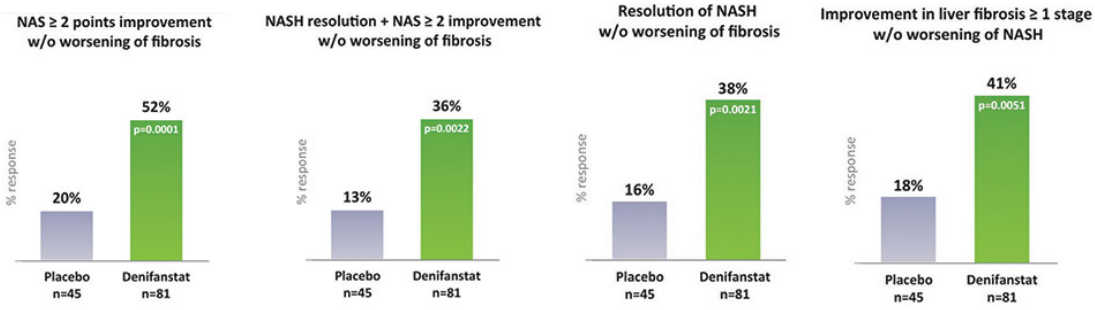

Figure 5. FASCINATE-2 liver biopsy analysis at Week 52, primary and secondary endpoints.

Results from FASCINATE-1 and -2 will enable us to design the pivotal Phase 3 program for denifanstat in NASH. In March of 2021, we received fast track designation for denifanstat for the treatment of NASH, which will enable us to work expeditiously with the U.S. Food and Drug Administration (FDA) to align on the design of this critical registration program. For more information regarding the fast track designation program, see "—Government regulation and product approval—Expedited development and review programs."

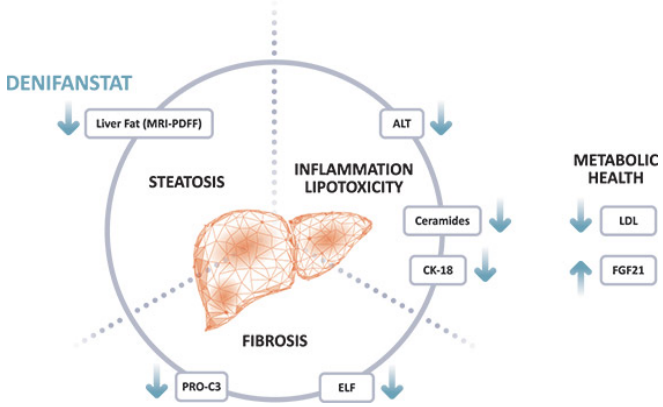

Figure 6. Comprehensive improvement across biomarkers

Proposed mechanisms 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 causes 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 inhibiting FASN has the potential to minimize side effects in NASH patients for several reasons. First, the enzymatic inhibition of FASN is targeted and directly acts within the DNL pathway, unlike nuclear receptor modulators such as THRß or FXR agonists that activate multiple transcription pathways. Second, FASN is aberrantly overactivated in the liver in NASH, and normalizing activity through inhibition of FASN may avoid side effects. Furthermore, mice genetically engineered to have the FASN gene knocked-out in their livers appear normal, whereas mice with the ACC gene, an enzyme one step earlier in the lipid synthesis pathway, knocked-out have high liver and plasma triglycerides.

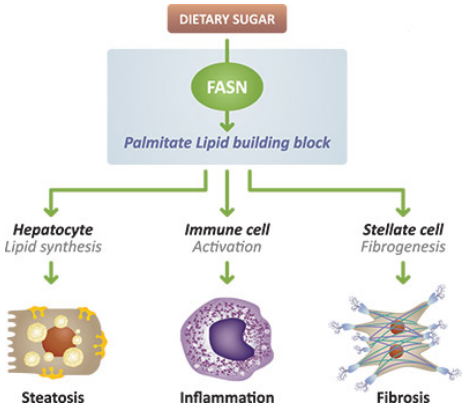

Figure 7. Denifanstat impacts key drivers of NASH

We believe that denifanstat has the potential to alleviate NASH by inhibiting FASN and thereby impacting key drivers of NASH by:

1. Blocking liver fat accumulation (steatosis) by reducing liver fat synthesis in hepatocytes;
2. Minimizing inflammation by blocking the activation and cytokine secretion by inflammatory cells; and
3. Reducing fibrosis by blocking the activation and fibrogenic activity of stellate cells.

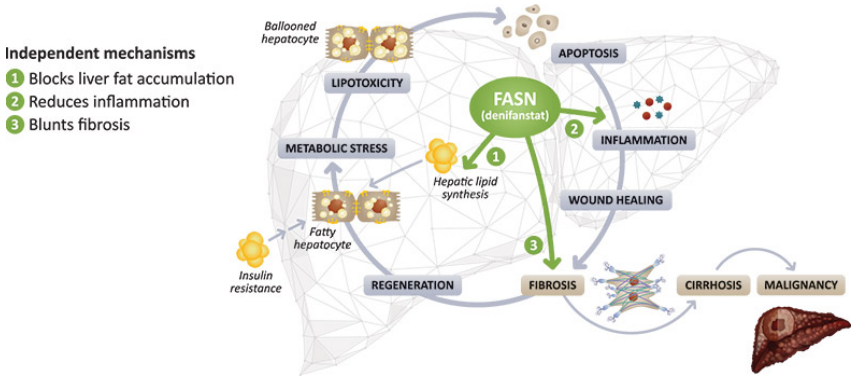

Figure 8. The cycle of NASH pathogenesis

The diagram above of the cycle of NASH pathogenesis shows how excess dietary sugar, particularly in someone with decreased sensitivity to insulin, produces excess palmitate in hepatocytes 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 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 trigger fibrotic responses to repair the wound. As additional excess sugars come in via the diet, this process continues, 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 to persist, some patients will progress to cirrhosis and may develop hepatocellular carcinoma.

Recent studies, including evidence presented at the European Association for the Study of the Liver in Paris, France in 2018, have shown that the liver also continues to produce fat in the later stages of NAFLD, including in patients with early stages of cirrhosis. This broadens the number of patients who could benefit from FASN inhibition. These late-stage patients can progress to liver cirrhosis, which can lead to acute liver decompensation events that 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 denifanstat could address these patients with NASH cirrhosis, preventing further liver damage.

NASH clinical program

Denifanstat has been studied in over 740 people to date including healthy volunteers, patients with solid tumors, patients with acne, and patients with NASH. In NASH, we have completed a Phase 2 clinical trial, FASCINATE-1, which examined multiple doses of denifanstat from patients in both the United States and China. We completed a Phase 2b trial, FASCINATE-2, in patients with biopsy confirmed NASH with moderate to advanced fibrosis (F2-F3). FASCINATE-1 examined doses ranging from 25mg to 75mg daily for 12 weeks and demonstrated improvement in non-invasive measurements of steatosis, inflammation, fibrotic and metabolic parameters. FASCINATE-2 evaluated the 50mg dose daily for one year. In January 2024, we announced positive topline results at week 52 from our FASCINATE-2 Phase 2b clinical trial. The FASCINATE-2 Phase 2b clinical trial achieved statistically significant results on primary and multiple secondary endpoints at week 52 in 168 NASH patients.

FASCINATE-2 Phase 2b clinical trial results

In August 2021, we initiated enrollment of a randomized, placebo-controlled, double-blind Phase 2b clinical trial, FASCINATE-2, which is designed to evaluate the impact of denifanstat on NASH assessed by biopsy following 52 weeks of daily oral treatment. In September 2022, we completed full enrollment of 168 NASH patients with F2-F3 fibrosis confirmed by liver biopsy and randomized overall 2:1 to receive 50mg of denifanstat or placebo for 52 weeks. Following 52 weeks of therapy, a second liver biopsy was obtained. A central pathologist who is unaware of the patients' assignment to denifanstat or placebo cohorts evaluated these biopsies. Patients were followed for an additional four weeks after the biopsy for safety. In January 2024, we announced positive topline results at week 52 from our FASCINATE-2 Phase 2b clinical trial. The FASCINATE-2 Phase 2b clinical trial achieved statistically significant results on primary and multiple secondary endpoints at week 52 in 168 NASH patients, including statistically significant improvements in NASH resolution without worsening of fibrosis with ≥2-point reduction in NAS (denifanstat 36% vs. placebo 13%, p=0.0022), and ≥2-point reduction in NAS without worsening of fibrosis (denifanstat 52% vs. placebo 20%, p=0.0001). Denifanstat-treated patients also showed statistically significant fibrosis improvement by ≥ 1 stage with no worsening of NASH (denifanstat 41% vs. placebo 18%, p=0.0051), and also showed statistical significance in fibrosis improvement by an independent approach of AI digital pathology-based qfibrosis assessment. Analyses of liver fat showed a greater proportion of MRI-PDFF ≥30% responders relative to placebo (denifanstat 65% vs. placebo 21%, p<0.0001).

FASCINATE-2 Phase 2b clinical trial design

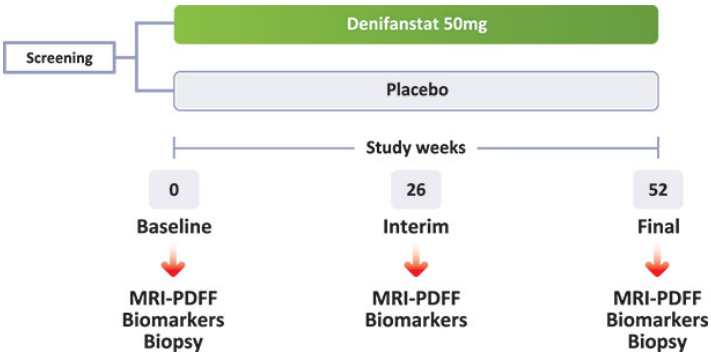

Figure 9. FASCINATE-2 Phase 2b clinical trial design

The co-primary efficacy endpoints were histological improvement at week 52 in NAS ≥2 points (with ≥1 point improvement in ballooning or inflammation) and without worsening of fibrosis (by NASH Clinical Research Network (CRN) fibrosis score); OR resolution of steatohepatitis and no worsening of liver fibrosis (by NASH CRN fibrosis score) and ≥2 points improvement in NAS at Week 52. Resolution of steatohepatitis is defined as absence of fatty liver disease or isolated or simple steatosis without steatohepatitis and a NAS of 0 or 1 for inflammation, 0 for ballooning, and any value for steatosis. The study also had multiple secondary endpoints such as AI-based digital pathology assessment of liver biopsies and non-invasive markers of fibrosis.

Interim analysis

In November 2022, we announced results from a planned interim analysis of non-invasive biomarkers and tolerability. The earliest 52 patients enrolled with baseline MRI-PDFF value of ≥8% liver fat were evaluated after 26 weeks of treatment or an early termination visit after week 22. The purpose of the planned interim analysis was to examine the secondary efficacy endpoint of the proportion of MRI-PDFF ≥30% responders at week 26.

Patients in the interim analysis cohort were representative of a NASH population with moderate to advanced fibrosis (F2-F3). At the start of the trial, the mean age of patients in this subset was 56.4, 59.7% were female, mean weight of 99.6 kg, 65.4% had type 2 diabetes mellitus, F2-F3 fibrosis 46.2%/53.8%, liver fat content by MRI-PDFF 19.3%, ALT 62.7 U/L, LDL-cholesterol 102.9 mg/dL, ELF score 9.7, and PRO-C3 33.9 ng/mL. This interim cohort included 30 patients who received denifanstat and 22 patients who received placebo. Statistical analysis was performed on results for denifanstat compared to placebo at week 26 versus baseline.

Liver fat biomarker: MRI-PDFF imaging

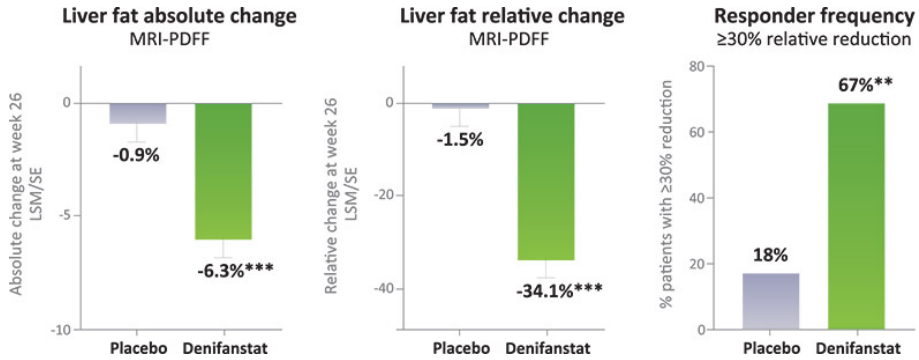

Figure 10. Liver fat biomarkers. ** p<0.01, *** p<0.001.

Treatment with denifanstat resulted in 67% (p<0.001) of patients becoming MRI-PDFF responders compared with 18% in placebo, and approximately half of these denifanstat responders decreased liver fat by an even greater amount of ≥50%. MRI-PDFF responders achieve ≥30% relative reduction of liver fat. 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. The relative reduction in liver fat measured by MRI-PDFF of -34.1% (p<0.001) in patients treated with 50mg denifanstat compared with -1.5% in the placebo group. 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.

In addition to liver fat, several inflammation/lipotoxicity, fibrosis and metabolic health biomarkers that are important to NASH were assessed in this interim analysis.

Inflammation biomarkers

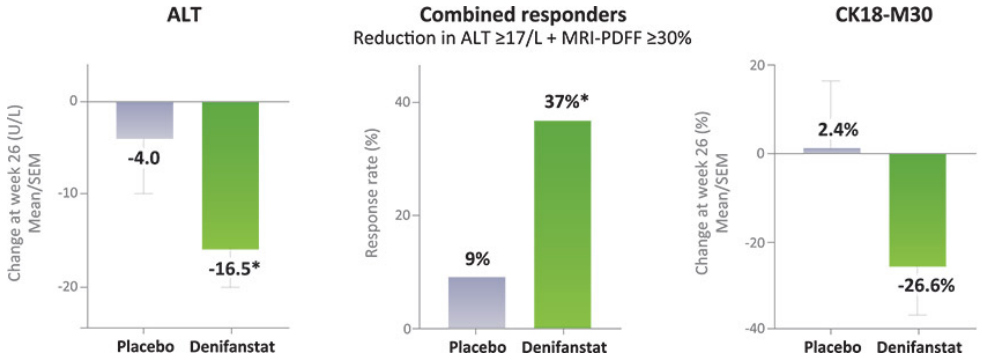

Figure 11. Inflammation biomarkers. * p<0.05

- ***ALT.*** Denifanstat showed a statistically significant decrease of ALT by 16.5 U/L (p<0.05), or a 25% decrease. 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 correlate with improvement of liver biopsy.
- ***ALT/MRI-PDFF combined responders.*** Recent studies show that an MRI-PDFF reduction of ≥30% combined with an ALT reduction of ≥17 U/L highly correlate with histological improvement. Denifanstat patients achieving this combined metric was significantly higher than placebo (37% vs 9%, p<0.05).
- ***CK18-M30.*** Denifanstat decreased CK18-M30 by 26.6% (p=ns). Cytokeratin 18 (CK18) is a major cytoskeleton protein in hepatocytes that is released into the bloodstream when the cell is damaged. CK18-M30, a major fragment of CK18, is often elevated in NASH patients. Decreasing CK18 levels is indicative of improved liver tissue.

Fibrosis biomarkers

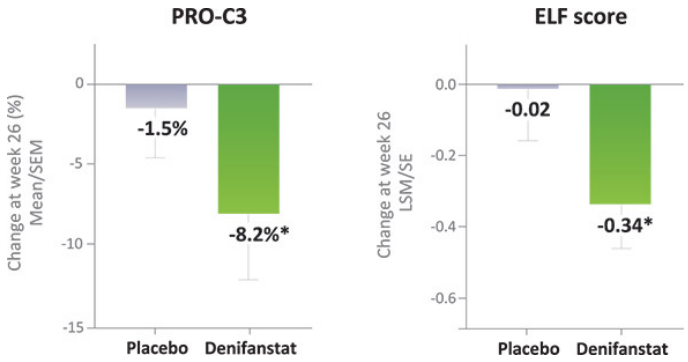

Figure 12. Fibrosis biomarkers. * p<0.05

- ***PRO-C3***. Denifanstat showed a statistically significant decrease of 8.2% (-4.4 ng/mL, p<0.05) in PRO-C3 levels (measured by Roche Cobas assay) compared with a decrease of 1.5% (-0.3 ng/mL) in the placebo group. 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.
- ***ELF score***. Denifanstat showed a statistically significant decrease of 0.34 (p<0.05) in ELF score compared with a decrease of 0.02 with placebo. Decreases in ELF score suggest reduced levels of fibrosis in the liver and ELF is reported to have prognostic value.

Metabolic/lipid biomarkers

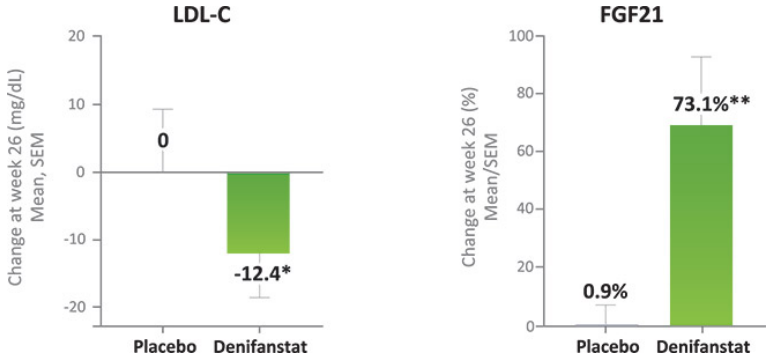

Figure 13. Metabolic / lipid biomarkers. * p<0.05, ** p<0.01

- ***LDL-cholesterol***. Denifanstat showed a statistically significant decrease in LDL-cholesterol levels of 12.4 mg/dL (p<0.05), or -5.89%, as compared to a change of 0.0 mg/dL or +2.4%, with placebo. Elevated LDL-cholesterol levels are associated with increased risk of cardiovascular disease and often elevated in NASH patients.
- ***FGF-21.*** Denifanstat showed a statistically significant increase in FGF-21 levels of 73.1% (p<0.01). Elevated FGF-21 levels are indicative of a protective response to restore insulin sensitivity particularly in obese subjects.

We also assessed other laboratory values in patients in the interim cohort as described below:

- ***Tripalmitin.*** Denifanstat decreased tripalmitin levels by 41.95% (p<0.001) after 13 weeks of treatment. 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 23mg/dL ($p<0.01$). Based on metabolomic analyses from our FASCINATE-1 trial, we believe these triglycerides contain a higher proportion of polyunsaturated fatty acids, which may have health benefits for patients. Polyunsaturated fatty acids are a class of fatty acids that include omega-3 and omega-6 fatty acids that have been shown to reduce the risk of cardiovascular disease.
- ***Total and HDL cholesterol***. Denifanstat decreased total cholesterol levels by 3.18%, and 1.36% ($p<0.01$) in HDL-cholesterol.

Safety data

In FASCINATE-2 the safety population included all 168 subjects enrolled. As in prior clinical trials, no treatment-related SAEs were observed, and the majority of AEs were mild to moderate in nature (Grades 1 and 2). There were no Grade ≥3 treatment-related AEs. The most common treatment-related AEs by system organ class (observed in ≥5% of patients in the study) were eye disorders (denifanstat 15.2%, placebo 16.1%), gastrointestinal disorders (denifanstat 11.6%, placebo 8.9%), and skin and subcutaneous tissue disorders (denifanstat 22.3%, placebo 7.1%). The incidence of treatment emergent adverse events (TEAEs) leading to treatment discontinuation was 19.6% in the denifanstat group compared to 5.4% in placebo. Sixteen subjects experienced treatment emergent SAEs, none of which were considered by the investigator to be related to study drug. Additionally, there was no evidence of drug-induced liver injury (DILI) and no deaths in the trial.

FASCINATE-1 Phase 2 clinical trial results

We completed our FASCINATE-1 Phase 2 clinical trial in 2021 and demonstrated that a once-daily, oral dose of 50mg denifanstat for 12 weeks was well tolerated and led to a statistically significant reduction in excess liver fat in patients with NASH, the study's primary and key secondary endpoints. The 25mg dose level was also well tolerated, and led to non-statistically significant improvements in comparison to placebo. The 75mg dose level was a small, open-label, non-randomized cohort, which was not powered to show statistical significance.

Denifanstat demonstrated improvements in biomarkers across all three hallmarks of NASH:

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

Denifanstat 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 denifanstat to treat NASH patients.

FASCINATE-1 Phase 2 clinical trial design

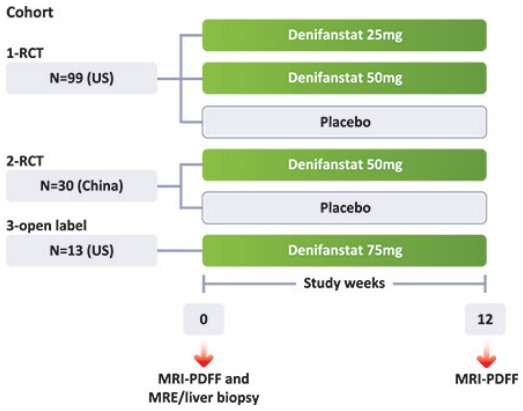

Figure 14. FASCINATE-1 Phase 2 trial design

The trial was conducted over three cohorts. Cohort 1 and Cohort 2 were randomized, placebo-controlled, single-blind, dose escalation clinical trials based in the United States and China. Cohort 3 was a small, open-label, non-randomized trial in the United States to evaluate a higher 75mg dose level which did not demonstrate a discernable benefit and was less well tolerated. Based on these results, we selected the 50mg dose to advance into further clinical development.

Key enrollment criteria included male and female subjects aged ≥18 years with either biopsy-proven NASH within two years before randomization or magnetic resonance elastography (MRE) ≥2.5 kPa (Cohorts 1 and 2 only); and MRI-PDFF ≥8%. A total of 142 patients were enrolled across the three cohorts, with 112 patients enrolled in the United States and 30 patients enrolled in China.

Cohort 1 clinical activity—United States

Baseline demographics. The median age of patients in Cohort 1 was 55 years, 46% were female, and 93% were white with 72% identifying as Hispanic or Latino. As expected for a NASH population, the median liver fat was 15.6%, the majority of patients had type 2 diabetes and the median body mass index (BMI) was 32.6 kg/m^2. Safety data was reported for all 99 patients enrolled in the clinical trial. The primary analysis of clinical activity was performed on 85 patients that had an end-of-treatment MRI-PDFF. Two patients discontinued the trial early due to a TEAE and five patients had an end of treatment MRI-PDFF later than planned between 12 and 16 weeks of treatment as a result of COVID-19 visit restrictions; they were not included in the primary efficacy analysis.

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, and was statistically significant at 50mg of denifanstat. The patients in the placebo group, on average, had a 4.5% relative increase in 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 denifanstat and of 28.1% (p<0.01) in patients treated with 50mg.

The secondary endpoint of this clinical trial was percentage of subjects with at least a 30% reduction in liver fat at week 12, and was statistically significant at 50mg of denifanstat; 23% of patients in the 25mg arm achieved an MRI-PDFF response (p=ns), defined as ≥30% relative reduction of liver fat, and 61% of patients treated with 50mg of denifanstat achieved a response (p<0.001), compared with 11% of the placebo group, as depicted below.

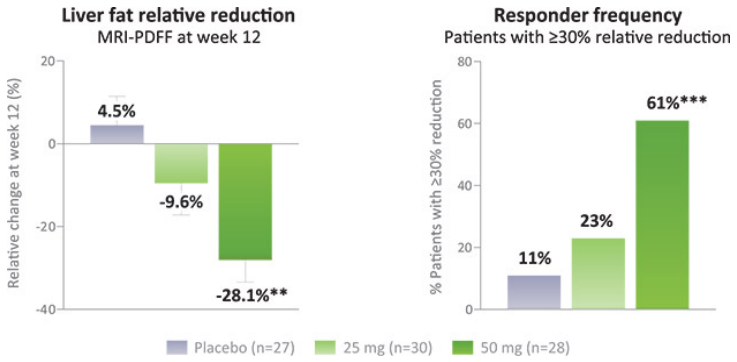

Figure 15. Liver fat biomarkers. **p<0.01, *** p<0.001

MRI-PDFF images for one patient treated with 50mg of denifanstat 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 content, 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 the image on the right.

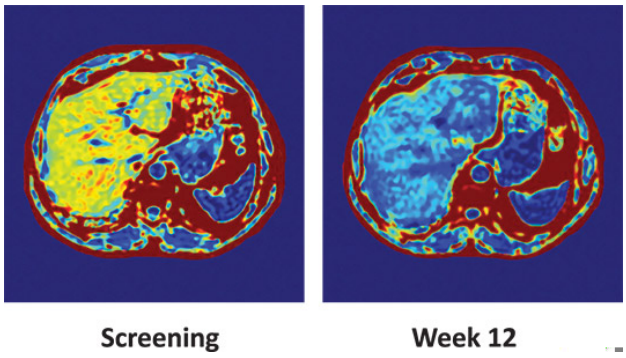

Figure 16. MRI-PDFF images for one patient treated with 50mg denifanstat

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

Inflammation/lipotoxicity biomarkers

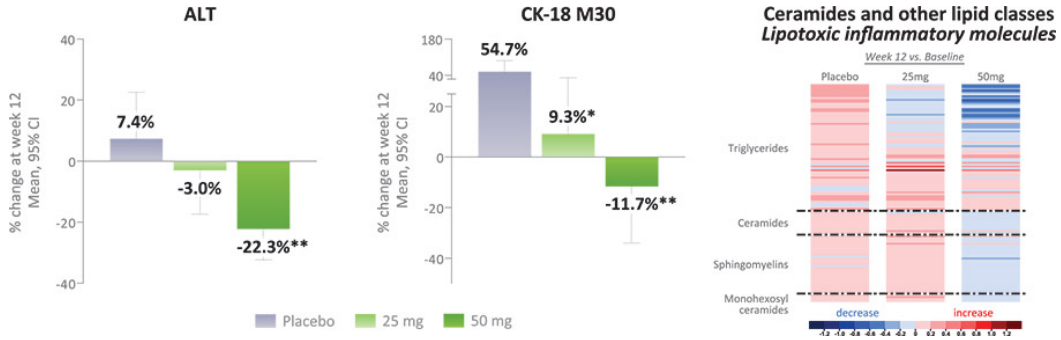

Figure 17. Inflammation / lipotoxicity biomarkers. *p<0.05,**p≤0.01

- ***ALT.*** Denifanstat showed a statistically significant decrease of ALT up to 22.3% (p<0.01) in a dose-dependent manner. Approximately one-third of the patients in each arm had abnormal ALT levels at baseline.
- In this subgroup, 33% of placebo patients normalized ALT post-treatment compared to 60% of the patients treated with 50mg of denifanstat.
- ***CK-18(M30).*** Denifanstat showed a statistically significant decrease of CK-18(M30) up to 11.7% (p<0.01) in a dose-dependent manner.
- ***Ceramides.*** Denifanstat showed a statistically significant decrease in multiple ceramides. Excess accumulation of ceramides, a type of fat often increased in NASH patients, is toxic and leads to inflammation and fibrosis. Decreasing ceramide levels likely reflects the reduction of excess palmitate and suggests an improved inflammatory environment.

Fibrosis biomarkers

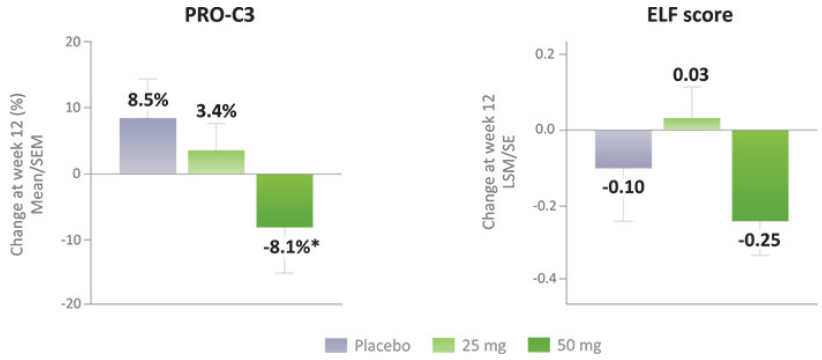

Figure 18. Fibrosis biomarkers. *p<0.05

- ***PRO-C3***. Denifanstat showed a statistically significant decrease in PRO-C3 levels (measured by ELISA) in a dose-dependent manner. PRO-C3 levels increased in the placebo group by 8.5% and decreased in the denifanstat 50mg-treated group by 8.1% ($p < 0.05$).
- ***ELF Score***. Denifanstat showed a 0.25 decrease in ELF score compared to a decrease of 0.1 with placebo (p = ns).

Metabolic/lipid biomarkers

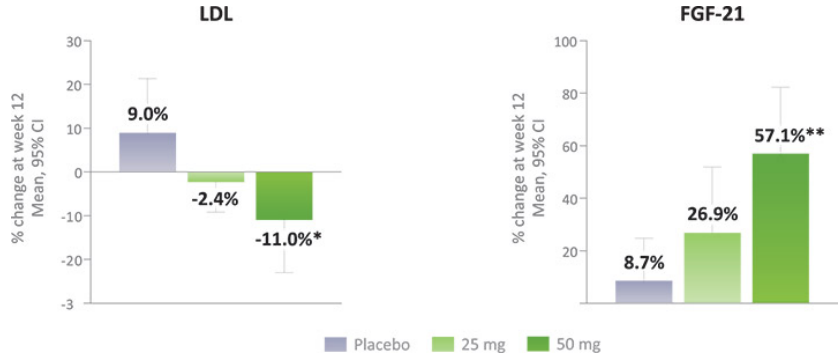

Figure 19. Metabolic / lipid biomarkers. *p<0.05 **p<0.01

- ***LDL-cholesterol***. Denifanstat showed a statistically significant decrease in LDL-cholesterol levels up to 11% (p<0.05) in a dose-dependent manner.
- ***FGF-21.*** Denifanstat showed a statistically significant increase in FGF-21 levels up to 57% (p<0.01) in a dose-dependent manner. Over the course of the clinical trial, we also assessed other laboratory values in the patients as described below:
- ***Tripalmitin.*** Denifanstat decreased tripalmitin levels up to 40% (p<0.0001) in a dose-dependent manner.
- ***Total plasma triglycerides***. There were minor elevations of triglyceride levels of 22mg/dL (p=ns) and 13mg/dL (p=ns) in the 25mg and 50mg arms, respectively. We believe the lack of dose-dependence suggests that these small, statistically nonsignificant increases were not due to the action of denifanstat.
- ***Total and HDL cholesterol***. Denifanstat decreased total cholesterol levels up to 5.1% (p<0.05) and HDL-cholesterol up to 4.4% (p<0.01) in a dose dependent manner. The ratio of total-cholesterol and HDL-cholesterol (4.4-4.6) did not change in any arm 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.

Cohorts 2 and 3

Cohort 2—China. Under our license agreement with Ascletis, we evaluated the profile of denifanstat (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 ASC40 (n=21) or placebo (n=9) once-daily for 12 weeks. The median age of patients in the China in this clinical trial was 34 years, 23.3% were female, 100% were Asian, median liver fat was 18.0%, and the median BMI was 28.9 kg/m2. In March 2021, together with Ascletis, we announced results showing ASC40 reduced liver fat with a 50% responder rate in patients treated with ASC40. ASC40 also demonstrated a decrease of ALT by 28% (p=ns) (mean decrease of 31 U/L at week 12). 63% of patients had at least at 17 unit decrease in ALT, a threshold that has been associated with liver fibrosis biopsy response.

Cohort 3—75mg Open-Label. A small, open-label 75mg once-daily cohort was conducted in the United States (N=13 patients) to explore the safety and efficacy of denifanstat at this dose level. The median age of Cohort 3 in this clinical trial was 48 years, 38.5% were female, 100% were Hispanic/Latino, median liver fat was 14.0%, and the median BMI was 28.4 kg/m2. At the end of 12 weeks of treatment, denifanstat 75mg led to a mean relative decline of liver fat content by MRI-PDFF of 35.8% and a responder rate of 57.1%. The liver fat decline was mostly driven by one single patient that had a decline of 82.6%. Denifanstat 75mg once-daily also decreased ALT by 3.2% (9.6 U/L) and LDL cholesterol by 13.5%.

Safety data

	Cohort 1			Cohort 2		Cohort 3
Treatment Emergent Adverse Event (TEAE) Classification	US Placebo N=31	US 25mg N=33	US 50 mg N=35	China Placebo N=9	China 50 mg N=21	US 75mg N=13
Any TEAE	Gr 1: 12 (38.7%) Gr 2: 7 (22.6%)	Gr 1: 18 (54.5%) Gr 2: 7 (21.2%)	Gr 1: 12 (34.3%) Gr 2: 6 (17.1%)	Gr 1: 3 (33%) Gr 2: 2 (22%)	Gr 1: 11 (52%) Gr 2: 4 (19%) Gr 3: 2 (10%)	Gr 1: 3 (23%) Gr 2: 6 (46%)
TEAE leading to drug withdrawal	0	2 (6.1%)	0	0	0	4 (31%)
Treatment Emergent Serious Adverse Event (SAE)	0	0	0	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%)	0	Gr 1: 9 (43%) Gr 2: 4 (19%)	Gr 1: 1 (8%) Gr 2: 6 (46%)

Figure 20. FASCINATE-1 safety summary

Denifanstat was considered well tolerated in the FASCINATE-1 Phase 2 trial at the 25mg and 50mg dose levels, with AEs that were mostly mild and similar among the cohorts. Safety data were collected from all 99 patients, of whom 68 were treated with denifanstat. Overall, 62 (63%) patients experienced at least one TEAE, all of which were assessed by the investigator as Grade 1 or mild except one incidence of Grade 2 urinary tract infection, one incidence of Grade 2 increased appetite at 25mg, and one incidence of Grade 2 shortness of breath at 50mg. All three of these Grade 2 TEAEs resolved without dose adjustment. No denifanstat-related SAEs occurred in any dose group. Overall, the most common TEAEs, regardless of drug-relatedness, among denifanstat-treated patients included headache (six patients; 9%), peripheral edema, rash, and upper respiratory tract infection (four patients; 6%); bronchitis, diarrhea, nausea, and urinary tract infection (four patients; 6%); and hypertriglyceridemia (noted as unrelated to treatment; two patients; 5.7%). Two (3%) patients discontinued denifanstat due to a TEAE: (1) mild eye allergy on day two of the clinical trial and (2) mild conjunctivitis. Both events occurred at the 25mg dose and resolved following discontinuation. No discontinuations for a TEAE were observed in the 50mg dose cohort.

In the Chinese cohort of 30 patients, 21 and nine of whom were treated with denifanstat and placebo, respectively, the 50mg denifanstat daily dose was well tolerated with a benign adverse event profile and no SAEs. Most TEAEs were Grade 1 (11 patients: 52% on denifanstat and 3 patients; 33% on placebo) or Grade 2 (four patients; 19% on denifanstat and two patients; 22% on placebo). No patients in the China cohort discontinued due to a TEAE Treatment-related AEs, as determined by the investigator, were observed in 13 patients (62%) on denifanstat.

In the 75mg open-label cohort of 13 patients, there was an increased incidence of TEAEs compared to U.S. patients who received 25mg or 50mg, 23% of TEAES were Grade 1 and 46% of TEAES were Grade 2, including four cases of dry skin (30.8%, including possible PPE syndrome), five cases of dry eye (38.5%) and four cases of hair thinning (30.8%). Hair thinning was not observed in the 25mg or 50mg cohorts. The 75mg cohort had an overall discontinuation rate of 46.2% (N=6) due to AEs. Four patients discontinued treatment due to more than one on-target AE; hair thinning (N=4; 30.8%), dry skin (N=4; 30.8%, including possible PPE syndrome), dry eye (N=2; 15.4%). Two patients (15.4%) discontinued due to one or more AEs of headache, lower abdominal pain, constipation, and diarrhea. All TEAEs were Grades 1 or 2, and there were no SAEs. While the 75mg dose demonstrated clinical activity, the adverse effects, which were reversible, were not balanced by the clinical activity observed. As such, this dose level was not pursued in the FASCINATE-2 Phase 2b trial.

