

**CONFIDENTIAL TREATMENT REQUESTED BY ALUMIS INC.  
PURSUANT TO 17 C.F.R. SECTION 200.83**

As confidentially submitted to the Securities and Exchange Commission on April 10, 2024.

This draft registration statement has not been publicly filed with the  
Securities and Exchange Commission and all information herein remains strictly confidential.

Registration No. 333-

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

**FORM S-1  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933**

**Alumis Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**2834**  
(Primary Standard Industrial  
Classification Code Number)

**86-1771129**  
(I.R.S. Employer  
Identification Number)

**Alumis Inc.**  
**280 East Grand Avenue**  
**South San Francisco, California 94080**  
**(650) 231-6625**

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

**Martin Babler**  
**President and Chief Executive Officer**  
**280 East Grand Avenue**  
**South San Francisco, California 94080**  
**(650) 231-6625**

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

**Dave Peinsipp**  
**Kristin VanderPas**  
**Lauren Creel**  
**Cooley LLP**  
**3 Embarcadero Center, 20th Floor**  
**San Francisco, California 94111**  
**(415) 693-2000**

**Copies to:**  
**John Schroer**  
**Chief Financial Officer**  
**280 East Grand Avenue**  
**South San Francisco, California 94080**  
**(650) 231-6625**

**B. Shayne Kennedy**  
**Ross McAloon**  
**Latham & Watkins LLP**  
**505 Montgomery Street, Suite 2000**  
**San Francisco, California 94111**  
**(415) 391-0600**

**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, 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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** \_\_\_\_\_, 2024.**Shares****alumis****Common Stock**

This is an initial public offering of shares of common stock of Alumis Inc. We are offering \_\_\_\_\_ shares of our common stock to be sold in the offering.

Prior to this offering, there has been no public market for our common stock. It is currently estimated that the initial public offering price per share will be between \$ \_\_\_\_\_ and \$ \_\_\_\_\_. We intend to apply to list our common stock on the Nasdaq Global Market under the symbol "ALMS."

We have two classes of common stock: the voting common stock offered hereby and non-voting common stock. The rights of the holders of common stock and non-voting common stock are identical, except with respect to voting and conversion. Each share of common stock is entitled to one vote and is not convertible into any other class of our share capital. Shares of non-voting common stock are non-voting, except as otherwise expressly provided in our amended and restated certificate of incorporation and as may be required by law. Each share of non-voting common stock may be converted at any time into one share of common stock at the option of its holder, subject to the beneficial ownership limitations provided for in our amended and restated certificate of incorporation. See the section titled "Description of Capital Stock" beginning on page 165 of this prospectus for more information on the rights of the holders of our common stock and non-voting common stock. We are offering voting common stock in this offering, and unless otherwise noted, all references in this prospectus to our "common stock" "common shares" or "shares" refer to our voting common stock. The non-voting common stock will not be listed for trading on any securities exchange.

See the section titled "Risk Factors" beginning on page 13 to read about factors you should consider before buying shares of the common stock.

Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

We are an "emerging growth company" and a "smaller reporting company" as defined under the U.S. federal securities laws and, as such, may elect to comply with certain reduced public company reporting requirements in future reports after the closing of this offering. See the section titled "Prospectus Summary—Implications of Being an Emerging Growth Company and a Smaller Reporting Company."

	Per Share	Total
Initial public offering price	\$ _____	\$ _____
Underwriting discounts and commissions <sup>(1)</sup>	\$ _____	\$ _____
Proceeds, before expenses, to Alumis	\$ _____	\$ _____

(1) See the section titled "Underwriting" beginning on page 176 for additional information regarding underwriter compensation.

At our request, the underwriters have reserved up to \_\_\_\_\_ shares of common stock, or up to \_\_\_\_\_ % of the shares offered by this prospectus, for sale at the initial public offering price through a directed share program to certain individuals identified by management. See the section titled "Underwriting—Directed Share Program."

We have granted the underwriters an option to purchase up to an additional \_\_\_\_\_ shares from us at the initial public offering price, less the underwriting discount and commissions. The underwriters may exercise this right at any time within 30 days after the date of this prospectus.

The underwriters expect to deliver the shares to purchasers on or about \_\_\_\_\_, 2024.

**Morgan Stanley**

Prospectus dated \_\_\_\_\_, 2024.

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

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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 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 common stock and the distribution of this prospectus outside of the United States.

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**PROSPECTUS SUMMARY**

*This summary highlights selected information contained elsewhere in this prospectus and is qualified in its entirety by the more detailed information and financial statements included elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should carefully read this entire prospectus, including the information under the sections titled “Risk Factors,” “Special Note Regarding Forward-Looking Statements” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and related notes included elsewhere in this prospectus, before making an investment decision. Unless the context requires otherwise, references in this prospectus to “Alumis,” the “Company,” “we,” “us” and “our” refer to Alumis Inc.*

**Overview**

Our mission is to significantly improve the lives of patients by replacing broad immunosuppression with targeted therapies. Our name, Alumis, captures our mission to enlighten immunology, and is inspired by the words “allumer”—French for illuminate—and “immunis”—Latin for the immune system.

We are a clinical stage biopharmaceutical company with an initial focus on developing our two Tyrosine Kinase 2 (TYK2) inhibitors: ESK-001, a second-generation inhibitor that we are developing to safely achieve maximum target inhibition and A-005, a central nervous system (CNS) penetrant molecule. ESK-001 has demonstrated significant therapeutic effect in our Phase 2 program in patients with PsO, which we define as moderate-to-severe plaque psoriasis (PsO), and is currently being evaluated in additional Phase 2 clinical trials in patients with systemic lupus erythematosus (SLE) and non-infectious uveitis (Uveitis), for which we expect to report results in                      and                      , respectively. With the favorable results in our Phase 2 clinical trial in PsO, we intend to initiate multiple Phase 3 clinical trials of ESK-001 in                      in this indication. TYK2 genetic mutations are associated with a strong protective effect in multiple sclerosis, motivating us to develop our second product candidate, A-005, as a CNS penetrant, allosteric TYK2 inhibitor for neuroinflammatory and neurodegenerative diseases. In                      2024, we initiated our Phase 1 program of A-005 in healthy volunteers and expect to report results in                      .

We utilize our precision data analytics platform, biological insights and team of experienced research and development experts to deepen our understanding of disease pathologies, accelerate research and development and increase the probability of clinical success. Our collective insights informed our selection of TYK2 as the target for our two lead programs. Beyond TYK2, our precision data analytics platform and drug discovery expertise have led to the identification of additional preclinical programs that exemplify our precision approach.

We recognize that patients living with immune-mediated diseases need alternatives to currently available therapies. Despite recent advances and innovations in the treatment of immune-mediated diseases, many patients continue to suffer, cycling through currently approved therapies while looking for a solution that alleviates the debilitating impact of their disease without life-limiting side effects.

Addressing the needs of these patients is why we exist. We are pioneering a precision approach that leverages insights derived from powerful data analytics to select the right target, right molecule, right indication, right patient, right endpoint and right combination to dramatically improve patient outcomes. We believe that combining our insights with an integrated approach to drug development will produce the next generation of treatments to address immune dysfunction.

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## Our Pipeline

We are building a pipeline of molecules with the potential to address a broad range of immune-mediated diseases as monotherapy or combination therapies. Within our TYK2 franchise, we are developing our most advanced product candidate, ESK-001, to be a potential best-in-class allosteric TYK2 inhibitor for the treatment of PsO, SLE and Uveitis. We are developing our second TYK2 product candidate, A-005, as a CNS penetrant, allosteric TYK2 inhibitor, to offer the therapeutic benefit of TYK2 inhibition within the CNS for a broad range of neuroinflammatory and neurodegenerative diseases.

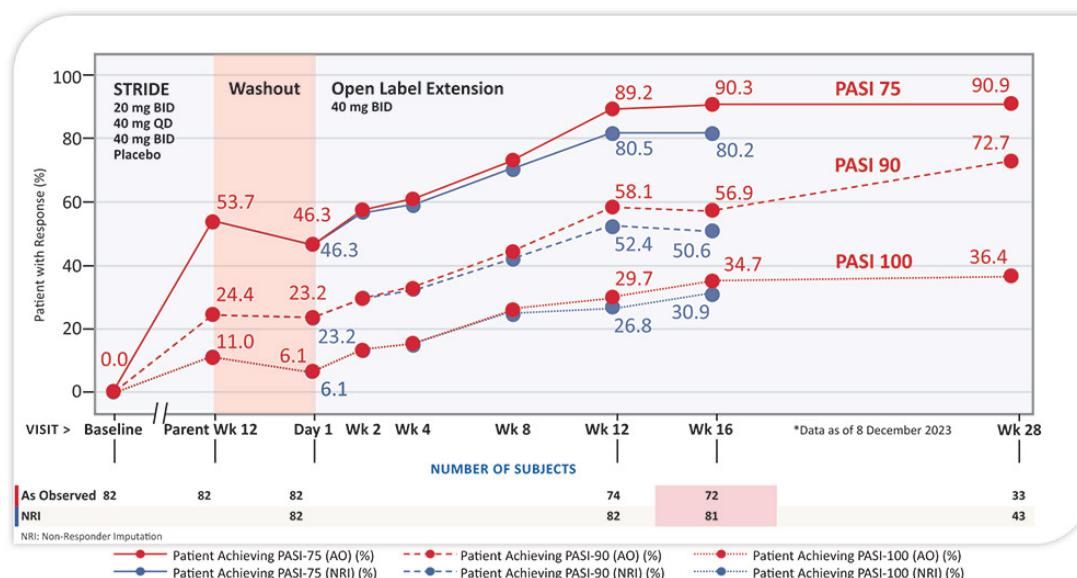
TYK2 MODULATION	INDICATION	DEVELOPMENT				ANTICIPATED MILESTONE	GLOBAL RIGHTS
		DISCOVERY/PRECLINICAL	PHASE 1	PHASE 2	PHASE 3		
ESK-001 (TYK2)	PsO						
	Systemic Lupus Erythematosus						
	Non-infectious Uveitis						
A-005 (TYK2)	Neuroinflammation						

Our most advanced product candidate, ESK-001, is an oral, highly selective, small molecule, allosteric inhibitor of TYK2. At the 2024 American Academy of Dermatology (AAD) Annual Meeting in March 2024, we announced positive data from our Phase 2 clinical program of ESK-001 in patients with PsO, which included the results of our Phase 2 STRIDE trial and interim results of our open label extension (OLE) as of a December 8, 2023 data cut. Our data demonstrated that ESK-001's ability to maximally inhibit TYK2 translates to the achievement of high rates of response, as measured by the Psoriasis Area and Severity Index (PASI), in patients, with response rates in the range observed with existing biologic therapies. Our Phase 2 STRIDE trial, in which 228 patients with PsO were randomized to one of five ESK-001 dose cohorts or placebo, met its primary endpoint, the proportion of patients achieving a 75% improvement in the PASI Score (PASI 75) at week 12 compared to placebo, and key secondary efficacy endpoints at all clinically relevant doses tested. Clear dose-dependent responses were observed, with the highest response rates and maximal TYK2 inhibition achieved at the highest dose of 40 mg twice daily (BID). At the 40 mg BID dose and at the 40 mg once daily (QD) dose, 64% and 56% of evaluable patients, respectively, achieved PASI 75 at week 12 compared to 0% for placebo.

Patients who completed the randomized placebo-controlled Phase 2 STRIDE trial were eligible to participate in the open label extension (OLE). In the OLE, 164 patients were assigned to receive either 40 mg BID or 40 mg QD. As shown in the figure below, as of the December 8, 2023 data cut, interim OLE data following 16 weeks of treatment in the extension period showed sustained increases in PASI response rates over time, with the majority of patients (90% of evaluable patients, 80% using a conservative non-responder imputation (NRI)) achieving PASI 75 at the 40 mg BID dose, as well as a continued favorable tolerability profile. Maximal target inhibition at the 40 mg BID dose, confirmed by blood and skin biopsy biomarkers, translated into the highest response rates, as compared with substantially lower response rates at the 40 mg QD dose. Given the tolerability profile we observed at the highest dose in our Phase 2 program, we intend to advance that dose into Phase 3 pivotal clinical trials. We are also developing a once-a-day modified release formulation that we plan to have available at the time of market launch, if approved, or within the first year post approval. Data in the table below are presented both "as observed" (AO) and applying an NRI where patients who dropped out during the trial were assumed to be non-responders for all time points after dropping out.

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*OLE ESK-001 40 mg BID Cohort  
As Observed (AO) and Non-Responder Imputation (NRI) Analyses*



NOTE: The shaded column in the figure above represents a four-week period during which no treatment was administered (the washout period).

These data suggest a differentiated profile of ESK-001 relative to first-generation TYK2 inhibitors. We plan to initiate our Phase 3 pivotal clinical trials in PsO in . We are also evaluating ESK-001 in LUMUS, a Phase 2b clinical trial of ESK-001 for the treatment of patients with SLE, and in OPTYK-1, a proof-of-concept Phase 2a clinical trial in patients with Uveitis. We expect to report results for these trials in and , respectively.

Beyond our initial three ongoing clinical indications of ESK-001, we plan to leverage our large clinical and genetic datasets to prioritize future indications, such as psoriatic arthritis and gastrointestinal and other indications where we believe ESK-001 could be differentiated from existing therapies. We believe ESK-001 has the potential to address a broad range of immune-mediated diseases and unmet patient needs that represent substantial commercial opportunities.

We have incorporated our learnings from ESK-001 to develop A-005, as a CNS penetrant, allosteric TYK2 inhibitor with potential application in multiple sclerosis (MS) and other neuroinflammatory and neurodegenerative diseases. Our large proprietary genetic data set as well as scientific literature have shown that the naturally occurring TYK2 loss of function genetic variant has a protective effect in MS. In our preclinical studies, A-005 has demonstrated protective effects in multiple *in vivo* disease models of neuroinflammation. In 2024, we initiated the first Phase 1 study of A-005 in healthy volunteers and expect to report results in .

### Our Team

We have assembled an executive team of industry veterans experienced in small-molecule compound drug development for immune-mediated diseases. Our senior leaders bring together a wealth of scientific, clinical, business and commercial expertise in the biopharmaceutical industry. Many of our employees and executives previously worked together at Genentech, Roche, Principia and MyoKardia and have united to work together again. Collectively, our executives have contributed to the research, development, approval and commercial launch of multiple drugs across several therapeutic areas, including Adbry, Avastin, Camzyos, Fasenna, Lucentis, Ocrevus, Rituxan, Saphnelo, Siliq, Tarceva, Tezspire, Uplizna, Xeljanz and Xolair. To date, we have raised more than \$600 million and are backed by established blue-chip life science investors.