The results from the FASCINATE-1 Phase 2 trial showed that a once-daily, oral dose of 25mg or 50mg of denifanstat for 12 weeks was well tolerated and led to rapid and robust reduction in excess liver fat in patients with NASH, which was statistically significant in the 50mg cohort, 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. Based on the results, we elected to use the once-daily, oral 50mg dose in the FASCINATE-2 Phase 2b trial.

Phase 1 DNL clinical trial results

To evaluate the impact of denifanstat on liver fat synthesis in 12 healthy male adults with characteristics of metabolic syndrome, we collaborated with the University of Missouri. 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 the subject received denifanstat and again after 10 days of taking a once-daily oral dose of either 50mg, 100mg or 150mg of denifanstat. This second measurement was taken approximately 10 hours after the last dose in order to measure the impact of steady-state drug levels on liver fat synthesis. This trial 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 denifanstat 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.

Denifanstat inhibited DNL in human volunteers

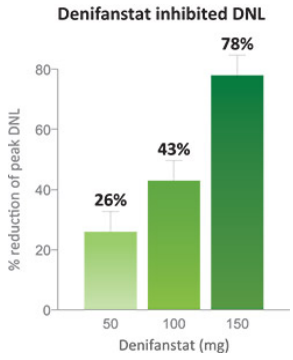

Figure 21. Inhibition of liver fat synthesis in Phase 1 DNL trial

We believe the results from this clinical trial established the clinical proof of mechanism for denifanstat. The results showed that an oral dose of denifanstat reached the liver of adults who were overweight. By inhibiting FASN, fat synthesis was reduced in the liver. Prior studies have shown subjects with increased amounts of liver fat have an approximately 3-fold higher rate of FASN-mediated DNL compared to subjects with lower liver fat. The conceptual goal of denifanstat treatment in NASH patients is to normalize the

rate of DNL; the goal does not include ablation of the pathway. The data from this Phase 1 trial suggested that doses below 100mg should be evaluated for their ability to reduce liver fat by reducing the rate of DNL.

Preclinical studies in NASH models

We characterized the effect of FASN inhibitors in preclinical models of NASH using a comprehensive strategy. We performed mechanistic *in vitro* studies in isolated human cell types to confirm the mode of action of FASN inhibitors. The *in vitro* results demonstrated that FASN inhibition via DNL pathway directly targets a) liver fat accumulation in hepatocytes, the initiating event of NASH, b) pro-inflammatory signaling in immune cells, and c) fibrogenesis by hepatic stellate cells, as described below. We used several different *in vivo* mouse models of NASH that encompass the full physiology of diet induced NASH and liver histology. In these models FASN inhibitors showed consistently that FASN inhibitors had in vivo activity and improved liver health biomarkers including ALT, pro-inflammatory cytokines, and liver histology endpoints of steatosis, inflammation and fibrosis. Collectively, these preclinical results suggest that FASN inhibitors effect change in the histologic parameters of NASH resolution and fibrosis improvement in two distinct ways. Not only do they act by preventing inflammation and fibrosis secondary to the excess accumulation of fat, but they also act by inhibiting inflammation and fibrosis mechanisms directly.

Disease models—direct impact on steatosis, inflammation and fibrosis

Steatosis—FASN inhibition directly reduced lipid accumulation in liver models. In human liver microtissues, denifanstat decreased cellular triglycerides, a marker of lipid accumulation or steatosis. This is a consequence of FASN inhibition leading to decreased hepatic DNL. These findings were extended in animal models where decreased lipid content was observed after FASN inhibitor treatment by Oil Red staining or steatosis by histology.

Inflammation—FASN inhibition directly reduced pro-inflammatory activity in immune cells. Two types of immune cells relevant for inflammation in the liver were used to test the effect of FASN inhibitors on pro-inflammatory activity: human white blood cells and human primary CD4+ T-cells. In human white blood cells were activated with lipopolysaccharide (LPS) or related stimulants, treatment with FASN inhibitors dramatically decreased production of interleukin-1 beta, a pro-inflammatory cytokine. A similar effect was observed in mice fed with a high fat, high cholesterol diet where interleukin-1 beta plus several other pro-inflammatory cytokines and chemokines were reduced. Th17 cells are immune cells that can cause pro-inflammatory damage in the liver and the DNL pathway is important for Th17 cell differentiation and function. In human primary CD4+ T cells, denifanstat significantly reduced the number of Th_{17} cells and increased the number of regulatory T-cells (T_{reg}). T_{reg} cells are more common in healthy livers and expected to blunt the damage caused by the inflammation producing Th_{17} and other immune cells.

Fibrosis—FASN inhibition directly reduced activation and fibrogenic activity of human hepatic stellate cells (HSCs). HSCs are the main cell type responsible for fibrosis and the deposition of scar tissue in the liver. HSCs need the DNL pathway to become activated to accomplish fibrogenic activity, which leads to production of fibrotic scar. In the human HSC cell line LX-2, FASN inhibitor decreased expression of several fibrogenic genes, as seen in Figure 22. This includes the genes encoding collagen 1α1, αSMA, two important markers of HSC activation and pro-fibrogenic activity. The protein levels of collagen 1α1 and SMA were also decreased by FASN inhibitor treatment. These results provide mechanistic evidence that FASN inhibition can directly reduce fibrogenic activity in HSCs. We believe that this would be expected to reduce fibrosis. In more complex disease models such as mice with NASH, decreased expression of fibrogenic markers was also observed after FASN inhibitor treatment.

	% inhibition of gene expression in hepatic stellate cells at 48hr vs baseline	
Gene	50 nM FASNi	150 nM FASNi
Col1α1	37%**	68%****
αSMA	37%	60%**
TGFβ-R1	0%	53%*
PDGF-Rβ	0%	54%**
TIMP1	19%	9%
TIMP2	12%	24%
MMP2	0%	50%**

Figure 22. Expression of fibrogenic genes
in a human stellate cell line. *p<0.01, **p<0.05, ****p<0.0001

FASN inhibition not only directly inhibits the fibrogenic activity of stellate cells, but it also removes the fibrogenic stimuli required to activate these cells. These stimuli result from excess fat in hepatocytes. By reducing liver fat via FASN inhibition, the levels of fibrogenic stimuli, including lipotoxins are reduced. We believe this is an important and unique facet of using FASN inhibition to treat NASH.

Disease models—in vivo activity in NASH

We evaluated the effect of FASN inhibitors in three different mouse models of NASH spanning the spectrum of disease severity: a prevention model, a therapeutic model with diet-induced NASH, and a therapeutic model with diet-induced NASH and advanced fibrosis and tumor formation (FAT-NASH). The results showed that FASN inhibition alleviated established features of NASH. For mouse models, we used a surrogate FASN inhibitor TVB-3664 for these experiments due to its improved pharmacokinetics in mice. TVB-3664 has a chemical structure highly related to denifanstat and inhibited FASN with similar potency.

FASN inhibition ameliorated disease progression in diet-induced NASH mouse model (a therapeutic model). After 44 weeks on a high-fat/fructose/cholesterol diet, mice developed obesity, steatohepatitis and liver fibrosis before FASN inhibitor treatment was initiated at that point in time for eight additional weeks, while the mice continued the same diet. After treatment with the FASN inhibitor, livers showed reduced steatosis and NAS score, despite being on 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 had in vivo activity in the diet induced FAT-NASH model with established liver fibrosis and liver cancer (a therapeutic model). 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. This was visualized by the picrosirius red staining of liver slices as shown below (left panel) In contrast, mice that received the FASN inhibitor (middle and right panels) for 12 weeks had 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. Quantitation of collagen content by digital pathology showed that this decrease is statistically significant, as shown in the graph 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.

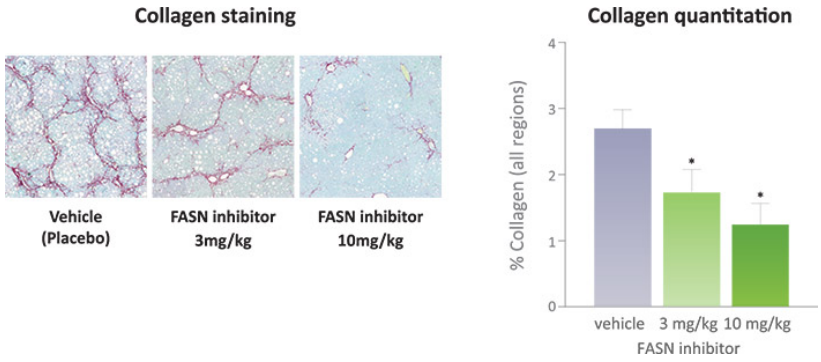

Figure 23. FASN inhibitor decreased liver fibrosis in mouse model of NASH. * p<0.05

Precision medicine—enabling the right intervention for NASH patients

We have initiated a comprehensive biomarker program as part of denifanstat development. Biomarkers are indicators of the disease state and/or response to treatment, and typically measured using convenient, non-invasive approaches. In addition to disease-associated biomarkers, we are developing two types of biomarkers specific to denifanstat and FASN. We believe the identification of these biomarkers has the potential to prospectively identify appropriate patients that will respond to therapy with denifanstat alone or in combination, monitor treatment response to drive clinical outcomes for NASH patients, and help differentiate denifanstat as a potential therapy for NASH.

NASH, the hepatic manifestation of metabolic syndrome, is a complex, progressive disease with no approved treatments in the United States or Europe. Published clinical trials with different drug candidates in NASH typically show liver histology response rates less than 30%, which means that the majority of patients do not show obvious benefit. With the large and growing global NASH population, we believe that it would be beneficial to develop precision medicine approaches to i) confirm that the drug is having a positive impact based on biomarker assessments, and ii) match NASH patients prior to initiation with the most appropriate treatment for their disease. These have the potential to provide physicians with a helpful tool to better manage their patients, and increase the market opportunity for denifanstat.

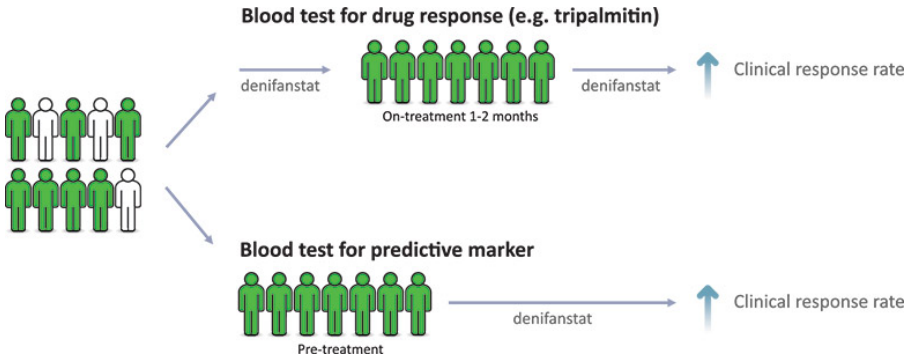

Figure 24. Precision medicine strategy

Drug response biomarkers

Pharmacodynamic (PD) biomarkers are drug response markers and provide evidence that a drug has modulated its target. This is important to test in clinical trials because lack of sufficient target modulation can cause lack of clinical activity. Over the past several years, we identified tripalmitin as a PD biomarker for FASN inhibition in several clinical trials and developed a reliable assay to measure serum tripalmitin in patients. Tripalmitin is a triglyceride with palmitate, a fatty acid produced by FASN, at each of the acyl moieties; therefore, a decrease of tripalmitin confirms FASN inhibition. At 50mg denifanstat, tripalmitin

levels are statistically significantly decreased by an average of approximately 42% in the FASCINATE-1 trial and in the FASCINATE-2 interim analysis.

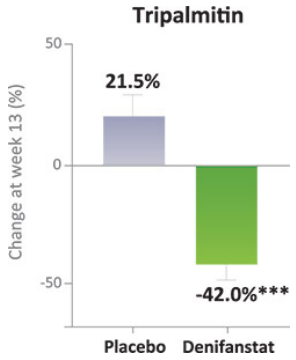

Figure 25. Tripalmitin levels at 13 weeks of dosing. ***p<0.001

We anticipate that other biomarkers may be used in conjunction with PD biomarkers such as tripalmitin to refine and enhance the robustness of demonstrating drug response in treated patients. These markers may include ALT, AST or other parameters that change upon denifanstat treatment.

Predictive biomarkers

We also plan to develop a predictive test to select NASH patients most likely to have an efficacious clinical response.

This program includes two distinct technical approaches, both using blood samples to identify biomarkers or biomarker panels that may predict clinical response to denifanstat: metabolomic profiling to measure metabolic state, and SNP profiling to incorporate genetic markers associated with metabolic disease. We have identified a preliminary biomarker signature (termed Sig-A) that predicts liver fat response to denifanstat. We measured the metabolomic profile of patients in our FASCINATE-1 clinical trial by examining approximately 470 metabolites in blood samples collected before treatment. Machine learning algorithms then identified Sig A, which consists of a panel of blood biomarkers. Figure 26 shows the predicted liver fat change score on a per patient basis for Sig-A (Y axis) derived by machine learning, compared to the actual liver fat change (X axis) for patients in our FASCINATE-1 clinical trial. Sig-A gave accuracy of 84%, positive predictive value of 73% and negative predictive value of 90% for a liver fat decrease of $\geq$25% by denifanstat.

Biomarker signature predicted liver fat response to denifanstat

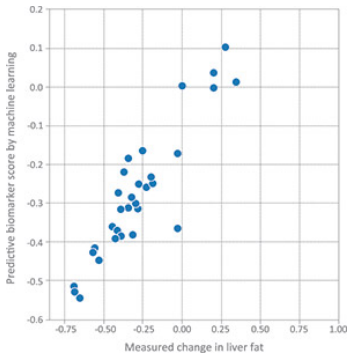

Figure 26. Biomarker signature correlation with liver fat change. Sig-A consists of 6 metabolites; ursodeoxycholic acid (UDCA), DL-2-aminocaprylic acid, sarcosine, 21lycol-UDCA, D(-)-2-aminobutyric acid, phosphatidylcholine (O-18:0/22:4).

We believe that these results are encouraging, and we will consider including this predictive metabolomic panel as a stratification factor in a Phase 3 clinical trial for NASH, with the hypothesis that patients positive for the predictive biomarker panel would have increased response rate, eventually to develop a diagnostic. We may also identify whether potential partial responder patients may benefit from combination therapy.

Combination strategy in NASH patients

Currently there are no agents approved in the United States or Europe to treat NASH. Clinical results of single agent trials have often been modest, with the majority of patients not responding. Combination therapy may increase the depth and breadth of clinical response across patient populations and decrease tolerability concerns for the treatment of NASH. The magnitude of patients combined with the disease complexity support the concept that multiple combinations of drugs targeting different mechanisms will be required to effectively manage this disease in a large, diverse population.

Based on its proposed mechanism of action, we believe that denifanstat, if successfully developed and approved, has the potential to be a backbone therapy and improve clinical activity in combination with a broad set of other drugs. Denifanstat's convenient once a day oral administration and tolerability profile make it a potentially desirable combination partner. The activity of denifanstat may be further empowered by additional drugs targeting other aspects of NASH or metabolic disease.

Our combination strategy is to use preclinical models to mechanistically evaluate the combination potential prior to considering clinical studies with the combination. We focused on combination partners that have clinical validation in NASH, and complementary mechanism of action to denifanstat. We have experience with models of human liver microtissues, human liver slices, 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.

For example, we have evaluated a GLP-1 agonist in a preclinical mouse combination study. In November 2023, at the 7th Obesity and NASH Drug Development Summit, we presented the results of a study assessing treatment with FASN inhibitor alone, semaglutide alone, or combination of FASN inhibitor with semaglutide for 12 weeks in a NASH mouse model. FASN inhibitor or semaglutide alone improved NAS and decreased several biomarkers associated with NASH. Only the FASN inhibitor, but not semaglutide, showed significant reduction of liver fibrosis by digital AI pathology assessment. FASN inhibitor and semaglutide in combination showed further histological improvement of NAS and liver fibrosis compared to treatment with FASN inhibitor alone or semaglutide alone. We believe such preclinical data support further clinical evaluation of denifanstat and GLP-1 combination therapy for NASH.

We are also interested in a combination with THRß agonists. THRß agonists do not act directly on hepatic stellate cells. Therefore, any improvement in fibrosis by THRß agonists is likely to be indirect. A combination of denifanstat with a THRß agonist may improve clinical activity on fibrosis endpoints. In addition, the complementary mechanisms of denifanstat (inhibiting fat synthesis) and THRß (increasing fat removal) might further normalize liver fat in NASH patients.

We may conduct exploratory clinical trials with relatively short durations to evaluate combinations of denifanstat and other complementary mechanisms. These trials will allow us to evaluate potential improvements in non-invasive biomarkers directly in NASH patients and select combinations for further development.

Additional NASH indications

Cirrhotic NASH. According to a study published in 2022, when left unchecked, over time approximately 10%-20% of patients with NASH will progress to liver cirrhosis (histological stage F4). Once cirrhosis has developed, the risk of developing a major complication of is 17%, 23%, and 52% at one, three, and 10 years, respectively. The survival of patients with NASH cirrhosis falls markedly once decompensation occurs, with a median survival of approximately two years. Conversely, histological regression of cirrhosis has been shown to reduce the risk of cirrhosis-related complications by 6-fold. A recent randomized, placebo-controlled Phase 2b clinical trial conducted by a third-party demonstrated that a combination of an FXR agonist (cilofexor) and a DNL inhibitor (firsocostat, ACC inhibitor) for 48

weeks in patients with bridging fibrosis and cirrhosis due to NASH was numerically better than placebo at reducing steatosis, lobular inflammation and ballooning. This trial also showed evidence of fibrosis improvement with the combination using NITs as well as a machine learning supported digital pathology assessment. This trial demonstrated that a lipogenesis inhibitor has the potential to address the underlying disease in compensated cirrhotic patients.

Pediatric NASH. According to a study published in 2022, NASH is the most common form of liver disease in children; approximately 10% of children in the United States have NAFLD, NASH was observed in 23% of children with NAFLD, and 15% have F2-F3 fibrosis. We intend to submit plans to regulatory authorities for the development of denifanstat in pediatric NASH patients, including the conduct of toxicology studies in juvenile animals with initiation expected in 2024, and an assessment of the safety of denifanstat in young adults (18-24 years old) across all studies. The information provided could enable the design of a Phase 2 clinical trial in pediatric patients with NASH.

Other indications—research programs

FASN plays a pathogenic role in several diseases beyond NASH. The overall strategy of our decade long research follows four core steps, a) identify diseases where FASN contributes to the underlying pathology, b) generate proof of concept data to demonstrate the mechanism of action, c) use precision medicine to identify patient populations enriched for clinical response where feasible and, d) accelerate the program to the appropriate clinical development stage. We believe that this rigorous research process optimizes clinical development. Based on this framework and the clinical and preclinical data we have collected to date, we have prioritized acne and oncology as the next potential clinical indications for our FASN inhibitors.

Denifanstat is an advanced, selective FASN inhibitor in clinical-stage development and has been shown to block the enzyme's activity in humans and has been administered to over 740 people since 2013. This set of attributes uniquely affords the company the ability to investigate several diseases where FASN treatment may have therapeutic benefits for patients. In addition, we have identified a second clinical candidate FASN inhibitor TVB-3567 that we believe is IND-ready and could be taken into one of these indications. We also have additional FASN inhibitors at earlier stages of development.

Acne

Disease rationale. Acne is the most common skin condition in the United States, affecting up to 50 million Americans annually. Acne usually begins in puberty and affects many adolescents and young adults. Approximately 85% of people between the ages of 12 and 24 experience at least minor acne and the prevalence of severe acne may be as high as 20% of those affected by acne. FASN is responsible through lipid synthesis for the production of skin oils (sebum). More than 80% of key sebum lipids such as palmitate and sapienic acid are produced by DNL/FASN. In acne, excess sebum can lead to skin lesions and is a pro-inflammatory stimulus leading to exacerbation of those lesions, including development of nodules (nodular acne) and cysts (cystic acne). Studies in patients with acne vulgaris demonstrated that levels of sebum palmitate and sebum sapienate (a derivative of palmitate found in the skin) were increased 20% compared to healthy volunteers. 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. An oral ACC inhibitor, another DNL inhibitor, studied by Pfizer reduced total sebum levels in the skin as a result of inhibiting lipogenesis.

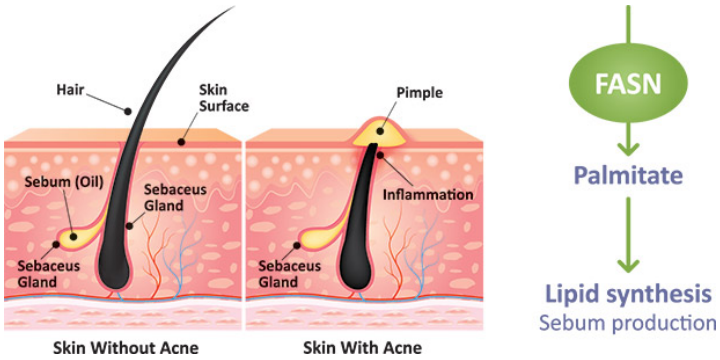

Figure 27. FASN role in acne

Our acne program. We have shown, in two separate Phase 1 clinical trials, that denifanstat can reduce the amount of sebum on patients' skin. Sebum samples were collected from patients in the Phase 1 DNL trial described above and in the Phase 1 oncology solid tumor trial described below. Sebum changes were exploratory lipidomic assessments incorporated into these trials to provide a potential non-invasive assessment of pharmacodynamic activity, and not prospectively powered for statistical significance. In the Phase 1 DNL trial, denifanstat reduced total lipid secretion in sebum in a dose-dependent manner by an average of 7% (50mg, n=6), 29% (100 mg, n=4) and 64% (150 mg, n=2) on day 10 of once daily treatment. In the Phase 1 oncology trial that tested higher denifanstat dose levels (typically 150 mg or 200 mg once daily), sebum total triacylglycerol levels decreased from pretreatment levels by an average of 28% on day 8 or 16 ($p \leq 0.05$ vs baseline) and by 69% on day 28 ($p \leq 0.05$ vs baseline). This included significant reductions in total sapienic acid, a sebum fatty acid produced only by de novo lipogenesis, confirming FASN inhibition. We believe these results provide mechanistic proof of concept for denifanstat in acne.

In May 2023, Ascletis Pharma announced positive topline results with the achievement of primary and key secondary endpoints in a Phase 2 clinical trial in 179 patients with moderate to severe acne vulgaris in China. These patients were randomized and dosed with 25mg, 50mg or 75mg of denifanstat (ASC40) or placebo daily for 12 weeks. Ascletis Pharma reported that denifanstat met the primary endpoint of percentage change from baseline in total lesion count at week 12 with median reductions of 53.1% in the 25mg group (p=0.006, n=45), 61.3% in the 50mg group (p=0.008, n=44), and 53.1% in the 75mg group (p=0.008, n=45) versus a reduction of 34.2% with placebo (n=45). The incidence rates of treatment-related AEs were comparable among 25 mg (grade 1=28.9%; grade 2=20.0%), 50 mg (grade 1=36.4%; grade 2=11.4%), 75 mg (grade 1=44.4%; grade 2=17.8%) denifanstat groups and the placebo group (grade 1=35.6%; grade 2=13.3%). The majority of treatment-related AEs were dry eye, and all dose levels had a rate of dry eye similar to placebo (grade 1=28.9%; grade 2=6.6%). There were no denifanstat-related grade 3 or 4 AEs, no treatment-related SAEs and no deaths reported.

In December 2023, Ascletis Pharma announced the initiation of a randomized, double-blind, placebo-controlled, multicenter Phase 3 clinical trial to evaluate the safety and efficacy of denifanstat for the treatment of moderate to severe acne vulgaris in 480 patients in China. The patients will be randomized into one active treatment arm and one placebo control arm at the ratio of 1:1 to receive 50mg of denifanstat or placebo orally, once daily for 12 weeks. The co-primary efficacy endpoints are: proportion of subjects achieving treatment success at week 12, percentage change from baseline in total lesion count, and percentage change from baseline in ILC at week 12. Based on Ascletis Pharma's reported Phase 2 results and initiation of Phase 3 clinical development of denifanstat in acne, we are evaluating options to move forward with our own acne program in the U.S., Europe and other markets.

Oncology

Oncology disease rationale—Dysregulation of lipid metabolism is a hallmark of cancer. Increased expression of FASN has been associated with poor prognosis and reduced survival in several tumor cell types. While most normal cells get their palmitate from dietary sources, cancer cells have a high requirement of lipids for membrane synthesis and cell signaling to meet the demands of high proliferation. Some cancer cells become dependent upon the FASN pathway for proliferation to provide a reliable and self-sufficient source of fatty acids, referred to as onco-metabolism. This is the case for specific cancers driven by driver oncogenes such as mutant KRAS (KRASM), tyrosine kinase receptors and hormone receptors, such as the androgen receptor. The fatty acids made by FASN are relatively resistant to oxidative stress which allows the highly proliferating cancer cells to avoid cell death. We believe that this dependence on FASN provides a vulnerability that can be attacked with FASN inhibitors.

FASN inhibition can also potentially address the enormous challenge of resistance to cancer therapies. Several cancer types have been shown to upregulate FASN to rewire lipid metabolism and change 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.

The following diagram depicts the role of FASN in the molecular mechanisms associated with cancer:

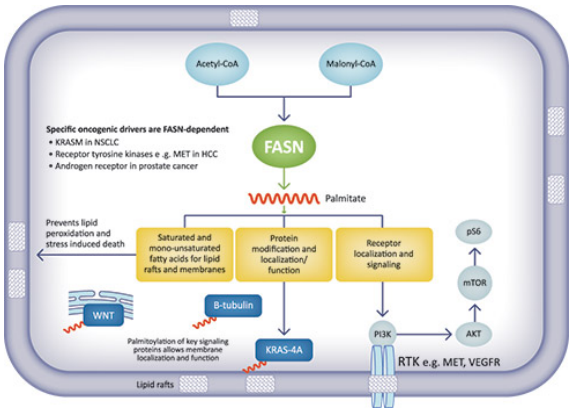

Figure 28. FASN role in molecular mechanisms associated with cancer. i) FASN derived lipids play a structural role in membranes to avoid oxidative stress, and create lipid rafts for oncogenic signaling (for example in KRASM or Androgen receptor signaling). This also contributes to resistance to targeted therapies ii) Palmitate itself (the immediate product of FASN) covalently modifies critical oncogenes to allow them to localize in membranes and function properly (for example KRAS4A). iii) FASN derived lipids are important to create lipid rafts that anchor receptor tyrosine kinases appropriately in the plasma membrane for signaling, and the MET tyrosine kinase is one example of this class.

Our oncology program—We are developing FASN inhibitors to treat specific subsets of solid tumors that are FASN-dependent in combination with other classes of oncology drugs. Our first-in-human Phase 1 clinical trial for denifanstat was conducted in patients with advanced solid tumors. The results provided a foundation and path for future clinical trials. The data from our preclinical, translational studies have identified three FASN-dependent tumor subtypes with potential clinical application, as described below.

Oncology—identification of FASN-dependent tumor types

(i) Non-small cell lung cancer (NSCLC) with KRAS mutations: KRAS mutations are among the most common mutant driver genes in NSCLC tumors and these patients have a poor prognosis. KRASM signaling depends on FASN, and also depends on reactive oxygen species to maintain its pathogenic nature and high proliferation. Introduction of the KRAS mutation into a NSCLC adenocarcinoma induces the cancer cell to be highly dependent on FASN for proliferation and survival. We have generated preclinical and clinical results that demonstrate the potential of FASN inhibitors for the treatment of NSCLC KRASM, as follows:

- In preclinical screening of a large panel of cancer lines for drug sensitivity, we observed that treatment of NSCLC KRASM cells with FASN inhibitor resulted in cell death, whereas KRAS wild type (KRASWT) are less sensitive. Similar findings were made in mouse models.
- The mechanism that underpins FASN-dependence has recently been demonstrated in published studies using models of human cancer; KRASM tumors hijack the FASN pathway to make membrane lipids that are enriched for saturated or mono-unsaturated triglycerides. These membranes are more robust and resistant to oxygen free radicals that KRASM creates. FASN inhibition disrupts this protective circuit meaning that cancer cells need to use poly unsaturated oxidation-prone fatty acids, which leads to stress induced cell death.
- In our Phase 1 clinical trial in patients with solid tumors (described below), patients with NSCLC KRASM tumors treated with denifanstat exhibited stable disease significantly longer than NSCLC patients who did not have a KRAS mutation. The median time to disease progression was 22 weeks for KRASM versus five weeks for KRASWT ($p<0.02$, one sided ANOVA). These clinical results with denifanstat validate the preclinical finding that KRASM is FASN-dependent.
- Preclinical combination studies of one of our FASN inhibitors plus a marketed KRASM G12C inhibitor, adagrasib, further decreased the growth of NSCLC KRASM tumors compared to either agent alone.

In collaboration with a third party, we are further validating that the combination of our FASN inhibitors and a KRASM targeted drug show benefit in preclinical studies. Upon successful completion of these preclinical studies, we will explore a Phase 1b/2 study in patients with NSCLC KRASM to evaluate the effect of denifanstat or another FASN inhibitor from our portfolio, combined with a KRASM targeted agent.

(ii) Hepatocellular carcinoma (HCC) FASN-dependent: We have identified a subset of HCC tumors that are FASN-dependent, in a collaboration with Dr. Xin Chen at the University of California, San Francisco. This subset termed MET-hi, PTEN-lo represents approximately 34% of human HCC, and is defined by high levels of the receptor tyrosine kinase MET and low levels of the tumor suppressor PTEN, which indicates high proliferation activity. Published clinical trials using mouse genetic HCC models support that these cancer pathways are FASN-dependent. Our results are described below.

- Treatment of a mouse HCC MET-hi, PTEN-lo model with FASN inhibitor plus the standard of care kinase inhibitor cabozantinib triggered regression of HCC tumors. In addition, FASN inhibitor therapy combined with either cabozantinib or sorafenib, a second standard of care kinase inhibitor, improved the in vivo activity for c-MYC driven HCC.
- We plan to collaborate with an academic institution to identify more readily available biomarkers that would identify patients with these HCC subtypes, and to explore the etiology of MET-hi PTEN-lo HCC tumors. We have also shown in preclinical models that FASN inhibitor treatment of mice with HCC that develops after NASH significantly reduces the tumor burden compared to untreated mice. NASH-related HCC is an area that we will explore in bioinformatics analysis.
- Upon completion of the biomarker work, a Phase 1b/2 clinical trial enriched for HCC patients, these markers would be conducted to evaluate the initial activity of denifanstat or TVB-3567 combined with cabozantinib.

(iii) Metastatic castration resistant prostate cancer, FASN-dependent: Prostate cancer is a highly lipogenic tumor type. The androgen receptor (AR) is the main driver of disease progression in prostate cancer and upregulates levels of FASN to maintain membrane production and avoid oxidative stress. Several androgen receptor modulators are approved for treatment such as enzalutamide or abiraterone, but resistance emerges leading to relapse, often associated with new variants in AR such as Arv7.

- Results in preclinical models from our collaborator show that FASN inhibition can decrease the levels of resistance markers. Combination of FASN inhibitor with enzalutamide has a better anti-tumor effect than either agent alone. These results provide a strong mechanistic basis for clinical trial combining a FASN inhibitor with an AR inhibitor. Our collaborators at Weill Cornell are conducting an Investigator Sponsored Study in men with metastatic castration resistant prostate cancer to explore this combination.

Oncology—glioblastoma

GBM is a disease of high unmet need. High FASN expression has been observed in glioblastoma tumors and may be associated with resistance to agents such as bevacizumab.

A Phase 2 investigator sponsored clinical trial was conducted in glioblastoma patients (Grade 4 astrocytoma) by Dr. Andrew Brenner from the University of Texas, San Antonio. In this trial, 25 bevacizumab naïve patients in their first relapse were treated with denifanstat (100mg/m2 once daily) plus bevacizumab (10mg/kg once every 2 weeks). The overall response rate was 56% (complete response 17%, partial response 39%) and six-month progression free survival was 31.4%. This represents a statistically significant improvement in six-month progression free survival over historical bevacizumab monotherapy such as the BELOB study 16% ($p<0.01$) and met the primary study endpoint. The observed six-month overall survival was 68%, with survival not reaching significance by log rank test ($p=0.56$). The most frequently reported AEs were PPE syndrome, hypertension, mucositis, dry eye, fatigue and skin infection. Most were Grade 1 or 2 in intensity. Based on these results, Ascletis Pharma initiated in early 2022 a Phase 3 registrational trial in China in patients with recurrent GBM. In September 2023, Ascletis Pharma announced the enrollment of 120 recurrent GBM patients, which it expects will provide a sufficient basis for its planned

interim analysis of the Phase 3 trial. If the results of this study are positive, we will explore with regulatory authorities initiating our own registrational trial with denifanstat for the treatment of recurrent GBM.

Oncology—Phase 1 results in multiple solid tumors

We conducted a first-in-human Phase 1 clinical trial of denifanstat in patients with advanced, heavily pretreated and mostly metastatic solid tumors which included dose escalation. Importantly, in cancer patients we expect the dose of denifanstat for clinical activity to be higher than in NASH because the objective is to completely shut down FASN activity and cause cell death in cancer, rather than normalize FASN activity. Overall, 136 patients were treated with denifanstat, 76 treated with denifanstat only (monotherapy) and 60 treated in combination with a taxane, a commonly used class of anti-cancer drugs. The study identified the maximum tolerable dose as 100mg per square meter of body surface area ($100mg/m^2$), or approximately 150mg to 200mg daily, whether denifanstat was used alone or in combination. Denifanstat monotherapy treatment resulted in a disease control rate (DCR) of 42%. 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 denifanstat monotherapy, evaluation of time-to-progression (TTP) among patients with NSCLC revealed notably longer TTP for patients with a mutation in the KRAS gene (KRASM) (N=11) compared to those with a normal, or wild-type, KRAS gene (KRASW) (N=6) (22 weeks versus five weeks; p<0·02).

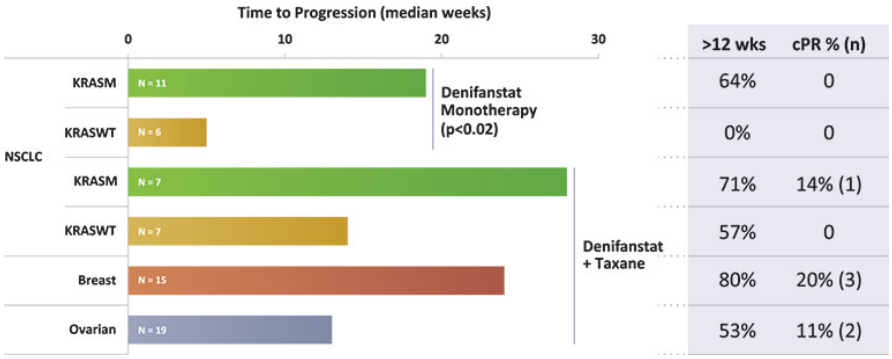

Figure 29. Time to progression in Phase 1 oncology trial

As anticipated, based on prior nonclinical toxicology clinical trial findings, the principal toxicities associated with denifanstat monotherapy were skin and ocular effects, with most being Grade 1 or 2. Common (i.e., incidence >10%) skin effects included alopecia (61%), PPE syndrome (46%), dry skin (22%), skin exfoliation (12%), and rash (11%). Ocular effects included dry eye (17%) and increased lacrimation increased (13%). Six episodes of serious pneumonitis were experienced by five patients receiving denifanstat and paclitaxel, one of which was fatal, all assessed by the investigator as at least possibly related to both denifanstat and paclitaxel. Pneumonitis was not observed in patients treated with denifanstat monotherapy. ECG and Holter monitoring data revealed no clinically relevant QTc prolongation with denifanstat.

This Phase 1 clinical trial was successful and provided a recommended Phase 2 dose of $100mg/m^2$, which corresponds to 150mg or 200mg in most patients. It also identified several tumor types that may merit further development, including KRASM NSCLC, breast cancer, and ovarian cancer. Investigator sponsored Phase 2 clinical trials are ongoing in KRASM NSCLC and breast cancer, as well as a Phase 1b pharmacodynamic clinical trial in colorectal cancer.

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. 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, and tested through iterative cycles, with several emerging as leading candidates based on their laboratory properties. A few were selected for further characterization leading to the identification of denifanstat 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 denifanstat out of more than 1,200 compounds within our library of FASN inhibitors.

Denifanstat 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. Denifanstat 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 denifanstat, supporting our belief that this compound may be highly selective for FASN and is unlikely to interact with unintended proteins or pathways.

TVB-3567. In addition to our lead drug candidate, we have completed IND-enabling studies with a second selective FASN inhibitor designated as TVB-3567. This compound also showed potent FASN inhibitory activity based on inhibition of palmitate synthesis in human, rat, mouse, and dog cell lines; a single dose of TVB-3567 inhibited palmitate synthesis in a rat model. These studies include the standard suite of IND-enabling, GLP-compliant safety pharmacology and genotoxicity studies, and GLP-compliant general toxicology studies of up to four weeks treatment duration in rats and dogs. We plan to initiate a TVB-3567 clinical development program in the U.S. for the treatment of acne. We expect to file an IND with the FDA in the first half of 2024 to conduct a first-in-human Phase 1 clinical trial, as a basis for further clinical development in acne.

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 89bio, Inc., Akero Therapeutics, Inc., Altimmune, Inc., Bristol-Myers Squibb Company, Eli Lilly and Company, Galmed Pharmaceuticals Ltd., Gilead Sciences, Inc., Intercept Pharmaceuticals, Inc., Inventiva S.A., Madrigal Pharmaceuticals, Inc., NGM Biopharmaceuticals, Inc., NorthSea Therapeutics B.V., Novartis AG, Novo Nordisk A/S, Pfizer Inc., Terns Pharmaceuticals, Inc., Viking Therapeutics, Inc., and Zydus 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.

Denifanstat 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 denifanstat's potential mechanism of action, and its potential complementary mechanism to other therapies, we believe that denifanstat 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 a license agreement with Ascletis, a subsidiary of Ascletis Pharma, a biotechnology company incorporated in the Cayman Islands and headquartered in Hangzhou, 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 and its affiliates 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 denifanstat and products containing denifanstat-related compounds in the People's Republic of China, Hong Kong, Macau and Taiwan (referred to collectively in this prospectus as Greater China). We retained certain manufacturing rights in Greater China and the right to practice our intellectual property in Greater China as necessary to perform our obligations under the license agreement. Ascletis granted us a non-exclusive, sublicensable, royalty-free license under certain intellectual property of Ascletis to develop, manufacture, and commercialize denifanstat and products containing denifanstat-related compounds outside Greater China.

Under the license agreement, we conducted all development activities in connection with the FASCINATE-1 Phase 2 clinical trial in the United States and Greater China at our sole expense, except for certain in-kind contributions by Ascletis in Greater China. Ascletis is solely responsible at its sole expense for conducting development activities in connection with obtaining and maintaining regulatory approvals for denifanstat in Greater China. Ascletis will solely own all regulatory filings and approvals in Greater China other than those regulatory filings jointly applied for in connection with the FASCINATE-1 Phase 2 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 Greater China.

We are eligible to receive development and commercial milestone payments from Ascletis in aggregate of up to $122.0 million. In January 2022, Ascletis initiated dosing of a Phase 3 trial for recurrent GBM, triggering a $2.0 million milestone payment under the license agreement. The parties were in discussions regarding the form and amount of consideration related to this milestone until July 2023, at which time we concluded that the risk of reversal was no longer present. In August 2023, we received a $1.7 million milestone payment (representing the $2.0 million development milestone payment, net of applicable taxes) from Ascletis.

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 denifanstat and other products containing licensed compounds in the Territory, subject to customary reductions. Ascletis' 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. Termination of the license agreement will not terminate the non-exclusive license granted to us by Ascletis, except, in the event of early termination by Ascletis for certain of our material breach, we will pay Ascletis single digit royalties on net sales of products outside the territory covered by such non-exclusive license. 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 Greater China, subject to our obligation to pay Ascletis royalties in the low single digit percentages on net sales of any reverted products in Greater China.

In October 2019, we entered into a Patent Assignment Agreement and Patent Re-Assignment Agreement with Gannex, an affiliate of Ascletis and subsidiary of Ascletis Pharma, 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. In July 2023, we amended and restated each of the Patent Assignment Agreement and Patent Re-Assignment Agreement to assign additional patents and patent applications to Gannex, effective as of October 2019, which additional patents and patent applications relate solely to licensed compounds under the license agreement, specifically, denifanstat and related compounds, and their use in the treatment of cancers, fatty liver diseases, inflammatory diseases, and diseases related thereto in Greater China. Also in July 2023, we entered into an Assignment and Assumption Agreement with Ascletis and Gannex under which Ascletis, while remaining responsible for performance under the License Agreement, assigned all of its rights and obligations under the License Agreement to Gannex and Gannex assumed such rights and obligations, effective as of October 2019. The assignment of patents 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. Additionally, we retain control of the prosecution of the pending patent application assigned to Gannex.

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 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. To date, we have relied on three CMOs based in the United States and China to produce denifanstat drug substance and two CMOs in the United States and China to produce denifanstat drug product. We will need to manufacture additional material to support late-stage studies such as Phase 3 trials. Under the terms of our license agreement with Ascletis, we cannot source drug substance from within Greater China, but we are not restricted outside of Greater China.

We currently rely on several manufacturers for the production of raw materials, APIs, and the finished products of denifanstat and we believe that there are multiple sources for all raw materials employed in the manufacturing of our drug substance and drug product, and we believe that several CMOs are able to manufacture lots as needed.

There are extensive regulations that govern the manufacturing of biopharmaceutical products, and the third-party manufacturing organizations we work with are required to adhere to these. Our CMOs are required to manufacture our drug candidates under cGMP requirements, alongside other applicable laws and regulations.

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, denifanstat 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, see “Risk Factors—Risks related to our intellectual property.”

As of December 5, 2023, we owned and/or had control of 12 U.S. patents, 143 issued foreign patents, which includes European patents that have been validated in various European countries, two pending non-provisional U.S. patent applications, one pending U.S. provisional patent application, one pending international PCT application, and 16 pending foreign patent applications.

With regard to denifanstat, as of December 5, 2023, we owned one issued U.S. patent with composition of matter and pharmaceutical composition claims directed to denifanstat. The issued U.S. patent is expected to expire in 2032, without taking any potential patent term extension (PTE) into account. In addition, we own and/or have control of patents that have been granted in various jurisdictions including Australia, Argentina, Brazil, countries across Europe, Japan, China, South Korea, India, Israel, Macau, Mexico, New Zealand, Taiwan, and South Africa, which are expected to expire in 2032, without taking potential PTEs or other forms of extension into account. We also own three issued U.S. patents with claims directed to methods of using denifanstat and combinations of denifanstat with additional agents. The issued U.S. patents are expected to expire in 2035 and 2036, without taking a potential PTE into account. Specifically, U.S. Patent No. 10,363,249, which is expected to expire in 2035, issued with claims directed to a method of treating a taxane-resistant tumor or cancer comprising administering a combination of denifanstat and a taxane. U.S. Patent No. 10,189,822, which is expected to expire in 2036, issued with claims directed to a method of treating various types of cancers (mantle cell lymphoma, chronic myelogenous leukemia, sarcoma; endometrial tumors, non-small cell lung carcinoma, gastric carcinomas, hepatocellular tumors, and head and neck cancer) comprising administering denifanstat, or a combination of denifanstat with additional agents. U.S. Patent No. 11,034,690, which is expected to expire in 2036, issued with claims directed to methods of treating NASH, NAFLD, liver cirrhosis and liver fibrosis comprising administering denifanstat. In addition we own and/or have control of patents with claims directed to methods of using denifanstat, and/or methods of using combinations of denifanstat with additional agents, in China, Japan, various countries across Europe, South Korea, Israel, New Zealand, and Russia, which are expected to expire in 2035, 2036 and/or 2037. We also own and/or have control of at least 12 pending applications in jurisdictions including Australia, China, Canada, Europe, Japan, South Korea, Singapore, and South Africa, which, if issued, are expected to expire in 2036 and/or 2037, without taking potential PTEs into account.

With regard to TVB-3567, as of December 5, 2023, we owned one issued U.S. patent with composition of matter claims, as well as claims directed to methods of using TVB-3567 to treat various types of cancer. The issued U.S. Patent No. 9,994,550 is expected to expire in 2035, without taking a potential PTE into account. In addition, we own and/or have control of patents that have been granted in Australia, Brazil, Canada, South Africa, Japan, South Korea, China, Hong Kong, Macau, Israel, India, Singapore, New Zealand, Russia, Mexico, and various countries across Europe, which are expected to expire in 2035, without taking potential term extensions into account. Furthermore, we own one pending application in Singapore which, if issued, is also expected to expire in 2035, without taking potential PTEs into account. We also own and/or have control of granted patents in China, Israel, and New Zealand, which are expected to expire in 2037, without taking potential PTEs into account, and 11 pending patent applications in various countries and regions in North America, Europe, and Asia, which, if issued, are expected to expire in 2037 (2036 in the United States), without taking potential PTEs into account.

With respect to claims specifically directed to the treatment of NASH, as of December 5, 2023, we owned U.S. Patent No. 11,034,690, which is expected to expire in 2036, without taking potential term extensions into account. In addition, we own and/or have control of patents that have been granted in Israel, China, and New Zealand which are expected to expire in 2037, without taking potential term extensions into account. We also own and/or have control of 11 applications pending in the U.S., Australia, and various countries and regions in North America, Europe, Asia, and Africa, that disclose chemical genera encompassing denifanstat and TVB-3567 for the treatment of NASH. Any patents issuing from these applications are expected to expire in 2037 (2036 in the United States), without taking potential PTEs 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 or international PCT application.

In the United States, the term of a patent covering an FDA-approved drug may, in certain cases, be eligible for a PTE 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 U.S. patents covering denifanstat and TVB-3567 may be entitled to PTE. If our drug candidates receive FDA approval, we intend to apply for PTE, if available, to extend the term of patents that cover the approved drug candidates. We also intend to seek PTE 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, see "Risk Factors—Risks related to our intellectual property."

U.S. patent term restoration

Depending upon the timing, duration and specifics of the potential FDA approval of denifanstat and any future drug candidates, some of our U.S. patents may be eligible for limited PTE. The Hatch-Waxman Amendments permit a patent restoration term, often referred to as PTE, of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug or biologic is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves or denies the application for any PTE or restoration. In the future, we intend to apply for extension of patent term for one of our patents covering denifanstat to add patent life beyond its current expected expiration date.

Government regulation and product approval

As a pharmaceutical company that operates in the United States, and in foreign countries, 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 authority 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.

U.S. 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 applicable 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 IND, which must become effective before human clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an 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 GCP regulations and other clinical-trial related regulations to establish the safety and efficacy of the proposed drug for its proposed indication;
- preparation and submission to the FDA of an NDA for a new drug after completion of all pivotal trials, which includes not only the results of the clinical trials, but also detailed information on the chemistry, manufacture and quality controls for the drug candidate and proposed labeling;
- 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 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.

Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the proposed drug or disease.

U.S. preclinical and clinical development

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 chemistry, manufacturing and controls information, analytical data, any available clinical data or literature and a proposed clinical trial 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 (i.e., the drug candidate) to humans.

An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions or 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, non-compliance or other issues affecting the integrity of the trial. Accordingly, submission of an IND may or may not result in the FDA allowing clinical trials to commence and, once begun, issues may arise that could cause the trial to be suspended or terminated.

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 factors such 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 data monitoring 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 registration of ongoing clinical trials and posting of completed clinical trial results to public registries.

A sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of an NDA. The FDA may accept a well-designed and well-conducted foreign clinical study not conducted under an IND if the study was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

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 a limited population of healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution, and excretion, and if possible, to gain early evidence of effectiveness. In the case of some drug candidates for severe or life-threatening diseases, especially when the candidate 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 with the targeted disease or condition to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the drug candidate for the targeted disease or condition 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, to provide substantial evidence of clinical efficacy and to further test for safety. These clinical trials are intended to establish the overall benefit/risk relationship of the drug candidate and provide adequate basis for the labeling of the drug candidate. 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 drugs granted accelerated approval, FDA may mandate the performance of Phase 4 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 candidate 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 AEs, along with any findings from other studies suggesting a significant risk to humans exposed to the drug candidate and from animal or *in vitro* testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. 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.

U.S. NDA 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 candidate, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the drug candidate. 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 drug candidate 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. Sponsors of approved NDAs are also subject to an annual program fee. These fees are typically increased annually.

The FDA reviews all NDAs submitted before it accepts them for filing. As a result of such review, the FDA may refuse to file any NDA that it deems incomplete or not properly reviewable at the time of submission 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 of the application. 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 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 ensure that the benefits of the drug outweigh the potential risks. 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. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use (ETASU). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the product. Moreover, product approval may also be conditioned on substantial post approval testing, such as Phase 4 post-market studies, and surveillance to monitor the product's safety or efficacy, and FDA may limit further marketing of the product based on the results of these post-approval studies. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission to and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs. As with new NDAs, the review process is often significantly extended by the FDA requests for additional information or clarification.

In addition, the Pediatric Research Equity Act (PREA) requires a sponsor to conduct pediatric clinical trials 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 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 may send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current, or 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 designation program is intended to expedite or facilitate the process for reviewing new drug candidates that are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the drug candidate and the specific indication for which it is being studied. The sponsor of a fast track designated 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 designated 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.

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 designation 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 candidate 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 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 drug candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing confirmatory clinical studies which must be conducted with due diligence to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. Under the FDORA, the FDA may require, as appropriate, that such confirmatory studies be underway prior to approval or within a specific time period after the date accelerated approval is granted. Under FDORA, the FDA has increased authority for expedited procedures to withdraw approval of a drug or indication approved under accelerated approval if, for example, the sponsor fails to conduct the required confirmatory studies or if such studies fail to verify the predicted clinical benefit. In addition, for products being considered for accelerated approval, the FDA generally requires, unless otherwise informed by the agency, pre-approval of all advertising and promotional materials, which could adversely impact the timing of the commercial launch of the product. Thus, even if we seek to utilize the accelerated approval pathway, we may not be able to obtain accelerated approval and, even if we do, we may not experience a faster development, regulatory review or approval process for that drug candidate. In addition, receiving accelerated approval does not assure that the product's accelerated approval will eventually be converted to a traditional approval.

Fast track designation, breakthrough therapy designation, priority review, and accelerated approval do not change the standards for approval, but may expedite the development, review or approval process. Even if a drug candidate qualifies for one or more of these programs, the FDA may later decide that the drug

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

Orphan drug designation

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.

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 (off-label use), limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet.

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 that are consistent with the FDA-approved labeling. The FDA and other agencies 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 regarding 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 authorities 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 non-misleading information that is otherwise consistent with a product's FDA-approved labelling.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval. 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. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. Drug manufacturers using contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. These firms and, where applicable, their suppliers are subject to inspections by the FDA at any time, and the discovery of violative conditions, including failure to conform to cGMP, could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute products manufactured, processed or tested by them. Manufacturers and other parties involved in the drug supply chain for prescription drug products must also comply with product tracking and tracing requirements and notify the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the United States. 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 product approvals or request product recalls if a company fails to maintain compliance with regulatory requirements and standards if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including AEs of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; requirements for 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 authorities 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.

U.S. marketing exclusivity

Market exclusivity provisions under the FDCA can delay the submission or the approval of certain marketing applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not approve or accept for review an abbreviated new drug application (ANDA) or a Section 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. 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. 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 Section 505(b)(2) NDAs for drugs referencing the approved application for review.

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.

Regulation of companion diagnostics and complementary diagnostics

As a part of our later stage product development strategy, we may develop and commercialize one or more companion diagnostics or complementary diagnostics. Companion diagnostics and complementary diagnostics can identify patients who are most likely to benefit from a particular therapeutic product; identify patients likely to be at increased risk for serious side effects as a result of treatment with a particular therapeutic product; or monitor response to treatment with a particular therapeutic product for the purpose of adjusting treatment to achieve improved safety or effectiveness. Companion diagnostics and complementary diagnostics are regulated as medical devices by the FDA. Such diagnostic tests generally require marketing clearance or approval from the FDA prior to commercialization. The two primary types of FDA marketing authorization applicable to a medical device are clearance of a premarket notification, or 510(k), and approval of a premarket approval application, or PMA. For a novel therapeutic product for which a companion diagnostic device is essential for the safe and effective use of the product, the companion diagnostic device should be developed and approved or 510(k)-cleared contemporaneously with the therapeutic. The use of the companion diagnostic device will be stipulated in the labeling of the therapeutic product. A complementary diagnostic is not considered essential for the safe and effective use of the therapeutic product and does not need to be approved or cleared contemporaneously with the therapeutic.

After a companion diagnostic device is cleared or approved, it is subject to applicable post-marketing requirements including the FDA's Quality System Regulation, or QSR, adverse event reporting, recalls and corrections, and product marketing requirements. Device manufacturers must register and list their devices with the FDA. Applicable portions of the QSR may include the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging and shipping of medical devices. Companion and complementary diagnostic manufacturers are subject to unannounced FDA inspections at any time during which the FDA will conduct an audit of the product(s) and the facilities for compliance with regulatory requirements.

Disclosure of clinical trial information

Sponsors of applicable clinical trials of FDA regulated products are required to register their clinical trials and disclose certain clinical trial results information. Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of the clinical trial is made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved. Competitors and patients may use this publicly available information to gain knowledge regarding the progress of development programs.

Other U.S. 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. A claim includes "any request or demand" for money or property presented to the U.S. 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 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 U.S. 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), other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals, certain ownership and investment interests held by such physicians and their immediate family members.

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, significant 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 U.S. 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. Discounted prices must also be offered for certain U.S. 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.

Additionally, we may develop complementary diagnostic tests for use with our drug candidates. We, or our collaborators, may be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we seek for our drug candidates, once approved. While we have not yet developed any complementary diagnostic tests for our drug candidates, if we do, there is significant uncertainty regarding our ability to obtain coverage and adequate reimbursement for the same reasons applicable to our drug candidates.

Different pricing and reimbursement schemes exist in other countries. In the European Union, 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 U.S. 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 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), which, effective January 1, 2024, is eliminated as a result of the American Rescue Plan Act of 2021;
- a 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 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, effective January 2020, the "Cadillac" tax on high-cost employer-sponsored health coverage and, effective January 2021, the health insurer tax were eliminated. In June 2021, in a case involving individual mandate, the U.S. Supreme Court ruled that certain challengers to the ACA lacked standing and upheld the ACA. In February 2021, the executive branch withdrew the federal government's support for overturning the Affordable Care Act and 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 any future litigation, and the healthcare reform measures of the current executive 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. For example, the Budget Control Act of 2011 and subsequent legislation, among other things, created measures for spending reductions by Congress that include aggregate reductions of Medicare payments to providers of on average 2% per fiscal year, which remain in effect through 2032. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers will be further reduced starting in 2025 absent further legislation. The U.S. American Taxpayer Relief Act of 2012 further reduced Medicare payments to several types of providers and increased the statute of limitations period for the

government to recover overpayments to providers from three to five years. These laws and regulations may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our drug candidates for which we may obtain regulatory approval or the frequency with which any such drug candidate is prescribed or used.

In May 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, and review the relationship between pricing and manufacturer patient programs. The Inflation Reduction Act of 2022 (IRA), for example, includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket spending cap for Medicare Part D beneficiaries from $7,050 to $2,000 starting in 2025, thereby eliminating the so-called coverage gap; impose new manufacturer financial liability on certain drugs under Medicare Part D; allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay until January 2032 the implementation of the HHS rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. If a product receives multiple orphan designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. The effects of the IRA on our business and the healthcare industry in general is not yet known.

Multiple executive orders have also been issued that have sought to reduce prescription drug costs. In February 2023, HHS issued a proposal in response to an October 2022 executive order that includes a proposed prescription drug pricing model that will test whether targeted Medicare payment adjustments will sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through FDA's accelerated approval pathway. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights that would be voluntary for federal government agencies to follow when deciding whether to exercise march-in rights and which for the first time includes the price of a product as a factor a federal government agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain whether the federal government will actually exercise such march-in rights in connection with pharmaceutical products or whether any such exercise will be subject to judicial review or challenge. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the current administration may reverse or otherwise change these measures, both the current administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

We cannot predict the healthcare reform initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our approved products;

- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. Federal Government will pay for healthcare drugs and services, which could result in reduced demand for our drug candidates or additional pricing pressures.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain drug access and marketing cost disclosure and transparency measures, and 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, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our drugs or put pressure on our drug pricing, which could negatively affect our business, financial condition, results of operations and prospects.

Data privacy and security laws

We may also be subject to federal, state, local, and foreign data privacy and security obligations such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security. In the United States, numerous federal, state, and local laws and regulations, including state data breach notification laws, state health information privacy laws, and federal, consumer protection laws and regulations (e.g., Section 5 of the FTC Act), and similar laws (e.g., wiretapping laws) govern the collection, use, disclosure, protection, and other processing of health-related and other personal data and may apply to our operations or the operations of our partners upon which we rely. For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, 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.

In addition, U.S. state laws govern the privacy and security of personal data, many of which differ from each other in significant ways and may be subject to different interpretations, thus complicating our compliance efforts. By way of example, the California Consumer Privacy Act (CCPA) applies to personal data of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals. The CCPA provides for administrative fines of up to $7,500 per violation, as well as a private right of action for individuals affected by certain data breaches to recover significant statutory damages. In addition, the California Privacy Rights Act of 2020 (CPRA) expanded the CCPA's requirements, including by adding a new right for individuals to correct their personal data and establishing a new regulatory agency (CPPA) to implement and enforce the law. Other states, such as Virginia and Colorado, have also passed comprehensive privacy laws, and similar laws are being considered in several other states, as well as at the federal and local

levels. These state laws and the CCPA provide individuals with certain rights concerning their personal data, including the right to access, correct, or delete certain personal data, and opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. While these states, like the CCPA, also exempt some data processed in the context of clinical trials, these developments may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely.

Outside the United States, an increasing number of laws, regulations, and industry standards govern data privacy and security, including the European Union's General Data Protection Regulations (EU GDPR) and the United Kingdom's GDPR (UK GDPR, and together with the EU GDPR, referred to as GDPR). The GDPR applies to any company established in the EEA or United Kingdom as well as to those outside the EEA or United Kingdom if they collect and use personal data in connection with the offering of goods or services to individuals in the EEA or United Kingdom or the monitoring of their behavior.

The GDPR creates significant and complex compliance burdens for covered companies, including strict requirements for processing personal data. Companies violating the GDPR may face temporary or definitive bans on data processing and other corrective actions; fines of up to €20 million (£17.5 million) or 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. The processing of "special category personal data" (including health-related data) may also impose heightened compliance burdens under the GDPR and is a topic of active interest among relevant regulators.

Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the GDPR restricts the transfer of personal data from the EEA and United Kingdom to the United States and other countries whose privacy laws are believed to be inadequate. Although there are various mechanisms that may be used to transfer personal data from the EEA and the United Kingdom to the United States in compliance with law, such as the EEA and United Kingdom's standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers for relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer rules.

The EU GDPR also provides that EEA Member States may make their own further laws and regulations to introduce specific requirements related to the processing of personal data and "special categories of personal data," which may lead to greater divergence on the law that applies to the processing of such data across Europe. Country-specific regulations could also limit our ability to collect, use and share European data, and/or could cause our compliance costs to increase, ultimately having an adverse impact on our business and harming our business and financial condition.

Our employees and personnel may use generative AI technologies to perform their work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and consumer lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages.

In addition to data privacy and security laws, we are or may become contractually subject to industry standards adopted by industry groups and may become subject to such obligations in the future. We are also bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. We publish privacy policies, marketing materials, and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

Obligations related to data privacy and security are quickly changing, becoming increasingly stringent, and creating regulatory uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources and may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

The U.S. Foreign Corrupt Practices Act

The FCPA prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the 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 also be subject to a variety of comparable regulatory requirements in other jurisdictions governing, 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. 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.

Clinical trials in the EU

Similar to the United States, the various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls.

In the EU, clinical trials are governed by the Clinical Trials Regulation (EU) No 536/2014 (CTR), which entered into application on January 31, 2022 repealing and replacing the former Clinical Trials Directive 2001/20 (CTD).

The CTR is intended to harmonize and streamline clinical trial authorizations, simplify adverse-event reporting procedures, improve the supervision of clinical trials and increasing their transparency. Specifically, the CTR, which is directly applicable in all EU Member States, introduces a streamlined application procedure through a single-entry point, the Clinical Trials Information System (CTIS); a single set of documents to be prepared and submitted for the application; as well as simplified reporting procedures for clinical trial sponsors. A harmonized procedure for the assessment of applications for clinical trials has been introduced and is divided into two parts. Part I assessment is led by the competent authorities of a reference Member State selected by the trial sponsor and relates to clinical trial aspects that are considered to be scientifically harmonized across EU Member States. This assessment is then submitted to the competent authorities of all concerned Member States in which the trial is to be conducted for their review. Part II is assessed separately by the competent authorities and ethics committees in each concerned EU Member State. Individual EU Member States retain the power to authorize the conduct of clinical trials on their territory.

The extent to which on-going clinical trials will be governed by the CTR will depend on the duration of the individual clinical trial. Sponsors could choose to submit a clinical trial application under either the CTD or the CTR until January 31, 2023. By January 31, 2025, all ongoing trials will become subject to the provisions of the CTR. The CTR will apply to clinical trials from an earlier date if the clinical trial has already transitioned to the CTR framework.

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.

EU review and approval process

In the EU, medicinal products can only be commercialized after a marketing authorization (MA), has been granted. To obtain an MA for a product in the EEA (which is comprised of the 27 Member States of the European Union plus Norway, Iceland and Liechtenstein), an applicant must submit a marketing authorization application (MAA) either under a centralized procedure administered by the EMA or one of the procedures administered by the competent authorities of EU Member States (decentralized procedure, national procedure or mutual recognition procedure). An MA may be granted only to an applicant established in the EU.

The centralized procedure provides for the grant of a single MA by the European Commission that is valid throughout the EEA. Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for (i) medicinal products derived from biotechnological processes, (ii) products designated as orphan medicinal products, (iii) advanced therapy medicinal products (ATMPs) (gene therapy, somatic-cell therapy and tissue engineered medicines), and (iv) products with a new active substance indicated for the treatment of HIV/AIDS, cancer, neurodegenerative diseases, diabetes, auto-immune and other immune dysfunctions and viral diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, authorization through the centralized procedure is optional.

Under the centralized procedure, the EMA's Committee for Medicinal Products for Human Use (CHMP), conducts the initial assessment of a product. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing MA.

Under the centralized procedure, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated assessment may be granted by the CHMP in exceptional cases, when a medicinal product targeting an unmet medical need is expected to be of major interest from a public health perspective and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts a request for accelerated assessment, the time limit of 210 days will be reduced to 150 days (excluding clock stops). The CHMP can, however, revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment.

Unlike the centralized authorization procedure, the decentralized MA procedure requires a separate application to, and leads to separate approval by, the competent authorities of each EU Member State in which the product is to be marketed. This application is identical to the application that would be submitted to the EMA for authorization through the centralized procedure. The reference EU Member State prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned EU Member States who, within 90 days of receipt, must decide whether to approve the assessment report and related materials. If a concerned EU Member State cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the Heads of Medicines Agencies' Coordination Group for Mutual Recognition and Decentralised Procedures—Human (CMDh), for review. The subsequent decision of the European Commission is binding on all EU Member States.

The mutual recognition procedure allows companies that have a medicinal product already authorized in one EU Member State to apply for this authorization to be recognized by the competent authorities in other EU Member States. Like the decentralized procedure, the mutual recognition procedure is based on the acceptance by the competent authorities of the EU Member States of the MA of a medicinal product by the competent authorities of other EU Member States. The holder of a national MA may submit an application to the competent authority of an EU Member State requesting that this authority recognize the MA delivered by the competent authority of another EU Member State.

An MA has, in principle, an initial validity of five years. The MA may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the EU Member State in which the original MA was granted. To support the application, the MA holder must provide the EMA or the competent authority with a consolidated version of the eCTD (Common Technical

Document) providing up-to-date data concerning the quality, safety and efficacy of the product, including all variations introduced since the MA was granted, at least nine months before the MA ceases to be valid. The European Commission or the competent authorities of the EU Member States may decide on justified grounds relating to pharmacovigilance to proceed with one further five-year renewal period for the MA. Once subsequently definitively renewed, the MA shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the EU market (for a centralized MA) or on the market of the authorizing EU Member State within three years after authorization ceases to be valid (the so-called sunset clause).

Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the PRIority MEdicines (PRIME), scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicinal products that target unmet medical needs. Eligible products must target conditions for which there is an unmet medical need (there is no satisfactory method of diagnosis, prevention or treatment in the EU or, if there is, the new medicinal product will bring a major therapeutic advantage) and they must demonstrate the potential to address the unmet medical need by introducing new methods of therapy or improving existing ones. Benefits accrue to sponsors of drug candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted.

In the EU, a "conditional" MA may be granted in cases where all the required safety and efficacy data are not yet available. The European Commission may grant a conditional MA for a medicinal product if it is demonstrated that all of the following criteria are met: (i) the benefit-risk balance of the medicinal product is positive; (ii) it is likely that the applicant will be able to provide comprehensive data post-authorization; (iii) the medicinal product fulfils an unmet medical need; and (iv) the benefit of the immediate availability to patients of the medicinal product is greater than the risk inherent in the fact that additional data are still required. The conditional MA is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and must be renewed annually until all related conditions have been fulfilled. Once any pending studies are provided, the conditional MA can be converted into a traditional MA. However, if the conditions are not fulfilled within the timeframe set by the EMA and approved by the European Commission, the MA will cease to be renewed.

An MA may also be granted "under exceptional circumstances" where the applicant can show that it is unable to provide comprehensive data on efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. These circumstances may arise in particular when the intended indications are very rare and, in the state of scientific knowledge at that time, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. Like a conditional MA, an MA granted in exceptional circumstances is reserved to medicinal products intended to be authorized for treatment of rare diseases or unmet medical needs for which the applicant does not hold a complete data set that is required for the grant of a standard MA. However, unlike the conditional MA, an applicant for authorization in exceptional circumstances is not subsequently required to provide the missing data. Although the MA "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually, and the MA will be withdrawn if the risk-benefit ratio is no longer favorable.

Manufacturing regulation in the EU

Various requirements apply to the manufacturing and placing on the EU market of medicinal products. The manufacturing of medicinal products in the EU requires a manufacturing authorization and import of medicinal products into the EU requires a manufacturing authorization allowing for import. The manufacturing authorization holder must comply with various requirements set out in the applicable EU laws, regulations and guidance, including EU cGMP standards. Similarly, the distribution of medicinal products within the EU is subject to compliance with the applicable EU laws, regulations and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of EU Member States. MA holders and/or manufacturing and import authorization (MIA)

holders and/or distribution authorization holders may be subject to civil, criminal or administrative sanctions, including suspension of manufacturing authorization, in case of non-compliance with the EU or EU Member States' requirements applicable to the manufacturing of medicinal products.

Post-approval requirements

Where an MA is granted in relation to a medicinal product in the EU, the holder of the MA is required to comply with a range of regulatory requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the individual EU Member States. The holder of an MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports (PSURs).

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

In the EU, the advertising and promotion of medicinal products are subject to both EU and EU Member States' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. Although general requirements for advertising and promotion of medicinal products are established under EU legislation, the details are governed by regulations in individual EU Member States and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics (SmPC), as approved by the competent authorities in connection with an MA. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU. Direct-to-consumer advertising of prescription medicinal products is also prohibited in the EU.

Data and marketing exclusivity

The EU also provides opportunities for market exclusivity. Upon receiving an MA in the EU, innovative medicinal products generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents generic or biosimilar applicants from referencing the innovator's preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar MA during a period of eight years from the date on which the reference product was first authorized in the EU. During the additional two-year period of market exclusivity, a generic or biosimilar MA can be submitted, and the innovator's data may be referenced, but no generic or biosimilar product can be marketed until the expiration of the market exclusivity period. The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to authorization, is held to bring a significant clinical benefit in comparison with existing therapies.

In the EU, there is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product. For such products, the results of appropriate preclinical or clinical trials must be provided in support of an application for MA. Guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product.

Pediatric development

In the EU, Regulation (EC) No 1901/2006 provides that all marketing authorization applications for new medicinal products must include the results of trials conducted in the pediatric population, in compliance

with a pediatric investigation plan (PIP), agreed with the EMA's Pediatric Committee (PDCO). The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the medicinal product for which MA is being sought. The PDCO may grant a deferral of the obligation to implement some or all of the measures provided in the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Furthermore, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all EU Member States and study results are included in the product information, even when negative, the product is eligible for a six-month extension to the Supplementary Protection Certificate (SPC), if any is in effect at the time of authorization or, in the case of orphan medicinal products, a two-year extension of orphan market exclusivity. For other countries outside of the EU, such as certain countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product approval, pricing and reimbursement vary from country to country. In all cases, the clinical trials are to be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

Orphan designation

In the EU, Regulation (EC) No. 141/2000, as implemented by Regulation (EC) No. 847/2000 provides that a medicinal product can be designated as an orphan medicinal product by the European Commission if its sponsor can establish that: (i) the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating conditions; (ii) either (a) such condition affects not more than 5 in 10,000 persons in the EU when the application is made, or (b) the product without the benefits derived from orphan status, would not generate sufficient return in the EU to justify the necessary investment in developing the medicinal product; and (iii) there exists no satisfactory authorized method of diagnosis, prevention, or treatment of the condition that has been authorized in the EU, or even if such method exists, the product will be of significant benefit to those affected by that condition.

Regulation (EC) No 847/2000 sets out further provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product. An application for the designation of a medicinal product as an orphan medicinal product must be submitted at any stage of development of the medicinal product but before filing of an MAA. An MA for an orphan medicinal product may only include indications designated as orphan. For non-orphan indications treated with the same active pharmaceutical ingredient, a separate MA has to be sought.

Orphan medicinal product designation entitles an applicant to incentives such fee reductions or fee waivers, protocol assistance, and access to the centralized marketing authorization procedure. Upon grant of a MA, orphan medicinal products are entitled to a ten-year period of market exclusivity for the approved therapeutic indication, which means that the EMA cannot accept another MAA or accept an application to extend an MA for a similar medicinal product and the European Commission cannot grant an MA for the same indication for a period of ten years. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed PIP. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan medicinal product designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The period of market exclusivity may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria on the basis of which it received orphan medicinal product destination, including where it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, an MA may be granted to a similar medicinal product with the same orphan indication during the 10 year exclusivity period if: (i) the MA holder for the authorized orphan product consents to a second orphan medicinal product application, (ii) the manufacturer of the authorized orphan medicinal product is unable to supply sufficient quantities of the product; or (iii) the second applicant can establish that its product, although similar to

an authorized orphan product, is safer, more effective or otherwise clinically superior to the authorized orphan medicinal product. A company may voluntarily remove a product from the register of orphan products.

Clinical trial data disclosure

Many jurisdictions have mandatory clinical trial information obligations incumbent on sponsors. In the EU, transparency requirements relating to clinical trial information are established in the CTR. The CTR establishes a general principle according to which information contained in CTIS shall be made publicly accessible unless confidentiality is justified on grounds of protecting personal data, or commercially confidential information, necessary to protect confidential communications between EU Member States in relation to the preparation of an assessment report, or necessary to ensure effective supervision of the conduct of a clinical trial by EU Member States. This confidentiality exception may be overruled if there is an overriding public interest in disclosure. The publication of data and documents in relation to the conduct of a clinical trial will take place in accordance with specific timelines. The timelines are established by the EMA and are determined based on the documents and the categorization of the clinical trial. In addition, sponsors of clinical trials may apply for deferral of publication of certain documents at the time of submission of the initial clinical trial application. The application for deferral of publication should be based on justified grounds and include a reasoned proposed deferral period. Applications for deferral of publication are subject to the approval of concerned EU Member States.