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**Our Precision Approach and Capabilities**

We apply our precision approach to immunology by focusing on the key drivers of immune dysfunction. We have established and continue to uncover key genetic and translational insights to significantly impact clinical outcomes. Foundational to our approach is our precision data analytics platform that allows us to leverage genetic, genomic, proteomic, and biological and clinical disease insights to potentially increase speed of development, probability of success and precision of therapy. We employ our insights and capabilities through every stage of development, always aiming to improve the likelihood of clinical success while achieving the best outcomes for patients. We believe our precision approach can bring forth paradigm-shifting advances in each of the following key areas:

- **Right target:** We select drug targets based on our understanding of their role in immune-mediated diseases in an effort to maximize clinical benefit and probability of success.
- **Right molecule:** We design our molecules to achieve maximal target engagement and a safe pharmacological profile.
- **Right indication:** We select indications based on weight of evidence and biological insights from our precision data analytics platform.
- **Right endpoint:** We seek to accelerate drug development and improve the clinical probability of success through selection of optimal clinical endpoints for our trials.
- **Right patient:** We gain insights from our proprietary clinical samples to identify patients that we believe are most likely to benefit from our therapies.
- **Right combinations:** We identify future combination strategies with the potential to break through efficacy limitations of existing therapies without broadly suppressing the immune system.

**Our Strategy**

Our mission is to significantly improve the lives of patients by replacing broad immunosuppression with targeted therapies. As our driving principle, we are using our precision approach focused on the important drivers of immune dysfunction. We use our key insights to pursue our mission of significantly improving outcomes for patients. We select drug targets that have been previously validated by strong human genetic evidence and human clinical data.

The core components of our business strategy include:

- **Maximize the opportunity by developing a best-in-class profile for ESK-001.**
- **Expand our TYK2 franchise with A-005, our potential first-in-class allosteric TYK2 inhibitor designed to penetrate the CNS to treat neuroinflammation.**
- **Discover and advance earlier-stage product candidates into clinical development.**
- **Leverage our precision approach to increase speed of development, probability of success and precision of therapy.**
- **Evaluate strategic collaborations to maximize the global impact of our product candidates.**

**Risk Factor Summary**

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

- We are a clinical stage biopharmaceutical company with a limited operating history and no products approved for commercial sale, and have incurred substantial losses since our inception and anticipate incurring substantial and increasing losses for the foreseeable future.
- Enrollment and retention of participants in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control,

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including difficulties in identifying patients, the availability of competitive products, and significant competition for recruiting participants in clinical trials.

- We will require substantial additional financing to achieve our goals and failure to obtain additional capital when needed, or on acceptable terms to us, could cause us to delay, limit, reduce, or terminate our product development or future commercialization efforts.
- Preclinical and clinical development involves a lengthy and expensive process, with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our current product candidates or any future product candidates.
- Our clinical trials may reveal significant adverse events not seen in our preclinical studies or prior clinical trials and may result in a safety or tolerability profile that could delay or prevent regulatory approval or market acceptance of ESK-001, A-005 or any future product candidates.
- We face competition from entities that have made substantial investments into the rapid development of competitor treatments for immunological indications, including large and specialty pharmaceutical and biotechnology companies, many of which already have approved therapies in our current indications.
- Our business is highly dependent on the success of our most advanced product candidate, ESK-001, and we cannot guarantee that ESK-001 will successfully complete development, receive regulatory approval or be successfully commercialized. If we are unable to develop, receive regulatory approval for, and ultimately successfully commercialize our product candidates, or if we experience significant delays in doing so, our business will be materially harmed.
- 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 product candidates, our business will be substantially harmed.
- We are dependent on the services of our management team and other clinical and scientific personnel, and if we are not able to retain these individuals or recruit additional management or clinical and scientific personnel, our business will suffer.
- If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates and any future product candidates we may develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully develop and commercialize our product candidates may be adversely affected.
- We cannot ensure that patent rights relating to inventions described and claimed in our or any future licensors pending patent applications will issue or that patents based on our or any future licensors patent applications will not be challenged and rendered invalid and/or unenforceable.
- We may form or seek collaborations or strategic alliances or enter into licensing arrangements in the future, and we may neither enter into, nor realize the benefits of, such alliances or licensing arrangements.
- Even if we receive regulatory approval for our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal. We may also be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.
- We may have conflicts with any future licensors or collaborators that could delay or prevent the development or commercialization of our product candidates.
- As a result of our history of losses and negative cash flows from operations, our consolidated financial statements contain a statement regarding a substantial doubt about our ability to continue as a going concern.



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**Corporate Information**

We were founded in January 2021 as a Delaware corporation under the name FL2021-001, Inc. We changed our name to Esker Therapeutics, Inc. in March 2021, and subsequently to Alumis Inc. in January 2022. Our principal executive offices are located at 280 East Grand Avenue, South San Francisco, California 94080, and our telephone number is (650) 231-6625. Our website address is [www.alumis.com](http://www.alumis.com). Information contained in, or accessible through, our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is only an inactive textual reference.

**Trademarks, Trade Names and Service Marks**

We use the Alumis logo and other marks as trademarks in the United States and other countries. This prospectus contains references to our trademarks and service marks and to those belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such 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 rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other entities' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity.

**Implications of Being an Emerging Growth Company and a Smaller Reporting Company**

We are an emerging growth company, as defined in Section 2(a) of the Securities Act of 1933, as amended (the Securities Act), as modified by the Jumpstart Our Business Startups Act of 2012 (the JOBS Act), and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to present only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this prospectus,
- relief from the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended (the Sarbanes-Oxley Act),
- relief from compliance with the requirements of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor's report on the financial statements,
- less extensive disclosure obligations regarding executive compensation in our registration statements, periodic reports and proxy statements,
- exemptions from the requirements to hold a nonbinding advisory vote on executive compensation, and
- exemptions from stockholder approval of any golden parachute payments not previously approved.

We may also elect to take advantage of other reduced reporting requirements in future filings. As a result, our stockholders may not have access to certain information that they may deem important and the information that we provide to our stockholders may be different than, and not comparable to, information presented by other public reporting companies. We could remain an emerging growth company until the earlier of (i) the last day of the year following the fifth anniversary of the completion of this offering, (ii) the last day of the year in which we have total annual gross revenue of at least \$1.235 billion, (iii) the last day of the year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended (the Exchange Act), which would occur if the market value of our common stock and non-voting common stock held by non-affiliates exceeded \$700.0 million as of the last business day of the second fiscal quarter of such year or (iv) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period.

In addition, the JOBS Act also provides that an emerging growth company may take advantage of the extended transition period provided in the Securities Act for complying with new or revised accounting standards. An emerging growth company may therefore delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption

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and, as a result, will not be subject to the same implementation timing for new or revised accounting standards as are required of other public companies that are not emerging growth companies, which may make comparison of our financial information to those of other public companies more difficult.

We are also a “smaller reporting company,” meaning that the market value of our common stock and non-voting common stock held by non-affiliates is less than \$700.0 million and our annual revenue is less than \$100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company after this offering if either (i) the market value of our common stock and non-voting common stock held by non-affiliates is less than \$250.0 million or (ii) our annual revenue is less than \$100.0 million during the most recently completed fiscal year and the market value of our common stock and non-voting common stock held by non-affiliates is less than \$700.0 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.

**Basis of Presentation**

Certain monetary amounts, percentages, and other figures included elsewhere in this prospectus have been subject to rounding adjustments. Accordingly, figures shown as totals in certain tables or charts may not be the arithmetic aggregation of the figures that precede them, and figures expressed as percentages in the text may not total 100% or, as applicable, when aggregated may not be the arithmetic aggregation of the percentages that precede them.

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<b>The Offering</b>	
<b>Common stock offered by us</b>	shares.
<b>Underwriters' over-allotment option of common stock</b>	shares.
<b>Total common stock and non-voting common stock to be outstanding immediately after this offering</b>	shares (of which            shares will be common stock), or shares (of which            shares will be common stock) if the underwriters exercise their over-allotment option in full.
<b>Use of proceeds</b>	<p>We estimate that the net proceeds from this offering will be approximately \$            million (or approximately \$            million if the underwriter's over-allotment option is exercised in full), based on the assumed initial public offering price of \$            per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.</p> <p>We currently intend to use the net proceeds from this offering, together with our existing cash, cash equivalents and marketable securities, to fund clinical development and related studies for our product candidates as well as our activities in preparation for such clinical development. See the section titled "Use of Proceeds" for additional information.</p>
<b>Voting rights</b>	We have two classes of common stock: the common stock offered hereby and non-voting common stock. For a description of the rights of the common stock and non-voting common stock, see the section titled "Description of Capital Stock."
<b>Risk factors</b>	See the section titled "Risk Factors" and other information included in this prospectus for a discussion of factors you should consider carefully before deciding to invest in our common stock.
<b>Proposed Nasdaq Global Market trading symbol</b>	"ALMS"
<b>Directed Share Program</b>	At our request, the underwriters have reserved up to    % of the shares of common stock being offered by this prospectus for sale, at the initial public offering price, to certain individuals identified by management. We do not know if these parties will choose to purchase all or any portion of these reserved shares, but the number of shares of common stock available for sale to the general public will be reduced to the extent these individuals purchase such reserved shares. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same basis as the other shares offered by this prospectus. See "Underwriting—Directed Share Program."
<p>The number of shares of our common stock and non-voting common stock to be outstanding immediately after this offering is based on an aggregate of            shares of common stock and non-voting common stock (which includes            shares of unvested restricted common stock subject to a repurchase option by us) outstanding as of March 31, 2024, after giving effect to the Preferred Stock Conversion and the Common Stock Reclassification (each as defined below), as if each had occurred as of March 31, 2024, and excludes:</p> <ul style="list-style-type: none"> <li>•            shares of our common stock issuable upon the exercise of outstanding stock options as of March 31, 2024, with a weighted-average exercise price of \$            per share;</li> </ul>	

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- shares of our common stock issuable upon the exercise of outstanding stock options granted subsequent to March 31, 2024, with a weighted-average exercise price of \$ \_\_\_\_\_ per share;
- shares of our common stock reserved for future issuance under our 2024 Equity Incentive Plan (2024 Plan), which will become effective once the registration statement of which this prospectus forms a part is declared effective, including \_\_\_\_\_ new shares plus the number of shares (not to exceed \_\_\_\_\_ shares) that (i) remain available for grant of future awards under our 2021 Stock Plan (2021 Plan) and will cease to be available for issuance under the 2021 Plan at the time our 2024 Plan becomes effective in connection with this offering, and (ii) are underlying outstanding stock awards granted under our 2021 Plan, that expire or are repurchased, forfeited, cancelled or withheld, as well as any future automatic annual increases in the number of shares of common stock reserved for issuance under our 2024 Plan and, as more fully described in the section titled “Executive Compensation—Equity Benefit Plans;” and
- shares of our common stock reserved for issuance under our 2024 Employee Stock Purchase Plan (ESPP), which will become effective once the registration statement of which this prospectus forms a part is declared effective, as well as any future automatic annual increases in the number of shares of common stock reserved for future issuance under our ESPP, as more fully described in the section titled “Executive Compensation—Equity Benefit Plans.”

Unless otherwise indicated, this prospectus assumes or gives effect to:

- a \_\_\_\_\_ -for- \_\_\_\_\_ reverse stock split of our Class A and Class B common stock effected on \_\_\_\_\_, 2024;
- the automatic conversion of \_\_\_\_\_ outstanding shares of our redeemable convertible preferred stock into \_\_\_\_\_ shares of our Class A common stock and \_\_\_\_\_ shares of our Class B common stock, which will occur immediately prior to the closing of this offering (the Preferred Stock Conversion);
- the redesignation of all outstanding shares of Class A and Class B common stock (following the Preferred Stock Conversion) into an equivalent number of shares of common stock and non-voting common stock, respectively, which will occur immediately prior to the completion of this offering (the Common Stock Reclassification);
- the redesignation of all shares of Class A common stock underlying outstanding options under our 2021 Plan into shares of common stock, which will occur immediately prior to the completion of this offering;
- no exercise of outstanding stock options referred to above;
- no repurchases by us of unvested restricted common stock subsequent to \_\_\_\_\_, 2024;
- no exercise by the underwriters of their over-allotment option;
- an assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the estimated price range set forth on the cover page of this prospectus; and
- the filing and effectiveness of our amended and restated certificate of incorporation and the effectiveness of our amended and restated bylaws, each of which will occur immediately prior to the completion of this offering.

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**Summary Consolidated Financial Data**

The following tables set forth our summary consolidated financial data for the periods and as of the dates indicated. The following summary consolidated statements of operations data for the years ended December 31, 2022 and 2023 have been derived from our audited consolidated financial statements included elsewhere in this prospectus. The following summary interim condensed consolidated statements of operations data for the three months ended March 31, 2023 and 2024, and the summary interim condensed consolidated balance sheet data as of March 31, 2024, have been derived from our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus. Our audited consolidated financial statements and unaudited interim condensed consolidated financial statements included elsewhere in this prospectus have been prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP). Our unaudited interim condensed consolidated financial statements were prepared on a basis consistent with our audited consolidated financial statements and include, in our opinion, all adjustments of a normal and recurring nature that are necessary for the fair statement of the financial information set forth in those statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected for any period in the future and results for the three months ended March 31, 2024 are not necessarily indicative of results to be expected for the year ending December 31, 2024.

You should read the following summary consolidated financial data together with the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our audited consolidated financial statements and unaudited interim condensed consolidated financial statements and the related notes included elsewhere in this prospectus. The summary consolidated financial data included in this section are not intended to replace the consolidated financial statements and the related notes included elsewhere in this prospectus.

	Year Ended December 31,		Three Months Ended March 31,	
	2022	2023	2023	2024
<b>Consolidated Statements of Operations Data:</b>				
(in thousands, except share and per share data)				
<b>Operating expenses:</b>				
Research and development expenses, including related party expenses of \$1,570 and \$1,519 for the years ended December 31, 2022 and 2023, respectively	\$ 101,304	\$ 137,676	\$	\$
General and administrative expenses	12,546	20,498		
Total operating expenses	113,850	158,174		
Loss from operations	(113,850)	(158,174)		
<b>Other income (expense):</b>				
Interest income	1,992	3,368		
Change in fair value of derivative liability	—	(119)		
Other income (expenses), net	(72)	(68)		
Total other income (expense), net	1,920	3,181		
Net loss	\$ (111,930)	\$ (154,993)	\$	\$
Net loss per share attributable to Class A common stockholders, basic and diluted <sup>(1)</sup>	\$ (14.93)	\$ (15.42)	\$	\$
Weighted-average Class A common shares outstanding, basic and diluted <sup>(1)</sup>	7,497,622	10,052,198		
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited) <sup>(2)</sup>		\$ (1.61)		\$
Pro forma weighted-average common shares outstanding, basic and diluted (unaudited) <sup>(2)</sup>		96,012,286		

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- (1) See Note 2 to our audited consolidated financial statements and Note \_\_\_\_\_ to our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus for a description of how we compute basic and diluted net loss per share attributable to Class A common stockholders.
- (2) See “Unaudited Pro Forma Net Loss Per Share Attributable to Common Stockholders” subsection below for details on our unaudited pro forma calculations.

**Unaudited Pro Forma Net Loss Per Share Attributable to Common Stockholders**

The unaudited pro forma basic and diluted net loss per share for the year ended December 31, 2023 and for the three months ended March 31, 2024 were computed using the weighted-average number of shares of common stock and non-voting common stock outstanding, including the pro forma effect of the Preferred Stock Conversion and the Common Stock Reclassification, as if such conversion and reclassification had occurred at the beginning of the period. Pro forma net loss per share does not include the shares expected to be sold in this offering.

The following table sets forth the computation of the unaudited pro forma basic and diluted net loss per share of common stock and non-voting common stock for the periods presented:

	<u>Year Ended December 31, 2023</u>	<u>Three Months Ended March 31, 2024</u>
	<u>(in thousands, except share and per share data)</u>	
<b>Numerator:</b>		
Net loss attributable to common stockholders	\$ (154,993)	\$
Pro forma other income adjustments related to the derivative liability <sup>(1)</sup>	119	
Pro forma net loss attributable to common stockholders, basic and diluted	<u>\$ (154,874)</u>	<u>\$</u>
<b>Denominator:</b>		
Weighted-average shares of common stock outstanding	10,052,198	
Pro forma adjustment to reflect the Preferred Stock Conversion <sup>(2)(3)</sup>	85,960,088	
Pro forma weighted-average shares outstanding, basic and diluted	<u>96,012,286</u>	
Pro forma net loss per share, basic and diluted	<u>\$ (1.61)</u>	<u>\$</u>

- (1) Reflects the reversal of the change in fair value of the derivative liability related to the second closing of Series B-2 and B-2A financing recorded in our consolidated statement of operations and comprehensive loss for the year ended December 31, 2023, as if the second tranche closed at the beginning of the period.
- (2) Reflects the Common Stock Reclassification, as if such reclassification had occurred at the beginning of the period.
- (3) Reflects the Preferred Stock Conversion, as if such conversion had occurred at the beginning of the period.

	<u>As of March 31, 2024</u>		
	<u>Actual</u>	<u>Pro Forma<sup>(1)</sup></u>	<u>Pro Forma As Adjusted<sup>(2)(3)</sup></u>
	<u>(in thousands)</u>		
<b>Consolidated Balance Sheet Data:</b>			
Cash and cash equivalents	\$	\$	\$
Marketable securities			
Working capital <sup>(4)</sup>			
Total assets			
Total liabilities			
Redeemable convertible preferred stock		—	—
Accumulated deficit			
Total stockholders' equity (deficit)			

- (1) The pro forma balance sheet data gives effect to (i) the Preferred Stock Conversion, (ii) the Common Stock Reclassification (as if

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each had occurred as of March 31, 2024) and (iii) the filing and effectiveness of our amended and restated certificate of incorporation to be in effect immediately prior to the closing of this offering.

- (2) The pro forma as adjusted column in the consolidated balance sheet data gives effect to (i) the pro forma adjustments described in footnote (1) above and (ii) the issuance and sale of \_\_\_\_\_ shares of our common stock in this offering at the assumed initial public offering price of \$ \_\_\_\_\_ per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.
- (3) The pro forma as adjusted information is illustrative only and will depend on the actual initial public offering price and other terms of this offering determined at pricing. Each \$1.00 increase or decrease in the assumed initial public offering price of \$ \_\_\_\_\_ per share would increase or decrease, as applicable, each of our cash and cash equivalents, working capital, total assets and total stockholders' equity (deficit) by \$1.0 million, assuming that the number of shares 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 common stock offered by us would increase or decrease, as applicable, each of our cash and cash equivalents, working capital, total assets and total stockholders' equity (deficit) by \$1.0 million, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.
- (4) We define working capital as current assets less current liabilities. See our consolidated financial statements and the related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

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**RISK FACTORS**

*Investing in our common stock involves a high degree of risk. Before deciding to invest in shares of our common stock, you should carefully consider the risks described below, together with the other information contained in this prospectus, including in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in our audited financial statements and the related notes included elsewhere in this prospectus. We cannot assure you that any of the events discussed below will not occur. These events could adversely impact our business, financial condition, results of operations and prospects. If that were to happen, the trading price of our common stock could decline, and you could lose all or part of your investment.*

**Risks Related to Our Financial Position and Need for Capital**

***We are a clinical stage biopharmaceutical company with a limited operating history and no products approved for commercial sale, and have incurred substantial losses since our inception and anticipate incurring substantial and increasing losses for the foreseeable future.***

We are a clinical stage biopharmaceutical company with a limited operating history on which to base your investment decision. We have no product candidates approved for commercial sale and have not generated any revenue. Biopharmaceutical product development is a highly speculative undertaking. It entails substantial upfront capital expenditures and significant risk that any product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval or become commercially viable.

Our most advanced candidate is ESK-001, an oral, small molecule allosteric inhibitor of Tyrosine Kinase 2 (TYK2). We are currently conducting Phase 2 clinical trials of ESK-001 in each of moderate-to-severe plaque psoriasis (PsO), systemic lupus erythematosus (SLE) and non-infectious uveitis (Uveitis). We plan to commence Phase 3 pivotal trials of ESK-001 in PsO . In addition, we are advancing A-005, an investigational central nervous system (CNS) penetrant allosteric inhibitor of TYK2 that has a potential application in multiple sclerosis (MS) and other neuroinflammatory and neurodegenerative diseases, currently in clinical development. Our ability to achieve profitability in the future is dependent upon obtaining regulatory approval for and successfully commercializing our most advanced candidate, ESK-001, either alone or with third parties. However, our operations may not be profitable even if ESK-001 is successfully developed, approved and thereafter commercialized.

We have and will continue to incur significant development and other expenses related to our research and clinical development programs and ongoing operations. For the years ended December 31, 2022 and 2023, our net losses were approximately \$111.9 million and \$155.0 million, respectively. As of December 31, 2023, we had an accumulated deficit of approximately \$364.3 million. Substantially all of our losses have resulted from expenses incurred in connection with the acquisition and development of our pipeline and from general and administrative costs associated with our operations. We expect to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our development of our product candidates.

We anticipate that our expenses will increase substantially if, and as, we:

- conduct preclinical studies and clinical trials for ESK-001, A-005, and other programs;
- identify additional product candidates and acquire rights from third parties to those product candidates through licenses or other acquisitions, and conduct development activities, including preclinical studies and clinical trials;
- procure the manufacturing of preclinical, clinical and commercial supply of our current and future product candidates;
- seek regulatory approvals for our product candidates or any future product candidates;
- commercialize our current product candidates or any future product candidates, if approved;
- take steps toward our goal of being an integrated biopharma company capable of supporting commercial activities, including establishing sales, marketing and distribution infrastructure;
- attract, hire and retain qualified clinical, scientific, operations and management personnel;



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- add and maintain operational, financial and information management systems;
- protect, maintain, enforce and defend our rights in our intellectual property portfolio;
- defend against third-party interference, infringement and other intellectual property claims, if any;
- address any competing therapies and market developments;
- experience any delays in our preclinical studies or clinical trials and seeking regulatory approval for our product candidates due to public health concerns, macroeconomic conditions or geopolitical conflicts; and
- incur additional costs associated with operating as a public company following the completion of this offering.

Even if we succeed in commercializing one or more product candidates, we expect to incur substantial development costs and other expenditures to develop and market additional product candidates. We may also 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 revenue or raise additional capital. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity (deficit) and our working capital.

We could also encounter delays if a clinical trial is suspended, put on clinical hold or terminated by us, the investigational review boards (IRBs) of the institutions in which such trials are being conducted, the U.S. Food and Drug Administration (the FDA), or other regulatory authorities, or if a clinical trial is recommended for suspension or termination by the Data Safety Monitoring Board for such trial. A suspension, clinical hold or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, failure by our contract research organizations (CROs) or clinical trial sites to perform in accordance with good clinical practices (GCP) requirements, or applicable regulatory guidelines in other countries, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Clinical trials may also be delayed or terminated as a result of ambiguous or negative interim results. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA or other regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials.

We may also, in the future, conduct preclinical and clinical research in collaboration with other academic, pharmaceutical and biotechnology entities in which we combine our research or development efforts with those of our collaborators. Such collaborations may be subject to additional delays because of the management of the trials, contract negotiations, the need to obtain agreement from multiple parties and may increase our future costs and expenses.

Our product development costs will increase if we experience delays in clinical testing or regulatory approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates. Any delays or increase in costs in our clinical development programs may harm our business, financial condition, results of operations and prospects.

***Enrollment and retention of participants in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control, including difficulties in identifying patients, the availability of competitive products, and significant competition for recruiting participants in clinical trials.***

Participant enrollment, a significant factor in the timing of clinical trials, is affected by many conditions including the size and nature of the patient population, the number and location of clinical sites we enroll, the

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proximity of participants to clinical sites, the eligibility and exclusion criteria for the trial, the design of the clinical trial, the inability to obtain and maintain participant consents, the risk that enrolled participants will drop out before completion, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs or biologics that may be approved for the indications being investigated by us. Risks related to patient enrollment are heightened in longer clinical trials, including the 48-week trial period contemplated by our ongoing Phase 2b clinical trial of ESK-001 in SLE. In particular, this trial may also be challenging to enroll due to the fact that patients must be experiencing active disease at the time of screening to be eligible for enrollment. In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same areas as our product candidates, and this competition will reduce the number and types of participants available to us, because some participants who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors, or to use currently marketed therapies. Additionally, participants, including participants in any control groups, may withdraw from the clinical trial if they are not experiencing improvement in their underlying disease or condition or if they experience other difficulties or issues. Additionally, we could encounter delays if treating clinicians encounter unresolved ethical issues associated with enrolling participants in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles.

We have in the past and may in the future experience participant withdrawals or discontinuations from our trials. Withdrawal of participants from our clinical trials may compromise the quality of our data. Even if we are able to enroll a sufficient number of participants in our clinical trials, delays in enrollment or small population size may result in increased costs or may affect the timing or outcome of our clinical trials. Any of these conditions may negatively impact our ability to complete such trials or include results from such trials in regulatory submissions, which could adversely affect our ability to advance the development of our product candidates.

***We will require substantial additional financing to achieve our goals and failure to obtain additional capital when needed, or on acceptable terms to us, could cause us to delay, limit, reduce, or terminate our product development or future commercialization efforts.***

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through equity offerings, debt financings, or other capital sources, including potential collaborations, licenses and other similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our common stock. Any future debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, selling or licensing our assets, making capital expenditures, declaring dividends or encumbering our assets to secure future indebtedness. Such restrictions could adversely impact our ability to conduct our operations and execute our business plan.

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

#### **Risks Related to Product Candidate Development and Commercialization**

***Preclinical and clinical development involves a lengthy and expensive process, with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our current product candidates or any future product candidates.***

Our product candidates are either in clinical or preclinical development, and their risk of failure is high. It is impossible to predict when or if our product candidates will receive regulatory approval. To obtain the requisite

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regulatory approvals to commercialize any product candidates, we must demonstrate through extensive preclinical studies and lengthy, complex and expensive clinical trials that our product candidates are safe and effective in humans for their intended uses. Before obtaining approval from regulatory authorities for the commercialization of any of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidate in humans. Before we can initiate clinical trials for any product candidates, we must submit the results of preclinical studies to the FDA or comparable foreign regulatory authorities along with other information, including information about product candidate chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an Investigational New Drug application (IND) or similar regulatory submission. The FDA or comparable foreign regulatory authorities may require us to conduct additional preclinical studies for any product candidate before allowing us to initiate clinical trials under any IND or similar regulatory submission, which may lead to delays and increase the costs of our preclinical development programs.

Once initiated, clinical testing can take many years to complete, and its outcome is inherently uncertain. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials and results in one indication may not be predictive of results to be expected for the same product candidate in another indication. For example, notwithstanding extensive preclinical testing demonstrating that A-005 can penetrate the CNS, our clinical trials of A-005 may show that it cannot penetrate the human CNS as fully as was observed in preclinical testing. Differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unfavorable safety profiles, notwithstanding promising results in earlier trials. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain regulatory approval of such product candidates.

Commencing any future clinical trials is subject to finalizing the trial design and submitting an application to the FDA or a similar foreign regulatory authority. Even after we make our submission, the FDA or other regulatory authorities could disagree that we have satisfied their requirements to commence our clinical trials or disagree with our study design, which may require us to complete additional trials or amend our protocols or impose stricter conditions on the commencement of clinical trials. There is typically a high rate of failure of product candidates proceeding through clinical trials, and failure can occur at any time during the clinical trial process. Most product candidates that commence clinical trials are never approved as products and there can be no assurance that any of our current or future clinical trials will ultimately be successful or support the approval of our current or any future product candidates.