In addition, Regulation No. 1049/2001 on access to documents, or the ATD Regulation, and the related EMA policy 0043 on access to documents, provide for a wide right for EU-based interested parties to submit an access to documents request to the EMA to access certain information held by the EMA. Only very limited information is exempted from disclosure (i.e., commercially confidential information, which is construed increasingly narrowly and protected personal data). It is possible for competitors to access and use this data in their own research and development programs anywhere in the world, once these data are in the public domain.

Pricing, coverage and reimbursement

In the EU, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Other countries may require the completion of additional studies that compare the cost-effectiveness of a particular drug candidate to currently available therapies (so called health technology assessments) in order to obtain reimbursement or pricing approval. For example, some EU Member States may approve a specific price for a product, or they may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other EU Member States allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many EU Member States have increased the amount of discounts that pharmaceutical companies are requirement to offer. These efforts could continue as countries attempt to manage healthcare expenditures. The downward pressure on healthcare costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products onto national markets. Political, economic, and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU Member States, and parallel trade (arbitrage between low-priced and high-priced member states), can further reduce prices.

In addition, some EEA countries may require the completion of additional studies that compare the cost-effectiveness of a particular medicinal drug candidate to currently available therapies. This Health Technology Assessment (HTA), process is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. In December 2021 the EU HTA Regulation was adopted. The purpose of the Regulation is to introduce joint clinical assessments at EU level. When it enters into application in 2025 the Regulation will be intended to harmonize the clinical benefit assessment of HTA across the European Union.

Regulation of Companion Diagnostics in the EU

In the EU, companion diagnostics are considered to be *in vitro* diagnostic medical devices and are governed by Regulation 2017/746 (IVDR), which entered into application in May 2022, repealing and replacing Directive 98/79/EC. The IVDR defines companion diagnostics as a device that is essential for the safe and effective use of a corresponding medicinal product to: (a) identify, before and/or during treatment, patients who are most likely to benefit from the corresponding medicinal product; or (b) identify, before and/or during treatment, patients likely to be at increased risk of serious adverse reactions as a result of treatment with the corresponding medicinal product.

The IVDR regulates the placing on the market, the general safety and performance requirements, the conformity assessment procedures, CE-marking, registration obligations for manufacturers and devices as well as the vigilance and post-market surveillance requirements related to such products. IVDs, including companion diagnostics, must conform with the general safety and performance requirements, or GSPR, of the IVDR. To demonstrate compliance with the GSPR laid down in Annex I to the IVDR, the manufacturer must conduct a conformity assessment procedure.

Companion diagnostics are specifically identified as falling within the scope of the IVDR. Prior to CE marking and marketing in the EU they must be the subject of a conformity assessment process that includes the intervention of a notified body. If the related medicinal product has been, or is in the process of being authorised through the centralized procedure for the authorization of medicinal products, the notified body will, before it can issue a CE Certificate of Conformity, be required to seek a scientific opinion from the EMA on the suitability of the companion diagnostic for use in relation to the medicinal product concerned. For medicinal products that have been or are in the process of authorisation through any other route provided in EU legislation, the notified body must seek the opinion of the national competent authority of an EU Member State.

Brexit

Following the result of a referendum in 2016, the United Kingdom left the European Union in January 2020, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed between the United Kingdom and the European Union, the United Kingdom was subject to a transition period until December 2020 (the Transition Period) during which European Union rules continued to apply. The United Kingdom and the European Union have signed a EU-UK Trade and Cooperation Agreement (TCA), which became provisionally applicable and has been fully applicable since May 2021. The TCA primarily focuses on ensuring free trade between the European Union and the United Kingdom in relation to goods, including medicinal products. Although the body of the TCA includes general terms which apply to medicinal products, greater detail on sector-specific issues is provided in an Annex to the TCA. The Annex provides a framework for the recognition of Good Manufacturing Practice (GMP), inspections and for the exchange and acceptance of official GMP documents. The regime does not, however, extended to procedures such as batch release certification. The TCA does not provide for wholesale mutual recognition of UK and European Union pharmaceutical regulations.

As regards to MAs, Great Britain has a separate regulatory submission process, approval process and a national MA. Under the Northern Ireland protocol, Northern Ireland is, for the time being, covered by the MAs granted by the European Commission. Since January 1, 2021, an applicant for a centralized procedure MA in the EU can no longer be established in the United Kingdom. Since this date, companies established in the United Kingdom cannot use the centralized procedure and instead must follow one of the UK national authorization procedures to obtain an MA to market products in the United Kingdom. Until December 2023, the MHRA may rely on a decision taken by the European Commission on the approval of a new centralized procedure marketing authorization when determining an application for a Great Britain MA; or use the MHRA's decentralized or mutual recognition procedures which enable marketing authorizations approved in EU Member States through decentralized and mutual recognition procedures to be granted in the United Kingdom or Great Britain. The MHRA has been updating various aspects of the regulatory regime for medicinal products in the United Kingdom. These include: introducing the Innovative Licensing and Access Procedure to accelerate the time to market and facilitate patient access for innovative medicinal products; updates to the UK national approval procedure, introducing a 150-day objective for assessing applications for MAs in the United Kingdom, Great Britain and Northern Ireland and a rolling review process for MA

applications (rather than a consolidated full dossier submission). The MHRA has also announced a new framework for MAs that was put in place on January 1, 2024, whereby the MHRA takes into account decisions on the approval of MAs from the EMA (and certain other regulators) when considering an application for a Great Britain MA.

Orphan designation in Great Britain following Brexit is, unlike in the EU, not available pre-marketing authorization. Applications for orphan designation are made at the same time as an application for a MA. The criteria to be granted an orphan medicinal product designation or essentially identical to those in the EU but based on the prevalence of the condition in Great Britain. It is therefore possible that conditions that were or would have been designated as orphan conditions in Great Britain prior to the end of the Transition Period are or would no longer be and that conditions that were not or would not have been designated as orphan conditions in the EU will be designated as such in Great Britain.

The UK regulatory framework in relation to clinical trials is derived from the EU Clinical Trials Directive (as implemented into UK law, through secondary legislation). In January 2022, the MHRA launched an eight-week consultation on reframing the UK legislation for clinical trials. The consultation closed in March 2022 and aims to streamline clinical trials approvals, enable innovation, enhance clinical trials transparency, enable greater risk proportionality, and promote patient and public involvement in clinical trials. The outcome of the consultation will be closely watched and will determine whether the United Kingdom chooses to align with the CTR or diverge from it to maintain regulatory flexibility.

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

As of December 31, 2023, we had a total of 10 employees, two of which work 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.

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 in June 2024. We believe that our facilities are adequate to meet our current needs. We plan to reassess our facilities needs on a quarterly basis.

Legal proceedings

From time to time, we may become involved in material 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 party to any legal proceedings material to our operations 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, key employees and directors

The following table sets forth information regarding our executive officers, key employees and directors as of January 23, 2024:

Name	Age	Position
Executive Officers and Employee Director:		
David Happel	61	President, Chief Executive Officer and Director
Anthony Rimac	60	Chief Financial Officer*
Eduardo Bruno Martins, M.D., D.Phil.	61	Chief Medical Officer
Elizabeth Rozek, Esq.	52	General Counsel and Chief Compliance Officer
Key Employee and Director:		
George Kemble, Ph.D.	64	Executive Chairman of the Board
Non-Employee Directors:		
Elizabeth Grammer, Esq.[(2)(3)]	60	Director
Merdad Parsey, M.D., Ph.D.[(1)(2)]	60	Director
Richard Rodgers[(1)(3)]	57	Director
Beth Seidenberg, M.D.[(1)(3)]	66	Director
Jinzi J. Wu, Ph.D.	60	Director

* On December 28, 2023, Mr. Rimac provided notice of his intent to step down as our Chief Financial Officer effective January 31, 2024.

(1) Member of the compensation committee.

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

(3) Member of the audit committee.

Executive officers and employee director

David Happel has been our chief executive officer and a director since October 2022. From March 2020 through October 2022, he was president and chief executive officer of Cognoa Inc., a pediatric behavioral health company developing AI-based technologies for developmental and behavioral health conditions, including the first FDA-authorized diagnostic aid, Canvas Dx, for autism. From February 2018 to March 2020, Mr. Happel was previously president and chief executive officer and a board member of Chrono Therapeutics Inc. In addition, he has held several executive and commercial positions at Horizon Therapeutics PLC (Nasdaq: HZNP), Raptor Pharmaceuticals Corp., Dynavax Technologies Corporation (Nasdaq: DVAX) and Chiron Corporation. Mr. Happel has a B.A. in chemistry from Indiana University and an M.B.A. from Indiana State University. We believe that Mr. Happel is qualified to serve on our board of directors due to his significant leadership experience in the life science industry.

Eduardo Bruno Martins, M.D., D.Phil. has been our chief medical officer since February 2021. In September 2017, Dr. Martins co-founded Bruno Martins Consulting LLC, a boutique consulting firm that provides scientific advice and services to biotechnology and pharmaceutical companies. From May 2020 to December 2020, prior to joining us, he served as vice president of clinical development at Abbvie Inc. Prior to that, from August 2018 to May 2020, he served as vice president of clinical development—liver disease for Allergan, Inc. 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. From December 2010 to October 2015, he also served as senior director of medical affairs for hepatitis at Gilead Sciences, Inc., a biopharmaceutical company. Dr. Martins received his M.D. from the Universidade Federal do Rio de Janeiro in Rio de Janeiro, Brazil and his D.Phil. from the University of Oxford in Oxford, England.

Anthony Rimac has been our chief financial officer since August 2023 and previously served as our chief operating officer from April 2023 until August 2023. Prior to joining us, Mr. Rimac served as chief financial officer of Cognoa, Inc. from September 2021 to November 2022. From December 2019 to September 2021, he was chief financial officer of ESCAPE Bio, Inc. Previously, he served as chief financial officer and chief business officer of Chrono Therapeutics Inc. from November 2015 to October 2019. He served as chief financial officer of Aldea Pharmaceuticals, Inc. from December 2014 to July 2015, chief financial officer of Adamas Pharmaceuticals, Inc. (Nasdaq: ADMS) from July 2011 to August 2014 and chief financial officer and vice president of finance of Aerovance, Inc. from November 2007 to March 2011 and April 2005 to November 2007, respectively. Mr. Rimac received his B.A. in business economics—accounting emphasis from the University of California at Santa Barbara and his M.B.A. from Santa Clara University. Mr. Rimac is also a licensed Certified Public Accountant in the State of California (inactive).

On December 28, 2023, Mr. Rimac provided notice of his intent to step down as our Chief Financial Officer effective January 31, 2024. Mr. Rimac resigned for personal reasons and not as a result of any disagreement with us or our independent registered public accountants on any matter relating to our financial or accounting operations, policies or practices. We have retained Stout, a global advisory firm specializing in corporate finance, accounting and transaction advisory services, to provide interim support until we are able to hire a new Chief Financial Officer. Gaeton Biscardi, Managing Director of Stout, will serve as our Interim VP of Finance during this transition period, and Joe Oriti, Director of Stout, will provide his services as a consultant during the period. Contingent on the approval of our board of directors, we intend to appoint Mr. Oriti as our Interim Principal Financial Officer following Mr. Rimac's departure to serve in such role while the board of directors conducts a search of potential candidates to replace Mr. Rimac.

Elizabeth Rozek, Esq. has been our general counsel and chief compliance officer since April 2023. From December 2020 to December 2022, Ms. Rozek served as general counsel and chief compliance officer of Cognoa, Inc., a pediatric behavioral digital health company. From January 2010 to April 2023, she held various positions at Basilea Pharmaceutica International Ltd., a Swiss-listed biopharmaceutical company with global operations developing and commercializing anti-infective and oncology products, including litigation counsel (January 2010 to July 2010), general counsel and corporate secretary (March 2011 to July 2017), advisory external counsel (August 2017 to December 2020), and consultant (December 2020 to April 2023). From 2001 to 2006, Ms. Rozek served as an U.S. Department of Justice civil prosecutor on the team that successfully prosecuted the tobacco industry under RICO. Ms. Rozek received her B.A. in literature from Brown University, M.A. in literature from the University of California at San Diego and J.D. from the University of California at Berkeley.

Key employee and director

George Kemble, Ph.D. has been a director since October 2015 and has served as our executive chairman of the board and overseeing research and development since October 2022. He previously served as our chief executive officer from October 2015 through October 2022, in addition to serving as our chief scientific officer from August 2011 through October 2022. From 2001 through 2011, he held various leadership positions at MedImmune LLC, a biologics company and subsidiary of AstraZeneca PLC beginning in 2007, 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, from 1993 until 2001, he was a research scientist at Aviron Ltd. 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 and 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.

Non-employee directors

Elizabeth Grammer, Esq., has served as a member of our board of directors since April 2021. Since January 2020, Ms. Grammer has served as the chief legal and administrative officer of Ardelyx, Inc. (Nasdaq: ARDX). From May 2014 to January 2020, she served as the general counsel of Ardelyx, Inc. and from December 2012 until May 2014, she served as the vice president of legal affairs of Ardelyx, Inc. 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. In addition, Ms. Grammer previously served as independent outside corporate counsel to GelTex Pharmaceuticals Inc. Ms. Grammer received a B.A. in political science 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. From September 2010 to October 2015, Dr. Parsey served as chief executive officer of our company. Since November 2019, Dr. Parsey has served as executive vice president and chief medical officer at Gilead Sciences, Inc. 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 October 2015 to November 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 assistant professor of medicine and director of critical care medicine at the NYU School of Medicine and has been in clinical development roles at Merck & Co., Inc., Regeneron Pharmaceuticals, Inc. and Sunovion Pharmaceuticals, Inc. (fka Sepracor, Inc.). Dr. Parsey has served on the board of directors of Arcus Biosciences, Inc. (NYSE: RCUS) since July 2020. 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.

Richard Rodgers has served as a member of our board of directors since March 2015. From 2010 to 2013, Mr. Rodgers was co-founder, executive vice president, chief financial officer, secretary, and treasurer of TESARO, Inc., a biopharmaceutical company that was acquired in January 2019 by GSK. From 2009 to 2010, Mr. Rodgers served as the chief financial officer and senior vice president of Abraxis BioScience, Inc., a biotechnology company that was acquired by Celgene. From 2004 to 2008, he served as senior vice president, controller and chief accounting officer of MGI PHARMA, Inc., which was acquired in January 2008 by Eisai Co. Ltd. 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), Novavax, Inc. (Nasdaq: NVAX) 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.

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. Since May 2005, Dr. Seidenberg has been a general partner at Kleiner Perkins Caufield & Byers, LLC, a venture capital firm, 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. In addition, Dr. Seidenberg was a senior executive in research and development at Bristol Myers Squibb Company and Merck & Co., Inc. From February 2008 to September 2019, Dr. Seidenberg served as a director of Epizyme, Inc. (Nasdaq: EPZM). Dr. Seidenberg served on the boards of directors of TESARO, Inc. and ARMO BioSciences, Inc. from June 2011 to February 2019, and December 2012 to June 2018, respectively. 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), Vera Therapeutics, Inc. (Nasdaq: VERA), and Progyny, Inc. (Nasdaq: PGNY), and several privately held life sciences companies. 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.

Jinzi J. Wu, Ph.D. has served as a member of our board of directors since February 2019. In 2013, Dr. Wu founded Ascletis, where he has served as chief executive officer since founding. In 2011, he co-founded

Ascletis Pharmaceuticals (Hangzhou) Co., Ltd., where he has served as chief executive officer since its founding. 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 (NYSE: GSK). From June 2004 to June 2008, Dr. Wu served as a vice president of pre-clinical and basic research at Ambrilia Biopharma, Inc. (formerly known as Procyon), 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., 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. From 1997 to 2000, Dr. Wu served as a senior scientist at Novartis Pharmaceuticals Corporation (NYSE: NVS). Dr. Wu received his B.S. in physiology from Nanjing University in the People's Republic of China, his M.S. 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.

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 seven 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.

Dr. Wu, Dr. Seidenberg,Dr. Kemble and Mr. Rodgers were elected to our board of directors pursuant to the Amended and Restated Voting Agreement we entered into in December 2020 (the Voting Agreement) which terminated upon the closing of our IPO.

On April 15, 2021, we entered into an amended and restated nominating agreement, as amended by Amendment No. 1 to Amended and Restated Nominating Agreement, entered into on June 22, 2023 (the BBA Funds Nominating Agreement), with Baker Brothers Life Sciences L.P. and 667, L.P. (together, the BBA Funds). Pursuant to the BBA Funds Nominating Agreement, at any time at which the BBA Funds, together with their affiliates, collectively beneficially own (i) at least 1,449,543 shares of our Series A common stock and Series B common stock, and (ii) at least 2% of our then-outstanding voting common stock, we would 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 the BBA Funds (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 Nasdaq Stock Market LLC, or other stock exchange on which our shares are listed, or our amended and restated bylaws. On December 21, 2023, the BBA Funds delivered a waiver to the Company under the BBA Funds Nominating Agreement, waiving such right to propose the nomination of the Baker Designee. 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 the BBA Funds (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 the BBA Funds is determined by our board of directors to be a competitor, or other customary conditions. The BBA Funds Nominating Agreement automatically terminates upon the earliest of (i) such time when the BBA Funds together with their affiliates no longer beneficially own at least 1,449,543 shares of our Series A common stock and Series B common stock, (ii) July 18, 2026, 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 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, our board of directors is 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 are divided among the three classes as follows:

- the Class I directors are Jinzi J. Wu, Ph.D. and Richard Rodgers and their terms will expire at the annual meeting of stockholders to be held in 2024;
- the Class II directors are Merdad Parsey, M.D., Ph.D., Elizabeth Grammer, Esq. and Beth Seidenberg, M.D. and their terms will expire at the annual meeting of stockholders to be held in 2025; and
- the Class III directors are David Happel and George Kemble Ph.D. and their terms will expire at the annual meeting of stockholders to be held in 2026.

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., 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 each of Mr. Happel, by virtue of his position as our current chief executive officer, Dr. Kemble, by virtue of his prior position as our former chief executive officer, and Dr. Wu, by virtue of his executive officer role at Ascletis, are not independent under applicable rules and regulations of 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 "Certain relationships and related person transactions."

Board leadership structure and board's role in risk oversight

Dr. Kemble is the current executive chairman of our board of directors and Mr. Happel is our current chief executive officer, hence the roles of executive 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 executive chairman 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 second amended and restated bylaws and corporate governance guidelines do not require that our board chair 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 "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 has adopted a written charter that satisfies the application rules and regulation of the SEC and the Nasdaq Listing Rules, which we have posted to our website at www.sagimet.com. Our board of directors may establish other committees as it deems necessary or appropriate from time to time.

Audit committee

Our audit committee consists of Richard Rodgers, Elizabeth Grammer and Beth Seidenberg, 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 Exchange Act. 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;

- reviewing significant existing and emerging cybersecurity risks, including material cybersecurity incidents, the impact on the Company and its stockholders of any significant cybersecurity incident and any disclosure obligations arising from any such incidents;
- 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.

Compensation committee

Our compensation committee consists of Beth Seidenberg, Richard Rodgers and Merdad Parsey. The chair of our compensation committee is Beth Seidenberg. 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, compensation recovery plans, 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.

Nominating and corporate governance committee

Our nominating and corporate governance committee consists of Elizabeth Grammer and Merdad Parsey. The chair of our nominating and corporate governance committee is Merdad Parsey. 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.

Code of business conduct and ethics

We have adopted 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 is posted on our website at sagimet.com. We intend to disclose on our website any 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 in summary form information concerning the compensation that we paid or awarded during the year ended December 31, 2023 to each of our non-employee directors who served on our board of directors during 2023. No equity awards were granted to our non-employee directors during 2023. Mr. Happel, our president and chief executive officer, did not receive any additional compensation from us for his service as a director. The compensation of Mr. Happel as a named executive officer is described below in the section entitled "Executive Compensation—2023 summary compensation table."

2023 non-employee director compensation

Name	Fees Earned or Paid in Cash ($)	Total ($)
Elizabeth Grammer[1]	43,000	43,000
Merdad Parsey, M.D., Ph.D[2] .	41,500	41,500
Gordon Ringold, Ph.D[3]	31,413	31,413
Richard Rodgers[4]	45,000	45,000
Beth Seidenberg, M.D.[5]	14,375	14,375
James F. Young, Ph.D.[6]	31,413	31,413
Jinzi J. Wu, Ph.D.[7]	—	—

(1) As of December 31, 2023, Ms. Grammer held 49,533 unexercised stock options.

(2) As of December 31, 2023, Dr. Parsey held 98,661 unexercised stock options.

(3) As of December 31, 2023, Dr. Ringold held 48,901 unexercised stock options. Dr. Ringold resigned from our board of directors in July 2023.

(4) As of December 31, 2023, Mr. Rodgers held 49,031 unexercised stock options.

(5) As of December 31, 2023, Dr. Seidenberg held 23,216 unexercised stock options.

(6) As of December 31, 2023, Dr. Young held 48,901 unexercised stock options. Dr. Young resigned from our board of directors in July 2023.

(7) As of December 31, 2023, Dr. Wu held 23,216 unexercised stock options. Payments to Dr. Wu for his services as a director in 2023 will be made in 2024.

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.

Non-employee director compensation policy

Our board of directors has adopted a non-employee director compensation policy. The policy is designed to enable us to attract and retain, on a long-term basis, highly qualified non-employee directors. Under the policy, our non-employee directors are eligible to receive cash retainers (which will be payable quarterly in arrears and prorated for partial years of service) and equity awards as set forth below, provided that our non-employee directors may opt to receive their cash retainers in fully vested shares of our Series A common stock:

Annual retainer for board membership

$40,000 for general availability and participation in meetings and conference calls of our board of directors

Additional annual retainer for committee membership

Audit Committee Chairperson:	$15,000
Audit Committee member (other than Chairperson):	$ 7,500
Compensation Committee Chairperson:	$10,000
Compensation Committee member (other than Chairperson):	$ 5,000
Nominating and Corporate Governance Committee Chairperson:	$10,000
Nominating and Corporate Governance Committee member (other than Chairperson):	$ 4,500
Additional retainer for non-executive Chairperson of the board:	$30,000

In addition, the non-employee director compensation policy provides that, upon initial election or appointment to our board of directors, each non-employee director will be granted an equity award consisting of a stock option grant with a fair value of $300,000 (Initial Grant). The Initial Grant will vest in equal monthly installments over three years following the grant date, subject to continued service through the applicable vesting date. Furthermore, on the date of each annual meeting of stockholders, each non-employee director will be granted an annual equity award with a fair value of $180,000 (Annual Grant). The Annual Grant will vest in equal monthly installments over one year following the grant date, subject to continued service through the applicable vesting date. If a non-employee director joins our board of directors on a date other than the date of the annual meeting of stockholders, then such non-employee director will be granted a prorated portion of the Annual Grant corresponding to such partial year of service at the next annual meeting of stockholders. The Initial Grant and the Annual Grant are subject to full accelerated vesting upon the sale of the company.

The aggregate amount of compensation, including both equity compensation and cash compensation, paid to any non-employee director for service as a non-employee director in a calendar year period will not exceed $750,000 in the first calendar year such individual becomes a non-employee director and $500,000 in any other calendar year.

We reimburse all reasonable out-of-pocket expenses incurred by directors for their attendance at meetings of our board of directors or any committee thereof.

EXECUTIVE COMPENSATION

The following discussion contains forward-looking statements that are based on our current plans and expectations regarding our future compensation programs. The actual amount and form of compensation that we pay and the compensation policies and practices that we adopt in the future may differ materially from the currently-planned programs that are summarized in this discussion.

The compensation provided to our named executive officers for the year ended December 31, 2023 is detailed in the 2023 summary compensation table and accompanying footnotes and narrative that follow. Our named executive officers for the year ended December 31, 2023 are:

- David Happel, President, chief executive officer and director;
- George Kemble, Ph.D., executive chairman and former president, chief executive officer and chief scientific officer;
- Eduardo Bruno Martins, M.D., D.Phil., chief medical officer; and
- Dennis Hom, former chief financial officer.

2023 summary compensation table

The following table presents all the compensation awarded to, earned by or paid to our named executive officers during the fiscal year ended December 31, 2023.

Name and Principal Position	Year	Salary ($)[1]	Stock Awards ($)[2]	Option Awards ($)[3]	Non-Equity Incentive Plan Compensation ($)[4]	All Other Compensation ($)[5]	Total ($)
David Happel	2023	502,894	1,849,734	—		3,564	2,356,192
President and chief executive officer	2022	97,917	—	6,198,479	211,500[6]	297	6,508,193
George Kemble, Ph.D	2023	458,630	446,220	—		25,373[7]	930,223
Executive chairman and former president, chief executive officer and chief scientific officer[8]	2022	404,856[9]	—	129,713	—	40,297[10]	574,866
Eduardo Bruno Martins, M.D., D.Phil.,	2023	442,930	265,127	594,620		3,564	1,306,241
Chief medical officer	2022	411,083	—	—	125,750	297	537,130
Dennis Hom	2023	226,069	—	—		519,438[11]	745,507
Former chief financial officer[12]	2022	357,473	—	—	109,351	68	466,892

(1) The amounts reported for 2023 reflect annual salary adjustments that were made during 2023. For more information, see "Annual base salary" below.

(2) The amounts reported represent the aggregate grant date fair value of the restricted stock units granted to our named executive officers during 2023, calculated in accordance with FASB ASC Topic 718. Such grant date fair values do not take into account any estimated forfeitures. The assumptions used in calculating the grant date fair values of the restricted stock units reported in this column are set forth in note 10 of our financial statements included elsewhere in this prospectus. These amounts reported in this column reflect the accounting cost for these restricted stock units and do not correspond to the economic value that may be received by our named executive officers upon vesting and settlement of such awards or any sale of the shares of our Series A common stock received.

(3) The amounts reported represent the aggregate grant date fair value of the stock options granted to our named executive officers in the applicable year, calculated in accordance with FASB ASC Topic 718. Such grant date fair values do not take into account any estimated forfeitures. The assumptions used in calculating the grant date fair values of the stock options reported in this column are set forth in note 10 of our financial statements included elsewhere in this prospectus. These amounts reported in this column reflect the accounting cost for these stock options and do not correspond to the economic

value that may be received by our named executive officers upon the exercise of such awards or any sale of the underlying shares of our Series A common stock.

(4) The amounts reported reflect performance-based cash bonus payments awarded based on the achievement of certain corporate performance goals. All of the bonuses earned by our named executive officers in 2022 were paid in cash in 2023. Bonus payments for our named executive officers for 2023 have not yet been determined as of the date of this prospectus. Once approved, which is expected to occur in late January 2024, these results will be disclosed on a Form 8-K.

(5) The amounts reported include life insurance premium payments made in 2022 for Mr. Happel, Dr. Kemble, Dr. Martins and Mr. Hom in the amount of $297, $297, $297 and $68, respectively. Life insurance premium payments were also made in 2023 for Mr. Happel, Dr. Kemble, Dr. Martins and Mr. Hom in the amount of $3,564, $3,564, $3,564 and $473, respectively.

(6) In 2022, Mr. Happel was awarded a full bonus that was not prorated.

(7) Amount reflects payment for Dr. Kemble's services as a director in 2023, prior to our IPO, in the amount of $21,809, and a life insurance premium payment described in note 5 above.

(8) Dr. Kemble resigned from his roles as president, chief executive officer and chief scientific officer in October 2022 to become executive chairman.

(9) Dr. Kemble's 2022 salary reflects a downward adjustment in connection with his resignation from his position as president and chief executive officer and transition to executive chairman in October 2022.

(10) Amount reflects director fees that Dr. Kemble received in connection with serving as our executive chairman beginning in October 2022 and a life insurance premium payment described in note 5 above.

(11) Amount reflects payments made in 2023 pursuant to Mr. Hom's transition services agreement, including retention payments in the amounts of $131,171 and $196,757, a separation payment in the amount of $187,387, and COBRA premium payments in the amount of $3,650. This amount also includes a life insurance premium payment described in note 5 above. For more information regarding Mr. Hom's transition services agreement, see "Employment arrangements" below.

(12) Mr. Hom's employment terminated in September 2023. For more information, see "Employment arrangements" below.

Narrative to the summary compensation table

Our compensation committee reviews and approves compensation annually for all employees, including our named executive officers, with the exception of our chief executive officer. The compensation committee reviews and recommends the chief executive officer's compensation to the board of directors for approval. 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.

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 2023 annual base salaries in effect on January 1, 2023 for Mr. Happel, Dr. Kemble, Dr. Martins, and Mr. Hom were $470,000, $393,588, $414,000 and $360,360, respectively. The 2023 annual base salaries for Dr. Martins and Mr. Hom were increased on February 1, 2023 to $430,560 and $374,774, respectively. The 2023 annual base salaries for Mr. Happel, Dr. Kemble, and Dr. Martins were increased to $545,000, $489,000 and $451,000, respectively, following our IPO. Beginning in August 2023 and pursuant to the

terms of his transition services agreement, Mr. Hom received $1,442 per week through September 15, 2023 in lieu of his annual base salary. See below for additional information regarding our transition services agreement with Mr. Hom.

Performance bonuses

During the year ended December 31, 2023, our named executive officers were each eligible to earn an annual bonus based on the achievement of certain individual objectives and company performance objectives. For the fiscal year ended December 31, 2023, the target annual bonuses for Mr. Happel and Dr. Martins were 55% and 40%, respectively. Dr. Kemble is not entitled to receive a cash bonus, but may receive cash incentive compensation as determined by the board of directors or compensation committee from time to time. Mr. Hom is not entitled to receive an annual bonus for 2023 pursuant to the terms of his separation agreement. Bonus payments for our named executive officers for 2023 have not yet been determined as of the date of this prospectus.

Equity compensation

We believe that equity awards provide our executive officers with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executives and stockholders. In addition, we believe that equity awards with a time-based vesting feature promote executive retention because this feature incentivizes our executive officers to remain in our employment during the applicable vesting period. Accordingly, our board of directors periodically reviews the equity incentive compensation of our named executive officers and from time to time may grant equity incentive awards to them. In 2023, we granted options and restricted stock units to our named executive officers with the aggregate grant date fair values set forth in the 2023 summary compensation table above.

On April 20, 2023, we granted Dr. Martins an option to purchase 44,009 shares of our common stock at an exercise price of $13.51 per share. The option vests in equal monthly installments over the course of 48 months, subject to Dr. Martin's continued employment with us. Following our IPO, after an analysis and assessment of our executive compensation program and potential adjustments as a result of becoming a public company, on November 17, 2023, we granted restricted stock units to Mr. Happel, Dr. Martins and Dr. Kemble in the amounts of 624,910, 89,570 and 150,750, respectively. The restricted stock units will vest 25% on July 18, 2024, with the remaining 75% vesting in equal annual installments for the three years thereafter, subject to each executive's continued employment with us through each such date. These awards are described in more detail in the "Outstanding equity awards as of December 31, 2023" table.

Outstanding equity awards as of December 31, 2023

The following table presents the outstanding equity awards held by each named executive officer as of December 31, 2023:

	Option Awards[1]					Stock Awards	
	Grant Date[2]	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price Per Share ($)[3]	Option Expiration Date	Number of shares or units of stock that have not vested (#)	Market value of shares or units of stock that have not vested ($)[4]
David Happel	10/17/2022[5]	295,119	716,707	$ 7.15	10/16/2032		
	11/17/23[6]					624,910	$3,387,012
George Kemble Ph.D.	3/13/2014[5]	3,179	—	$11.13	3/12/2024		
	12/17/2014[5]	7,146	—	$23.05	12/16/2024		
	10/13/2015[5]	26,352	—	$19.87	10/12/2025		
	4/28/2019[7]	367,824	—	$ 6.36	4/27/2029		
	4/28/2019[8]	46,432	—	$ 6.36	4/27/2029		
	1/27/2021[9]	383,788	142,544	$ 6.36	1/26/2031		
	10/17/2022[5]	6,177	14,996	$ 7.15	10/16/2032		
	11/17/23[6]					150,750	$ 817,065
Eduardo Bruno Martins, M.D., D.Phil.	2/19/2021[5]	140,351	57,781	$ 6.36	2/18/2031		
	4/20/2023[9]	7,336	36,673	$13.51	4/20/2033		
	11/17/23[6]					89,570	$ 485,469
Dennis Hom	4/28/2019[10]	111,438	—	$ 6.36	9/15/2024		
	4/28/2019[10]	9,285	—	$ 6.36	9/15/2024		
	1/27/2021[10]	136,846	—	$ 6.36	9/15/2024		

(1) All of the options were granted under either the 2007 Plan or the 2017 Plan, the terms of which are described below under "Executive Compensation—Equity benefit plans—2007 equity incentive plan" and "Executive Compensation—Equity benefit plans—2017 equity incentive plan."

(2) Except where otherwise noted, if within the twelve-month period that immediately follows a change of control (as defined in the named executive officer's employment agreement) the named executive officer's employment is terminated without cause or the named executive officer resigns for good reason (as defined in the named executive officer's employment agreement), then 100% of the award shall accelerate and become fully vested as of the termination date.

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

(4) The market value is based on the closing stock price of $5.42 on December 29, 2023 (the last trading date in the 2023 fiscal year).

(5) 25% of the shares subject to the option vest one year after the vesting commencement date and 1/48th of the shares subject to the option vest monthly thereafter subject to the named executive officer's continued service to the company through each vesting date.

(6) The restricted stock units vest in four equal annual installments beginning July 18, 2024, subject to the named executive officer's continued service to the company through each vesting date.

(7) 50% of the shares subject to the option vest upon the vesting commencement date and 1/24th of the shares subject to the option vest monthly thereafter subject to the named executive officer's continued service to the company through each vesting date.

(8) 1/24th of the shares subject to the option vest monthly following the vesting commencement date, subject to the named executive officer's continued service to the company through each vesting date.

(9) 1/48th of the shares subject to the option vest monthly following the vesting commencement date, subject to the named executive officer's continued service through each vesting date.

(10) The vesting of the options was accelerated such that all unvested portions of the options became vested as of Mr. Hom's September 15, 2023 termination date.

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(a) 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 pre-tax 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. 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 the date of this prospectus.

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 arrangements

We entered into new employment agreements with our named executive officers in connection in connection with our IPO providing for base salary, cash incentives, equity incentives, severance, and certain other benefits and payments. Below are descriptions of our executive employment agreements and other agreements with our named executive officers.

Mr. Happel. In October 2022, we entered into an offer letter with Mr. Happel (the Happel Letter). The Happel Letter provided for at-will employment, an initial base salary of $470,000, a discretionary annual target bonus opportunity equal to 45% of base salary, eligibility for an initial stock option award to purchase 1,011,826 shares of our Series A common stock, and eligibility to receive an additional stock option grant upon the closing of a qualified financing to purchase that number of shares sufficient to bring Mr. Happel's aggregate holdings up to 5% of our fully diluted shares at such time. Each option grant was subject to board approval and has or will have an exercise price equal to the fair market value of our Series A common stock on the grant date. If Mr. Happel experienced a qualifying termination (as defined in the Happel Letter), he was entitled to (i) 12 months of salary continuation payments, and (ii) COBRA continuation coverage for up to 12 months. In addition, if Mr. Happel experienced a qualifying termination upon or within the 12-month period that immediately follows a change of control (as defined in the Happel Letter), then 100% of his initial stock option would have accelerated and would become fully vested as of the termination date. These severance and equity acceleration benefits were conditioned upon Mr. Happel continuing to comply with his obligations under the Happel Letter and his delivery of a general release of claims.

On August 15, 2023, we entered into an employment agreement with David Happel, which was effective as of July 19, 2023 (the Happel Employment Agreement), memorializing the terms of his continued employment as Chief Executive Officer of the Company, and which supersedes the Happel Letter. The Happel Employment Agreement has an initial three-year term, subject to automatic renewal for additional one-year periods, unless either party gives written notice of termination to the other party and subject to earlier termination in accordance with the terms of the Happel Employment Agreement. The payments and benefits to which Mr. Happel is entitled under the Happel Employment Agreement include: (i) an annual base salary of $545,000; (ii) a target annual bonus opportunity equal to 55% of base salary; and (iii) participation in our employee benefit plans that are generally available to Company employees.

Pursuant to the Happel Employment Agreement, if we terminate Mr. Happel's employment without "cause" or Mr. Happel resigns for "good reason" (each, as defined in the Happel Employment Agreement)

outside of the Change in Control Period (as defined below), Mr. Happel will be entitled to the following severance benefits (in addition to certain accrued but unpaid amounts), subject to his execution of a general release of claims in favor of the Company: (i) a lump sum cash payment equal to 12 months of Mr. Happel's base salary and (ii) the payment by us of premiums for up to 12 months of COBRA coverage substantially similar to that provided under our health plan, provided that Mr. Happel properly elects such coverage. In addition, pursuant to the terms of the Happel Employment Agreement, if we terminate Mr. Happel's employment without "cause" or Mr. Happel resigns for "good reason" during the Change in Control Period, Mr. Happel will receive, subject to his execution of a general release of claims in favor of the Company, (i) a lump sum cash payment equal to 18 months of Mr. Happel's base salary, (ii) a pro-rated portion of Mr. Happel's target bonus for the year of termination (or, if higher, Mr. Happel's target bonus in effect immediately prior to the "change in control" (as defined in the Happel Employment Agreement)), (iii) the payment by us of premiums for up to 18 months of COBRA coverage substantially similar to that provided under our health plan, provided that Mr. Happel properly elects such coverage, (iv) 100% vesting acceleration of all of Mr. Happel's then-unvested equity awards (with any performance-based vesting deemed achieved and vested at target levels), and (v) an extension of the period of time (to a maximum of 12 months) following termination during which all of Mr. Happel's outstanding stock option awards may be exercised, to the extent vested as of the date of termination (including any awards that accelerate and vest in connection with his termination). The "Change in Control Period" is the date of a "change in control" and ending 12 months following the date of such "change in control."

Dr. Kemble. In October 2022, we entered into an amended and restated offer letter with Dr. Kemble (the Kemble Letter). The Kemble Letter provided for at-will employment, provided, however, that Dr. Kemble serve in his role as executive chairman until the earliest of (i) the completion of the end of the Phase 2 meeting with the FDA for FASCINATE-2; (ii) the consummation of a change of control (as defined in the Kemble Letter), or (iii) the board's approval and execution of an employment agreement as chief scientific officer (collectively, the Expected Events). The Kemble Letter provided an initial annual base salary of $393,588 and eligibility for an initial stock option to purchase 21,173 shares of our Series A common stock at an exercise price based on the fair market value of our Series A common stock on the grant date, subject to board approval. The Kemble Letter also provided for a $40,000 annual payment to Dr. Kemble in respect of his services on our board. If Dr. Kemble's employment was terminated without cause (as defined in the Kemble Letter), excluding termination upon the occurrence of an Expected Event 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 was entitled to (i) six months of salary continuation payments, and (ii) COBRA continuation coverage for up to six months. These severance benefits were conditioned upon Dr. Kemble's delivery of a general release of claims, resignation, as applicable, from all positions, and delivery of all property and confidential information in Dr. Kemble's possession (the Severance Conditions). Further, if Dr. Kemble's employment was terminated without cause or he was constructively terminated (as defined in the Kemble Letter) upon or within the 12-month period that immediately follows a change of control, in addition to the severance benefits provided above, 100% of all of his outstanding stock options and equity awards would have accelerated and would become fully vested as of the termination date, and any options would remain exercisable for a period of 12 months following such termination, subject to Dr. Kemble's compliance with the Severance Conditions and his obligations under his proprietary information assignment agreement.

On August 15, 2023, we entered into an employment agreement with George Kemble, which was effective as of July 19, 2023 (the Kemble Employment Agreement), memorializing the terms of his continued employment as Executive Chairman of the Company, and which supersedes the Kemble Letter. The Kemble Employment Agreement has an initial three-year term, subject to automatic renewal for additional one-year periods, unless either party gives written notice of nonrenewal to the other party and subject to earlier termination in accordance with the terms of the Kemble Employment Agreement. The payments and benefits to which Dr. Kemble is entitled under the Kemble Employment Agreement include: (i) an annual base salary of $489,000; (ii) participation in our employee benefit plans that are generally available to Company employees; and (iii) eligibility to receive annual cash incentive awards that may be approved by the Compensation Committee or the board of directors. Pursuant to the Kemble Employment Agreement, Dr. Kemble also continues to serve as the chair of our board of directors.

Pursuant to the Kemble Employment Agreement, if we terminate Dr. Kemble's employment without "cause" or Dr. Kemble resigns for "good reason" (each, as defined in the Kemble Employment Agreement) outside of the Change in Control Period (as defined below), Dr. Kemble will be entitled to the following severance benefits (in addition to certain accrued but unpaid amounts), subject to his execution of a general release of claims in favor of the Company: (i) a lump sum cash payment equal to six months of Dr. Kemble's base salary and (ii) the payment by us of premiums for up to six months of COBRA coverage substantially similar to that provided under our health plan, provided that Dr. Kemble properly elects such coverage. In addition, pursuant to the terms of the Kemble Employment Agreement, if we terminate Dr. Kemble's employment without "cause" or Dr. Kemble resigns for "good reason" during the Change in Control Period, Dr. Kemble will receive, subject to his execution of a general release of claims in favor of the Company, (i) a lump sum cash payment equal to 12 months of Dr. Kemble's base salary, (ii) the payment by us of premiums for up to 12 months of COBRA coverage substantially similar to that provided under our health plan, provided that Dr. Kemble properly elects such coverage, (iii) 100% vesting acceleration of all of Dr. Kemble's then-unvested equity awards (with any performance-based vesting deemed achieved and vested at target levels), and (iv) an extension of the period of time (to a maximum of 12 months) following termination during which all of Dr. Kemble's outstanding stock option awards may be exercised, to the extent vested as of the date of termination (including any awards that accelerate and vest in connection with his termination). The "Change in Control Period" is the date of a "change in control" (as defined in the Kemble Employment Agreement) and ending 12 months following the date of such "change in control."

Dr. Martins. In February 2021, we entered into an offer letter with Dr. Martins (the Martins Letter). The Martins Letter provided for at-will employment, an annual base salary of $400,000, a discretionary annual target bonus opportunity equal to 35% of base salary, and eligibility for an initial stock option grant to purchase 198,132 shares of our Series A common stock at an exercise price based on the fair market value of our Series A common stock on the grant date, subject to board approval. If Dr. Martins experienced a qualifying termination (as defined in the Martins Letter), then in addition to any amounts accrued and payable under the terms of our benefit plans through the date of termination, Dr. Martins was entitled to (i) six months of salary continuation payments, and (ii) COBRA continuation coverage for up to six months. Further, if Dr. Martins experienced a qualifying termination (as defined in the Martins Letter) upon or within the 12-month period that immediately follows a change of control (as defined in the Martins Letter), then 100% of his initial stock option would have accelerated and would become fully vested as of the termination date. These severance and equity acceleration benefits were conditioned upon Dr. Martins continuing to comply with his obligations under the Martins Letter and his delivery of a general release of claims in favor of us.

On August 15, 2023, we entered into an employment agreement with Eduardo Martins, which was effective as of July 19, 2023 (the Martins Employment Agreement) memorializing the terms of his continued employment as Chief Medical Officer of the Company, and which supersedes the Martins Letter. The Martins Employment Agreement has an initial three-year term, subject to automatic renewal for additional one-year periods, unless either party gives written notice of termination to the other party and subject to earlier termination in accordance with the terms of the Martins Employment Agreement. The payments and benefits to which Dr. Martins is entitled under the Martins Employment Agreement include: (i) an annual base salary of $461,000; (ii) a target annual bonus opportunity equal to 40% of base salary; and (iii) participation in our employee benefit plans that are generally available to Company employees.

Pursuant to the Martins Employment Agreement, if we terminate Dr. Martins' employment without "cause" or Dr. Martins resigns for "good reason" (each, as defined in the Martins Employment Agreement) outside of the Change in Control Period (as defined below), Dr. Martins will be entitled to the following severance benefits (in addition to certain accrued but unpaid amounts), subject to his execution of a general release of claims in favor of the Company: (i) a lump sum cash payment equal to six months of Dr. Martins' base salary and (ii) the payment by us of premiums for up to six months of COBRA coverage substantially similar to that provided under our health plan, provided Dr. Martins properly elects such coverage. In addition, pursuant to the terms of the Martins Employment Agreement, if we terminate Dr. Martins' employment without "cause" or Dr. Martins resigns for "good reason" during the Change in Control Period, Dr. Martins will receive, subject to his execution of a general release of claims in favor of the Company, (i) a lump sum cash payment equal to 12 months of Dr. Martins' base salary, (ii) a pro-rated portion of Dr. Martins' target bonus for the year of termination (or, if higher, Dr. Martins' target bonus in effect

immediately prior to the "change in control" (as defined in the Martins Employment Agreement)), (iii) the payment by us of premiums for up to 12 months of COBRA coverage substantially similar to that provided under our health plan, provided Dr. Martins properly elects such coverage, (iv) 100% vesting acceleration of all of Dr. Martins' then-unvested equity awards (with any performance-based vesting deemed achieved and vested at target levels), and (v) an extension of the period of time (to a maximum of 12 months) following termination during which all of Dr. Martins' outstanding stock option awards may be exercised, to the extent vested as of the date of termination (including any awards that accelerate and vest in connection with his termination). The "Change in Control Period" is the date of a "change in control" and ending 12 months following the date of such "change in control."

Mr. Hom. In January 2019, we entered into an amended and restated employment agreement with Mr. Hom that governed the terms of Mr. Hom's employment with us (the Hom Agreement). The Hom Agreement provided for at-will employment, an initial annual base salary of $315,000, an annual target bonus opportunity equal to 30% of base salary, and eligibility for an initial stock option grant to purchase that number of shares that would represent 1.2% of our fully diluted shares following our Series E financing at an exercise price based on the fair market value of our Series A common stock on the grant date, subject to board approval. If Mr. Hom's employment terminated without cause (as defined in the Hom Agreement), 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 was entitled to (i) six months of salary continuation payments, and (ii) COBRA continuation coverage for up to six months. Further, if within the 12-month period that immediately follows a change of control (as defined in the Hom Agreement) Mr. Hom's employment terminated without cause or he was constructively terminated (as defined in the Hom Agreement), then 100% of all of his outstanding stock options and equity awards would accelerate and become fully vested as of the termination date, and any options would remain exercisable for a period of 12 months following such termination. These severance and equity accelerations benefits were conditioned upon Mr. Hom's delivery of a general release of claims, resignation from all positions, and delivery to us of all property and confidential information in Mr. Hom's possession.

In April 2023, we entered into a transition services agreement with Mr. Hom, which was amended in June 2023. Pursuant to the terms of the transition services agreement, as amended, Mr. Hom served as our chief financial officer until July 31, 2023. Following July 31, 2023 through September 15, 2023, Mr. Hom remained employed by us as a part-time, at-will employee and worked approximately eight hours per week and was paid $1,442 per week. Pursuant to the transition services agreement, we also paid for his COBRA premiums, and Mr. Hom received retention payments in the amount of $327,928. We also agreed to provide Mr. Hom with additional separation benefits beyond those he was entitled to in the Hom Agreement. Those additional benefits include accelerating Mr. Hom's options to purchase our common stock to the extent unvested on his termination date and extending the time period for him to exercise his vested options to the later of (i) 12 months following the termination of his employment, or (ii) September 15, 2024.

In September 2023, we entered into a separation agreement and release with Mr. Hom, pursuant to which his employment with the Company terminated effective September 15, 2023. In addition, pursuant to the separation agreement and release, Mr. Hom received (i) a one-time lump sum payment in the amount of $187,387, (ii) monthly payments by us of premiums for up to six months of COBRA coverage, (iii) accelerated vesting of Mr. Hom's unvested stock options, and (iv) an extended time period for him to exercise his vested options to the later of 12 months following the termination of his employment, or September 15, 2024.

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 plans, in each case on the same basis as all of our other employees. We pay the premiums for the medical, disability and 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.

Equity benefit plans

2023 stock option and incentive plan

The 2023 Plan was adopted by our board of directors on June 22, 2023, approved by our stockholders on July 4, 2023 and became effective on July 12, 2023. The 2023 Plan replaced the 2017 Plan. The 2023 Plan

provides flexibility to our compensation committee to use various equity-based incentive awards as compensation tools to motivate our workforce.

We have initially reserved 2,585,968 shares of Series A common stock for the issuance of awards under the 2023 Plan, or the Initial Limit. The 2023 Plan provides that the number of shares reserved and available for issuance under the 2023 Plan will automatically increase on January 1, 2024 and each January 1 thereafter, by 4% of the outstanding number of shares of our Series A common stock on the immediately preceding December 31, or such lesser number of shares as determined by our compensation committee, or the Annual Increase. The number of shares reserved under the 2023 Plan is subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization.

The shares issuable under the 2023 Plan are and will be authorized but unissued shares or shares that we reacquire. The shares of Series A common stock underlying any awards under the 2023 Plan that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by us prior to vesting, satisfied without the issuance of stock or are otherwise terminated (other than by exercise) will be added back to the shares of Series A common stock available for issuance under the 2023 Plan.

The maximum aggregate number of shares that may be issued in the form of incentive stock options shall not exceed the Initial Limit, cumulatively increased on January 1, 2024 and on each January 1 thereafter by the lesser of the Annual Increase for such year or shares of Series A common stock.

The grant date fair value of all awards made under the 2023 Plan and all other cash compensation paid by us to any non-employee director in any calendar year for services as a non-employee director shall not exceed $500,000; provided, however, that such amount shall be $750,000 for the calendar year in which the applicable non-employee director is initially elected or appointed to the board of directors.

The 2023 Plan is administered by our compensation committee. Our compensation committee has the full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted and the number of shares subject to such awards, to make any combination of awards to participants, to accelerate at any time the exercisability or vesting of any award, to impose any limitations and/or vesting conditions on each award and to determine the specific terms and conditions of each award, subject to the provisions of the 2023 Plan. Persons eligible to participate in the 2023 Plan are full or part-time officers, employees, non-employee directors and consultants as selected from time to time by our compensation committee in its discretion.

The 2023 Plan permits the granting of both options to purchase Series A common stock intended to qualify as ISOs under Section 422 of the Code and options that do not so qualify. The option exercise price of each option will be determined by our compensation committee but may not be less than 100% of the fair market value of our Series A common stock on the date of grant unless the option is granted (i) pursuant to a transaction described in, and in a manner consistent with, Section 424(a) of the Code or (ii) to individuals who are not subject to U.S. income tax. The term of each option will be fixed by our compensation committee and may not exceed ten years from the date of grant. Our compensation committee will determine at what time or times each option may be exercised.

Our compensation committee may award stock appreciation rights subject to such conditions and restrictions as it may determine. Stock appreciation rights entitle the recipient to shares of Series A common stock, or cash, equal to the value of the appreciation in our stock price over the exercise price. The exercise price of each stock appreciation right may not be less than 100% of the fair market value of our Series A common stock on the date of grant unless the stock appreciation right is granted (i) pursuant to a transaction described in, and in a manner consistent with, Section 424(a) of the Code or (ii) to individuals who are not subject to U.S. income tax. The term of each stock appreciation right will be fixed by our compensation committee and may not exceed ten years from the date of grant. Our compensation committee will determine at what time or times each stock appreciation right may be exercised.

Our compensation committee may award restricted shares of Series A common stock and restricted stock units to participants subject to such conditions and restrictions as it may determine. These conditions and restrictions may include the achievement of certain performance goals and/or continued employment with us through a specified vesting period. Our compensation committee may also grant shares of Series A

common stock that are free from any restrictions under the 2023 Plan. Unrestricted stock may be granted to participants in recognition of past services or for other valid consideration and may be issued in lieu of cash compensation due to such participant.

Our compensation committee may grant dividend equivalent rights to participants that entitle the recipient to receive credits for dividends that would be paid if the recipient had held a specified number of shares of our Series A common stock. Our compensation committee may grant cash bonuses under the 2023 Plan to participants, subject to the achievement of certain performance goals.

The 2023 Plan provides that upon the effectiveness of a "sale event," as defined in the 2023 Plan, an acquirer or successor entity may assume, continue or substitute outstanding awards under the 2023 Plan. To the extent that awards granted under the 2023 Plan are not assumed or continued or substituted by the successor entity, upon the effective time of the sale event, such awards shall terminate. In such case, except as may be otherwise provided in the relevant award certificate, all awards with time-based vesting conditions or restrictions shall become fully vested and exercisable or nonforfeitable as of the effective time of the sale event, and all awards with conditions and restrictions relating to the attainment of performance goals may become vested and exercisable or nonforfeitable in connection with a sale event in the administrator's discretion or to the extent specified in the relevant award certificate. In the event of such termination, individuals holding options and stock appreciation rights (i) may be permitted to exercise such options and stock appreciation rights (to the extent exercisable) within a specified period of time prior to the sale event or (ii) we may make or provide for a payment, in cash or in kind, to participants holding vested and exercisable options and stock appreciation rights equal to the difference between the per share consideration payable to stockholders in the sale event and the exercise price of the options or stock appreciation rights. In addition, we may make or provide for a payment, in cash or in kind, to participants holding other vested awards.

Our board of directors may amend or discontinue the 2023 Plan and our compensation committee may amend or cancel outstanding awards for purposes of satisfying changes in law or any other lawful purpose but no such action may adversely affect rights under an award without the holder's consent. Certain amendments to the 2023 Plan require the approval of our stockholders. The administrator of the 2023 Plan is specifically authorized to exercise its discretion to reduce the exercise price of outstanding stock options and stock appreciation rights or effect the repricing of such awards through cancellation and re-grants without stockholder consent. No awards may be granted under the 2023 Plan after the date that is ten years from the effective date of the 2023 Plan.

2023 employee stock purchase plan

The ESPP was adopted by our board of directors on June 22, 2023, approved by our stockholders on July 4, 2023 and became effective on July 12, 2023. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Code. The ESPP initially reserved and authorized the issuance of up to a total of 215,497 shares of Series A common stock to participating employees. The ESPP provides that the number of shares reserved and available for issuance will automatically increase on January 1, 2024 and each January 1 thereafter through January 1, 2033, by the least of (i) 215,497 shares of Series A common stock, (ii) 1% of the outstanding number of shares of our Series A common stock on the immediately preceding December 31 or (iii) such lesser number of shares of Series A common stock as determined by the administrator of the ESPP. The number of shares reserved under the ESPP will be subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization.

All employees will be eligible to participate in the ESPP. However, any employee who owns 5% or more of the total combined voting power or value of all classes of stock will not be eligible to purchase shares under the ESPP.

We may make one or more offerings each year to our employees to purchase shares under the ESPP. Offerings will usually begin on each May 1 and November 1 and will continue for six-month periods, referred to as offering periods. Each eligible employee will be able to elect to participate in any offering by submitting an enrollment form at least 15 business days before the relevant offering date.

Each employee who is a participant in the ESPP will be able to purchase shares by authorizing payroll deductions of up to 15% of his or her eligible compensation during an offering period. Unless the participating

employee has previously withdrawn from the offering, his or her accumulated payroll deductions will be used to purchase shares of Series A common stock on the last business day of the offering period at a price equal to 85% of the fair market value of the shares on the first business day or the last business day of the offering period, whichever is lower, provided that no more than a number of shares of Series A common stock determined by dividing $25,000 by the fair market value of the Series A common stock on the first day of the offering may be purchased by any one employee during any offering period. Under applicable tax rules, an employee may purchase no more than $25,000 worth of shares of Series A common stock, valued at the start of the purchase period, under the ESPP in any calendar year.

The accumulated payroll deductions of any employee who is not a participant on the last day of an offering period will be refunded. An employee's rights under the ESPP will terminate upon voluntary withdrawal from the plan or when the employee ceases employment with us for any reason.

The ESPP may be terminated or amended by our board of directors at any time. An amendment that increases the number of shares of Series A common stock authorized under the ESPP and certain other amendments will require the approval of our stockholders.

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 was the successor to and continuation of the 2007 Plan. The 2017 Plan provided 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 was terminated in July 2023. However, any outstanding awards granted under the 2017 Plan remain outstanding, subject to the terms of the 2017 Plan and award agreements, until such outstanding options are exercised or until any awards terminate or expire by their terms.

Authorized Shares. As of September 30, 2023, options to purchase 3,702,976 shares of Series A common stock were outstanding under the 2017 Plan with a weighted-average exercise price of $7.80 per share.

Plan Administration. Our board or a duly authorized committee of our board administers the 2017 Plan and the awards granted under it. The administrator has the power to modify outstanding awards under the 2017 Plan. The administrator has the authority to reprice any outstanding option with the consent of any adversely affected participant.

Corporate Transactions. The 2017 Plan provides that in the event of certain specified significant corporate transactions, as defined under the 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 the 2017 Plan, awards granted under the 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 the 2017 Plan other than by will, the laws of descent and distribution or as otherwise provided under the 2017 Plan.

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 the 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 September 30, 2023, options to purchase 63,529 shares of Series A common stock were outstanding under the 2007 Plan with a weighted-average exercise price of $19.61 per share.

Plan Administration. Our board or a duly authorized committee of our board administers the 2007 Plan and the awards granted under it. The administrator has the power to modify outstanding awards under the 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. The 2007 Plan provides that in the event of certain specified acquisitions, as defined under the 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 with respect to awards held by participants that did not terminate status as a service provider, the vesting for such awards will be accelerated and the awards 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 the 2007 Plan other than by will, the laws of descent and distribution or as otherwise provided under the 2007 Plan.

Senior executive cash incentive bonus plan

On June 22, 2023, our board of directors adopted the Senior Executive Cash Incentive Bonus Plan (the Bonus Plan). The Bonus Plan provides for cash bonus payments based upon company and individual performance targets established by our compensation committee. The payment targets are related to financial and operational measures or objectives with respect to our company, or one or more of the "Corporate Performance Goals" (as described below), as well as individual performance objectives.

Our compensation committee establishes the Corporate Performance Goals which may include the following: research, pre-clinical, non-clinical, developmental, publication, clinical or regulatory milestones; scientific or technological advances; R&D or manufacturing capabilities; cash flow (including, but not limited to, operating cash flow and free cash flow); revenue; corporate revenue; earnings before interest, taxes, depreciation and amortization; net income (loss) (either before or after interest, taxes, depreciation and/or amortization); changes in the market price of our common stock; economic value-added; acquisitions, licenses, collaborations or strategic transactions; financing or other capital raising transactions; operating income (loss); return on capital, assets, equity, or investment; shareholder returns; return on sales; total shareholder return; gross or net profit levels; productivity; expense efficiency; margins; operating efficiency; satisfaction of, or other achievement metrics relating to, key third parties; working capital; earnings (loss) per share of our common stock; bookings, new bookings or renewals; sales or market shares; number of prescriptions or prescribing physicians; coverage decisions; leadership development, employee retention, and recruiting and other human resources matters; operating income and/or net annual recurring revenue; or any other performance goal selected by the compensation committee, any of which may be measured in absolute terms, as compared to any incremental increase, in terms of growth, or as compared to results of a peer group, against the market as a whole, compared to applicable market indices and/or measured on a pre-tax or post-tax basis.

Each executive officer who is selected to participate in the Bonus Plan will have a target bonus opportunity set for each performance period and may also have a minimum and/or maximum bonus opportunity. The bonus formulas are adopted in each performance period by the compensation committee

and communicated to each executive officer. The Corporate Performance Goals are measured at the end of each performance period after our financial reports have been published. If the Corporate Performance Goals and individual performance objectives are met, payments will be made as soon as practicable following the end of each performance period, but not later than 2½ months after the end of the fiscal year in which such performance period ends. Subject to the rights contained in any agreement between the executive officer and us, an executive officer shall be required to be employed by us on the bonus payment date to be eligible to receive a bonus payment.

Limitations on liability and indemnification

Our amended and restated certificate of incorporation, 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 authorizes us to indemnify our directors, officers, employees and other agents to the fullest extent permitted by Delaware law. Our amended and restated bylaws 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 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 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, executive officers and employees 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 Series 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 material nonpublic information, subject to compliance with the terms of our insider trading policy.

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, 2021 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.

BBA Funds nominating agreement

On April 15, 2021, we entered into an amended and restated nominating agreement with the BBA Funds and on June 22, 2023, we entered into a subsequent amendment. On December 21, 2023, the BBA Funds waived certain rights under the amended and restated nominating agreement. Please see "Management—Composition of our board of directors" for a description of this agreement.

Employment arrangements

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 "Executive Compensation" and "Management—Non-employee director compensation."

Executive Officer and Director Compensation

Please see "Executive Compensation" and "Director Compensation" for information regarding the compensation of our directors and executive officers.

Indemnification agreements

Our amended and restated certificate of incorporation contains provisions limiting the liability of directors and officers, and our amended and restated bylaws 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 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 indemnification agreements with each of our directors and executive officers, which require us to indemnify them. For more information regarding these agreements, see "Executive Compensation—Limitations on liability and indemnification."

Policies and procedures for transactions with related persons

We have adopted a written policy that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of any series 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 series 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 January 1, 2024 by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our Series A common stock, which is our only series of voting capital stock;
- each of our directors;
- each of our 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.

The following table excludes our non-voting Series B common stock. Entities associated with Baker Brothers Life Sciences, L.P. (Baker Brothers) hold all 1,520,490 outstanding shares of Series B common stock. Baker Brothers has the right to convert each share of Series B common stock into one share of Series A common stock at such its election, provided that as a result of such conversion, Baker Brothers would not beneficially own in excess of 4.99% of any series of our securities registered under the Exchange Act, except as expressly provided for in our amended and restated certificate of incorporation.

Applicable percentage ownership before the offering is based on an aggregate of 21,375,402 shares of Series A common stock deemed to be outstanding as of January 1, 2024.

Applicable percentage ownership after the offering is based on 30,375,402 shares of Series A common stock outstanding immediately upon the closing of this offering and assuming no exercise of the underwriters' option to purchase additional shares and no purchase of any shares of Series A common stock in this offering by the beneficial owners identified in the table below.

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 January 1, 2024. 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.

Name of Beneficial Owner	Number of Shares Beneficially Owned Before the Offering		Percentage of Shares Beneficially Owned Before the Offering		Percentage of Shares Beneficially Owned After the Offering	
	Series A Common Stock	Series B Common Stock	Series A Common Stock	Series B Common Stock	Series A Common Stock	Series B Common Stock
Greater than 5% Holders:						
AP11 Limited[1]	1,654,701	—	7.7%	—	5.4%	—
FMR LLC[2]	2,630,160	—	12.3%	—	8.7%	—
KPCB Holdings. Inc., as nominee[3]	1,899,475	—	8.9%	—	6.3%	—
Entities affiliated with New Enterprise Associates 13, Limited Partnership[4]	3,850,275	—	18.0%	—	12.7%	—
SGMT Holdings Limited[5]	1,449,543	—	6.8%	—	4.8%	—
Directors and Named Executive Officers:						
David Happel[6]	339,470	—	1.6%	—	1.1%	—
Dennis Hom[7]	257,569	—	1.2%	—	*	—
Eduardo Bruno Martins, M.D., D.Phil.[8]	157,777	—	*	—	*	—
George Kemble, Ph.D.[9]	869,339	—	3.9%	—	2.8%	—
Elizabeth Grammer, Esq[10]	35,088	—	*	—	*	—
Merdad Parsey, M.D., Ph.D.[11]	65,441	—	*	—	*	—
Richard Rodgers[12]	49,031	—	*	—	*	—
Beth Seidenberg, M.D.[13]	2,054,334	—	9.6%	—	6.8%	—
Jinzi J. Wu, Ph.D.[14]	1,677,917	—	7.8%	—	5.5%	—
All directors and executive officers as a group (10 persons)[15]	5,505,966	—	23.8%	—	17.1%	—

* Represents beneficial ownership of less than 1%.

(1) Based on information provided to the Company, consists of 1,654,701 shares of Series A common 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) Based upon information set forth in the Schedule 13G filed on September 11, 2023, by FMR LLC, consists of 2,630,160 shares of Series A common stock beneficially owned, or that may be deemed to be beneficially owned, by FMR LLC, certain of its subsidiaries and affiliates, and other companies. Abigail P. Johnson is a Director, the Chairman, the Chief Executive Officer and the President of FMR LLC. Members of the Johnson family, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders' voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC. Neither FMR LLC nor Abigail P. Johnson has the sole power to vote or direct the voting of the shares owned directly by the various investment companies registered under the Investment Company Act (Fidelity Funds) advised by Fidelity Management & Research Company (FMR Co), a wholly owned subsidiary of FMR LLC, which power resides with the Fidelity Funds' Boards of Trustees. Fidelity Management & Research Company carries out the voting of the shares under written guidelines established by the Fidelity Funds' Boards of Trustees. The address of FMR LLC is 245 Summer Street, V13H, Boston, Massachusetts 02110.

(3) Based upon information set forth in the Form 4 filed on July 20, 2023, by KPCB PBD Associates, LLC (KPCB PBD Associates), consists of 1,899,475 shares of Series A common stock held by KPCB Pandemic and Bio Defense Fund, LLC (KPCB PBD). All shares are held for convenience in the name of "KPCB Holdings, Inc., as nominee" for the accounts of KPCB PBD. The managing member of KPCB PBD is 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 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) Based upon information set forth in the Form 4 filed on July 20, 2023, by New Enterprise Associates 13, L.P. (NEA 13), consists of 3,850,275 shares of Series A common stock held 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. 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) Based on information provided to the Company, consists of 1,449,543 shares of Series A common 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 Investment Management, Ltd. (HIM) acts as the sole management company of Hillhouse Venture Fund V, L.P. HIM is deemed to be the beneficial owner of, and to control the voting power of, the shares held by SGMT Holdings Limited. The registered address of SGMT Holdings Limited is 89 Nexus Way, Camana Bay, P.O. Box 31106, George Town Grand Cayman KY1-1205, Cayman Islands.

(6) Consists of 2,190 shares of Series A common stock and 337,280 shares of Series A common stock subject to options exercisable within 60 days of January 1, 2024.

(7) Consists of 257,569 shares of Series A common stock subject to options exercisable within 60 days of January 1, 2024.

(8) Consists of 157,777 shares of Series A common stock subject to options exercisable within 60 days of January 1, 2024.

(9) Consists of 5,630 shares of Series A common stock and 863,709 shares of Series A common stock subject to options exercisable within 60 days of January 1, 2024.

(10) Consists of 35,088 shares of Series A common stock subject to options exercisable within 60 days of January 1, 2024.

(11) Consists of 12,794 shares of Series A common stock and 52,647 shares of Series A common stock subject to options exercisable within 60 days of January 1, 2024.

(12) Consists of 49,031 shares of Series A common stock subject to options exercisable within 60 days of January 1, 2024.

(13) Consists of (i) 84,768 shares of Series A common stock held directly by Beth Seidenberg, M.D., (ii) 1,899,475 shares of Series A common stock held by "KPCB Holdings, Inc., as nominee," (iii) 46,875 shares of Series A common stock held by the Seidenberg/Vogel Revocable Trust UA 3/6/03, of which Dr. Seidenberg serves as a trustee and (ii) 23,216 shares of Series A common stock subject to options exercisable within 60 days of January 1, 2024.

(14) Consists of (i) 1,654,701 shares of Series A common stock held by AP11 Limited and (ii) 23,216 shares of Series A common stock subject to options exercisable within 60 days of January 1, 2024.

(15) Consists of (i) 3,706,433 shares of Series A common stock beneficially owned by our current executive

officers and directors and (ii) 1,799,533 shares subject to options exercisable within 60 days of January 1, 2024, all of which are vested as of such date.

Equity Compensation Plan Information

The following table presents aggregate summary information as of December 31, 2023, regarding the common stock that may be issued upon the exercise of options and rights under all of our existing equity compensation plans:

	Column (A)	Column (B)	Column (C)
Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Restricted Stock Units and Other Rights	Weighted Average Exercise Price of Outstanding Options	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column A)
Equity Compensation Plans Approved by Stockholders[1]	4,885,917[2]	$6.14	1,453,558[3]
Equity Compensation Plans Not Approved by Stockholders	—	—	—
Total	4,885,917	$6.14	1,453,558

(1) These plans consist of our 2007 Plan, 2017 Plan, 2023 Plan and our ESPP.

(2) As of December 31, 2023, (i) 1,453,558 shares remained available for future issuance under our 2023 Plan, (ii) and 215,497 shares remained available for future issuance under our ESPP (as of December 31, 2023 we have not commenced any purchase periods associated with our ESPP). No shares remained available for future issuance under the 2007 Plan or 2017 Plan as of December 31, 2023. However, the 2007 Plan and 2017 Plan continue to govern outstanding equity awards granted thereunder. Our 2023 Plan has an evergreen provision that allows for an annual increase in the number of shares available for issuance under the 2023 Plan to be added on the first day of January, starting with January 1, 2024, in an amount equal to the lesser of (i) 4% of the outstanding number of shares of our Series A common stock on the immediately preceding December 31 or (ii) such number of shares as determined by our compensation committee in each case subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization. Our ESPP has an evergreen provision that allows for an annual increase in the number of shares available for issuance under the ESPP to be added on the first day of each January, starting in January 2024, thereafter through January 1, 2033, by the lesser of (i) 215,497 shares of our Series A common stock, (ii) 1% of the outstanding number of shares of Series A common stock on the immediately preceding December 31, or (iii) such number of shares of Series A common stock as determined by the administrator of the ESPP. The number of shares reserved under the ESPP is subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization.

(3) This amount excludes 855,016 shares of common stock that became issuable under the 2023 Plan on January 1, 2024, pursuant to the evergreen provisions of the 2023 Plan.

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. Copies of these documents have been filed with the SEC as exhibits to our registration statement, of which this prospectus forms a part.

Our authorized capital stock consists of 500,000,000 shares of Series A common stock, par value $0.0001 per share, 15,000,000 shares of Series B common stock, par value $0.0001 per share, and 10,000,000 shares of preferred stock, par value $0.0001 per share. All of our authorized shares of preferred stock are undesignated.

As of January 1, 2024, there were 21,375,402 shares of Series A common stock outstanding and 1,520,490 shares of Series B common stock outstanding.

Series A common stock and Series B common stock

Holders of our Series A common stock and our Series 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 Series A common stock are entitled to one vote per share of Series A common stock, and holders of our Series B common stock are not entitled to any votes per share of Series B common stock, including for the election of directors, and (ii) holders of our Series A common stock have no conversion rights, while holders of our Series B common stock have the right to convert each share of our Series B common stock into one share of Series 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 series 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 Series B common stock upon 61 days' notice to us. Our Series A common stock and Series B common stock do not have cumulative voting rights. Accordingly, the holders of a majority of the outstanding shares of Series 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 Series A common stock and Series 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 Series A common stock and Series 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 Series A common stock and Series B common stock have no preemptive rights or other subscription rights and there are no redemption or sinking funds provisions applicable to our Series A common stock and Series B common stock. All outstanding shares of our Series A common stock and Series B common stock are, and the Series A common stock and Series B common stock to be outstanding upon the closing of this offering will be, duly authorized, validly issued, fully paid and nonassessable. The rights, preferences and privileges of holders of our Series A common stock and Series 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

Under our amended and restated certificate of incorporation, our board of directors has the authority, without further action by the stockholders, to issue up to 10,000,000 shares of 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.

The issuance of preferred stock with voting or conversion rights could adversely affect the voting power or other rights of the holders of the Series A common stock or the Series B common stock. The issuance of 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 Series A common stock and Series B common stock and may adversely affect the market price of the Series A common stock and the voting and other rights of the holders of Series A common stock and Series B common stock. We have no current plans to issue any shares of preferred stock.