We expect to continue to rely on our CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, including the participant enrollment process, and we have limited influence over their performance. We or any future collaborators may experience delays in initiating or completing clinical trials due to unforeseen events or otherwise, that could delay or prevent our ability to receive regulatory approval or commercialize our current and any future product candidates, including:

- we may be unable to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials;
- regulators, such as the FDA or comparable foreign regulatory authorities, may disagree with the design or implementation of our clinical trials;
- regulators, such as the FDA or comparable foreign regulatory agencies, IRBs, or ethics committees may impose additional requirements before permitting us to initiate a clinical trial, may not allow us or our investigators to commence or conduct a clinical trial at a prospective trial site, may not allow us to amend trial protocols, or regulators may require that we modify or amend our clinical trial protocols;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with trial sites and CROs, the terms of which can be subject to extensive negotiation and may vary significantly;
- we may be unable to identify, recruit, or train suitable clinical investigators;
- clinical trial sites may deviate from trial protocol or drop out of a trial;

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- the number of participants required for clinical trials may be larger than we anticipate, enrollment in clinical trials may be slower than we anticipate or participants may drop out or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- the cost of clinical trials may be greater than we anticipate, or we may have insufficient funds to initiate or complete a clinical trial or to pay the substantial user fees required by the FDA upon the submission of a New Drug Application (NDA) or comparable marketing application in another jurisdiction;
- the quality or quantity of data relating to our product candidates or other materials necessary to conduct our clinical trials may be inadequate to initiate or complete a given clinical trial;
- reports from clinical testing of other therapies may raise safety, tolerability or efficacy concerns about our product candidates;
- clinical trials of our product candidates may fail to show appropriate safety, tolerability or efficacy, may produce negative or inconclusive results, or may otherwise fail to improve on the existing standard of care, and we may decide, or regulators may require us, to conduct additional clinical trials or we may decide to abandon product development programs;
- our CROs or clinical trial sites may fail to perform in accordance with GCP requirements or other applicable regulations, rules or guidelines;
- we may be unable to manufacture our product candidates from our contract manufacturing organizations (CMOs) in accordance with current Good Manufacturing Practice (cGMP) regulations or other applicable requirements in sufficient quantities for use in our clinical trials;
- serious adverse events (SAEs) may occur in trials of the same class of agents conducted by other companies that could be considered similar to our product candidates;
- we may select clinical endpoints that require prolonged periods of clinical observation or extended analysis of the resulting data;
- we may be required to transfer our manufacturing processes to larger-scale facilities operated by a different CMO, or may experience delays or failure by our CMOs or us to make any necessary changes to such manufacturing process; and
- third parties may be unwilling or unable to satisfy their contractual obligations to us in a timely manner.

***Our clinical trials may reveal significant adverse events not seen in our preclinical studies or prior clinical trials and may result in a safety or tolerability profile that could delay or prevent regulatory approval or market acceptance of ESK-001, A-005 or any future product candidates.***

Undesirable or clinically unmanageable side effects observed in our clinical trials for our product candidates could occur and cause us or regulatory authorities to interrupt, delay or halt our clinical trials and could result in a more restrictive labeling or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities.

We have observed SAEs and adverse events (AEs) in our trials of ESK-001, and as more patients become exposed to ESK-001 over longer periods of time, we expect to see additional SAEs and AEs emerge. Further, long term treatment with ESK-001 continues to be evaluated in open label extension (OLE) and long term extension (LTE) trials, and additional AEs and SAEs will continue to accumulate. Certain conditions occur more frequently in patients with psoriasis compared to the general population. Examples include obesity, cardiovascular disease, psoriatic arthritis, and depression. Immune modulating treatments including ESK-001 may result in increasing susceptibility to various infections, including serious or life-threatening infections, and there is a theoretical risk with immune-modulating agents that dampening immune responses could increase the risk of malignancies. However, no increase in malignancy risk has been demonstrated to date with approved therapies targeting similar immunological pathways, including TYK-2, IL-23 and type I IFN. Furthermore, a naturally occurring TYK-2 loss-of-function-mutation (P1104A) that is present in 3-5% of Caucasian populations has not been associated with increased cancer risk in rigorous analyses of large genetic data sets.

Other TYK2 inhibitors, such as deucravacitinib (marketed as Sotyktu), which is approved for the treatment of adults with PsO, have shown AEs such as hypersensitivity reactions, infections, tuberculosis, malignancy,

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rhabdomyolysis, elevated PK and potential SAEs related to JAK inhibition, such as cardiovascular and thrombotic events. There can be no assurance that we will not observe such AEs in our ongoing and planned clinical trials of ESK-001.

As of March 31, 2024, we have observed five SAEs in our trials of ESK-001 in patients with PsO, two of which we have assessed to be possibly related to ESK-001. A case of wrist arthritis in a patient with a history of gout and osteoarthritis was reported. The patient declined arthrocentesis, thus an infectious etiology could not definitively be ruled out, and empiric treatment with antibiotics was administered. A case of peritonsillar abscess following COVID-19 infection was reported that required treatment with antibiotics. Both events were considered potentially related. Three additional SAEs were considered unrelated by the investigator, by us, or by both. A case of sepsis in a patient with diabetic leg ulcers was reported as unrelated. A case of EGFR-positive, adenocarcinoma of the lung in a patient with a strong familial history of lung cancer (the patient's father, sister and brother all diagnosed with lung cancer) was discovered when the patient asked to have a chest CT following the recent lung cancer diagnosis of the patient's sister. A case of advanced renal cell carcinoma was incidentally found when the patient was evaluated for left sided kidney stones, and imaging revealed a large mass on the right kidney. Because of the large size of the tumor (~7 cm diameter) and the slow-growing nature of renal cell carcinomas, this tumor very likely preceded exposure to ESK-001 and went undetected. In both cases of malignancy, the investigator could not definitively rule out relationship to ESK-001 but in our assessment, both cases were unrelated to ESK-001 treatment.

The most commonly reported AEs in our PsO trials include upper respiratory infections, nasopharyngitis and headaches.

If AEs, SAEs or other side effects are observed in any of our ongoing or future clinical trials that are atypical of, or more severe than, the known side effects of the respective class of agents that each of our product candidates are a part of, we may have difficulty recruiting participants to our clinical trials, participants may drop out of our trials, or we may be required to abandon those trials or our development efforts of one or more product candidates altogether. If such effects are more severe or less reversible than we expect, or not reversible at all, we may decide or be required to perform additional studies or to halt or delay further clinical development of ESK-001, A-005 or any future product candidates, which could result in the delay or denial of regulatory approval by the FDA or other regulatory authorities.

In addition, we believe that one of the potential benefits of ESK-001 includes the potential to improve on the safety and side-effect profile of the only currently approved allosteric TYK2 inhibitor in the United States. If ESK-001 is shown to have similar AEs, side effects or other safety or tolerability concerns, then our opportunity to disrupt the current standard of care may be limited. AEs and SAEs that emerge during clinical investigation of or treatment with ESK-001, A-005, or any future product candidates may be deemed to be related to our product candidates. This may require longer and more extensive clinical development, or regulatory authorities may increase the amount of data and information required to approve, market, or maintain ESK-001, A-005 or any future product candidates and could result in warnings and precautions in our product labeling or a restrictive risk evaluation and mitigation strategy (REMS). This may also result in an inability to obtain approval of ESK-001, A-005 or any future product candidates. We, the FDA or other applicable regulatory authorities, or an IRB, may suspend clinical trials of a product candidate at any time for various reasons, including a belief that participants in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential product candidates developed in the biotechnology industry that initially showed promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining regulatory approval, undesirable side effects, like those mentioned above, may inhibit market acceptance of the approved product due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition, results of operations and prospects.

Additionally, if any of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result. For example, the FDA could require us to adopt a REMS, to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. We or our collaborators may also be required to adopt a REMS or engage in similar actions,

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such as patient education, certification of health care professionals or specific monitoring, if we or others later identify undesirable side effects caused by any product that we develop alone or with collaborators. Other potentially significant negative consequences associated with AEs include:

- we may be required to suspend marketing of a product, or we may decide to remove such product from the marketplace;
- regulatory authorities may withdraw or change their approvals of a product;
- regulatory authorities may require additional warnings on the label or limit access of a product to selective specialized centers with additional safety reporting and with requirements that patients be geographically close to these centers for all or part of their treatment; and
- we may be required to create a medication guide outlining the risks of a product for patients, or to conduct post-marketing studies.

Any of these events could diminish the usage or otherwise limit the commercial success of our product candidates and prevent us from achieving or maintaining market acceptance of our product candidates, if approved by the FDA or other regulatory authorities.

***Preliminary, “top-line” and interim data from our clinical trials that we announce or publish from time to time may change as more patient data become available or 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 are based on preliminary analyses 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 preclinical study or clinical 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 trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line and preliminary data should be viewed with caution until the final data are available.

From time to time, we may also disclose data from interim analyses from our clinical trials. Interim analyses from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as participants enrollment continues and more participant data become available or as participants from our clinical trials continue other treatments for their disease. Adverse differences between interim data, topline data, or preliminary data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate and could adversely affect the success of our business. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, top-line or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects. Further, disclosure of interim, top-line or preliminary data by us or by our competitors could result in volatility in the price of our common stock after this offering.

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

We have conducted, are currently conducting, and may in the future conduct, clinical trials outside the United States, including in Argentina, Austria, Australia, Belgium, Bulgaria, Canada, Chile, Colombia, Croatia,

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Czech Republic, Denmark, Estonia, France, Georgia, Germany, Hungary, India, Israel, Japan, Latvia, Mexico, Netherlands, Peru, Philippines, Poland, Portugal, Puerto Rico, Romania, South Korea, Spain, Taiwan, and the UK. We expect to continue to conduct trials internationally in the future. The acceptance of 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 sole basis for regulatory 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 and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for regulatory approval unless the study is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar requirements for clinical data gathered outside of their respective jurisdictions. In addition, such foreign trials are subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop being delayed or not receiving approval for commercialization in the applicable jurisdiction.

***Even if we receive regulatory approval for our current or future product candidates in the United States, we may never receive regulatory approval to market outside of the United States.***

We plan to seek regulatory approval for our current and future product candidates outside of the United States and are currently conducting certain clinical trials internationally, including in the European Union and Japan. In order to market any product outside of the United States, however, we must establish and comply with the numerous and varying safety, efficacy and other regulatory requirements of other applicable countries. Approval procedures vary among countries and can involve additional product candidate testing and additional administrative review periods. The time required to obtain approvals in other countries might differ substantially from that required to obtain FDA approval. The regulatory approval processes in other countries generally implicate all of the risks detailed above regarding FDA approval in the United States as well as other risks. In particular, in many countries outside of the United States, products must receive pricing and reimbursement approval before the product can be commercialized. Obtaining this approval can result in substantial delays in bringing products to market in such countries. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others and would impair our ability to market our current or future product candidates in such foreign markets. Any such impairment would reduce the size of our potential market, which could adversely affect our business, financial condition, results of operations and prospects.

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

The availability of coverage and the adequacy of reimbursement by governmental healthcare programs, such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as our product candidates, if approved. Our ability to achieve coverage and acceptable levels of reimbursement for our products by third-party payors will have an effect on our ability to successfully commercialize those products. Even if we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the European Union, Japan or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

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Third-party payors increasingly are challenging prices charged for biopharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when equivalent generic drugs, biosimilars or less expensive therapies are available. It is possible that a third-party payor may consider our product candidates, if approved, as substitutable and only be willing to cover the cost of the alternative product. Even if we show improved efficacy, safety or improved convenience of administration with ESK-001, A-005 or any of our future product candidates, if approved, pricing of competitive products may limit the amount we will be able to charge for our product candidates, if approved. Third-party payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in our product candidates. In some cases, when new competitor generic and biosimilar products enter the market, there are mandatory price reductions for the innovator compound. In other cases, payors employ “therapeutic category” price referencing and seek to lower the reimbursement levels for all treatments in the respective therapeutic category. Additionally, new competitor brand drugs can trigger therapeutic category reviews in the interest of modifying coverage and/or reimbursement levels. The potential of third-party payors to introduce more challenging price negotiation methodologies could have a negative impact on our ability to successfully commercialize our product candidates, if approved.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered. Some third-party payors may require pre-approval of coverage for new or innovative devices or therapies before they will reimburse healthcare providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our products, if approved.

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

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

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



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***We face competition from entities that have made substantial investments into the rapid development of competitor treatments for immunological indications, including large and specialty pharmaceutical and biotechnology companies, many of which already have approved therapies in our current indications.***

The development and commercialization of therapies is highly competitive. Our product candidates, if approved, will face significant competition, including from well-established, currently marketed therapies, and our failure to demonstrate a meaningful improvement to the existing standard of care may prevent us from achieving significant market penetration. Many of our competitors have significantly greater resources and experience than we do, and we may not be able to successfully compete. We face substantial competition from multiple sources, including large and specialty pharmaceutical and biotechnology companies, academic research institutions and governmental agencies and public and private research institutions. Our competitors compete with us on the level of the technologies employed, or on the level of development of their products as compared to our product candidates. In addition, many small biotechnology companies have formed collaborations with large, established companies to (i) obtain support for their research, development and commercialization of products or (ii) combine several treatment approaches to develop longer lasting or more efficacious treatments that may potentially directly compete with our current or any future product candidates. We anticipate that we will continue to face increasing competition as new therapies and combinations thereof, and related data, emerge.

Our current product candidates, initially under development for treatment of patients with immune-mediated diseases, if approved, would face competition from existing approved immunological treatments, many of which have achieved commercial success. For example, we are currently developing ESK-001 for the treatment of PsO, SLE, and Uveitis. Other emerging and established life sciences companies have been focused on similar therapeutics. If approved, ESK-001 would compete with several currently approved or late-stage oral clinical therapeutics, including Sotyktu (marketed by Bristol Myers Squibb Company (BMS)), TAK-279 (in development by Takeda Pharmaceutical Company), VTX-958 (in development by Ventyx Biosciences, Inc.), JNJ-2113 (in development by Johnson & Johnson), DC-806 (in development by Lilly), as well as new early-stage therapeutic companies that may develop competing molecules. Other TYK2 agents are also under development in SLE by BMS, as well as other TYK2 clinical development programs at Galapagos NV, Innocare, and Priovent Therapeutics, Inc.

We are also developing A-005, which has potential applications in MS and other neuroinflammatory and neurodegenerative diseases. There are several therapies available for the treatment of relapsing forms of MS, including interferon beta regulators, monoclonal antibodies, synthetic immunomodulatory drugs and S1P receptor modulators. Ocrevus, a CD20 antibody marketed by Genentech, Inc., is approved for primary progressive multiple sclerosis (PPMS).

To compete successfully, we need to disrupt these currently marketed drugs, meaning that we will have to demonstrate that the relative cost, method of administration, safety, tolerability and efficacy of our product candidates provide a better alternative to existing and new therapies. Our commercial opportunity and likelihood of success will be reduced or eliminated if our product candidates are not ultimately demonstrated to be safer, more effective, more conveniently administered, or less expensive than the current standard of care. Furthermore, even if our product candidates are able to achieve these attributes, acceptance of our products may be inhibited by the reluctance of physicians to switch from existing therapies to our products, or if physicians choose to reserve our products for use in limited circumstances.

Many of our competitors have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we have. If we obtain regulatory approval for any product candidate, we will face competition based on many different factors, including the safety and effectiveness of our current or any future product candidates, the ease with which our current or any future product candidates can be administered and the extent to which participants accept relatively new routes of administration, the timing and scope of regulatory approvals for these product candidates, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, less expensive or marketed and sold more effectively than any products we may develop. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our current or any future product candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

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Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified management and other personnel in establishing clinical trial sites and enrolling patients in clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

#### **Risks Related to Our Business and Operations**

***Our business is highly dependent on the success of our most advanced product candidate, ESK-001, and we cannot guarantee that ESK-001 will successfully complete development, receive regulatory approval or be successfully commercialized. If we are unable to develop, receive regulatory approval for, and ultimately successfully commercialize our product candidates, or if we experience significant delays in doing so, our business will be materially harmed.***

We currently have no products approved for commercial sale or for which regulatory approval to market has been sought. We have invested a significant portion of our efforts and financial resources in the development of our most advanced product candidate, ESK-001, which is still in clinical development, and expect that we will continue to invest heavily in ESK-001, as well as our second product candidate, A-005, and any future product candidates we may develop. Our business and our ability to generate revenue, which we do not expect will occur for many years, if ever, are substantially dependent on our ability to develop, obtain regulatory approval for, and then successfully commercialize our product candidates, which may never occur.

Our product candidates will require substantial additional preclinical and clinical development time, regulatory approval, commercial manufacturing arrangements, establishment of a commercial organization, significant marketing efforts, and further investment before we can generate any revenue from product sales. We currently generate no revenue, and we may never be able to develop or commercialize any products. We cannot assure you that we will meet our timelines for our current or future clinical trials, which may be delayed or not completed for a number of reasons. Our product candidates are susceptible to the risks of failure inherent at any stage of product development, including the appearance of unexpected AEs or failure to achieve primary endpoints in clinical trials.

Even if our product candidates are successful in clinical trials, we are not permitted to market or promote our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive sufficient regulatory approval that will allow us to successfully commercialize any product candidates. If we do not receive FDA or comparable foreign regulatory approval with the necessary conditions to allow commercialization, we will not be able to generate revenue from those product candidates in the United States or elsewhere in the foreseeable future, or at all. Any significant delays in obtaining approval for and commercializing our product candidates could adversely affect our business, financial condition, results of operations and prospects.

We have not previously submitted an NDA or similar marketing application to the FDA or comparable foreign regulatory authorities for any product candidate, and we cannot be certain that our current or any future product candidates will be successful in clinical trials or receive regulatory approval. The FDA may also consider its approvals of competing products, which may alter the treatment landscape concurrently with their review of any NDA we may submit, and which may lead to changes in the FDA's review requirements that have been previously communicated to us and our interpretation thereof, including changes to requirements for clinical data or clinical study design. Such changes could delay approval or necessitate withdrawal of any such NDA submission.

If approved for marketing by applicable regulatory authorities, our ability to generate revenue from our product candidates will depend on our ability to:

- price our products competitively such that third-party and government reimbursement permits broad product adoption;
- demonstrate the superiority of our products compared to the standard of care, as well as to other therapies in development;

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- create market demand for our product candidates through our own marketing and sales activities, and any other arrangements to promote these product candidates that we may otherwise establish;
- receive regulatory approval for the targeted patient populations and claims that are necessary or desirable for successful marketing;
- effectively commercialize any of our products that receive regulatory approval;
- manufacture product candidates through CMOs in sufficient quantities and at acceptable quality and manufacturing cost to meet commercial demand at launch and thereafter;
- establish and maintain agreements with wholesalers, distributors, pharmacies, and group purchasing organizations on commercially reasonable terms;
- obtain, maintain, protect and enforce patent and other intellectual property protection and regulatory exclusivity for our products;
- achieve market acceptance of our products by patients, the medical community, and third-party payors;
- maintain a distribution and logistics network capable of product storage within our specifications and regulatory guidelines, and further capable of timely product delivery to commercial clinical sites; and
- assure that our product will be used as directed and that additional unexpected safety risks will not arise.

***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 product candidates, our business will be substantially harmed.***

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of our product candidates are subject to extensive regulation by the FDA in the U.S. and by comparable foreign regulatory authorities in foreign markets. In the U.S., we are not permitted to market our product candidates in the U.S. until we receive regulatory approval of an NDA from the FDA. The process of obtaining such regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications and patient population. Approval policies or regulations may change, and the FDA and comparable regulatory authorities have substantial discretion in the approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons.

Prior to obtaining approval to commercialize a product candidate in the U.S. or abroad, we must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. Clinical testing is expensive, time consuming and subject to uncertainty. We cannot guarantee that any current or future clinical trials will be conducted as planned or completed on schedule, if at all, or that our product candidates will receive regulatory approval. Our planned Phase 3 pivotal trials of ESK-001 in PsO, even if successfully completed, may not be sufficient for approval of ESK-001 in that disease. Although we have discussed and intend to further discuss our Phase 3 clinical trial design and overall development plan with the FDA to align on its sufficiency to support an NDA submission, the feedback is typically non-binding and dependent on the strength of the ultimate clinical data and the FDA's perspective on the benefit—risk profile of the treatment in the intended population. For example, the the Committee for Medicinal Products for Human Use (CHMP) in Europe provided comments on the length of our two pivotal 24 week Phase 3 trials, and we plan to address their feedback with our comparator trials. These modifications could delay our development timelines for EU regulatory approval and require substantially more resources. Phase 3 clinical trials typically involve hundreds of patients, have significant costs and take years to complete. In addition to our planned Phase 3 program in PsO, we plan to initiate additional trials of ESK-001 in SLE and Uveitis. Even as these trials progress, issues may arise that could require us to suspend or terminate such clinical trials or could cause the results of one cohort to differ from a prior cohort. For example, we may experience slower than anticipated enrollment in our clinical trials, which may consequently delay our development timelines or permit competitors to obtain approvals that may alter our strategy. A failure of one or more clinical trials can occur at any stage of testing, and our future clinical trials may not be successful.

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In addition, even if such clinical trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. To the extent that the results of the clinical trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional clinical trials in support of potential approval of our product candidates.

In addition, if the FDA grants approval for our product candidates, then, as a condition for approval, the FDA may require us to perform costly post-marketing testing, including Phase 4 clinical trials or surveillance to monitor the effects of the marketed product.

Our clinical trial results may also not support approval. In addition, our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe and effective for any of their proposed indications;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval, including due to the heterogeneity of patient populations, or apparent improvement in trial participants receiving placebo;
- we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- The data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of an NDA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- such authorities may disagree with us regarding the formulation, labeling and/or the product specifications of our product candidates;
- approval may be granted only for indications that are significantly more limited than those sought by us, and/or may include significant restrictions on distribution and use;
- the FDA or comparable foreign regulatory authorities will review CMOs' manufacturing process and inspect our CMOs' commercial manufacturing facilities and may not approve our CMOs' manufacturing process or facilities with respect to our product candidates; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Even if we eventually complete clinical trials and receive approval of an NDA or comparable foreign marketing application for our product candidates, the FDA or comparable foreign regulatory authority may grant approval contingent on the performance of costly additional clinical trials and/or the implementation of a REMS, which may be required because the FDA believes it is necessary to ensure safe use of the product after approval. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects.

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

The ability of the FDA and foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy

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changes, the FDA's or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's or foreign regulatory authorities' ability to perform routine functions. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs or modifications to approved drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the global COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations, any resurgence of the virus or emergence of new variants may lead to inspectional or administrative delays. If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

***If our product candidates, if approved, do not achieve broad market acceptance, the revenue that we generate from their sales will be limited.***

We have never commercialized a product candidate for any indication. Even if our product candidates are approved by the appropriate regulatory authorities for marketing and sale, they may not gain acceptance among physicians, patients, third-party payors and others in the medical community. If any product candidate for which we obtain regulatory approval does not gain an adequate level of market acceptance, we may not generate sufficient product revenue or become profitable.

The degree of market acceptance of our product candidates, if approved, will depend on a number of factors, some of which are beyond our control, including:

- the safety, efficacy, tolerability and ease of administration of our product candidates;
- the clinical indications for which the products are approved and the approved claims that we may make for the products;
- limitations or warnings contained in the product's FDA-approved labeling, including potential limitations on the use of the product or warnings for such products that may be more restrictive than other competitive products;
- distribution and use restrictions imposed by the FDA with respect to such product candidates or to which we agree as part of a mandatory REMS or voluntary risk management plan;
- changes in the standard of care for the targeted indications for such product candidates;
- the relative difficulty of administration or compliance with administration instructions of such product candidates;
- cost of treatment as compared to the clinical benefit in relation to alternative treatments or therapies;
- the availability of adequate coverage and reimbursement by third parties, such as insurance companies and other healthcare payors, and by government healthcare programs, including Medicare and Medicaid;
- the extent and strength of our marketing and distribution of such product candidates;
- the safety, efficacy and other potential advantages of, and availability of, alternative treatments already used or that may later be approved for any of our intended indications;
- the timing of market introduction of such product candidates, as well as competitive products;
- the reluctance of physicians to switch their patients' current standard of care;
- the reluctance of patients to switch from their existing therapy regardless of the safety and efficacy of newer products;

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- our ability to offer such product candidates for sale at competitive prices;
- the extent and strength of our third-party manufacturer and supplier support;
- adverse publicity about our product or favorable publicity about competitive products; and
- potential product liability claims.

Our efforts to educate the medical community and third-party payors as to the benefits of our product candidates may require significant resources and may never be successful. Even if the medical community accepts that our product candidates are safe and effective for their approved indications, physicians and patients may not immediately be receptive to such product candidates and may be slow to adopt them as an accepted treatment of the approved indications. If our current or future product candidates are approved, but do not achieve an adequate level of acceptance among physicians, patients, and third-party payors, we may not generate meaningful revenue from our product candidates and may never become profitable.

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

Because we have limited financial and managerial resources, we focus our development efforts on certain selected product candidates in certain selected indications. For example, we are initially focused on our most advanced product candidate, ESK-001, currently in development for the treatment of PsO, SLE, and Uveitis, and our second product candidate, A-005, currently in development for the treatment of neuroinflammatory and neurodegenerative diseases. As a result, we may forgo or delay pursuit of opportunities with other product candidates, or other indications for our existing product candidates that later prove to have greater commercial potential. 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 development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

***We will need to grow our organization, and we may experience difficulties in managing our growth and expanding our operations, which could adversely affect our business.***

As of March 31, 2024, we had 107 full-time employees and 2 part-time employees. As our development and commercialization plans and strategies develop, and as we transition into operating as a public company, we expect to expand our employee base for managerial, operational, financial and other resources. In addition, we have limited experience in manufacturing and commercialization. As our product candidates enter and advance through preclinical studies and clinical trials, we will need to expand our development and regulatory capabilities and contract with other organizations to provide manufacturing and other capabilities for us. In the future, we expect to have to manage additional relationships with future collaborators or partners, suppliers and other organizations. Our ability to manage our operations and future growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. We may not be able to implement improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. Our inability to successfully manage our growth and expand our operations could adversely affect our business, financial condition, results of operations and prospects.

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

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon the members of our senior management team. The loss of services of any of these individuals could delay or prevent the successful

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development of our product pipeline, initiation or completion of our preclinical studies and clinical trials or the commercialization of our product candidates. Although we have executed employment agreements or offer letters with each member of our senior management team, these agreements are terminable at will with or without notice and, therefore, we may not be able to retain their services as expected. We do not currently maintain “key person” life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

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

***Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.***

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners, CROs, CMOs and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with FDA or other regulations, provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies, respect our confidentiality and intellectual property rights, comply with manufacturing standards we may establish, comply with healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. If we obtain FDA approval for our product candidates and begin commercializing those products in the United States, our potential exposure under these laws will increase significantly, and our costs associated with compliance with these laws are likely to increase. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended 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 programs and other business arrangements. Employee 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. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material and adverse effect on our business, financial condition, results of operations and prospects, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, integrity oversight and reporting obligations, or reputational harm.

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

Our future growth may depend, in part, on our ability to develop and commercialize our product candidates in foreign markets, including in the European Union, the United Kingdom and Japan, for which we may rely on collaboration with third parties. We are not permitted to market or promote our product candidates before we receive regulatory approval from the applicable regulatory authority in that foreign market and may never receive such regulatory approval for our product candidates. To obtain separate regulatory approval in many other countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions. If we fail to

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comply with the regulatory requirements in international markets and receive applicable regulatory approvals, our target market will be reduced, our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected. We may not obtain foreign regulatory approvals on a timely basis, if at all. Our failure to obtain approval for our product candidates by regulatory authorities in another country may significantly diminish the commercial prospects of that product candidate and our business, financial condition, results of operations and prospects could be adversely affected. Moreover, even if we obtain approval of our product candidates and ultimately commercialize our product candidates in foreign markets, we would be subject to these risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and reduced protection of intellectual property rights in some foreign countries.

***Our business entails a significant risk of product liability and our ability to obtain sufficient insurance coverage could adversely affect our business, financial condition, results of operations and prospects.***

As we conduct clinical trials of our current or future product candidates, we are exposed to significant product liability risks inherent in the development, testing, manufacturing and marketing of new treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in FDA or other regulatory authority investigation of the safety and effectiveness of our future product candidates, our manufacturing processes and facilities or our marketing programs and potentially a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our product candidates, termination of clinical trial sites or entire trial programs, withdrawal of clinical trial participants, injury to our reputation and significant negative media attention, significant costs to defend the related litigation, a diversion of management's time and our resources from our business operations, substantial monetary awards to trial participants or patients, loss of revenue, the inability to commercialize and products that we may develop, and a decline in our stock price. We may need to obtain higher levels of product liability insurance for later stages of clinical development or marketing of our product candidates. Any insurance we may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could adversely affect our business, financial condition, results of operations and prospects.

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

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include commercial general liability, general liability, cyber liability, workers' compensation, clinical trials and directors' and officers' liability insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our business, financial condition, results of operations and prospects.

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

We may enter into strategic transactions in the future, including acquisitions of companies, asset purchases and in-licensing of intellectual property with the potential to acquire and advance new assets or product candidates where we believe we are well qualified to optimize the development of promising therapies. For example, we were founded in January 2021, and subsequently acquired ESK-001 via a stock purchase of FronThera U.S. Holdings, Inc. and its wholly owned subsidiary, FronThera U.S. Pharmaceuticals LLC. Additional potential transactions that we may consider in the future include a variety of business arrangements, including strategic partnerships, in-licensing of product candidates, strategic collaborations, joint ventures, restructurings, divestitures, business combinations and investments. Any future transactions could increase our near and long-term expenditures, result in potentially dilutive issuances of our equity securities, including our common stock, or the incurrence of debt, contingent liabilities, amortization expenses



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or acquired in-process research and development expenses, any of which could affect our financial condition, liquidity and results of operations.