Stock options

As of September 30, 2023, 3,766,505 shares of Series A common stock were issuable upon the exercise of outstanding stock options at a weighted-average exercise price of $8.11 per share. As of September 30, 2023, 2,585,968 shares of our Series A common stock were reserved for future issuance under the 2023 Plan, as well as any future automatic annual increases in the number of shares of Series A common stock reserved for issuance under the 2023 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 "Executive Compensation—Equity benefit plans."

Warrants

As of September 30, 2023, we had an outstanding warrant to purchase 1,000 shares of Series A common stock. The warrant is exercisable at any time after its issuance date and expires on July 18, 2026. The exercise price is $69.94 per share and the warrant is exercisable in whole or in part in exchange for cash payment of the exercise price.

Registration rights

Certain holders of shares of our Series A common stock and Series B common stock, are 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 Series A 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 all 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 four years after the closing of our IPO.

Demand registration rights

Certain holders of our Series A common stock, including shares issuable upon conversion of our Series B common stock, are entitled to certain demand registration rights. The holders of at least 35% 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.

Piggyback registration rights

Certain holders of our Series A common stock, including shares issuable upon conversion of our Series 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

Certain holders of our Series A common stock, including shares issuable upon conversion of our Series B common stock, are entitled to certain Form S-3 registration rights. Holders of a majority 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 $1 million. We will not be required to effect more than two 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

Because our stockholders do not have cumulative voting rights, stockholders holding a majority of the voting power of our shares of Series A common stock will be able to elect all of our directors. Our amended and restated certificate of incorporation and our amended and restated bylaws provide for stockholder actions at a duly called meeting of stockholders. A special meeting of stockholders may be called by a majority of our board of directors. Our amended and restated bylaws have established 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, our board of directors is divided into three classes with staggered three-year terms.

The foregoing provisions 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

We are 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 bylaws provide that the Court of Chancery of the State of Delaware is the sole and exclusive forum for the following claims or causes of action under the Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of, or a claim based on, a breach of a fiduciary duty owed by any of our current or former directors, officers or other employees or stockholders to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL or our amended and restated certificate of incorporation or amended and restated bylaws (including the interpretation, validity or enforceability thereof) or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware, or (iv) any action asserting a claim governed by the internal affairs doctrine.

However, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all claims brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Consequently, this choice of forum provision does 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. Moreover, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder.

In addition, our amended and restated bylaws 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 bylaws 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 “Executive Compensation—Limitations on liability and indemnification.”

Exchange listing

Our Series A common stock is listed on The Nasdaq Global Market under the symbol “SGMT.”

Transfer agent and registrar

The transfer agent and registrar for our Series A common stock and Series B common stock is American Stock Transfer & Trust Company, LLC. The transfer agent’s address is 6201 15th Avenue, Brooklyn, NY 11219.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES FOR NON-U.S. HOLDERS

The following is a summary of material U.S. federal income tax consequences to non-U.S. holders (as defined below) of the purchase, ownership and disposition of our Series A common stock issued pursuant to this offering. This discussion is not a complete analysis of all potential U.S. 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 U.S. 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 IRS all as in effect on the date hereof. These authorities are subject to differing interpretations and may change, possibly retroactively, resulting in U.S. 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-U.S. holders who purchase our Series A common stock pursuant to this offering and who hold our Series 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 U.S. federal income tax consequences that may be relevant to a non-U.S. holder in light of such non-U.S. holder's particular circumstances. This discussion also does not consider any specific facts or circumstances that may be relevant to non-U.S. holders subject to special rules under the U.S. 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 U.S. federal income tax purposes (and investors therein);
- "controlled foreign corporations";
- "passive foreign investment companies";
- corporations that accumulate earnings to avoid U.S. 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 Series 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 Series A common stock;
- persons that own or have owned, actually or constructively, more than 5% of our Series A common stock;
- persons who have elected to mark securities to market; and
- persons holding our Series 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 U.S. federal income tax purposes holds our Series A common stock, the U.S. 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 Series A common stock and the partners in such

partnerships are urged to consult their tax advisors about the particular U.S. federal income tax consequences to them of holding and disposing of our Series 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 U.S. FEDERAL INCOME TAX CONSEQUENCES TO THEM OF ACQUIRING, OWNING AND DISPOSING OF OUR SERIES A COMMON STOCK, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL OR FOREIGN TAX LAWS AND ANY OTHER U.S. FEDERAL TAX LAWS OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Definition of non-U.S. holder

For purposes of this discussion, a non-U.S. holder is any beneficial owner of our Series A common stock that is not a "U.S. holder" or a partnership (including any entity or arrangement treated as a partnership) for U.S. federal income tax purposes. A U.S. holder is any person that, for U.S. 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 U.S. federal income tax regardless of its source; or
- a trust (1) whose administration is subject to the primary supervision of a U.S. court and which has one or more U.S. 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 U.S. person.

Distributions on our Series A common stock

As described under "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 Series A common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. 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 Series A common stock, but not below zero. Any excess will be treated as gain realized on the sale or other disposition of our Series A common stock and will be treated as described under "Material U.S. federal income tax consequences for non-U.S. holders—Gain on disposition of our Series 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-U.S. holder of our Series A common stock generally will be subject to U.S. 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-U.S. 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 the dividends and must be updated periodically. In the case of a non-U.S. 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-U.S. holder holds our Series A common stock through a financial institution or other agent acting on the non-U.S. holder's behalf, the non-U.S. 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-U.S. holder holds our Series A common stock in connection with the conduct of a trade or business in the United States, and dividends paid on our Series A common stock are effectively connected with such holder's U.S. 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-U.S. holder will be exempt

from U.S. federal withholding tax. To claim the exemption, the non-U.S. 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 Series A common stock generally will be subject to U.S. federal income tax on a net income basis at the regular U.S. federal income tax rates in the same manner as if such holder were a resident of the United States. A non-U.S. 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 dividends, as adjusted for certain items.

Non-U.S. 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-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

Gain on disposition of our Series A common stock

Subject to the discussion below regarding backup withholding and FATCA (as defined below), a non-U.S. holder generally will not be subject to U.S. federal income tax on any gain realized on the sale or other disposition of our Series A common stock, unless:

- the gain is effectively connected with the non-U.S. 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-U.S. holder in the United States;
- the non-U.S. 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 Series 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 U.S. federal income tax purposes at any time within the shorter of the five-year period preceding the disposition or the non-U.S. holder's holding period for our Series A common stock, and our Series 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 U.S. federal income tax on a net income basis at the regular U.S. federal income tax rates in the same manner as if such holder were a resident of the United States. A non-U.S. 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 U.S. 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 U.S.-source capital losses (even though the individual is not considered a resident of the United States), provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses.

Determining whether we are a USRPHC depends on the fair market value of our U.S. 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 U.S. 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-U.S. Holder on a disposition of our Series A common stock will not be subject to U.S. federal income tax so long as (1) the non-U.S. Holder owned, directly, indirectly and constructively, no more than 5% of our Series 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 Series A common stock is regularly traded on an established securities market within the meaning of applicable U.S. Treasury regulations. There can be no assurance that our Series A common stock qualifies as regularly traded on an established securities market. If any gain on a non-U.S. holder's disposition of our Series A common stock is taxable because we are a USRPHC and such holder's ownership of our Series A common stock exceeds 5%, such holder will be taxed on such disposition generally in the manner applicable to U.S. persons and in addition, a purchaser of such holder's Series A common stock may be required to withhold tax with respect to that obligation.

Non-U.S. 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-U.S. holder indicating the amount of distributions on our Series 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 U.S. 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-U.S. holder resides or is established. Backup withholding, currently at a 24% rate, generally will not apply to payments to a non-U.S. holder of dividends on or the gross proceeds of a disposition of our Series A common stock provided the non-U.S. holder furnishes the required certification for its non-U.S. status, such as by providing a valid IRS Form W-8BEN, IRS Form W-8BEN-E or IRS Form W-8ECI, or otherwise establishes an exemption, and if the payor does not have actual knowledge, or reason to know, that the holder is a U.S. 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-U.S. holder should consult with a U.S. tax advisor regarding the possibility of and procedure for obtaining a refund or a credit against the non-U.S. holder's U.S. 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 U.S. 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 U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding certain U.S. 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 U.S. owners) or an exemption applies. FATCA also generally imposes a U.S. federal withholding tax of 30% on certain payments made to a "non-financial foreign entity" (as specially defined under these rules) unless such entity provides the withholding agent a certification that it does not have any "substantial United States owners" or provides information identifying certain direct and indirect U.S. 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-U.S. holder might be eligible for refunds or credits of such taxes. FATCA currently applies to dividends paid on our Series A common stock and would have applied also to payments of gross proceeds from the sale or other disposition of our Series A common stock. However, the U.S. 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 U.S. 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 Series A common stock.

Prospective investors are encouraged to consult with their tax advisors regarding the possible implications of FATCA on their investment in our Series A common stock.

EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS TAX ADVISOR REGARDING THE TAX CONSEQUENCES OF PURCHASING, HOLDING AND DISPOSING OF OUR SERIES 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-U.S. OR U.S. FEDERAL NON-INCOME TAX LAWS.

UNDERWRITING

We and the underwriters named below have entered into an underwriting agreement with respect to the shares being offered. Subject to certain conditions, each underwriter has severally agreed to purchase the number of shares indicated in the following table. Goldman Sachs & Co. LLC, Cowen and Company, LLC and Leerink Partners LLC are the representatives of the underwriters.

Underwriter	Number of Shares
Goldman Sachs & Co. LLC	
Cowen and Company, LLC	
Leerink Partners LLC	
Citizens JMP Securities, LLC	
Total	9,000,000

The underwriters are committed to take and pay for all of the shares being offered, if any are taken, other than the shares covered by the option described below unless and until this option is exercised.

The underwriters have an option to buy up to an additional 1,350,000 shares of our Series A common stock from us to cover sales by the underwriters of a greater number of shares than the total number set forth in the table above. They may exercise that option for 30 days from the date of this prospectus. If any shares are purchased pursuant to this option, the underwriters will severally purchase shares in approximately the same proportion as set forth in the table above.

The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters by us. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase up to an additional 1,350,000 shares of Series A common stock from us.

	No Exercise	Full Exercise
Per Share	$	$
Total	$	$

Shares sold by the underwriters to the public will initially be offered at the public offering price set forth on the cover of this prospectus. Any shares sold by the underwriters to securities dealers may be sold at a discount of up to $ per share from the public offering price. After the initial offering of the shares, the representatives may change the offering price and the other selling terms. The offering of the shares by the underwriters is subject to receipt and acceptance and subject to the underwriters' right to reject any order in whole or in part.

We and our executive officers, directors and certain of our stockholders agreed or will agree with the underwriters, subject to certain exceptions, during the period from the date of this prospectus continuing through the date 90 days after the date of this prospectus with respect to us, 75 days with respect to our executive officers and directors and 30 to 75 days with respect to certain of our stockholders affiliated with our directors (such period, as applicable, the restricted period), except with the prior written consent of Goldman Sachs & Co. LLC, not to (i) offer, sell, contract to sell, pledge, grant any option to purchase, loan, hedge, make any short sale or otherwise transfer or dispose of, directly or indirectly, or file with or confidentially submit to the SEC a registration statement under the Securities Act relating to, any of our securities that are substantially similar to the shares of Series A common stock in this offering, including but not limited to any options or warrants to purchase shares of Series A common stock or any securities that are convertible into or exchangeable for, or that represent the right to receive, Series A common stock or any such substantially similar securities, (ii) enter into any hedging, swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the Series A common stock or any such other securities, whether any such transaction described in clauses (i) or (ii) above is to be settled by delivery of Series A common stock or such other securities, in cash or otherwise (other than the shares of Series A common stock to be sold in this offering or pursuant to employee stock option plans existing on, or upon the conversion or exchange of convertible or exchangeable securities outstanding as of, the date of this prospectus) or (iii) publicly disclose the intention to do any of the foregoing.

The restrictions described above do not apply to us for certain transactions, including (i) the sale of shares by us in this offering; (ii) any shares of Series A common stock issued by us upon the exercise of an option or warrant or the conversion of a security outstanding on the date of this prospectus and as described in this prospectus, (iii) any shares of Series A common stock issued or options to purchase Series A common stock granted pursuant to an employee benefit or equity incentive plans as described in this prospectus, (iv) any shares of Series A common stock issued pursuant to any non-employee director stock plan or dividend reinvestment plan as described in this prospectus, (v) the filing by us of a registration statement on Form S-8 or any successor form thereto with respect to the registration of securities to be offered under any of our employee benefit or equity incentive plans as described in this prospectus; or (vi) shares of Series A common stock or other securities issued in connection with a transaction that includes a commercial relationship (including strategic alliances, commercial lending relationships, joint ventures and strategic acquisitions), provided that (i) the aggregate number of shares issued pursuant to this clause (vi) (on an as-converted or as-exercised basis, as the case may be) shall not exceed five percent (5%) of the total number of outstanding shares of Series A common stock immediately following the issuance and sale of the shares of Series A common stock hereunder and (ii) the recipient of any such shares of Series A common stock or securities issued pursuant to this clause (vi) during such period shall enter into a lock-up agreement with the underwriters.

The restrictions described above do not apply, subject in certain cases to various conditions, to our officers, directors and certain of our stockholders with respect to certain transactions, including:

i. as one or more bona fide gifts or charitable contributions, or for bona fide estate planning purposes;

ii. upon death by will, testamentary document or intestate succession;

iii. if the securityholder is a natural person, to any member of the securityholder's immediate family (for purposes of the lock-up agreement, "immediate family" shall mean any relationship by blood, current or former marriage, domestic partnership or adoption, not more remote than first cousin) or to any trust for the direct or indirect benefit of the securityholder or the immediate family of the securityholder or, if the securityholder is a trust, to a trustor or beneficiary of the trust or the estate of a beneficiary of such trust;

iv. to a corporation, partnership, limited liability company or other entity of which the securityholder and the immediate family of the securityholder are the legal and beneficial owner of all of the outstanding equity securities or similar interests;

v. to a nominee or custodian of a person or entity to whom a disposition or transfer would be permissible under clauses (i) through (iv) above;

vi. if the securityholder is a corporation, partnership, limited liability company or other business entity, (A) to another corporation, partnership, limited liability company or other business entity that is an affiliate (as defined in Rule 405 under the Securities Act) of the securityholder, or to any investment fund or other entity which fund or entity is controlled or managed by the securityholder or affiliates of the securityholder, or (B) as part of a distribution by the securityholder to its stockholders, partners, members or other equityholders or to the estate of any such stockholders, partners, members or other equityholders;

vii. by operation of law, such as pursuant to a qualified domestic order, divorce settlement, divorce decree or separation agreement;

viii. to us from our employee upon death, disability or termination of employment, in each case, of such employee;

ix. if the securityholder is not our officer or director, in connection with a sale of the securityholder's shares of Series A common stock acquired (A) from the underwriters in this offering or (B) in open market transactions after the closing date of this offering;

x. to us in connection with the vesting, settlement or exercise of restricted stock units, options, warrants or other rights to purchase shares of Series A common stock (including, in each case, by

way of "net" or "cashless" exercise), including any transfer to us for the payment of tax withholdings or remittance payments due as a result of the vesting, settlement or exercise of such restricted stock units, options, warrants or other rights, or in connection with the conversion of convertible securities, in all such cases pursuant to equity awards granted under a stock incentive plan or other equity award plan, or pursuant to the terms of convertible securities, each as described in the Registration Statement, the preliminary prospectus relating to the Shares included in the Registration Statement immediately prior to the time the Underwriting Agreement is executed and the Prospectus, provided that any securities received upon such vesting, settlement, exercise or conversion shall be subject to the terms of this Lock-Up Agreement;

xi. otherwise with the prior written consent of Goldman Sachs & Co. LLC on behalf of the underwriters;

xii. transfers to us pursuant to an agreement under which we have the option to repurchase shares or a right of first refusal with respect to transfer of such shares, provided that no filing under the Exchange Act or other public filing, report or announcement shall be voluntarily made, and if any such filing, report or announcement shall be legally required during the restricted period, such filing, report or announcement shall clearly indicate in the footnotes thereto the circumstances of such transfer or distribution;

xiii. entering into a written plan meeting the requirements of Rule 10b5-1 under the Exchange Act relating to the transfer, sale or other disposition of the securityholder's securities, if then permitted by us, provided that none of the securities subject to such plan may be transferred, sold or otherwise disposed of until after the expiration of the restricted period and no public announcement, report or filing under the Exchange Act, or any other public filing, report or announcement, shall be required or shall be voluntarily made regarding the establishment of such plan during the restricted period;

xiv. transfers pursuant to a bona fide third-party tender offer, merger, consolidation or other similar transaction that is approved by our board of directors and made to all holders of our capital stock involving a Change of Control (for purposes hereof, "Change of Control" shall mean the transfer (whether by tender offer, merger, consolidation or other similar transaction), in one transaction or a series of related transactions, to a person or group of affiliated persons, of shares of capital stock if, after such transfer, such person or group of affiliated persons would hold at least a majority of our outstanding voting securities (or the surviving entity)); provided that in the event that such tender offer, merger, consolidation or other similar transaction is not completed, the securityholder's securities shall remain subject to the provisions of the lock-up agreement; and

xv. for certain of our securityholders, create any charge, mortgage, lien, pledge, restriction, security interest or other encumbrance in in connection with the securityholder's (or any of its affiliates') bona fide margin loans entered into by the securityholder or its affiliates in the ordinary course of business, and the transfers in the event of any foreclosures or enforcements by the beneficiary of such transaction following default by the securityholder or any of its affiliates of such margin loans; provided, that any such securities received upon such transfers shall be subject to the restrictions on transfer set forth in the lock-up agreement and that no filing under the Exchange Act or other public announcement shall be required or made voluntarily in connection with such pledge or subsequent foreclosure, enforcement or transfer of such securities (other than a filing on Form 3, Form 4, Form 5 (if applicable), Form 13F, Schedule 13D (or 13D/A) or Schedule 13G (or 13G/A) that is required to be filed during the restricted period, in which case such required filing shall clearly indicate in the footnotes thereto the applicable circumstances that cause the applicable exception to the lock-up agreement to apply;

provided that (A) in the case of clauses (i), (ii), (iii), (iv), (v) and (vi) above, such transfer or distribution shall not involve a disposition for value, (B) in the case of clauses (i), (ii), (iii), (iv), (v), (vi) and (vii) above, it shall be a condition to the transfer or distribution that the donee, devisee, transferee or distributee, as the case may be, shall sign and deliver a lock up agreement, (C) in the case of clauses (i), (ii), (iii), (iv), (v) and (vi) above, no filing by any party (including, without limitation, any donor, donee, devisee, transferor, transferee, distributor or distributee) under the Exchange Act, or other public filing, report or announcement

reporting a reduction in beneficial ownership of the securityholder's holdings shall be required or shall be voluntarily made in connection with such transfer or distribution, and (D) in the case of clauses (vii), (viii), (ix) and (x) above, no filing under the Exchange Act or other public filing, report or announcement shall be voluntarily made, and if any such filing, report or announcement shall be legally required during the restricted period, such filing, report or announcement shall clearly indicate in the footnotes thereto (A) the circumstances of such transfer or distribution and (B) in the case of a transfer or distribution pursuant to clause (vii) above, that the donee, devisee, transferee or distributee has agreed to be bound by a lock-up agreement.

Our Series A common stock is listed on the Nasdaq Global Market under the symbol "SGMT."

In connection with the offering, the underwriters may purchase and sell shares of our Series A common stock in the open market. These transactions may include short sales, stabilizing transactions and purchases to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering, and a short position represents the amount of such sales that have not been covered by subsequent purchases. A "covered short position" is a short position that is not greater than the amount of additional shares for which the underwriters' option described above may be exercised. The underwriters may cover 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 cover 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 additional shares pursuant to the option described above. "Naked" short sales are any short sales that create a short position greater than the amount of additional shares for which the option described above may be exercised. The underwriters must cover any such 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 the Series A 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 Series A 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 them because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Purchases to cover a short position and stabilizing transactions, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of our Series A common stock, and together with the imposition of the penalty bid, may stabilize, maintain or otherwise affect the market price of our Series A common stock. As a result, the price of our Series A common stock may be higher than the price that otherwise might exist in the open market. The underwriters are not required to engage in these activities and may end any of these activities at any time. These transactions may be effected on the Nasdaq Global Market, in the over-the-counter market or otherwise.

We estimate that our share of the total expenses of the offering, excluding underwriting discounts and commissions, will be approximately $0.8 million. We have agreed to reimburse the underwriters for certain of their expenses in an amount up to $25,000.

We have agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial activities and services. Certain of the underwriters and their respective affiliates may in the future provide, a variety of these services to us and to persons and entities with relationships with us, for which they will receive customary fees and expenses. For example, certain of the underwriters also served as underwriters in our initial public offering in July 2023.

In the ordinary course of their various business activities, the underwriters and their respective affiliates, officers, directors and employees may purchase, sell or hold a broad array of investments and actively trade securities, derivatives, loans, commodities, currencies, credit default swaps and other financial instruments for their own account and for the accounts of their customers, and such investment and trading activities may involve or relate to assets, securities and/or instruments of ours (directly, as collateral securing other obligations or otherwise) and/or persons and entities with relationships with us. The underwriters and their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such assets, securities or instruments and may at any time hold, or recommend to clients that they should acquire, long and/or short positions in such assets, securities and instruments.

European Economic Area

In relation to each Member State of the European Economic Area (each a Relevant Member), no shares have been offered or will be offered pursuant to the offering to the public in that Relevant Member prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant Member or, where appropriate, approved in another Relevant Member and notified to the competent authority in that Relevant Member, all in accordance with the Prospectus Regulation, except that the shares may be offered to the public in that Relevant Member at any time:

(a) to any legal entity which is a qualified investor as defined under Article 2 of the Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of 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 the shares shall require us or the representatives to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression an "offer to the public" in relation to the shares in any Relevant Member 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.

United Kingdom

No shares have been offered or will be offered pursuant to the offering to the public in the United Kingdom prior to the publication of a prospectus in relation to the shares which has been approved by the Financial Conduct Authority, except that the shares may be offered to the public in the United Kingdom at any time:

(a) to any legal entity which is a qualified investor as defined under Article 2 of the UK Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the UK Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or

(c) in any other circumstances falling within Section 86 of the FSMA;

provided that no such offer of the shares shall require the Issuer or Manager to publish a prospectus pursuant to Section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation. For the purposes of this provision, the expression an "offer to the public" in relation to the shares in the United Kingdom 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. UK Prospectus Regulation means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018.

Canada

The securities may be sold in Canada 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 securities must be made in accordance with an exemption form, 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 of these rights or consult with a legal advisor.

Pursuant to section 3A.3 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.

Hong Kong

The shares may not be offered or sold in Hong Kong by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32 of the Laws of Hong Kong) ("Companies (Winding Up and Miscellaneous Provisions) Ordinance") or which do not constitute an invitation to the public within the meaning of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong) ("Securities and Futures Ordinance"), or (ii) to "professional investors" as defined in the Securities and Futures Ordinance and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance, and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case 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 in 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" in Hong Kong as defined in the Securities and Futures Ordinance and any rules made thereunder.

Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor (as defined under Section 4A of the Securities and Futures Act, Chapter 289 of Singapore (the "SFA")) under 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, in each case subject to conditions set forth in the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is 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, the securities (as defined in Section 239(1) of the SFA) of that corporation shall not be transferable for six months after that corporation has acquired the shares

under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (2) where such transfer arises from an offer in that corporation's securities pursuant to Section 275(1A) of the SFA, (3) where no consideration is or will be given for the transfer, (4) where the transfer is by operation of law, (5) as specified in Section 276(7) of the SFA, or (6) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore ("Regulation 32").

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a trust (where the trustee is not an accredited investor (as defined in Section 4A of the SFA)) whose sole purpose is to hold investments and each beneficiary of the trust is an accredited investor, the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferable for six months after that trust has acquired the shares under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (2) where such transfer arises from an offer that is made on terms that such rights or interest are acquired at a consideration of not less than $200,000 (or its equivalent in a foreign currency) for each transaction (whether such amount is to be paid for in cash or by exchange of securities or other assets), (3) where no consideration is or will be given for the transfer, (4) where the transfer is by operation of law, (5) as specified in Section 276(7) of the SFA, or (6) as specified in Regulation 32.

Solely for the purposes of its obligations pursuant to Section 309B of the SFA, we have determined, and hereby notify all relevant persons (as defined in the CMP Regulations 2018), that the shares are "prescribed capital markets products" (as defined in the CMP Regulations 2018) and Excluded Investment Products (as defined in MAS Notice SFA 04-N12: Notice on the Sale of Investment Products and MAS Notice FAA-N16: Notice on Recommendations on Investment Products).

Japan

The securities have not been and will not be registered under the Financial Instruments and Exchange Act of Japan (Act No. 25 of 1948, as amended), or the FIEA. The securities may not be offered or sold, directly or indirectly, in Japan or to or for the benefit of any resident of Japan (including any person resident in Japan or any corporation or other entity organized under the laws of Japan) or to others for reoffering or resale, directly or indirectly, in Japan or to or for the benefit of any resident of Japan, except pursuant to an exemption from the registration requirements of the FIEA and otherwise in compliance with any relevant laws and regulations of Japan.

Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission (ASIC), in relation to the offering. This offering document 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 12 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 offering document 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 offering document is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

Dubai International Financial Centre

This offering document relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority (DFSA). This offering document 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 in this prospectus and has no responsibility for the offering document. The securities to which this offering document relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the securities offered should conduct their own due diligence on the securities. If you do not understand the contents of this offering document you should consult an authorized financial advisor.

Switzerland

We have not and will not register with the Swiss Financial Market Supervisory Authority (FINMA) as a foreign collective investment scheme pursuant to Article 119 of the Federal Act on Collective Investment Scheme of 23 June 2006, as amended (CISA), and accordingly the securities being offered pursuant to this prospectus have not and will not be approved, and may not be licenseable, with FINMA. Therefore, the securities have not been authorized for distribution by FINMA as a foreign collective investment scheme pursuant to Article 119 CISA and the securities offered hereby may not be offered to the public (as this term is defined in Article 3 CISA) in or from Switzerland. The securities may solely be offered to "qualified investors," as this term is defined in Article 10 CISA, and in the circumstances set out in Article 3 of the Ordinance on Collective Investment Scheme of 22 November 2006, as amended (CISO), such that there is no public offer. Investors, however, do not benefit from protection under CISA or CISO or supervision by FINMA. This prospectus and any other materials relating to the securities are strictly personal and confidential to each offeree and do not constitute an offer to any other person. This prospectus may only be used by those qualified investors to whom it has been handed out in connection with the offer described in this prospectus and may neither directly or indirectly be distributed or made available to any person or entity other than its recipients. It may not be used in connection with any other offer and shall in particular not be copied and/or distributed to the public in Switzerland or from Switzerland. This prospectus does not constitute an issue prospectus as that term is understood pursuant to Article 652a and/or 1156 of the Swiss Federal Code of Obligations. We have not applied for a listing of the securities on the SIX Swiss Exchange or any other regulated securities market in Switzerland, and consequently, the information presented in this prospectus does not necessarily comply with the information standards set out in the listing rules of the SIX Swiss Exchange and corresponding prospectus schemes annexed to the listing rules of the SIX Swiss Exchange.

LEGAL MATTERS

The validity of the shares of our Series A common stock being offered in this prospectus will be passed upon for us by Goodwin Procter LLP, Philadelphia, Pennsylvania. Cooley LLP, Palo Alto, California, is representing the underwriters in this offering.

EXPERTS

The financial statements of Sagimet Biosciences Inc. as of December 31, 2022 and 2021, and for each of the two years in the period ended December 31, 2022, included in this prospectus have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report. Such financial statements are 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 Series 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 Series 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.

We also maintain a website at www.sagimet.com. You may access our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, Proxy Statements and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act with the SEC free of charge at our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. 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, 2022 and 2021, the related statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders' deficit, and cash flows, for each of the two years in the period ended December 31, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has incurred net losses and negative cash flows from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 Francisco, California
March 24, 2023 (July 9, 2023, as to the effects of the reverse stock split as described in Note 14)

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, 2022	As of December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 158	$ 56,731
Short-term investments in marketable securities	32,187	—
Prepaid expenses and other current assets	447	1,932
Total current assets	32,792	58,663
Operating lease right-of-use assets	212	342
Deposits	27	27
Total assets	$ 33,031	$ 59,032
Liabilities, redeemable convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 1,125	$ 761
Accrued expenses and other current liabilities	4,021	1,555
Operating lease liabilities	133	124
Total current liabilities	5,279	2,440
Long-term liabilities		
Operating lease liabilities, less current portion	78	224
Redeemable convertible preferred stock warrant liability	4	7
Total liabilities	5,361	2,671
Commitments and contingencies (Note 7)		
Redeemable convertible preferred stock: $0.0001 par value; 1,373,810,170 shares authorized at December 31, 2022 and 2021; 1,373,730,625 shares issued and outstanding at December 31, 2022 and 2021; liquidation value of $232,963 at December 31, 2022 and 2021	214,620	214,620
Stockholders' deficit:		
Common stock, $0.0001 par value; 1,608,370,000 and 1,590,550,754 shares authorized at December 31, 2022 and 2021, respectively; 185,084 and 183,457 shares issued and outstanding at December 31, 2022 and 2021, respectively	1	1
Additional paid-in capital	35,001	33,109
Accumulated other comprehensive loss	(84)	—
Accumulated deficit	(221,868)	(191,369)
Total stockholders' deficit	(186,950)	(158,259)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	$ 33,031	$ 59,032

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, 2022	Year ended December 31, 2021
Operating expenses:		
Research and development	$ 24,919	$ 19,340
General and administrative	6,136	4,379
Total operating expenses	31,055	23,719
Loss from operations	(31,055)	(23,719)
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	3	2
Interest income and other	553	26
Total other income (expense), net	556	(723)
Net loss	$ (30,499)	$ (24,442)
Other comprehensive loss:		
Net unrealized loss on investments in marketable securities	(84)	—
Total other comprehensive loss	(84)	—
Comprehensive loss	$ (30,583)	$ (24,442)
Net loss per share attributable to common stockholders, basic and diluted	$ (165.20)	$ (199.40)
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	184,619	122,579

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	Accumulated other comprehensive loss	Total stockholders' deficit
	Shares	Amount	Shares	Amount				
Balance at January 1, 2021	1,289,245,218	$202,885	96,507	$ 1	$31,016	$(166,927)	$ —	$(135,910)
Net loss	—	—	—	—	—	(24,442)	—	(24,442)
Issuance of Series F redeemable convertible preferred stock, net of issuance costs of $16	84,485,407	11,735	—	—	—	—	—	—
Exercise of stock options	—	—	23,266	—	149	—	—	149
Exercise of common stock warrants	—	—	63,684	—	40	—	—	40
Stock-based compensation expense	—	—	—	—	1,904	—	—	1,904
Balance at December 31, 2021	1,373,730,625	214,620	183,457	1	33,109	(191,369)	—	(158,259)
Net loss	—	—	—	—	—	(30,499)	—	(30,499)
Exercise of stock options	—	—	1,627	—	12	—	—	12
Unrealized loss on investments in marketable securities	—	—	—	—	—	—	(84)	(84)
Stock-based compensation expense	—	—	—	—	1,880	—	—	1,880
Balance at December 31, 2022	1,373,730,625	$214,620	185,084	$ 1	$35,001	$(221,868)	$(84)	$(186,950)

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

SAGIMET BIOSCIENCES INC.

STATEMENTS OF CASH FLOWS
(in thousands)

	Year ended December 31, 2022	Year ended December 31, 2021
Cash flows from operating activities		
Net loss	$(30,499)	$(24,442)
Adjustments to reconcile net loss to net cash used in operating activities:		
Accretion of discount on marketable securities, net	(212)	—
Non-cash lease expense	130	134
Stock-based compensation expense	1,880	1,904
Change in fair value of redeemable convertible preferred stock warrants	(3)	(2)
Change in fair value of redeemable convertible preferred stock tranche liability	—	751
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	1,436	(471)
Accounts payable and accrued expenses	2,915	560
Operating lease liabilities	(137)	(144)
Net cash used in operating activities	(24,490)	(21,710)
Cash flows from investing activities		
Purchases of marketable securities	(41,446)	—
Sales of marketable securities	9,436	—
Net cash used in investing activities	(32,010)	—
Cash flows from financing activities		
Proceeds from issuance of redeemable convertible preferred stock, net	—	10,804
Proceeds from exercise of stock options and warrants	12	189
Payment of deferred financing costs	(85)	(1,254)
Net cash (used in) provided by financing activities	(73)	9,739
Net decrease in cash and cash equivalents	(56,573)	(11,971)
Cash and cash equivalents at the beginning of the period	56,731	68,702
Cash and cash equivalents at the end of the period	$ 158	$ 56,731
Supplemental cash flow information		
Unpaid deferred financing costs included in accounts payable and accrued expenses	$ —	$ 171
Right-of-use assets obtained in exchange for operating lease obligations	$ —	$ 282

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.

Risks, uncertainties and going concern

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 if approved; 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 biotechnology industry or the approval of competitive products or therapies could adversely affect the Company's development and operating results.

To date, the Company has relied on private equity and debt financings to fund its operations. The Company has incurred net losses and negative cash flows from operations since inception, including net losses of $30.5 million and $24.4 million for the years ended December 31, 2022 and 2021, respectively. For the years ended December 31, 2022 and 2021, the Company had negative cash flows from operations of $24.5 million and $21.7 million, respectively. As of December 31, 2022, the Company had cash, cash equivalents and short-term investments in marketable securities of $32.3 million. The Company expects to incur additional losses and negative cash flows from operations for the next twelve months. Based on its recurring losses from operations incurred since inception, expectation of continuing operating losses for the foreseeable future, and need to raise additional capital to finance its future operations, the Company has concluded that there is substantial doubt regarding the Company's ability to continue as a going concern within one year after the date that these financial statements are issued.

The Company will require substantial additional capital to fund its research and development and ongoing operating expenses. The Company is seeking to complete an initial public offering (IPO) of its Series A common stock. In the event the Company does not complete an IPO, the Company expects to seek additional funding through private equity financings, debt financings or other sources. The Company may not be able to obtain funding on acceptable terms, or at all. The terms of any future financing may adversely affect the holdings or the rights of the Company's existing stockholders.

If the Company is unable to raise additional funds when needed, it may be required to delay, reduce or eliminate its research and development.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. These financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Impact of COVID-19 pandemic on financial statements

The outbreak of the 2019 novel coronavirus disease (COVID-19), which was declared a global pandemic by the World Health Organization on March 11, 2020, and the related responses by public health and governmental authorities to contain and combat its outbreak and spread has severely impacted the U.S. and

world economies during the end of the first quarter of 2020 and continuing through the end of 2022. COVID-19 and the U.S. response to the pandemic are significantly affecting the economy. There are no comparable events that provide guidance as to the effect the COVID-19 pandemic may have, and, as a result, the ultimate effect of the pandemic is highly uncertain and subject to change. The Company does not yet know the full extent of the effects on the economy, the markets it serves, its business, or its operations.

Moving forward, economic recessions, increased inflation and/or interest rates, including those brought on by the continued COVID-19 outbreak may have a negative effect on the Company's operating results. Any prolonged disruption to our operations or workforce availability is likely to have a significant adverse effect on the Company's results of operations and cash flows. All of the above may be exacerbated in the future as the COVID-19 outbreak and the governmental responses thereto continue.

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 and liabilities as of the date of the financial statements and reported amounts of expenses during the reporting period. Such estimates include accruals of research and development expenses, accrued costs for services rendered in connection with third-party contractor clinical trial activities, preferred stock, common stock and stock option valuations and stock-based compensation. 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, 2022 and 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.