Future acquisitions may also require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions may never be successful and may require significant time and attention of our management. In addition, the integration of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky and costly endeavor for which we may never realize the full benefits of the acquisition. Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could adversely affect our business, financial condition, results of operations and prospects.

***Our ability to use our net operating loss (NOL) carryforwards and certain other tax attributes to offset 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. As of December 31, 2023, we had federal NOL carryforwards of \$48.6 million and state NOL carryforwards of \$4.4 million. Under the Internal Revenue Code of 1986, as amended (the Code), our U.S. federal net operating losses generated post tax years beginning after December 31, 2017 will not expire and may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited to no more than 80% of current year taxable income.

In addition, under Sections 382 and 383 of the Code, if a corporation undergoes an “ownership change,” generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation’s ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We have not completed a Section 382 study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since our formation date, and there may be ownership changes in the future, some of which may be outside of our control. If we undergo an ownership change, and our ability to use our pre-change NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset our post-change income or taxes (if any) is limited, such limitation could harm our future results of operations by effectively increasing our future tax obligations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of net operating losses is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, even if we attain profitability, we may be unable to use all or a material portion of our net operating losses and other tax attributes, which could adversely affect our future cash flows.

***Recent and future changes to tax laws could materially adversely affect our company.***

The tax regimes we are subject to or operate under, including with respect to income and non-income taxes, are unsettled and may be subject to significant change. Changes in tax laws, regulations, or rulings, or changes in interpretations of existing laws and regulations, could materially adversely affect our company. For example, the Tax Cuts and Jobs Act, the Coronavirus Aid, Relief, and Economic Security Act, and the Inflation Reduction Act enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects thereof could be repealed or modified in future legislation. For example, the Inflation Reduction Act includes provisions that will impact the U.S. federal income taxation of certain corporations, including imposing a 15% minimum tax on the book income of certain large corporations and an excise tax on certain corporate stock repurchases that would be imposed on the corporation repurchasing such stock. In addition, many countries in Europe, as well as a number of other countries and organizations (including the Organization for Economic Cooperation and Development and the European Commission), have proposed, recommended, or (in the case of countries) enacted or otherwise become subject to changes to existing tax laws or new tax laws that could significantly increase our tax obligations in the countries where we do business or require us to change the manner in which we operate our business.

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***If our information technology systems, or those used by our CROs, CMOs, clinical sites or other third parties upon which we rely, are or were compromised, become unavailable or suffer security breaches, loss or leakage of data or other disruptions, we could suffer material adverse consequences resulting from such compromise, including but not limited to, operational or service interruption, harm to our reputation, regulatory investigations or actions, litigation, fines, penalties and liability, and other adverse consequences to our business, results of operations, and financial condition.***

In the ordinary course of our business, we, and the third parties upon which we rely, process personal information and other sensitive data, including intellectual property, trade secrets, proprietary or confidential business information, preclinical and clinical trial data, personal information related to relevant stakeholders, third-party data, and other sensitive data (collectively, sensitive information) and as a result, we and the third parties upon which we rely face a variety of evolving threats which could cause security incidents affecting or interruptions to our information technology systems and sensitive information.

Our information technology systems and those of our CROs, CMOs, clinical sites and other third parties upon which we rely are vulnerable to attack, damage and interruption from a variety of evolving threats, including but not limited to computer viruses, misconfigurations, software bugs, worms, or other vulnerabilities and malicious codes, malware (including ransomware and as a result of advanced persistent threat intrusions), application security attacks, social engineering (including through phishing attacks and deep fakes, which may be increasingly more difficult to identify as fake), supply chain attacks and vulnerabilities through our third-party service providers, denial or degradation-of-service attacks (such as credential stuffing), credential harvesting, personnel misconduct or error, fraud, server malfunctions, software or hardware failures, loss of data or other information technology assets, attacks enhanced or facilitated by AI, adware, telecommunications and electrical failures, terrorism, war, earthquakes, fires, floods, and other similar threats. Such threats are prevalent, are occurring more often, are increasingly difficult to detect, and come from a variety of sources, including traditional computer “hackers,” threat actors, “hacktivists,” organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. In particular, ransomware attacks, including those from organized criminal threat actors, nation-states and nation-state supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions, delays, or outages in our operations, loss of data (including sensitive information), loss of income, significant extra expenses to restore data or systems, reputational loss, the diversion of funds and other consequences. To alleviate the negative impact of a ransomware attack, it may be preferable to make extortion payments, but we may be unwilling or unable to do so (including, for example, if applicable laws or regulations prohibit such payments).

Some actors also now engage and are expected to continue to engage in cyberattacks, including without limitation nation-state actors, for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, and the third parties upon which we rely, may be vulnerable to a heightened risk of these attacks, including retaliatory cyberattacks, that could materially disrupt our systems, operations and supply chain. In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive data 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.

Additionally, remote work has become more common and has increased risks to our information technology systems and data, as more of our personnel utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations.

Furthermore, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities’ systems and technologies. Additionally, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate acquired entities into our information technology environment and security program.

We may expend significant resources or modify our business activities to try to protect against security incidents. While we take steps designed to anticipate, detect and remediate threats and vulnerabilities, because the threats and techniques used to exploit such vulnerabilities and gain unauthorized access to, to sabotage or otherwise compromise systems change frequently, are often sophisticated in nature, and are often are not

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recognized until launched against a target, we may be unable to anticipate these techniques or implement and maintain adequate preventative measures. Therefore, such vulnerabilities have and could be exploited but may not be detected until after a security incident has occurred. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities and we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. There can be no assurance that our information security policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems and sensitive information.

Our reliance on third-party service providers could introduce additional cybersecurity risks and vulnerabilities, including supply-chain attacks and other threats to our business operations. We rely on third-party service providers and technologies to operate critical business systems and to process sensitive information in a variety of contexts, including, without limitation, cloud-based infrastructure, data hosting, encryption and authentication technology, personnel email, human resource management, training and other functions. We also rely on third-party service providers to assist with our clinical trials or otherwise to operate our business, including to manage and store sensitive patient data from our clinical trials. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. Our third-party service providers have and may in the future experience a security incident or other interruption. While we may be entitled to damages if our third-party service providers fail to satisfy their 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 and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems or the third-party information technology systems that support our operations.

We and certain of our service providers have been and are from time to time subject to cyberattacks and security incidents. Any of the previously identified or similar threats have or could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure, or other processing of, or access to our sensitive information or our information technology systems, or those of the third parties upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to conduct clinical trials. Additionally, sensitive information of the company could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnels', or vendors' use of generative AI technologies.

The costs related to significant security breaches or disruptions could be material and cause us to incur significant expenses. If the information technology systems of our CROs, CMOs, clinical sites and other third parties become subject to disruptions or security incidents, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring. Further, our cyber liability insurance coverage may not be sufficient to cover the financial, legal, business reputational or other losses that may result from an interruption or breach.

If any such incidents were to occur and cause interruptions in our operations, it could result in a disruption of our business and development programs. For example, the loss of clinical trial data from completed or ongoing clinical trials for a product candidate could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data, or may limit our ability to effectively execute a product recall, if required in the future. To the extent that any disruption or security incident were to result in the loss of or damage to our data or applications, or inappropriate disclosure of sensitive information, we could incur liability and the further development of any product candidates could be delayed.

Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences.

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If we or a third party upon whom we rely experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences such as legal claims or proceedings, liability including litigation exposure, penalties and fines under relevant legal obligations, enforcement actions and investigations by regulatory authorities, additional reporting requirements or oversight, restrictions on processing sensitive information (including personal information), indemnification obligations, monetary fund diversions, diversion of management attention, other financial loss, and damage to our reputation and a loss of confidence in us and our ability to conduct clinical trials, which could delay the clinical development of our product candidates, and of which may adversely affect our business, results of operations or financial condition.

***Our operations are concentrated in one location, and we or the third parties upon whom we depend may be adversely affected by a wildfire, earthquake or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.***

Our current operations are predominantly located in California. Any unplanned event, such as flood, wildfire, explosion, earthquake, extreme weather condition, medical epidemic including the COVID-19 pandemic, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Any similar impacts of natural or manmade disasters on our third-party service providers, such as our CMOs and CROs located globally, could cause delays in our clinical trials and may have a material and adverse effect on our ability to operate our business and have significant negative consequences on our financial and operating conditions. If a natural disaster, power outage or other event occurred that prevented us from using our clinical trial sites, impacted clinical supply or the conduct of our clinical trials, that damaged critical infrastructure, such as the manufacturing facilities of our third-party CMOs, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we and third parties upon whom we rely have or may have in place may prove inadequate in the event of a serious disaster or similar event. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our CMOs, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our development programs may be harmed. Any business interruption could adversely affect our business, financial condition, results of operations and prospects.

***Our projections regarding the market opportunities for our product candidates may not be accurate, and the actual market for our products may be smaller than we estimate.***

The precise incidence and prevalence for all the conditions we aim to address with our product candidates are unknown. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including sales of our competitors, scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect in general, or as to their applicability to our company. Further, new trials may change the estimated incidence or prevalence of these diseases. The total addressable market across all of our product candidates will ultimately depend upon, among other things, the diagnosis criteria included in the final labeling for each of our product candidates approved for sale for these indications, the ability of our product candidates to improve on the safety, convenience, cost and efficacy of competing therapies or therapies in development, acceptance by the medical community and patients, drug pricing and reimbursement. The number of patients in the United States and other major markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our product candidates or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our business, financial condition, results of operations and prospects. Further, even if we obtain significant market share for our product candidates, because some of our potential target populations are very small, we may never achieve profitability despite obtaining such significant market share.

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***Our cash and cash equivalents may be exposed to failure of our banking institutions.***

While we seek to minimize our exposure to third-party losses of our cash and cash equivalents, we hold our balances in a number of large financial institutions. Notwithstanding, those institutions are subject to risk of failure. For example, on March 10, 2023, Silicon Valley Bank (“SVB”) was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (“FDIC”) as receiver. Similarly, on March 12, 2023, Signature Bank was also swept into receivership. The U.S. Department of Treasury, the Federal Reserve Board (the “Federal Reserve”), and the FDIC released a statement that indicated that all depositors of SVB would have access to all of their funds, including funds held in uninsured deposit accounts, after only one business day of closure. The U.S. Department of Treasury, FDIC and Federal Reserve have announced a program to provide up to \$25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program. There is no guarantee, however, that the U.S. Department of Treasury, FDIC and Federal Reserve will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.

Although we expect to assess our banking relationships as we believe necessary or appropriate, our access to cash in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect the financial institutions with which we have banking relationships, and in turn, us.

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. These factors could also include factors involving financial markets or the financial services industry generally. The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets; or termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, widespread 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 financial and/or 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 current and/or projected business operations and financial condition and results of operations.

In addition, one or more of our critical vendors, third party manufacturers, or other business partners could be adversely affected by any of the liquidity or other risks that are described above, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition. Any business partner bankruptcy or insolvency, or any breach or default by a business partner, or the loss of any significant supplier relationships, could result in material adverse impacts on our current and/or projected business operations and financial condition.

***Public opinion and scrutiny of immunology treatments may impact public perception of our company and product candidates, or may adversely affect our ability to conduct our business and our business plans.***

Public perception may be influenced by claims, such as claims that our product candidates are unsafe, unethical or immoral and, consequently, our approach may not gain the acceptance of the public or the medical community. Adverse public attitudes may also adversely impact our ability to enroll clinical trials. Moreover,

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our success will depend upon physicians specializing in the treatment of those diseases that our product candidates target prescribing, and their patients being willing to receive, treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments they are already familiar with and for which greater clinical data may be available. AEs in our clinical trials, even if not ultimately attributable to our product candidates, and the resulting publicity could result in withdrawal of clinical trial participants, increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates. In addition, side effects generally associated with TYK2 or JAK inhibitors may negatively impact public perception of us or ESK-001 and A-005. More restrictive government regulations or negative public opinion could have an adverse effect on our business, financial condition, results of operations and prospects, and may delay or impair the development and, if approved, commercialization of our product candidates or demand for any products we may develop.

**Risks Related to Intellectual Property**

*If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates and any future product candidates we may develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully develop and commercialize our product candidates may be adversely affected.*

We rely upon a combination of patents, know-how and confidentiality agreements to protect the intellectual property related to our product candidates and technologies and to prevent third parties from copying and surpassing our achievements, thus eroding our competitive position in our market.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries for our product candidates and their uses, as well as our ability to operate without infringing, misappropriating or otherwise violating the proprietary rights of others. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates and novel discoveries that are important to our business. Our pending and future patent applications may not result in patents being issued. We cannot assure you that issued patents will afford sufficient protection of our product candidates or their intended uses against competitors, nor can there be any assurance that the patents issued will not be infringed, designed around, invalidated by third parties, or effectively prevent others from commercializing competitive products or product candidates.

Obtaining and enforcing patents is expensive and time-consuming, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications or maintain and/or enforce patents that may issue based on our patent applications, at a reasonable cost or in a timely manner. We may not be able to obtain or maintain patent applications and patents due to the subject matter claimed in such patent applications and patents being in disclosures in the public domain. It is also possible that we will fail to identify patentable aspects of our research and development results before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, CMOs, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Consequently, we may not be able to prevent any third parties from using any of our technology that is in the public domain to compete with our product candidates.

Composition of matter patents for pharmaceutical product candidates often provide a strong form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. However, we cannot be certain that the claims in our pending patent applications directed to composition of matter of our product candidates will be considered patentable by the United States Patent and Trademark Office (USPTO) or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product candidates

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for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, clinicians may prescribe these products “off-label.” Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation, resulting in court decisions, including Supreme Court decisions, which have increased uncertainties as to the ability to enforce patent rights in the future. As a result, the issuance, scope, validity, enforceability and commercial value of any patent rights are highly uncertain. Our pending and future owned or in-licensed patent applications may not result in issued patents that protect our product candidates effectively to prevent others from commercializing our product candidates or otherwise provide any competitive advantage. In fact, patent applications may not issue as patents at all. The coverage claimed in a patent application can also be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability and our pending patent applications may be challenged in patent offices in the United States and abroad. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. For example, our pending patent applications may be subject to third-party pre-issuance submissions of prior art to the USPTO, or our issued patents may be subject to post-grant review (PGR) proceedings, oppositions, derivations, reexaminations, interferences, inter partes review (IPR) proceedings or other similar proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. Such submissions may also be made prior to a patent’s issuance, precluding the granting of a patent based on one or more of our owned pending patent applications. An adverse determination in any such challenges may result in loss of exclusivity or in 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 product candidates, or limit the duration of the patent protection of our product candidates. 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 adversely affect our business, financial condition, results of operations and prospects.

A third party may also claim that our patent rights are invalid or unenforceable in a litigation. An adverse result in any legal proceeding could put one or more of our owned or patents at risk of being invalidated or interpreted narrowly and could allow third parties to commercialize our products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize our technology, products or product candidates without infringing third-party patent rights.

In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such candidates are commercialized. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Any failure to obtain or maintain patent protection with respect to our product candidates or their uses could adversely affect our business, financial condition, results of operations and prospects.

***We cannot ensure that patent rights relating to inventions described and claimed in our or any future licensors pending patent applications will issue or that patents based on our or any future licensors patent applications 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 potential future licensors or collaborators will be successful in protecting our product candidates by obtaining and defending patents. We have several pending United States and foreign patent applications in our portfolio. 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;

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- whether the claims of any patent issuing based on our patent applications 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;
- whether the patent applications that we own will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries; or
- whether, if the COVID-19 pandemic continues to spread around the globe, we may experience patent office interruption or delays to our ability to timely secure patent coverage to our product candidates.

We cannot be certain that the claims in our or any future licensors' pending patent applications directed to our product candidates will be considered patentable by the USPTO or by patent offices in foreign countries. There can be no assurance that any such patent applications will issue as granted patents. One aspect of the determination of patentability of our or any future licensors' inventions depends on the scope and content of the "prior art," information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our or any future licensors' patent claims or, if issued, affect the validity or enforceability of a patent claim. Even if the patents do issue based on our or any future licensors' patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our or any future licensors' portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop and threaten our ability to commercialize our product candidates. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our issued patents will be considered valid by courts in the United States or foreign countries.

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

Patents are of national or regional effect, and filing, prosecuting and defending patents on all of our research programs and product candidates in all countries throughout the world would be prohibitively expensive. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, even in jurisdictions where we do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing our or any future licensors' inventions in all countries outside the United States, even in jurisdictions where we or any future licensors do pursue patent protection, or from selling or importing products made using our or any future licensors' inventions in and into the United States or other jurisdictions. Competitors may use our or any future licensors' 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 or any future licensors have patent protection, but enforcement is not as strong as that in the United States. These competitor products may compete with our product candidates, and our or any future licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Various companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our or any future licensors' patents or marketing of competing products in violation of our proprietary rights.

Certain countries outside the United States have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. As a result, a patent owner may have limited remedies



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in certain circumstances, which could materially diminish the value of such patent. If we or any future licensors 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. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license in the future.

Further, the standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. As such, we do not know the degree of future protection that we will have on our product candidates. While we will endeavor to try to protect our product candidates with intellectual property rights, such as patents, as appropriate, the process of obtaining patents is time consuming, expensive and unpredictable.

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

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

- others may be able to make product candidates that are similar to ours but that are not covered by the pending patent applications that we own or any patents or patent applications that we may in-license in the future;
- we or any future licensors or collaborators might not have been the first to make the inventions covered by the pending patent application that we own or may in-license in the future;
- we or any future licensors or 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 or otherwise violating our owned intellectual property rights or any patent applications that we may license in the future;
- it is possible that noncompliance with the USPTO and foreign governmental patent agencies requirement for a number of procedural, documentary, fee payment and other provisions during the patent process can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- it is possible that our pending owned patent applications or those that we may own or license in the future will not lead to issued patents;
- issued patents, if any arise in the future, that we either own or that we may license in the future may be revoked, modified, or held invalid or unenforceable, as a result of legal challenges by our competitors;
- others may have access to the same intellectual property rights licensed to us in the future on a non-exclusive basis;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- we cannot predict the scope of protection of any patent issuing based on our or any future licensors' patent applications, including whether the patent applications that we own, or, in the future, in-license will result in issued patents with claims directed to our product candidates or uses thereof in the United States or in other foreign countries;
- there may be significant pressure on the United States government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns;

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- countries other than the United States may have patent laws less favorable to patentees than those upheld by United States courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates; the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties;
- if enforced, a court may not hold that our patents, if they issue in the future, are valid, enforceable and infringed;
- we may need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property;
- we may fail to adequately protect and police our trademarks and trade secrets; and
- the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patent applications.

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

***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 product candidates.***

As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. There can be no assurance that our operations do not, or will not in the future, infringe, misappropriate or otherwise violate existing or future third-party patents or other intellectual property rights. Identification of third-party patent rights that may be relevant to our operations is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. 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 product candidates in any jurisdiction.

Numerous United States and foreign patents and pending patent applications exist in our market that are owned by third parties. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our product candidates. We do not always conduct independent reviews of pending patent applications and patents issued to third parties. Patent applications in the United States and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain United States applications that will not be filed outside the United States can remain confidential until patents issue. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived. Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our product candidates. As such, there may be applications of others now pending or recently revived patents of which we are unaware. These patent applications may later result in issued patents, or the revival of previously abandoned patents, that may be infringed by the manufacture, use or sale of our product candidates or will prevent, limit or otherwise interfere with our ability to make, use or sell our product candidates.

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 product candidates are not

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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 product candidates.

We cannot provide any assurances that third-party patents and other intellectual property rights do not exist which might be enforced against our current technology, including our research programs, product candidates, their respective methods of use, manufacture and formulations thereof, and could result in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

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

Competitors or other third parties may infringe our patents, trademarks or other intellectual property. To counter infringement or unauthorized use, we or any future licensors 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. Our or any future licensors' pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents or any future licensors' patents are invalid or unenforceable, or both. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement, insufficient written description or failure to claim patent-eligible subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours or any future licensors is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention 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 or any future licensors' patent claims do not cover the invention, or decide that the other party's use of our or any future licensors' patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). An adverse outcome in a litigation or proceeding involving our or any future licensors' patents could limit our ability to assert our or any future licensors' 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 position, and our business, financial condition, results of operations and prospects. 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 adversely affect the price of shares of our common stock. Moreover, we cannot assure you 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.

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***We may become involved in third-party claims of intellectual property infringement, which may prevent or delay our product discovery and development efforts.***

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving the infringement of patents and other intellectual property rights in the biotechnology and pharmaceutical industries. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights and who allege that our product candidates, uses and/or other proprietary technologies infringe their intellectual property rights. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk that our product candidates may give rise to claims of infringement of the patent rights of others increases. Moreover, it is not always clear to industry participants, including us, which patents exist which may be found to cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications currently pending in our fields, there may be a risk that third parties may allege they have patent rights which are infringed by our product candidates, technologies or methods.

If a third party alleges that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property misappropriation which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement or misappropriation, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third-party's rights, and, if the court finds we have willfully infringed intellectual property rights, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- an injunction prohibiting us from manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third party agrees to license its patent rights to us;
- even if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights protecting our products; and
- we may be forced to try to redesign our product candidates or processes so they do not infringe third-party intellectual property rights, an undertaking which may not be possible or which may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Third parties may assert that we are employing their proprietary technology without authorization. Generally, conducting preclinical and clinical trials and other development activities in the United States is not considered an act of infringement. While we may believe that patent claims or other intellectual property rights of a third party would not have a materially adverse effect on the commercialization of our product candidates, we may be incorrect in this belief, or we may not be able to prove it in litigation. In this regard, patents issued in the United States by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof. There may be issued third-party patents of which we are currently unaware with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Patent applications can take many years to issue. There may be currently pending patent applications which may later result in issued patents that may be infringed by our product candidates. Moreover, we may fail to identify relevant patents or incorrectly conclude that a patent is invalid, not enforceable, exhausted, or not infringed by our activities. If any third-party patents, held now or obtained in the future by a third party, were found by a court of competent jurisdiction to cover the manufacturing process of our product candidates, the holders of any such patents may be able to block our

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ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover any aspect of our formulations, any combination therapies or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, could involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need or may choose to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly.

***We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.***

Because our development programs may in the future require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license, or use these third-party proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates on commercially reasonable terms or at all. Even if we are able to in-license any such necessary intellectual property, it could be on nonexclusive terms, thereby giving our competitors and other third parties access to the same intellectual property licensed to us, and it could require us to make substantial licensing and royalty payments. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have obtained, we may have to abandon development of the relevant program or product candidate, which could adversely affect our business, financial condition, results of operations and prospects.

We may enter into license agreements in the future with others to advance our existing or future research or allow commercialization of our existing or future product candidates. These licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and product candidates in the future. In that event, we may be required to expend significant time and resources to redesign our product candidates, or the methods for manufacturing them, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot

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provide any assurances that third-party patents do not exist which might be enforced against our current manufacturing methods, product candidates, or future methods or product candidates resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

***We may become subject to claims challenging the inventorship or ownership of our or any future licensors' patents and other intellectual property.***

We may be subject to claims that former employees, collaborators or other third parties have an interest in our or any future licensors' patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could adversely affect our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Any future licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as the United States government, such that these licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights or other rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could adversely affect our competitive position, business, financial condition, results of operations and prospects.

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

***We may form or seek collaborations or strategic alliances or enter into licensing arrangements in the future, and we may neither enter into, nor realize the benefits of, such alliances or licensing arrangements.***

Any future collaborations that we enter into may not be successful and we may not enter into such collaborations at all. The success of our collaboration arrangements will depend heavily on the efforts and activities of any future collaborators. Collaborations are subject to numerous risks, which may include that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities, or the ongoing COVID-19 pandemic;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;

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- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our future product candidates or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable future product candidates;
- collaborators may own or co-own intellectual property covering our product candidates that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws, resulting in civil or criminal proceedings.

***If we fail to comply with our obligations in agreements under which we in-license or acquire development or commercialization rights to product candidates, or data from third parties, we could lose such rights that are important to our business.***

We may in the future in-license or otherwise acquire development or commercialization rights to product candidates or data from third parties, and any future licensors may rely upon third-party companies, consultants or collaborators, or on funds from third parties such that licensors are not the sole and exclusive owners of the patents we in-license. If any future licensors fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize future product candidates that may be subject of such licensed rights could be adversely affected. In spite of our efforts, any future licensors might conclude that we are in material breach of obligations under our license agreements and may therefore have the right to terminate the license agreements, thereby removing our ability to develop and commercialize product candidates and technology covered by such license agreements. If such in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, our competitors will have the freedom to seek regulatory approval of, and to market, products identical to our product candidates and the licensors to such in-licenses could prevent us from developing or commercializing product candidates that rely upon the patents or other intellectual property rights which were the subject matter of such terminated agreements. Any of these events could adversely affect our business, financial condition, results of operations, and prospects.

Disputes may arise regarding intellectual property subject to a licensing agreement, including:

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

In addition, any future license agreements are likely to be 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

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or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could adversely affect our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we may license in the future prevent or impair our ability to maintain future licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could adversely affect our business, financial condition, results of operations, and prospects.

***Any license agreements we enter into in the future may be subject to certain rights retained by third parties.***

Any future licensors may retain certain rights under the relevant agreements with us, including the right to use the underlying product candidates for academic and research use, to publish general scientific findings from research related to the product candidates, to make customary scientific and scholarly disclosures of information relating to the product candidates, or to develop or commercialize the licensed product candidates in certain regions.

In addition, the United States federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act (Bayh-Dole Act). The federal government retains a “nonexclusive, nontransferable, irrevocable, paid-up license” for its own benefit. The Bayh-Dole Act also provides federal agencies with “march-in rights.” March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a “nonexclusive, partially exclusive, or exclusive license” to a “responsible applicant or applicants.” If the patent owner refuses to do so, the government may grant the license itself. We may at times choose to collaborate with academic institutions to accelerate our preclinical research or development. While we do not currently engage, and it is our policy to avoid engaging, university partners in projects in which there is a risk that federal funds may be commingled, we cannot be sure that any co-developed intellectual property will be free from government rights pursuant to the Bayh-Dole Act. Although none of our licenses to date are subject to march-in rights, if, in the future, we co-own or license in technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining, defending, maintaining 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, and may diminish our ability to protect our inventions, obtain, maintain, enforce and protect our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our future owned and licensed patents. Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act (Leahy-Smith Act), signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of patent applications filed after March 2013 and the enforcement or defense of our future issued patents or claiming priority to patent applications filed after March 2023. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings.

Further, because of a lower evidentiary standard in these USPTO post-grant proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our or any future



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licensors' patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our or any future licensors' patent applications and the enforcement or defense of our or any future licensors' future issued patents, all of which could adversely affect our business, financial condition, results of operations and prospects.

After March 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third-party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before we file an application covering the same invention, could therefore be awarded a patent covering an invention of ours or any future licensors even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or any future licensors were the first to either (i) file any patent application related to our product candidates and other proprietary technologies we may develop or (ii) invent any of the inventions claimed in our or any future licensors' patents or patent applications. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing the claimed invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future issued patents, all of which could adversely affect our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. The United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the United States Congress, the United States 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 or any future licensors' ability to obtain new patents and patents that we or any future licensors might obtain in the future. We cannot predict how future decisions by the courts, the United States Congress or the USPTO may impact the value of our patents. Any similar adverse change in the patent laws of other jurisdictions could also adversely affect our business, financial condition, results of operations and prospects.

In 2012, the European Union Patent Package (EU Patent Package) regulations were passed with the goal of providing a single pan-European Unitary Patent and a new European Unified Patent Court (UPC) for litigation involving European patents. The EU Patent Package was implemented on June 1, 2023. As a result, all European patents, including those issued prior to ratification of the EU Patent Package, now by default automatically fall under the jurisdiction of the UPC. It is uncertain how the UPC will impact granted European patents in the biotechnology and pharmaceutical industries. Our European patent applications, if issued, could be challenged in the UPC. During the first seven years of the UPC's existence, the UPC legislation allows a patent owner to opt its European patents out of the jurisdiction of the UPC. We may decide to opt out our future European patents from the UPC, but doing so may preclude us from realizing the benefits of the UPC. Moreover, if we do not meet all of the formalities and requirements for opt-out under the UPC, our future European could remain under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents, and allow for the possibility of a competitor to obtain pan-European injunction. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and product candidates and, resultantly, on our business, financial condition, prospects and results of operations.

***Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated as a result of noncompliance with these requirements.***

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will be due to be paid to the USPTO and various government patent agencies outside of the

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United States over the lifetime of our patents and patent applications. We rely on our outside patent counsel to pay these fees due to United States and non-United States patent agencies. The USPTO and various non-United States government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market and this circumstance could adversely affect our business, financial condition, results of operations and prospects.