Marketable securities

The Company classifies its marketable securities as available-for-sale and records such assets at estimated fair value in the balance sheets, with unrealized gains and losses that are determined to be temporary, if any, reported as a component of other comprehensive income (loss) within the statements of operations and comprehensive loss and as a separate component of stockholders' deficit. The Company classifies marketable securities with remaining maturities greater than three months but less than one year as short-term investments, and those with remaining maturities greater than one year are classified as long-term investments. Investments are regularly reviewed for other-than-temporary declines in fair value. The review includes the consideration of the cause of the impairment, including the creditworthiness of the security issuers, the number of investments in an unrealized loss position, the severity and duration of the unrealized losses and whether it is more likely than not that the Company will be required to sell the investments before the recovery of their amortized cost basis. A decline in the fair value of any security below cost that is deemed other than temporary results in a charge to earnings and the establishment of a new cost basis for the security. The Company invests its excess cash balances primarily in corporate debt securities with strong credit ratings. Realized gains and losses are calculated on the specific identification method and recorded as interest income and were immaterial for all periods presented. As of December 31, 2022, the Company's short-term marketable securities were invested with Silicon Valley Bank (SVB), and custodied at U.S. bank.

Concentration of credit risk

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash, cash equivalents and marketable securities.

Deferred financing costs

Deferred financing costs, consisting of legal, accounting and other fees and costs relating to the Company's planned IPO are capitalized and recorded on the balance sheets. The deferred financing 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 financing costs will be written off within operating expenses in the Company's statements of operations and comprehensive loss. As of December 31, 2021, there were $1.4 million of deferred financing costs capitalized related to the Company's previous IPO plans in 2021. On March 21, 2022, the Company withdrew its Registration Statement on Form S-1 initially filed with the SEC on April 6, 2021. Concurrently, all of the deferred financing costs of $1.4 million capitalized as of December 31, 2021 were expensed within operating expenses in the statement of operations and comprehensive loss for the year ended December 31, 2022. As of December 31, 2022, there were no deferred financing costs capitalized.

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 determines if an arrangement is or contains a lease and the classification of that lease at inception of a contract. Specifically, the Company considers whether it controls the underlying asset and has the right to obtain substantially all the economic benefits or outputs from the asset. 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) The Company's operating lease asset is included in "operating lease right-of-use assets" (ROU assets), 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 sheets. As of December 31, 2022 and 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 twelve 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 rating, 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 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 in 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).

In January 2022, Ascletis initiated dosing of a Phase 3 trial for recurrent GBM, potentially triggering a $2.0 million development milestone payment under the license agreement. Due to the uncertainty around the achievement of the milestone and ongoing discussions with Ascletis around the consideration for the milestone, the Company concluded it was probable that a significant reversal of the revenue related to the milestone would occur, and therefore, no revenue was recognized.

Segment information

The Company operates and manages its business as a single operating 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 non-alcoholic steatohepatitis (NASH) and other diseases where FASN plays a pathogenic role. The Company has one operating segment and therefore one reportable segment. The determination of reportable segments is based on the chief operating decision maker's (CODM) use of financial information provided for the purpose of assessing performance and making operating decisions. The Company's CODM is its chief executive officer. The CODM evaluates the Company's financial information and assesses the performance of the Company based on the single operating segment. The Company assesses its determination of operating segments at least annually and continues to evaluate the internal reporting structure and potential impacts of any changes to its segment reporting.

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 statements of operations and comprehensive loss. Upon closing of the Series F redeemable convertible preferred stock financing 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. The Company accounts for warrants in accordance with the guidance contained in Financial Accounting Standards Board (FASB) ASC 815, *Derivatives and Hedging*.

Under ASC 815-40, warrants that meet the criteria for equity treatment are recorded in stockholders' deficit. The warrants are subject to re-evaluation of the proper classification and accounting treatment at each reporting period. If the warrants no longer meet the criteria for equity treatment, they will be recorded as a liability and remeasured each period with changes recorded in the statement of operations and comprehensive loss. 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. 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 and comprehensive loss 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 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, 2022 and 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. The cumulative amount of these changes is reported on the balance sheets.

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 inconformity 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.

Emerging growth company status

The Company is an emerging growth company (EGC) as defined in the Jumpstart Our Business Startups Acts of 2012, as amended (the JOBS Act), and may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not EGCs. The Company may take advantage of these exemptions until it is no longer an EGC under Section 107 of the JOBS Act and has elected to use the extended transition period for complying with new or revised accounting standards. As a result of this election, the Company's financial statements may not be comparable to companies that comply with public company FASB standards' effective dates.

New accounting pronouncements not yet adopted

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses of Financial Instruments*, which, together with subsequent amendments, amends the requirement on the measurement and recognition of expected credit losses for financial assets held. ASU 2016-13 is effective for the Company for the annual periods beginning after December 15, 2022, including interim periods within those fiscal years, with early adoption permitted. The Company has determined that there will be no material impact on the Company's financial statements upon the adoption of this ASU in 2023.

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 GAAP for certain financial instruments with characteristics of liabilities and equity. This amendment is effective for fiscal years beginning after December 15, 2023. 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. The Company's short-term investments including commercial paper, corporate debt and U.S. Treasury securities are Level 2 financial instruments.

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 redeemable convertible preferred stock warrant liability (Redeemable Convertible Preferred Stock Warrant Liability) and Redeemable Convertible Preferred Stock Tranche Liability are Level 3 financial instruments.

During the years ended December 31, 2022 and 2021, financial assets measured at fair value on a recurring basis consist of cash and cash equivalents which include deposits in a money market fund and short-term investments including commercial paper, corporate debt and U.S. Treasury securities. The carrying amount of cash and cash equivalents was $0.2 million and $56.7 million as of December 31, 2022 and 2021, respectively, which approximates the fair value and was determined based upon Level 1 inputs. The fair value of short-term investments is based upon market prices quoted on the last day of the fiscal period or other observable market inputs. The Company obtains pricing information from its investment manager and generally determines the fair value of investment securities using standard observable inputs, including reported trades, broker/dealer quotes, bids and/or offers.

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

Marketable securities, all of which are classified as available-for-sale securities, consisted of the following at December 31, 2022 (in thousands):

	December 31, 2022			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Commercial paper	$15,950	$ —	$ —	$15,950
Corporate debt securities	12,286	—	(65)	12,221
U.S. Treasury securities	4,035	—	(19)	4,016
Total	$32,271	$ —	$(84)	$32,187

There were no marketable securities at December 31, 2021.

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, 2022			
	Total fair value	Level 1	Level 2	Level 3
Assets:				
Cash and cash equivalents – money market funds	$ 38	$38	$ —	$—
Commercial paper	15,950	—	15,950	—
Corporate debt securities	12,221	—	12,221	—
U.S. Treasury securities	4,016	—	4,016	—
Total	$32,225	$38	$32,187	$—
Liabilities:				
Redeemable convertible preferred stock warrant liability	$ 4	$—	$ —	$ 4

	December 31, 2021			
	Total fair value	Level 1	Level 2	Level 3
Assets:				
Cash and cash equivalents – money market funds	$56,631	$56,631	$ —	$—
Liabilities:				
Redeemable convertible preferred stock warrant liability	$ 7	$ —	$ —	$ 7

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, 2021	**$ 9**	**$ —**
Change in fair value of redeemable convertible preferred stock warrant liability and establishment of Redeemable Convertible Preferred Stock Tranche Liability	(2)	751
Extinguishment of Redeemable Convertible Stock Tranche Liability upon subsequent issuance of Series F redeemable convertible preferred stock	—	(751)
Balance – December 31, 2021	**$ 7**	**$ —**
Change in fair value of Redeemable Convertible Preferred Stock Warrant Liability	(3)	—
Balance – December 31, 2022	**$ 4**	**$ —**

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.

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.

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 IPO.

As of December 31, 2022, the fair value of the Redeemable Convertible Preferred Stock Warrant Liability was determined to be $4 thousand assuming a volatility rate of 97.3%, an expected term of 2.28 years, no dividends, and a risk-free interest rate of 4.36%.

As of December 31, 2021, the fair value of the Redeemable Convertible Preferred Stock Warrant Liability was determined to be $7 thousand assuming a volatility rate of 87.2%, an expected term of 3.27 years, no dividends, and a risk-free interest rate of 1.01%.

The Company recorded other income of $3 thousand and $2 thousand for the change in fair value of the Redeemable Convertible Preferred Stock Warrant Liability in its statement of operations and comprehensive loss for the years ended December 31, 2022 and 2021, respectively.

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.

Immediately prior to the issuance and sale of Series F redeemable convertible preferred stock in February 2021, the fair value of the 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 Preferred 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 statement of operations and comprehensive loss for the year ended December 31, 2021.

4. Prepaid expenses and other current assets

Prepaid expenses and other current assets as of December 31, 2022 and 2021 consist of the following (in thousands):

	As of December 31, 2022	As of December 31, 2021
Prepaid clinical expenses	$352	$ 423
Deferred financing costs	—	1,425
Other	95	84
Total	$447	$1,932

5. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities as of December 31, 2022 and 2021 consist of the following (in thousands):

	As of December 31, 2022	As of December 31, 2021
Accrued clinical costs	$3,162	$ 852
Employees' compensation	636	463
Accrued pre-clinical costs	166	—
Accrued deferred financing costs	—	55
Other	57	185
Total	$4,021	$1,555

6. 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 canceled by either party. Upon execution of the agreement, the Company issued 192 shares of common stock to ETH Zurich and issued 96 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 subsidiary of Ascletis Pharma Inc. (Ascletis Pharma), biotechnology company incorporated in the Cayman Islands and headquartered in Hangzhou, China and a Company investor. The parties entered into this agreement with the intention to develop, manufacture, and commercialize the Company's proprietary FASN inhibitor, denifanstat. Under the terms of the license agreement, the Company granted Ascletis and its affiliates an exclusive, royalty-bearing sublicensable right and license under the Company's intellectual property to develop, manufacture, commercialize and otherwise exploit denifanstat and other products containing denifanstat-related compounds in Greater China, consisting of the People's Republic of China, Hong Kong, Macau and Taiwan.

The Company will bear all expenses related to development activities in Greater China as part of a global Phase 2 trial, except for clinical operations and regulatory staff provided by Ascletis. The Company conducted all development activities in connection with the FASCINATE-1 Phase 2 clinical trial in the United States and Greater China at its sole expense, except for certain in-kind contributions by Ascletis in Greater China. Ascletis is solely responsible for all development activities in connection with obtaining and maintaining regulatory approvals for denifanstat in Greater China. The Company received $60 thousand and $0.1 million as reimbursement pursuant to the license agreement for Greater China patent prosecution costs during the years ended December 31, 2022 and 2021, respectively.

The Company is eligible to receive development and commercial milestone payments from Ascletis in aggregate of up to $122.0 million as well as tiered royalties ranging from percentages in the high single digits to mid-teens on future net sales of denifanstat, which is referred to as ASC40 in Greater China. Ascletis Pharma, through a subsidiary, also led the Series E preferred stock financing in February 2019.

Under a separate manufacturing agreement with Ascletis, during the years ended December 31, 2022 and 2021, the Company paid $4 thousand and $0.9 million, respectively for the manufacture of denifanstat drug supply. The Company recorded these payments as research and development expense in the statement of operations and comprehensive loss for the respective year.

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. In January 2022, Ascletis initiated dosing of a Phase 3 trial for recurrent GBM, potentially triggering a $2.0 million development milestone payment under the license agreement. Due to the uncertainty around the achievement of the milestone and ongoing discussions with Ascletis around the consideration for the milestone, the Company concluded it was probable that a significant reversal of the revenue related to the milestone would occur, and therefore, no revenue was recognized.

7. Commitments and contingencies

Facility lease agreement

On March 12, 2019, the Company executed a 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 annual increases. On December 20, 2021, the lease agreement was amended to extend the term of the lease through June 2024. A security deposit of approximately $27 thousand is held by the lessor and is recorded as a long-term asset as of December 31, 2022. The Company has accounted for the lease as an operating lease.

Operating lease cost for the years ended December 31, 2022 and 2021 was $0.2 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, 2022 (in thousands):

2023	$157
2024	80
Total lease payments	237
Less: interest	(26)
Total	$211

Supplemental cash flow information related to leases was as follows for the years ended December 31, 2022 and 2021 (in thousands):

	Year ended December 31, 2022	Year ended December 31, 2021
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$157	$157
Right-of-use assets obtained in exchange for lease obligations (non-cash):		
Operating leases	$ —	$282

The weighted-average remaining lease term and discount rate related to the Company's lease liabilities as of December 31, 2022 and 2021 were 1.2 years and 7% and 2.5 years and 7%, 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, 2022, and 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.

8. Redeemable convertible preferred stock

The authorized, issued and outstanding shares of the redeemable convertible preferred stock, liquidation preferences and carrying values as of December 31, 2022 and 2021 were as follows (in thousands, except share numbers):

	As of December 31, 2022 and 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 F redeemable convertible preferred stock

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 $0.13020 per share (the Series F Original Issue Price).

Rights, preferences and privileges of the redeemable convertible preferred stock

The rights, preferences and privileges of the redeemable convertible preferred stock 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 0.012580 (except Series D-1). Series D-1 is not convertible into shares of common stock at the option of the holder.

All of 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 IPO 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. The Series D-1 is convertible into that number of fully-paid and nonassessable shares of common stock that is equal to $69.94 (as adjusted for stock splits, business combinations and reorganizations), divided by $18.0 million, subject to adjustments.

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 or 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.

9. Stockholders' deficit

Common stock

In connection with the adoption of an amendment to the Company's tenth amended and restated certificate of incorporation filed September 27, 2022, the number of shares of common stock that the Company is authorized to issue increased from 1,590,550,754 to 1,608,370,000. 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, 2022 and 2021 are as follows:

	As of December 31, 2022	As of December 31, 2021
Redeemable convertible preferred stock	1,322,399,477	1,322,399,477
Series D redeemable convertible preferred stock warrants	79,545	79,545
Options authorized and available for issuance	181,191	810,604
Options to purchase common stock	3,190,450	2,138,110
Warrants to purchase common stock	40,268	40,268
Total	1,325,890,931	1,325,468,004

Redeemable Convertible Preferred Stock Warrant Liability

In connection with a note payable entered into on April 10, 2015, which was repaid in full in May 2019, 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 2).

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 IPO 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 IPO. 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.

Stock warrants

As of December 31, 2022 and 2021, the following tables summarize the Company's outstanding common and redeemable convertible preferred stock warrants:

	As of December 31, 2022 and 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
June 2013	26,846	$0.79	June 2023	Common	$339	Redeemable convertible preferred stock
January 2014	13,422	$0.79	January 2024	Common	223	Redeemable convertible preferred stock
April 2015	79,545	$0.88	April 2025	Series D	68	Debt

10. 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 (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. As of December 31, 2022 and 2021, 181,191 and 810,604 shares are available for future grant under the 2017 Plan, respectively.

Options under the 2017 Plan may be granted for periods of up to ten 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 that is 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 year ended December 31, 2022 (in thousands, except share and per share data):

	Number of Shares Underlying Outstanding Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value
Outstanding, January 1, 2022	2,138,110	$ 7.15	8.1	$4,670
Options granted	1,080,304	$ 7.15		
Options exercised	(1,627)	$ 7.24		
Options cancelled	(887)	$31.46		
Options expired	(25,450)	$12.75		
Outstanding, December 31, 2022	3,190,450	$ 7.10	8.1	3,998
Shares vested and exercisable as of December 31, 2022	1,510,555	$ 7.15	6.8	2,303

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, 2022:

	Number of Shares Underlying Outstanding Options	Weighted-Average Exercise Price
Outstanding, January 1, 2022	1,537,241	$ 7.95
Options granted	1,061,431	$ 7.15
Options exercised	(1,627)	$ 7.24
Options cancelled	(887)	$31.46
Options expired	(25,450)	$12.75
Outstanding, December 31, 2022	2,570,708	$ 7.56
Vested, December 31, 2022	1,459,480	

Subsequent to the issuance of the financial statements for the year ended December 31, 2021, the Company identified and corrected an immaterial error related to the total number of shares of outstanding time-based option awards disclosed. 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, 2021.

The weighted-average grant date fair value of time-based options granted during the year ended December 31, 2022 was $6.36 per share. The total fair value of the time-based shares vested during the year ended December 31, 2022 was $1.8 million. As of December 31, 2022, there was $9.1 million of total unrecognized compensation cost related to the awards. The cost is being recognized over a remaining weighted-average period of 3.2 years.

Performance-based options

The Company may award grants of performance-based options to eligible individuals. Performance-based options 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 year ended December 31, 2022:

	Number of Shares Underlying Outstanding Options	Weighted-Average Exercise Price
Outstanding, January 1, 2022	600,869	$6.36
Options Granted	18,873	$7.15
Options Exercised	—	—
Outstanding, December 31, 2022	619,742	$6.38
Vested, December 31, 2022	51,075	

The weighted-average grant date fair value of performance-based options granted during the year ended December 31, 2022 was $7.15 per share. The total fair value of the performance-based shares vested during the year ended December 31, 2022 was $82 thousand. As of the year ended December 31, 2022, there was no unrecognized compensation cost related to the awards because it was improbable that the performance conditions would be met. The cost is being recognized over a remaining weighted-average period of less than one year.

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, 2022 and 2021 (in thousands):

	Year Ended December 31, 2022	Year Ended December 31, 2021
General and administrative	$1,204	$1,325
Research and development	676	579
Total stock-based compensation	$1,880	$1,904

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 years ended December 31, 2022 and 2021.

	Year Ended December 31, 2022
Expected volatility	88 – 90%
Risk-free interest rate	3.0 – 4.2
Dividend yield	—
Expected term	5.4 – 7.0 years

	Year Ended December 31, 2021
Expected volatility	89 – 94%
Risk-free interest rate	0.4 – 1.3
Dividend yield	—
Expected term	5.0 – 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.

11. 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, 2022 and 2021 (in thousands, except share and per share data):

	Year Ended December 31, 2022	Year Ended December 31, 2021
Numerator:		
Net loss attributable to common stockholders	$ (30,499)	$ (24,442)
Denominator:		
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	184,619	122,579
Net loss per share attributable to common stockholders, basic and diluted	$ (165.20)	$ (199.40)

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, 2022	Year Ended December 31, 2021
Redeemable convertible preferred stock	16,638,476	16,638,476
Options to purchase common stock	3,190,450	2,138,110
Warrants to purchase common stock	40,268	40,268
Warrants to purchase redeemable convertible preferred stock	79,545	79,545
Total	19,948,739	18,896,399

12. Income taxes

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, 2022 and 2021 is as follows:

	Year Ended December 31, 2022	Year Ended December 31, 2021
Federal income taxes at statutory rates	21.00%	21.00%
State income tax, net of federal benefit	0.43	0.40
Research and development credits	3.48	3.08
Stock-based compensation	(0.81)	(1.19)
Change in valuation allowance	(24.10)	(22.64)
Other permanent items	—	(0.65)
Effective income tax rate	—%	—%

For the years ended December 31, 2022 and 2021, the Company did not record a deferred income tax expense or benefit. Income tax expense has been nominal for the years ended December 31, 2022 and 2021.

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, 2022 and 2021 (in thousands):

	December 31, 2022	December 31, 2021
Deferred tax assets:		
Net operating loss carryforwards	$ 28,707	$ 28,350
Capitalized start-up costs and research expenses	13,004	7,358
Research and development credits	4,977	3,762
Accruals, reserves and other	1,144	1,013
Lease liabilities	47	73
Total gross deferred assets	47,879	40,556
Valuation allowance	(47,834)	(40,484)
Total deferred tax assets	45	72
Deferred tax liabilities:		
Right-of-use assets	(45)	(72)
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, 2022 and 2021. The valuation allowance increased $7.4 million and $5.6 million during the years ended December 31, 2022 and 2021, respectively.

As of December 31, 2022, the Company had U.S. federal net operating loss (NOL) carryforwards of approximately $128.2 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 2029 while federal NOLs incurred after December 31, 2017 of approximately $37.2 million will have an indefinite carryforward period, subject to annual limitations. As of December 31, 2022, the Company also had state NOL carryforwards of approximately $25.5 million which may be available to offset future state income and expire at various years beginning with 2028.

As of December 31, 2022, the Company had federal research and development tax credit carryforwards of approximately $4.4 million available to reduce future tax liabilities which expire at various years beginning with 2028. As of December 31, 2022, the Company had state credit carryforwards of approximately $2.5 million available to reduce future tax liabilities which do not expire.

Under Section 382 of the Internal Revenue Code of 1986, as amended (IRC), 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, 2022, 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, 2022 and 2021 (in thousands):

	Year Ended December 31, 2022	Year Ended December 31, 2021
Unrecognized tax benefits as of the beginning of the year	$1,035	$ 817
Decrease related to prior year tax positions	—	(17)
Increase related to current year tax positions	499	235
Unrecognized tax benefits as of the end of the year	$1,534	$1,035

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, 2022, 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 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.

In December 2017, the Tax Cuts and Jobs Act (TCJA) was signed into law, significantly reforming the IRC. Beginning January 1, 2022, the TCJA eliminated the option to deduct research and development expenditures in the current year and requires taxpayers to capitalize such expenses pursuant to IRC Section 174. The capitalized expenses are amortized over a 5-year period for domestic expenses and a 15-year period for foreign expenses. As a result of this provision of the TCJA, deferred tax assets related to capitalized research expenses increased by $4.6 million.

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.

On February 9, 2022, Governor Gavin Newsom signed California Senate Bill 113 (SB 113) into law. The legislation contains important California tax law changes, including reinstatement of business tax credits and net NOL deductions limited by California Assembly Bill 85 which suspended the net operating loss deduction for certain taxpayers from 2020 to 2022. The new tax law did not impact the Company's tax provision due to its taxable loss position in the current year.

In August 2022, the Inflation Reduction Act of 2022 (IRA) was signed into law in the United States. The IRA created a new corporate alternative minimum tax of 15% on adjusted financial statement income and an excise tax of 1% of the value of certain stock repurchases. The provisions of the IRA will be effective for periods beginning after December 31, 2022. The enactment of the IRA did not result in any material adjustments to the Company's income tax provisions or net deferred tax assets as of December 31, 2022.

13. Defined contribution plan

The Company has a defined-contribution savings plan under Section 401(k) of the IRC. 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 pre-tax basis. The Company has not made any employer contributions to the 401(k) Plan as of December 31, 2022 and 2021.

14. Subsequent events

The Company has evaluated subsequent events for financial statement purposes occurring through March 24, 2023, the date when these financial statements are available to be issued and July 9, 2023 for the reverse stock split referenced below. No material subsequent events have occurred that require disclosure, except those referenced below.

The Company's board of directors approved a one-for-79.4784 reverse stock split of its issued and outstanding common stock, effective on July 7, 2023. Stockholders entitled to fractional shares as a result of the reverse stock split will receive a cash payment in lieu of receiving fractional shares. Accordingly, all share and per share amounts for all periods presented in the accompanying financial statements and notes thereto have been retroactively adjusted, where applicable, to reflect the effects of the reverse stock split. Shares of common stock underlying outstanding stock options and common stock warrants were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased in accordance with the terms of the agreements governing such securities. Shares of common stock reserved for issuance upon the conversion of the Company's preferred stock were proportionately reduced and the respective conversion prices were proportionately increased.

SAGIMET BIOSCIENCES INC.

CONDENSED BALANCE SHEETS
(Unaudited)
(in thousands, except for share and per share amounts)

	As of September 30, 2023	As of December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 101,842	$ 158
Short-term investments in marketable securities	—	32,187
Prepaid expenses and other current assets	974	447
Total current assets	102,816	32,792
Operating lease right-of-use assets	109	212
Deposits	—	27
Total assets	$ 102,925	$ 33,031
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 1,702	$ 1,125
Accrued expenses and other current liabilities	3,244	4,021
Operating lease liabilities	103	133
Total current liabilities	5,049	5,279
Long-term liabilities		
Operating lease liabilities, less current portion	—	78
Series A common stock warrant liability	1	—
Redeemable convertible preferred stock warrant liability	—	4
Total liabilities	5,050	5,361
Commitments and contingencies (Note 7)		
Redeemable convertible preferred stock: $0.0001 par value; no shares and 1,373,810,170 shares authorized at September 30, 2023 and December 31, 2022, respectively; no shares and 1,373,730,625 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively; liquidation value of $232,963 at December 31, 2022	—	214,620
Stockholders' equity (deficit):		
Undesignated preferred stock, $0.0001 par value; 10,000,000 shares and no shares authorized at September 30, 2023 and December 31, 2022, respectively; no shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	—	—
Common stock, $0.0001 par value; no shares and 1,608,370,000 shares authorized at September 30, 2023 and December 31, 2022, respectively; no shares and 185,084 shares issued and 2023 and December 31, 2022, respectively	—	1
Series A common stock, $0.0001 par value; 500,000,000 shares and no shares authorized at September 30, 2023 and December 31, 2022, respectively; 21,375,402 shares and no shares issued and 2023 and December 31, 2022, respectively	2	—
Series B common stock, $0.0001 par value; 15,000,000 shares and no shares authorized at September 30, 2023 and December 31, 2022, respectively; 1,520,490 and no shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	—	—
Additional paid-in capital	339,466	35,001
Accumulated other comprehensive loss	—	(84)
Accumulated deficit	(241,593)	(221,868)
Total stockholders' equity (deficit)	97,875	(186,950)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 102,925	$ 33,031

The accompanying notes are an integral part of these unaudited condensed 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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenue:				
License revenue	$ 2,000	$ —	$ 2,000	$ —
Total revenue	2,000	—	2,000	—
Operating expenses:				
Research and development	4,958	6,838	14,121	19,072
General and administrative	4,494	848	9,153	4,595
Total operating expenses	9,452	7,686	23,274	23,667
Loss from operations	(7,452)	(7,686)	(21,274)	(23,667)
Other income, net:				
Change in fair value of redeemable convertible preferred stock warrant liability	—	1	(1)	3
Change in fair value of Series A common stock warrant liability	4	—	4	—
Interest income and other	1,095	218	1,546	360
Total other income, net	1,099	219	1,549	363
Net loss	$ (6,353)	$ (7,467)	$ (19,725)	$ (23,304)
Other comprehensive (loss) gain:				
Net unrealized (loss) gain on investments in marketable securities	—	(56)	84	(162)
Total other comprehensive (loss) gain	—	(56)	84	(162)
Comprehensive loss	$ (6,353)	$ (7,523)	$ (19,641)	$ (23,466)
Net loss per share attributable to common stockholders, basic and diluted	$ —	$ (40.34)	$ —	$ (126.13)
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	—	185,084	—	184,756
Net loss per share attributable to Series A and Series B common stockholders, basic and diluted	$ (0.35)	$ —	$ (3.22)	$ —
Weighted-average shares outstanding used in computing net loss per share attributable to Series A and Series B common stockholders, basic and diluted	18,194,682	—	6,131,541	—

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

SAGIMET BIOSCIENCES INC.

CONDENSED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(Unaudited)
(in thousands, except share amounts)

	Redeemable Convertible Preferred Stock		Common Stock		Series A Common Stock		Series B Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive (Loss) Income	Total Stockholders' (Deficit) Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at January 1, 2023	1,373,730,625	$ 214,620	185,084	$ 1	—	$—	—	$—	$ 35,001	$(221,868)	$(84)	$(186,950)
Net loss	—	—	—	—	—	—	—	—	—	(6,587)	—	(6,587)
Unrealized gain on investments in marketable securities	—	—	—	—	—	—	—	—	—	—	71	71
Stock-based compensation expense	—	—	—	—	—	—	—	—	767	—	—	767
Balance at March 31, 2023	1,373,730,625	$ 214,620	185,084	$ 1	—	$—	—	$—	$ 35,768	$(228,455)	$(13)	$(192,699)
Net loss	—	—	—	—	—	—	—	—	—	(6,785)	—	(6,785)
Exercise of common stock warrants	—	—	25,231	—	—	—	—	—	—	—	—	—
Unrealized gain on investments in marketable securities	—	—	—	—	—	—	—	—	—	—	13	13
Stock-based compensation expense	—	—	—	—	—	—	—	—	1,057	—	—	1,057
Balance at June 30, 2023	1,373,730,625	$ 214,620	210,315	$ 1	—	$—	—	$—	$ 36,825	$(235,240)	$ —	$(198,414)
Net loss	—	—	—	—	—	—	—	—	—	(6,353)	—	(6,353)
Conversion of Redeemable Convertible Preferred Stock to Series A and Series B Common Stock	(1,373,730,625)	(214,620)	—	—	15,117,912	1	1,520,490	—	214,619	—	—	214,620
Reclass of Common Stock to Series A Common Stock	—	—	(210,315)	(1)	210,315	1	—	—	—	—	—	—
Sale of Series A Common Stock in public offering, net of issuance costs of $10,267	—	—	—	—	6,026,772	—	—	—	86,161	—	—	86,161
Issuance of Series A Common Stock upon exercise of stock options	—	—	—	—	7,614	—	—	—	6	—	—	6
Exercise of common stock warrants	—	—	—	—	12,789	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	1,855	—	—	1,855
Balance at September 30, 2023	—	$ —	—	$—	21,375,402	$ 2	1,520,490	$—	$339,466	$(241,593)	$ —	$ 97,875

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

SAGIMET BIOSCIENCES INC.
CONDENSED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT) — (Continued)
(Unaudited)
(in thousands, except share amounts)

	Redeemable convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balance at January 1, 2022	1,373,730,625	$214,620	183,457	$ 1	$33,109	$(191,369)	$ —	$(158,259)
Net loss	—	—	—	—	—	(8,735)	—	(8,735)
Exercise of stock options	—	—	1,627	—	12	—	—	12
Stock-based compensation expense	—	—	—	—	387	—	—	387
Balance at March 31, 2022	1,373,730,625	$214,620	185,084	$ 1	$33,508	$(200,104)	$ —	$(166,595)
Net loss	—	—	—	—	—	(7,102)	—	(7,102)
Unrealized loss on investments in marketable securities	—	—	—	—	—	—	(106)	(106)
Stock-based compensation expense	—	—	—	—	383	—	—	383
Balance at June 30, 2022	1,373,730,625	$214,620	185,084	$ 1	$33,891	$(207,206)	$(106)	$(173,420)
Net loss	—	—	—	—	—	(7,467)	—	(7,467)
Unrealized loss on investments in marketable securities	—	—	—	—	—	—	(56)	(56)
Stock-based compensation expense	—	—	—	—	389	—	—	389
Balance at September 30, 2022	1,373,730,625	$214,620	185,084	$ 1	$34,280	$(214,673)	$(162)	$(180,554)

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

SAGIMET BIOSCIENCES INC.
CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (19,725)	$(23,304)
Adjustments to reconcile net loss to net cash used in operating activities:		
Accretion of discount on marketable securities, net	(39)	(129)
Non-cash lease expense	103	97
Stock-based compensation expense	3,679	1,159
Change in fair value of redeemable convertible preferred stock warrant liability	1	(3)
Change in fair value of Series A common stock warrant liability	(4)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(390)	1,326
Accounts payable and accrued liabilities	(200)	3,920
Operating lease liabilities	(108)	(103)
Net cash used in operating activities	(16,683)	(17,037)
Cash flows from investing activities:		
Purchases of marketable securities	—	(41,446)
Sales of marketable securities	32,200	4,000
Net cash provided (used in) by investing activities	32,200	(37,446)
Cash flows from financing activities:		
Proceeds from initial public offering, net of underwriters' commissions and discounts	86,161	—
Payment of deferred financing costs	—	(30)
Proceeds from exercise of stock options	6	12
Net cash provided by (used in) financing activities	86,167	(18)
Net increase (decrease) in cash and cash equivalents	101,684	(54,501)
Cash and cash equivalents at beginning of period	158	56,731
Cash and cash equivalents at end of period	$101,842	$ 2,230

The accompanying notes are an integral part of these unaudited condensed 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 developing novel therapeutics called fatty acid synthase (FASN) inhibitors that target dysfunctional metabolic pathways in diseases resulting from the overproduction of the fatty acid, palmitate.

Reverse stock split

A one-for-79.4784 reverse stock split of the Company's issued and outstanding common stock was effected on July 7, 2023. Stockholders entitled to fractional shares as a result of the reverse stock split received a cash payment in lieu of receiving fractional shares. Accordingly, all share and per share amounts for all periods presented in the accompanying financial statements and notes thereto have been retroactively adjusted, where applicable, to reflect the effects of the reverse stock split. Shares of common stock underlying outstanding stock options and common stock warrants were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased in accordance with the terms of the agreements governing such securities. Shares of common stock reserved for issuance upon the conversion of the Company's preferred stock were proportionately reduced and the respective conversion prices were proportionately increased.

Initial public offering

On July 18, 2023, the Company completed its initial public offering (IPO), in which it issued and sold 5,312,500 shares of Series A common stock at a price to the public of $16.00 per share. The aggregate gross proceeds of the IPO were $96.4 million, inclusive of an additional 714,272 shares of Series A common stock sold upon the partial exercise of the underwriters' purchase option. The Company received approximately $86.2 million in net proceeds after deducting underwriting discounts, commissions, and offering expenses.

In connection with the IPO, the Company's outstanding redeemable convertible preferred stock automatically converted into 15,117,912 shares of Series A common stock and 1,520,490 shares of Series B common stock. The rights of the holders of Series A common stock and Series B common stock are substantially identical, except with respect to voting and conversion. Each share of Series A common stock is entitled to one vote and shares of Series B common stock are non-voting, except as may be required by law. Each share of Series B common stock may be converted at any time into one share of Series A common stock at the option of its holder, subject to the ownership limitations provided for in the Company's eleventh amended and restated certificate of incorporation (the Charter). See Note 9.

Reclassification of common stock

On July 18, 2023, each share of the Company's common stock issued and outstanding became reclassified as one share of Series A common stock. Any stock certificate that immediately prior to July 18, 2023 represented shares of the Company's common stock was deemed to represent shares of Series A common stock, without the need for surrender or exchange thereof.

Risks, uncertainties and going concern

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 if approved; 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 biotechnology industry or the approval of competitive products or therapies could adversely affect the Company's development and operating results.

The Company will require substantial additional capital to fund its research and development and ongoing operating expenses. As of September 30, 2023, the Company has relied on public and private equity and debt financings, including its July 2023 IPO, to fund its operations. The Company has incurred net losses and negative cash flows from operations since inception, including net losses of $19.7 million for the nine months ended September 30, 2023 and $23.3 million for the nine months ended September 30, 2022. For the nine months ended September 30, 2023, and 2022, the Company had negative cash flows from operations of $16.7 million and $17.0 million, respectively. As of September 30, 2023, the Company had cash and cash equivalents of $101.8 million. The Company expects to incur additional losses and negative cash flows from operations for the next twelve months.

As of November 13, 2023, the issuance date of these unaudited condensed financial statements, the Company expects that its cash and cash equivalents as of September 30, 2023 will be sufficient to fund its operating expenses and capital expenditure requirements through at least 12 months from the issuance of these condensed financial statements. In the future, the Company may need to raise additional funds until it is able to generate sufficient revenues to fund its development activities. The Company's future operating activities, coupled with its plans to raise capital or issue debt financing, may provide additional liquidity in the future, however these actions are not solely within the control of the Company and the Company is unable to predict the outcome of these actions to generate the liquidity ultimately required.

Impact of COVID-19 pandemic on financial statements

We experienced modest delays in our development activities as a result of the COVID-19 pandemic, primarily due to temporary closures of certain clinical sites that delayed patient enrollment in our FASCINATE-2 trial. Although the public health emergency declarations related to COVID-19 in the United States ended on May 11, 2023, the extent to which the COVID-19 pandemic will continue to impact our operations or those of our consultants and collaborators, will depend on future developments, including the global macroeconomic effects of the virus. Economic recessions, increased inflation and/or interest rates, and any disruptions to our operations or workforce availability, including those brought on by the continued effects of the COVID-19 pandemic or a similar health epidemic may have a negative effect on our operating results.

Unaudited interim financial information

The accompanying condensed balance sheet as of September 30, 2023, the condensed statements of operations and comprehensive loss for the three and nine months ended September 30, 2023 and 2022, the condensed statements of redeemable convertible preferred stock and stockholders' equity (deficit) for the three and nine months ended September 30, 2023 and 2022, the condensed statements of cash flows for the nine months ended September 30, 2023 and 2022, 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, 2022 has been derived from the audited financial statements of the Company. 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 condensed financial statements and accompanying notes have been prepared in accordance with GAAP and the requirements of the Securities and Exchange Commission (SEC) for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by GAAP can be condensed or omitted. These condensed financial statements have been prepared on the same basis as the annual financial statements included elsewhere in this prospectus.

In the Company's opinion, the information furnished in these condensed financial statements reflects all adjustments, all of which are of a normal and recurring nature necessary for a fair presentation of the financial position and results of operations for the reported interim periods. The Company considers events or transactions that occur after the balance sheet date but before the financial statements are issued to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure. The results of operations for interim periods are not necessarily indicative of results to be expected for the full year or any other interim period.

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 as of the date of the financial statements and reported amounts of expenses during the reporting period. Such estimates include accruals of research and development expenses, accrued costs for services rendered in connection with third-party contractor clinical trial activities, preferred stock, common stock and stock option valuations and stock-based compensation. 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.

Significant accounting policies

The Company's significant accounting policies are disclosed in the audited financial statements for the year ended December 31, 2022, included elsewhere in this prospectus, and the unaudited financial statements as of March 31, 2023 filed with the SEC. Since the date of those financial statements, there have been no changes to the Company's significant accounting policies except as disclosed below in recently adopted accounting pronouncements.

Marketable securities

The Company classifies its marketable debt securities as available-for-sale and records such assets at estimated fair value in the balance sheets. The Company adopted Accounting Standards Update (ASU) No. 2016-13, *Financial Instruments — Credit Losses (Topic 326): Measurement of Credit Losses of Financial Instruments* on January 1, 2023. Marketable debt securities for which the estimated fair value is below amortized cost are evaluated for credit impairment. Credit impairment is recorded through the unaudited condensed statements of operations via an allowance for credit losses account, and any remaining unrealized gains and losses are reported as a component of other comprehensive income (loss) within the unaudited condensed statements of operations and comprehensive loss and as a separate component of stockholders' equity (deficit). The Company classifies marketable securities with remaining maturities greater than three months but less than one year as short-term investments, and those with remaining maturities greater than one year are classified as long-term investments. For all marketable securities which the estimated fair value was below amortized cost as of December 31, 2022, the decline in fair value was not driven by credit impairment.

The Company had no short-term investments in marketable securities as of September 30, 2023.

Deferred financing costs

Deferred financing costs, consisting of legal, accounting and other fees and costs relating to the Company's IPO are capitalized and recorded in the accrued expenses and other current liabilities in the

condensed balance sheets. Upon closing of the IPO in July 2023, all deferred offering costs were reclassified to additional paid-in-capital in the condensed statements of operations and comprehensive loss, representing a reduction in IPO proceeds.

On March 21, 2022, the Company withdrew its prior Registration Statement on Form S-1 initially filed with the SEC on April 16, 2021. Concurrently, all of the deferred financing costs of $1.4 million capitalized as of December 31, 2021 were expensed within operating expenses in the unaudited condensed statement of operations and comprehensive loss for the nine months ended September 30, 2022.

Revenue recognition

The Company enters into collaboration and licensing arrangements that generally contain multiple elements or deliverables, which may include (i) licenses to the Company's technology, (ii) research and development activities performed for the collaboration partner, (iii) participation on joint steering committees (JSCs), and (iv) 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 in 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).

In January 2022, Ascletis BioScience Co. Ltd. (Ascletis) initiated dosing of a Phase 3 trial for recurrent glioblastoma multiforme (GBM), potentially triggering a $2.0 million development milestone payment, net of applicable taxes, under the license agreement. The parties were in discussions regarding the form and amount of consideration related to this milestone until July 2023, at which time the Company concluded that the risk of reversal was no longer present, resulting in revenue recognition of $2.0 million. In August 2023, the Company received a $1.7 million milestone payment recorded as license revenue in the condensed statements of operations and comprehensive loss (representing the $2.0 million development milestone payment, net of applicable taxes) from Ascletis.

Concentration of credit risk

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash, cash equivalents and marketable securities.

Emerging growth company status

The Company is an emerging growth company (EGC) as defined in the Jumpstart Our Business Startups Acts of 2012, as amended (the JOBS Act), and may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not EGCs. The Company may take advantage of these exemptions until it is no longer an EGC under Section 107 of the JOBS Act and has elected to use the extended transition period for complying with new or revised accounting standards. As a result of this election, the Company's financial statements may not be comparable to companies that comply with public company Financial Accounting Standards Board (FASB) standards' effective dates.

Recently adopted accounting pronouncements

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses of Financial Instruments*, which, together with subsequent amendments, amends the requirement on the measurement and recognition of expected credit losses for financial assets held. ASU 2016-13 is effective for the Company for the annual periods beginning after December 15, 2022, including interim periods within those fiscal years, with early adoption permitted. The Company adopted ASU 2016-13 on January 1, 2023, using the modified retrospective approach, and no cumulative effect adjustment to accumulated deficit was needed as of the adoption date.

New accounting pronouncements not yet 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 GAAP for certain financial instruments with characteristics of liabilities and equity. This amendment is effective for fiscal years beginning after December 15, 2023. 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. The Company's short-term investments including commercial paper, corporate debt and U.S. Treasury securities are Level 2 financial instruments.

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 Series A common stock warrant liability (Series A Common Stock Warrant Liability) and redeemable convertible preferred stock warrant liability (Redeemable Convertible Preferred Stock Warrant Liability) are Level 3 financial instruments.

As of September 30, 2023 and December 31, 2022, financial assets measured at fair value on a recurring basis consist of cash and cash equivalents. The carrying amount of cash and cash equivalents was $101.8 million and $0.2 million as of September 30, 2023 and December 31, 2022, respectively, which approximates the fair value and was determined based upon Level 1 inputs. The fair value of short-term investments is based upon market prices quoted on the last day of the fiscal period or other observable market inputs. The Company obtains pricing information from its investment manager and generally determines

the fair value of investment securities using standard observable inputs, including reported trades, broker/dealer quotes, bids and/or offers.

The carrying values of the Company's accounts payable and accrued expenses and other current liabilities approximate their fair values due to the short-term nature of these 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 consists of the Series A Common Stock Warrant Liability and the Redeemable Convertible Preferred Stock Warrant Liability.

Marketable securities, all of which are classified as available-for-sale securities, consisted of the following (in thousands):

	As of December 31, 2022			
	Amortized cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Commercial paper	$15,950	$ —	$ —	$15,950
Corporate debt securities	12,286	—	(65)	12,221
U.S. Treasury securities	4,035	—	(19)	4,016
Total	$32,271	$ —	$(84)	$32,187

There were no investments in marketable securities as of September 30, 2023.

The following tables set 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):

	September 30, 2023			
	Total fair value	Level 1	Level 2	Level 3
Liabilities:				
Series A Common Stock Warrant Liability	$1	$ —	$ —	$1

	December 31, 2022			
	Total fair value	Level 1	Level 2	Level 3
Assets:				
Cash and cash equivalents - money market funds	$ 38	$38	$ —	$—
Commercial paper	15,950	—	15,950	—
Corporate debt securities	12,221	—	12,221	—
U.S. Treasury securities	4,016	—	4,016	—
Total	$32,225	$38	$32,187	$—
Liabilities:				
Redeemable Convertible Preferred Stock Warrant Liability	$ 4	$—	$ —	$ 4

The following tables provide a summary of changes in the estimated fair value of the financial instruments using significant Level 3 inputs (in thousands):

Balance – January 1, 2023	$ 4
Change in fair value of Redeemable Convertible Preferred Stock Warrant Liability	1
Change in fair value of Series A Common Stock Warrant Liability	(4)
Balance – September 30, 2023	$ 1
Balance – January 1, 2022	$ 7
Change in fair value of Redeemable Convertible Preferred Stock Warrant Liability	(3)
Balance – December 31, 2022	$ 4

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.

Redeemable Convertible Preferred Stock Warrant Liability and Series A Common Stock Warrant Liability

In connection with a note payable entered into on April 10, 2015, which was repaid in full in May 2019, the Company issued a warrant to purchase 79,545 shares of Series D redeemable convertible preferred stock. See Note 9. The Company completed its IPO on July 18, 2023. Subsequently, pursuant to the terms of the warrant, the warrant was converted into a warrant to purchase 1,000 shares of Series A common stock and the expiration date was automatically extended until July 18, 2026, the third anniversary date of the closing of the Company's IPO. The exercise was deemed a cashless exercise.

The Company estimates the fair value of the Series A Common Stock Warrant Liability and 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, Series A common stock market price, as well as assumptions for fair value of the underlying redeemable convertible preferred stock, expected volatility, expected life, dividends and risk-free interest rate.

As of September 30, 2023, the fair value of the Series A Common Stock Warrant Liability was determined to be $1.4 thousand assuming a volatility rate of 91.5%, an expected term of 2.80 years, no dividends, and a risk-free interest rate of 4.87%. As of December 31, 2022, the fair value of the Redeemable Convertible Preferred Stock Warrant Liability was determined to be $4.0 thousand assuming a volatility rate of 97.3%, an expected term of 2.28 years, no dividends, and a risk-free interest rate of 4.36%.

For the change in fair value of the Series A Common Stock Warrant Liability, the Company recorded other income of $4.0 thousand for both the three and nine months ended September 30, 2023, respectively, in its unaudited condensed statement of operations and comprehensive loss. For the change in fair value of the Redeemable Convertible Preferred Stock Warrant Liability, the Company recorded other expense of $1.0 thousand for the nine months ended September 30, 2023, and other income of $1.0 thousand and $3.0 thousand for the three and nine months ended September 30, 2022, respectively, in its unaudited condensed statement of operations and comprehensive loss.

4. Prepaid expenses and other current assets

Prepaid expenses and other current assets consist of the following (in thousands):

	As of September 30, 2023	As of December 31, 2022
Prepaid insurance	$865	$ 61
Prepaid clinical expenses	32	352
Other	77	34
Total	$974	$447

5. Accrued expenses and other current liabilities

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

	As of September 30, 2023	As of December 31, 2022
Accrued clinical costs	$2,239	$3,162
Employees' compensation	689	636
Accrued research	221	—
Accrued preclinical costs	—	166
Other	95	57
Total	$3,244	$4,021

6. Related parties

Ascletis BioScience Co. Ltd

In January 2019, the Company entered into a license agreement that became effective in February 2019 with Ascletis, a subsidiary of Ascletis Pharma Inc. (Ascletis Pharma), biotechnology company incorporated in the Cayman Islands and headquartered in Hangzhou, China and a Company investor. The parties entered into this agreement with the intention to develop, manufacture, and commercialize the Company's proprietary FASN inhibitor, denifanstat. Under the terms of the license agreement, the Company granted Ascletis and its affiliates an exclusive, royalty-bearing sublicensable right and license under the Company's intellectual property to develop, manufacture, commercialize and otherwise exploit denifanstat and other products containing denifanstat-related compounds in Greater China, consisting of the People's Republic of China, Hong Kong, Macau and Taiwan.

The Company will bear all expenses related to development activities in Greater China as part of a global Phase 2 trial, except for clinical operations and regulatory staff provided by Ascletis. The Company conducted all development activities in connection with the FASCINATE-1 Phase 2 clinical trial in the United States and Greater China at its sole expense, except for certain in-kind contributions by Ascletis in Greater China. Ascletis is solely responsible for all development activities in connection with obtaining and maintaining regulatory approvals for denifanstat in Greater China. The Company received $28.1 thousand as reimbursement pursuant to the license agreement for Greater China patent prosecution costs during the nine months ended September 30, 2022. The Company did not receive any reimbursements pursuant to the license agreement for Greater China patent prosecution costs during the nine months ended September 30, 2023.

The Company is eligible to receive development and commercial milestone payments from Ascletis in aggregate of up to $122.0 million as well as tiered royalties ranging from percentages in the high single digits to mid-teens on future net sales of denifanstat, which is referred to as ASC40 in Greater China. Ascletis Pharma, through a subsidiary, also led the Series E preferred stock financing in February 2019. As noted below, the Company received $2.0 million related to a development milestone in August, 2023.

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. In January 2022, Ascletis initiated dosing of a Phase 3 trial for recurrent GBM, potentially triggering a $2.0 million development milestone payment, net of applicable taxes, under the license agreement. The parties were in discussions regarding the form and amount of consideration related to this milestone until July 2023, at which time the Company concluded that the risk of reversal was no longer present, resulting in revenue recognition of $2.0 million. In August 2023, the Company received a $1.7 million milestone payment (representing the $2.0 million development milestone payment, net of applicable taxes which are recorded in general and administrative in the condensed statement of operations and comprehensive loss) from Ascletis.

There were no payments made to Ascletis during the nine months ended September 30, 2023. The Company paid Ascletis under their manufacturing arrangement $4.0 thousand during the nine months ended September 30, 2022.

Assignment and Assumption Agreement

In July 2023, the Company entered into an Assignment and Assumption Agreement with Ascletis and Ascletis' affiliate Gannex under which Ascletis, while remaining responsible for performance under the license agreement, assigned all of its rights and obligations under the license agreement to Gannex and Gannex assumed such rights and obligations, effective as of October 2019.

7. Commitments and contingencies

Facility lease agreement

On March 12, 2019, the Company executed a 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 annual increases. On December 20, 2021, the lease agreement was amended to extend the term of the lease through June 2024. The Company has accounted for the lease as an operating lease.

Operating lease cost for the three months ended September 30, 2023, and 2022 was $37.0 thousand and $38.0 thousand, respectively, and for the nine months ended September 30, 2023 and 2022 was $111.0 thousand and $113.0 thousand, respectively.

The following are schedules by year of future maturities of the Company's operating lease liabilities (in thousands):

	September 30, 2023
Remainder of 2023	$ 27
2024	79
Total lease payments	106
Less: interest	(3)
Total	$103

	December 31, 2022
2023	$157
2024	80
Total lease payments	237
Less: interest	(26)
Total	$211

Supplemental cash flow information related to leases was as follows (in thousands):

	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$118	$118

The weighted-average remaining lease term and discount rate related to the Company's lease liabilities as of September 30, 2023 and December 31, 2022 were 0.75 years and 7% and 1.2 years and 7%, 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. In addition, the Company has entered into indemnification agreements with members of its board of directors and its executive officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. As of September 30, 2023, 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.

8. Redeemable convertible preferred stock

Prior to the IPO, the authorized, issued and outstanding shares of the redeemable convertible preferred stock, liquidation preferences and carrying values were as follows as of December 31, 2022 (in thousands, except share numbers):

	December 31, 2022			
	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

In connection with the IPO, all of the Company's outstanding redeemable convertible preferred stock automatically converted into 15,117,912 shares of Series A common stock and 1,520,490 shares of Series B common stock.

9. Stockholders' equity (deficit)

Common stock

Per the Charter, the total number of shares of capital stock authorized for issuance is 500,000,000 shares of Series A common stock, 15,000,000 shares of Series B common stock and 10,000,000 shares of

undesignated preferred stock. Holders of Series A common stock are entitled to one vote and Series B common stock are not entitled to vote. Upon the voluntary or involuntary liquidation, dissolution or winding up of the Company, the net assets of the Company will be distributed pro rata to the holders of Series A common stock and Series B common stock. Each share of Series B common stock is convertible, at any time at the option of the holder, into one share of Series A common stock, unless that holder would beneficially own a number of Series A common stock in excess of 4.99% of the total number of shares of Series A common stock then issued and outstanding. On July 18, 2023, upon the Company's IPO, each share of the Company's common stock issued and outstanding became reclassified as one share of Series A common stock (see Note 1). The Company's reserved shares of common stock are as follows:

	As of September 30, 2023	As of December 31, 2022
Options to purchase Series A common stock	3,766,505	3,190,450
Options authorized and available for issuance	2,585,968	181,191
Warrant to purchase Series A Common Stock	1,000	—
Redeemable convertible preferred stock	—	1,322,399,477
Series D redeemable convertible preferred stock warrant	—	79,545
Warrants to purchase common stock	—	40,268
Total	6,353,473	1,325,890,931

Redeemable convertible preferred stock warrant liability and Series A Common Stock Warrant Liability

In connection with a note payable entered into on April 10, 2015, which was repaid in full in May 2019, the Company issued a warrant to purchase 79,545 shares of Series D redeemable convertible preferred stock with an exercise price of $0.88 per share. The warrant has 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.

The Company completed its IPO on July 18, 2023. Subsequently, the Redeemable Convertible Preferred Stock Warrant was converted to a warrant to purchase 1,000 shares of Series A common stock at an exercise price of $69.94 per share and the expiration date was automatically extended until July 18, 2026, the third anniversary date of the closing of the Company's IPO. 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.

The holder of the 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.

Stock warrants

The following tables summarize the Company's outstanding Series A Common Stock Warrant, Common Stock warrants and redeemable convertible preferred stock warrants:

	As of September 30, 2023					
Issuance Date	Number of Warrant Shares	Exercise Price per Share	Expiration Date	Exercisable for	Fair Value on Issuance (in thousands)	Fair Value Recorded Against
April 2015	1,000	$69.94	July 2026	Series A Common	$68	Debt

	As of December 31, 2022					
Issuance Date	Number of Warrant Shares	Exercise Price per Share	Expiration Date	Exercisable for	Fair Value on (in thousands)	Fair Value Recorded Against
June 2013	26,846	$0.79	June 2023	Common	$339	Redeemable convertible preferred stock
January 2014	13,422	0.79	January 2024	Common	223	Redeemable convertible preferred stock
April 2015	79,545	0.88	April 2025	Series D	68	Debt

10. Stock-based compensation

In 2007, the Company adopted the 2007 Equity Incentive Plan (2007 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 Plan expired pursuant to its terms and the Company adopted the 2017 Equity Incentive Plan (2017 Plan) which allowed 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 could be granted only to Company's employees, including officers and directors who are also employees. NSOs could be granted to employees, directors and consultants.

In 2023, the 2023 Stock Option and Incentive Plan (2023 Plan), was adopted by the board of directors, approved by the Company's stockholders on July 4, 2023, and became effective on July 13, 2023. The 2023 Plan replaced the 2017 Plan. The 2023 Plan permits the granting of both incentive stock options to purchase Series A common stock under Section 422 of the Code and non-qualified stock options. On July 18, 2023, each share of the Company's common stock issued and outstanding became reclassified as one share of Series A common stock, therefore, options prior to the IPO were to purchase common stock, and after the IPO are to purchase Series A common stock. The number of shares initially reserved for issuance under the 2023 Plan was 2,585,968, which will automatically increase on January 1, 2024 and each January 1 thereafter, by (i) 4% of the outstanding number of shares of our Series A common stock on the immediately preceding December 31 or (ii) a lesser number of shares as determined by the compensation committee of the board of directors. As of September 30, 2023, 2,585,968 shares are available for future grant under the 2023 Plan.

Options under the 2023 Plan can be granted for periods of up to ten 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 does not have an exercise price that is 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 (in thousands, except share and per share data):

	Number of Shares Underlying Outstanding Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value
Outstanding, January 1, 2023	3,190,450	$ 7.10	8.1	$ 3,998
Options granted	585,919	$13.51		
Options exercised	(7,614)	0.79		
Options cancelled	(498)	4.77		
Options expired	(1,752)	0.79		
Outstanding, September 30, 2023	3,766,505	$ 8.11	7.69	$17,737
Shares vested and exercisable as of September 30, 2023	1,784,725	$ 6.98	6.34	$10,206

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:

	Number of Shares Underlying Outstanding Options	Weighted-Average Exercise Price
Outstanding, January 1, 2023	2,570,708	$ 7.56
Options granted	585,919	13.51
Options exercised	(7,614)	0.79
Options cancelled	(498)	4.77
Options expired	(1,752)	0.79
Outstanding, September 30, 2023	3,146,763	$ 8.69
Shares vested and exercisable as of September 30, 2023	1,186,212	$14.42

The total fair value of the time-based shares vested during the nine months ended September 30, 2023 was $1.8 million. As of September 30, 2023, there was $12.0 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 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 total number of Series A common stock shares underlying outstanding options was 619,742 with a weighted-average exercise price of $6.38 as of December 31, 2022 and September 30, 2023, respectively. There were 598,513 shares vested and exercisable as of September 30, 2023.

The total fair value of the performance-based shares vested during the nine months ended September 30, 2023 was $11.1 thousand.

As of the nine months ended September 30, 2023, there was $28.2 thousand of unrecognized compensation cost related to the awards.

The cost is being recognized over a remaining weighted-average period of less than one year.

The Company has recorded aggregate stock-based compensation expense related to the issuance of stock option awards to employees and non-employees in the unaudited condensed statements of operations and comprehensive loss as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
General and administrative expense	$1,649	$ 220	$3,103	$ 663
Research and development expense	206	169	576	496
Total stock-based compensation expense	$1,855	$ 389	$3,679	$1,159

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.

The fair value of each award granted was estimated on the date of grant using the Black-Scholes option pricing model using the following assumptions:

	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022
Expected volatility	89 – 91%	88 – 90%
Risk-free interest rate	3.6%	2.3 – 3.0%
Dividend yield	—	—
Expected term	5.0 – 7.0 years	5.4 – 7.0 years

Employee stock purchase plan

The 2023 Employee Stock Purchase Plan (the ESPP), was adopted by the board of directors on June 22, 2023, approved by the Company's stockholders on July 4, 2023 and became effective on July 13, 2023. A total of 215,497 shares of Series A common stock were initially reserved for issuance under this plan, which will automatically increase on January 1, 2024 and each January 1 thereafter through January 1, 2033, by the least of (i) 215,497 shares of Series A common stock, (ii) 1% of the outstanding number of shares of the Company's Series A common stock on the immediately preceding December 31 or (iii) such lesser number of shares of Series A common stock as determined by the administrator of the ESPP. During the nine months ended September 30, 2023, no shares of Series A common stock were issued under the 2023 ESPP.

11. Net loss per share attributable to common stockholders

The table below is the calculation of basic and diluted loss per share attributable to common, Series A common and Series B common stockholders (in thousands, except share and per share data):

	Three Months Ended September 30, 2023	Three Months Ended September 30, 2022	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022
Numerator:				
Net loss attributable to common stockholders	$ —	$ (7,467)	$ —	$ (23,304)
Denominator:				
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	—	185,084	—	184,756
Net loss per share attributable to common stockholders, basic and diluted	$ —	$ (40.34)	$ —	$ (126.13)
Numerator:				
Net loss attributable to Series A and Series B common stockholders	$ (6,353)	$ —	$ (19,725)	$ —
Denominator:				
Weighted-average shares outstanding used in computing net loss per share attributable to Series A and Series B common stockholders, basic and diluted	18,194,682	—	6,131,541	—
Net loss per share attributable to Series A and Series B common stockholders, basic and diluted	$ (0.35)	$ —	$ (3.22)	$ —

The following outstanding shares of potentially dilutive securities were excluded from the computation of diluted net loss per share attributable to common, Series A common and Series B common stockholders for the periods presented because including them would have been antidilutive. On July 18, 2023, each share of the Company's common stock issued and outstanding became reclassified as one share of Series A common stock, therefore, options prior to the IPO were to purchase common stock, and after the IPO are to purchase Series A common stock.

	Three Months Ended September 30, 2023	Three Months Ended September 30, 2022	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022
Options to purchase Series A common stock	3,766,505	2,198,675	3,766,505	2,198,675
Warrant to purchase Series A Common Stock	1,000	—	1,000	—
Redeemable convertible preferred stock	—	16,638,476	—	16,638,476
Warrants to purchase common stock	—	40,268	—	40,268
Warrant to purchase redeemable convertible preferred stock	—	79,545	—	79,545
Total	3,767,505	18,956,964	3,767,505	18,956,964

12. 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 September 30, 2023.

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, 2022.

13. Subsequent events

The Company has evaluated subsequent events for financial statement purposes occurring through November 13, 2023, the date when these financial statements are available to be issued and noted that there are no subsequent events requiring disclosure in these condensed financial statements.

9,000,000 Shares

Series A Common Stock

P R O S P E C T U S

Goldman Sachs & Co. LLC **TD Cowen** **Leerink Partners**

JMP Securities
A CITIZENS COMPANY

, 2024

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 and the Financial Industry Regulatory Authority, Inc. (FINRA) filing fee.

SEC registration fee	$ 28,140.00
FINRA filing fee	29,098.00
Printing expenses	150,000.00
Legal fees and expenses	450,000.00
Accounting fees and expenses	150,000.00
Custodian transfer agent and registrar fees	10,000.00
Miscellaneous expenses	10,000.00
Total	$827,238.00

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 permits indemnification of our directors, officers, employees and other agents to the maximum extent permitted by the DGCL, and our amended and restated bylaws 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 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 23, 2021.

Equity plan-related issuances

1. Since January 23, 2021, we granted to certain of our directors, employees and consultants options to purchase 2,862,373 shares of our common stock at a $8.23 per share weighted-average exercise price under the 2017 Plan. The offers, sales and issuances of the securities described in this paragraph (1) 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.

Automatic conversion of preferred stock

2. On July 18, 2023, upon the closing of our IPO, all shares of outstanding convertible preferred stock automatically converted into 15,117,912 shares of Series A common stock and 1,520,490 shares of Series B common stock. The issuance of such shares common stock was exempt from the registration requirements of the Securities Act, pursuant to Section 3(a)(9) of the Securities Act, involving an exchange of securities exchanged by the issuer with its existing security holders exclusively where no commission or other remuneration is paid or given directly or indirectly for soliciting such exchange. No underwriters were involved in this issuance of shares.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits.

Exhibit Number	Description
1.1^	Form of Underwriting Agreement.
3.1	Eleventh Amended and Restated Certificate of Incorporation (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on July 18, 2023 (File No. 001-41742)).
3.2	Second Amended and Restated Bylaws, (incorporated herein by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed on July 18, 2023 (File No. 001-41742)).
4.1	Form of Series A Common Stock Certificate (incorporated herein by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1 filed on June 23, 2023 (File No. 333-272901)).
4.2	Form of Series B Common Stock Certificate (incorporated herein by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-1 filed on June 23, 2023 (File No. 333-272901)).
5.1	Opinion of Goodwin Procter LLP.
10.1•	2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1 filed on June 23, 2023 (File No. 333-272901)).
10.2•	Forms of Grant Notice, Stock Option Agreement and Notice of Exercise under the 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.2 to the Company's Registration Statement on Form S-1 filed on June 23, 2023 (File No. 333-272901)).
10.3•	Sagimet Biosciences Inc. 2017 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1 filed on June 23, 2023 (File No. 333-272901)).

Exhibit Number	Description
10.4•	Forms of Grant Notice, Stock Option Agreement and Notice of Exercise under the Sagimet Biosciences Inc. 2017 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-1 filed on June 23, 2023 (File No. 333-272901)).
10.5•	Sagimet Biosciences Inc. 2023 Stock Option and Incentive Plan (incorporated herein by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1/A filed on July 10, 2023 (File No. 333-272901)).
10.6•	Forms of Incentive Stock Option Agreement, Non-Qualified Stock Option Agreement for Non-Employee Directors and Non-Qualified Stock Option Agreement for Company Employees under the Sagimet Biosciences Inc. 2023 Stock Option and Incentive Plan under the Sagimet Biosciences Inc. 2023 Stock Option and Incentive Plan (incorporated herein by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-1 filed on June 23, 2023 (File No. 333-272901)).
10.7•	Forms of Restricted Stock Unit Award Agreement for Non-Employee Directors and Restricted Stock Unit Award Agreement for Company Employees under the Sagimet Biosciences Inc. 2023 Stock Option and Incentive Plan (incorporated herein by reference to Exhibit 10.7 to the Company's Registration Statement on Form S-1 filed on June 23, 2023 (File No. 333-272901)).
10.8•	Form of Restricted Stock Award Agreement under the Sagimet Biosciences Inc. 2023 Stock Option and Incentive Plan (incorporated herein by reference to Exhibit 10.8 to the Company's Registration Statement on Form S-1 filed on June 23, 2023 (File No. 333-272901)).
10.9•	Sagimet Biosciences Inc. 2023 Employee Stock Purchase Plan (incorporated herein by reference to Exhibit 10.9 to the Company's Registration Statement on Form S-1/A filed on July 10, 2023 (File No. 333-272901)).
10.10•	Sagimet Biosciences Inc. 2023 Non-Employee Director Compensation Policy (incorporated herein by reference to Exhibit 10.10 to the Company's Registration Statement on Form S-1 filed on June 23, 2023 (File No. 333-272901)).
10.11•	Form of Indemnification Agreement by and between the Registrant and its directors (incorporated herein by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-1 filed on June 23, 2023 (File No. 333-272901)).
10.12•	Form of Indemnification Agreement by and between the Registrant and its executive officers (incorporated herein by reference to Exhibit 10.12 to the Company's Registration Statement on Form S-1 filed on June 23, 2023 (File No. 333-272901)).
10.13•	Executive Employment Agreement by and between the Company and David Happel, dated August 15, 2023 (incorporated herein by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on August 21, 2023 (File No. 001-41742)).
10.14•	Executive Employment Agreement by and between the Company and George Kemble, dated August 15, 2023 (incorporated herein by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on August 21, 2023 (File No. 001-41742)).
10.15•	Executive Employment Agreement by and between the Company and Eduardo Martins, dated August 15, 2023 (incorporated herein by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed on August 21, 2023 (File No. 001-41742)).
10.16•	Executive Employment Agreement by and between the Company and Anthony Rimac, dated August 15, 2023 (incorporated herein by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q filed on August 21, 2023 (File No. 001-41742)).
10.17•	Executive Employment Agreement by and between the Company and Elizabeth Rozek, dated August 15, 2023 (incorporated herein by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q filed on August 21, 2023 (File No. 001-41742)).

Exhibit Number	Description
10.18•	Sagimet Biosciences Inc. Senior Executive Cash Incentive Bonus Plan (incorporated herein by reference to Exhibit 10.21 to the Company's Registration Statement on Form S-1 filed on June 23, 2023 (File No. 333-272901)).
10.19*	Exclusive License and Development Agreement by and between the Registrant and Ascletis BioScience Co. Ltd., dated as of January 18, 2019 (incorporated herein by reference to Exhibit 10.22 to the Company's Registration Statement on Form S-1 filed on June 23, 2023 (File No. 333-272901)).
10.20*	Patent Assignment Agreement by and between the Registrant and Gannex Pharma Co., Ltd., effective October 25, 2019 (incorporated herein by reference to Exhibit 10.23 to the Company's Registration Statement on Form S-1 filed on June 23, 2023 (File No. 333-272901)).
10.21*	Amended and Restated Patent Assignment Agreement by and between the Registrant and Gannex Pharma Co., Ltd., dated July 2, 2023 (incorporated herein by reference to Exhibit 10.24 to the Company's Registration Statement on Form S-1/A filed on July 10, 2023 (File No. 333-272901)).
10.22	Lease Agreement by and between the Registrant and Casiopea Bovet, LLC, dated as of March 1, 2019, as amended by the First Amendment to Lease Agreement, dated December 14, 2021 (incorporated herein by reference to Exhibit 10.25 to the Company's Registration Statement on Form S-1 filed on June 23, 2023 (File No. 333-272901)).
10.23	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. as amended by Amendment No. 1 to Amended and Restated Nominating Agreement, dated as of June 22, 2023, by and among the Registrant, Baker Brothers Life Sciences, L.P. and 667, L.P. (incorporated herein by reference to Exhibit 10.26 to the Company's Registration Statement on Form S-1 filed on June 23, 2023 (File No. 333-272901)).
10.24	Amended and Restated Investors' Rights Agreement, by and among the Registrant and certain of its stockholders, dated December 21, 2020 (incorporated herein by reference to Exhibit 10.27 to the Company's Registration Statement on Form S-1 filed on June 23, 2023 (File No. 333-272901)).
10.25	Assignment and Assumption Agreement, by and among the Registrant, Ascletis BioScience Co., Ltd. and Gannex Pharma Co., Ltd., effective October 25, 2019 (incorporated herein by reference to Exhibit 10.29 to the Company's Registration Statement on Form S-1/A filed on July 10, 2023 (File No. 333-272901)).
10.26•	Transition Services Agreement with Dennis Hom, dated April 4, 2023 (incorporated herein by reference to Exhibit 10.16 to the Company's Registration Statement on Form S-1 (File No. 333-272901) filed on June 23, 2023).
10.27•	Amendment to Transition Services Agreement with Dennis Hom, dated June 18, 2023 (incorporated herein by reference to Exhibit 10.16 to the Company's Registration Statement on Form S-1 (File No. 333-272901) filed on June 23, 2023).
10.28^	Amended and Restated Warrant to Purchase Stock, by and between the Registrant and Banc of California, Inc., dated January 4, 2024.
23.1	Consent of Independent Registered Public Accounting Firm.
23.2	Consent of Goodwin Procter LLP (included in Exhibit 5.1).
24.1^	Power of Attorney (included on signature page).
101.INS	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because iXBRL tags are embedded within the Inline XBRL document).
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.

Exhibit Number	Description
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)
107^	Fee Table.

^ Previously filed.

• Indicates management contract or compensatory plan.

* 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.

(c) Filing Fee Table.

The information required to be furnished by paragraph (c) of this Item is incorporated herein by reference to Exhibit 107.

Item 17. Undertakings.

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 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.

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 upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall 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, each post-effective amendment that contains a form of prospectus shall 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 January 24, 2024.

SAGIMET BIOSCIENCES INC.

By: /s/ David Happel
Name: David Happel
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/ David Happel David Happel	President, Chief Executive Officer and Director (Principal Executive Officer)	January 24, 2024
/s/ Anthony Rimac Anthony Rimac	Chief Financial Officer (Principal Financial and Accounting Officer)	January 24, 2024
* George Kemble, Ph.D.	Executive Chairman of the Board	January 24, 2024
* Elizabeth Grammer, Esq.	Director	January 24, 2024
* Merdad Parsey, M.D., Ph.D.	Director	January 24, 2024
* Richard Rodgers	Director	January 24, 2024
/* Beth Seidenberg, M.D.	Director	January 24, 2024
* Jinzi J. Wu, Ph.D.	Director	January 24, 2024

*By: /s/ David Happel
David Happel
Attorney-in-Fact

Exhibit 5.1

GOODWIN

January 24, 2024

Sagimet Biosciences Inc.
155 Bovet Road, Suite 303
San Mateo, California 94402

Re: Securities Registered under Registration Statement on Form S-1

We have acted as counsel to you in connection with your filing of a Registration Statement on Form S-1 (as amended or supplemented, the "Registration Statement") pursuant to the Securities Act of 1933, as amended (the "Securities Act"), relating to the registration of the offering by Sagimet Biosciences Inc., a Delaware corporation (the "Company"), of up to 10,350,000 shares (the "Shares") of the Company's Series A Common Stock, $0.0001 par value per share, including Shares purchasable by the underwriters upon their exercise of an over-allotment option granted to the underwriters by the Company. The Shares are being sold to the several underwriters named in, and pursuant to, an underwriting agreement among the Company and such underwriters (the "Underwriting Agreement").

We have reviewed such documents and made such examination of law as we have deemed appropriate to give the opinions set forth below. We have relied, without independent verification, on certificates of public officials and, as to matters of fact material to the opinions set forth below, on certificates of officers of the Company.

The opinion set forth below is limited to the Delaware General Corporation Law.

Based on the foregoing, we are of the opinion that the Shares have been duly authorized and, when delivered and paid for in accordance with the terms of the Underwriting Agreement, will be validly issued, fully paid and non-assessable.

This opinion letter and the opinion it contains shall be interpreted in accordance with the Core Opinion Principles as published in 74 *Business Lawyer* 815 (Summer 2019).

We hereby consent to the inclusion of this opinion as Exhibit 5.1 to the Registration Statement and to the references to our firm under the caption "Legal Matters" in the Registration Statement. In giving our consent, we do not admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations thereunder.

Very truly yours,

/s/ GOODWIN PROCTER LLP

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the use in this Registration Statement No. 333-276664 on Form S-1 of our report dated March 24, 2023, (July 9, 2023, as to the effects of the reverse stock split described in Note 14) 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 Francisco, California
January 24, 2024