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

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

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

Depending upon the timing, duration and specifics of any FDA regulatory approval of our product candidates, one or more of our issued United States patents or issued United States patents that we may own in the future may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984 (Hatch-Waxman Amendments). The Hatch-Waxman Amendments permit a patent extension term (PTE) of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. Similar patent term restoration provisions to compensate for commercialization delay caused by regulatory review are also available in certain foreign jurisdictions, such as in Europe under Supplemental Protection Certificate (SPC). However, we may not be granted any extensions for which we apply because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. In addition, to the extent we wish to pursue patent term extension based on a patent that we in-license from a third party, we would need the cooperation of that third party. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension, or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

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

In addition to the protection afforded by patents, we seek to rely on trade secret protection to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes that involve proprietary know-how, information, or technology that is not covered by our patents. We may not be able to meaningfully protect our trade secrets. Although we require all of our employees to assign their inventions to us, and require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed to our competitors or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent

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information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws within the United States. We may need to share our trade secrets and proprietary know-how with current or future 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. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

Monitoring and detecting unauthorized disclosure or other compromise of trade secrets is difficult, and we do not know whether the steps we have taken to prevent such compromise are, or will be, adequate. If we were to enforce a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time-consuming, and the outcome would be unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. For example, significant elements of our business, including confidential aspects of sample preparation, methods of manufacturing, proprietary assays, computational-biological algorithms, data analytics and machine learning related to genetics, genomics, proteomics, biomarkers and samples, and related processes and software, are based on unpatented trade secrets, including those of our collaborators. For example, our collaborator, Foresite Labs, utilizes extensive trade secret algorithms, machine learning and AI analysis techniques, and we rely on their maintenance of these trade secrets. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology.

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

Certain of our employees, consultants or advisors have in the past and may in the future be employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. An inability to incorporate such technologies or features would harm our business and may prevent us from successfully commercializing our technologies or product candidates. In addition, we may lose personnel as a result of such claims and any such litigation, or the threat thereof, may adversely affect our ability to hire employees or contract with independent contractors. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our technologies, or product candidates, which could adversely affect our business, financial condition, results of operations and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, we may in the future be subject to claims by former employees, consultants or other third parties asserting an ownership right in our patents or patent applications. An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in 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 technology and therapeutics, without payment to us, or could limit the duration of the patent protection covering our technologies and product candidates. Such challenges may also result in our inability to develop, manufacture or commercialize our technologies and product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future technologies and product candidates. Any of the foregoing could adversely affect our business, financial condition, results of operations and prospects.

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

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

#### **Risks Related to Government Regulation**

***Even if we receive regulatory approval for our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal. We may also be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.***

Any regulatory approvals that we or our future collaborators obtain for our product candidates may also be subject to limitations on the approved indicated uses for which a product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of the product candidate.

In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, post-approval monitoring and AE reporting, storage, import, export, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. The FDA has significant post-market authority, including the authority to require labeling changes based on new safety information and to require post-market studies or clinical trials to evaluate safety risks related to the use of a product or to require withdrawal of the product from the market. The FDA also has the authority to require a REMS after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug. The manufacturing facilities we use to make a future product, if any, will also be subject to periodic review and inspection by the FDA and other regulatory agencies, including for continued compliance with cGMP requirements. The discovery of any new or previously unknown problems with our third-party manufacturers, manufacturing processes or

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facilities may result in restrictions on the product, manufacturer or facility, including withdrawal of the product from the market. As we expect to rely on third-party manufacturers, we will not have control over compliance with applicable rules and regulations by such manufacturers.

In addition, any product promotion and advertising will also be subject to regulatory requirements and continuing regulatory review. For example, the FDA imposes stringent restrictions on manufacturers' communications regarding use of their products. Although clinicians may prescribe products for off-label uses, as the FDA and other regulatory agencies do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, the FDA and such regulatory agencies do restrict promotional communications from companies or their sales force with respect to off-label uses of products. Specifically, any regulatory approval that the FDA grants is limited to those specific diseases and indications for which a product is deemed to be safe and effective by FDA, and our ability to promote any products will be narrowly limited to those indications that are specifically approved by the FDA. If we are found to have promoted such off-label uses, we may become subject to significant liability. In addition, if we do not conduct head-to-head comparative clinical trials for our product candidates, we will be unable to make comparative claims regarding any other products in the promotional materials for our product candidates. If we promote our products, if approved, in a manner inconsistent with FDA-approved labeling or otherwise not in compliance with FDA regulations, we may be subject to enforcement action. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

Subsequent discovery of previously unknown problems with a product, including AEs of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure by us, our contract manufacturers or service providers, or collaborators to comply with regulatory requirements, may result in, among other things:

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

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

The FDA's and other regulatory authorities' policies may change and additional government regulations may be promulgated that could prevent, limit or delay marketing authorization of any product candidates we develop. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

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

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost-containment measures

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that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell any product candidates for which we obtain regulatory approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the ACA) was enacted in the United States, which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. The ACA included a number of provisions that may reduce the profitability of drug products, including provisions intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, the American Taxpayer Relief Act of 2021, effective January 1, 2024, eliminated the statutory cap on rebate amounts owed by drug manufacturers under the Medicaid Drug Rebate Program, which was previously capped at 100% of the Average Manufacturer Price (AMP) for a covered outpatient drug.

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Healthcare reform initiatives recently culminated in the enactment of the IRA in August 2022, which, among other things, allows the Department of Health and Human Services (HHS) to directly negotiate the selling price of a statutorily specified number of drugs and biologics each year that the Centers for Medicare & Medicaid Services (CMS) reimburses under Medicare Part B and Part D. Only high-expenditure single-source drugs that have been approved for at least 7 years for single-source drugs (11 years for biologics) are eligible to be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. Negotiations for Medicare Part D products take place in 2024 with the negotiated price taking effect in 2026, and negotiations for Medicare Part B products will begin in 2026 with the negotiated price taking effect in 2028. In August 2023, HHS announced the ten Medicare Part D drugs and biologics that it selected for negotiations. HHS will announce the negotiated maximum fair prices by September 1, 2024, and this price cap, which cannot exceed a statutory ceiling price, will go into effect on January 1, 2026. A drug or biological product that has an orphan drug designation for only one rare disease or condition will be excluded from the IRA's price negotiation requirements, but will lose that exclusion if it receives designations for more than one rare disease or condition, or if is approved for an indication that is not within that single designated rare disease or condition, unless such additional designation or such disqualifying approvals are withdrawn by the time CMS evaluates the drug for selection for negotiation. The negotiated prices will represent a significant discount from average prices to wholesalers and direct purchasers. The law also imposes rebates on Medicare Part D and Part B drugs whose prices have increased at a rate greater than the rate of inflation. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. These provisions may be subject to legal challenges. For example, the provisions related to the negotiation of selling prices of high-expenditure single-source drugs and biologics have been challenged in multiple lawsuits brought by pharmaceutical manufacturers. Thus, while it is unclear how the IRA will be implemented, it will likely have a significant impact on the pharmaceutical industry.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, restrictions on certain product access, reporting on price increases and the introduction of high-cost drugs. In some states, laws have been enacted to encourage importation of lower cost drugs from other countries and bulk purchasing. For example, the FDA released a final rule in September 2020 providing guidance for states to build and submit plans for importing drugs from Canada, and FDA authorized the first such plan in Florida in January 2024. 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 drug products that we successfully commercialize or put pressure on our product pricing.

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

***Our operations and relationships with healthcare providers, healthcare organizations, customers and third-party payors will be subject to applicable anti-bribery, anti-kickback, fraud and abuse, transparency and other healthcare laws and regulations, which could expose us to, among other things, enforcement actions, criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.***

Our future arrangements with healthcare providers, healthcare organizations, third-party payors and customers will expose us to broadly applicable anti-bribery, fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute our product candidates, if approved. Restrictions under applicable federal and state anti-bribery and healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal and state healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal criminal and civil false claims laws, including the federal False Claims Act, which can be enforced through civil whistleblower or qui tam actions against individuals or entities, and the Federal Civil Monetary Penalties Laws, which prohibit, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Moreover, the government may assert that a claim including items and 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;
- Health Insurance Portability and Accountability Act (HIPAA), which imposes criminal and civil liability, prohibits, among other things, knowingly and willfully executing, or attempting to execute a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal legislation commonly referred to as the Physician Payments Sunshine Act, enacted as part of the ACA, and its implementing regulations, which requires certain manufacturers of covered drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program, with certain exceptions, to report annually to CMS information on certain payments and other transfers of value to clinicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), teaching hospitals, and certain other health care providers (such as physician assistants and nurse practitioners), as well as ownership and investment interests held by the clinicians described above and their immediate family members;
- the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government

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officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof;

- analogous state and foreign laws and regulations, such as 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; and
- certain 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 in addition to requiring drug manufacturers to report information related to payments to clinicians and other healthcare providers or marketing expenditures and drug pricing information, and state and local laws that require the registration of pharmaceutical sales representatives.

If we or our future collaborators, manufacturers or service providers fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to enforcement actions, which could affect our ability to develop, market and sell our product candidates successfully and could harm our reputation and lead to reduced acceptance of our products, if approved by the market.

Efforts to ensure that our current and future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any such requirements, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, integrity oversight and reporting obligations, or reputational harm, any of which could adversely affect our financial results. These risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources.

***Governments outside the United States tend to impose strict price controls, which may adversely affect our revenue, if any.***

In some countries, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of regulatory approval for a drug. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In addition, many countries outside the United States have limited government support programs that provide for reimbursement of drugs such as our product candidates, with an emphasis on private payors for access to commercial products. If reimbursement of our products, if approved is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

***We are subject to stringent and evolving U.S. and foreign laws, regulations, rules; contractual obligations; policies; and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences for our business, results of operations and financial condition.***

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process or processing) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, employee data, intellectual property, data we collect about trial participants in connection with clinical trials, and other sensitive third-party data (collectively, sensitive data). Our data processing activities may subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry



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standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

Various federal, state, local and foreign legislative and regulatory bodies, or self-regulatory organizations, may expand current laws, rules or regulations, enact new laws, rules or regulations or issue revised rules or guidance regarding data privacy and security. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal information privacy laws, and consumer protection laws. For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and their respective implementing regulations (collectively, HIPAA) imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. 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 HIPAA. Depending on the facts and circumstances, we could be subject to significant penalties if we violate HIPAA.

Additionally, the California Consumer Privacy Act (CCPA) applies to personal information of California consumers, business representatives, and employees, and among other things requires regulated businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights, including the right to opt out of certain disclosures of their information. The CCPA provides for civil penalties as well as a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. The CCPA does not currently apply to us because we do not generate the requisite annual revenue, but it may apply to us in the future. In addition, although the CCPA includes limited exceptions, including for certain information collected as part of clinical trials, the CCPA may impact our processing of personal information and increases our compliance costs depending on how it is interpreted. Additionally, amendments to the CCPA expanded the CCPA's requirements, including by granting additional rights to California residents, such as the right to correct personal information and additional opt-out rights, and establishing a regulatory agency dedicated to enforcing the CCPA. Other states, such as Virginia, Connecticut, Utah and Colorado, have also passed comprehensive privacy laws, and similar laws are being considered or have been enacted in several other states, as well as at the federal and local levels. While U.S. state privacy laws, like the CCPA, may also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely. In addition to government activity, privacy advocacy groups and technology and other industries are considering various new, additional or different self-regulatory standards that may place additional burdens on us.

There are also various laws, regulations and industry standards in other jurisdictions outside the United States relating to data privacy and security, with which we may need to comply. For example, the European Union's General Data Protection Regulation (EU GDPR) and the United Kingdom's equivalent (UK GDPR), collectively, GDPR, impose strict requirements for processing personal data. Notably, under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to €20 million under the EU GDPR / £17.5 million under the UK GDPR, or, in each case, 4% of the annual global revenue of the noncompliant undertaking, whichever is greater. The GDPR also provides for 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. Additionally, EU member states may introduce further conditions, including limitations, and make their own laws and regulations further limiting the processing of "special categories of personal data", including personal data related to health, biometric data used for unique identification purposes and genetic information, which could limit our ability to process such special categories of personal data, and could cause our compliance costs to increase, ultimately adversely affecting our business, financial condition, results of operations and prospects.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. 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 EEA and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are

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inadequate. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, the EU-US Data Privacy Framework, and the UK extension thereto (which allows for transfers to 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 laws. If there is no lawful manner for us to transfer personal data from the EEA, the UK 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 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 UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

In addition to data privacy and security laws, 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.

Each of these laws, rules, regulations and contractual obligations relating to data privacy and security, and any other such changes or new laws, rules, regulations or contractual obligations could impose significant limitations, require changes to our business, or restrict our collection, use, storage or processing of personal information, which may increase our compliance expenses and make our business more costly or less efficient to conduct. In addition, any such changes could compromise our ability to develop an adequate marketing strategy and pursue our growth strategy effectively or even prevent us from providing certain products in jurisdictions in which we currently operate and in which we may operate in the future or incur potential liability in an effort to comply with such legislation, which, in turn, could adversely affect our business, financial condition, results of operations and prospects. Complying with these numerous, complex and often changing regulations is expensive and difficult, and failure to comply with any data privacy or security laws, whether by us, one of our CROs, CMOs or another third party, could adversely affect our business, financial condition, results of operations and prospects, including but not limited to: regulatory investigation costs; material fines and penalties; compensatory, special, punitive and statutory damages; litigation (including class claims); consent orders regarding our data privacy and security practices; requirements that we provide notices, bans on processing personal data (including clinical trial data), orders to destroy or not use personal data, credit monitoring services and/or credit restoration services or other relevant services to impacted individuals in the event of an information security incident impacting personal information; adverse actions against our licenses to do business; reputational damage; and injunctive relief. The implementation of the GDPR have increased our responsibility and liability in relation to sensitive data that we process, including in clinical trials, and we may be required to put in place additional mechanisms to comply with the GDPR and other applicable laws and regulations, which could divert management's attention and increase our cost of doing business. In addition, new regulation or legislative actions regarding data privacy and security (together with applicable industry standards) may increase our costs of doing business. In this regard, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the EEA, the UK and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Any actual or perceived failure by us or our third-party service providers to comply with any federal, state or foreign laws, rules, regulations, industry self-regulatory principles, industry standards or codes of conduct, regulatory guidance, orders to which we may be subject or other legal obligations relating to privacy, data protection, data security or consumer protection could adversely affect our reputation, brand and business. We may also be contractually required to indemnify and hold harmless third parties from the

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costs or consequences of non-compliance with any laws, rules and regulations or other legal obligations relating to privacy or any inadvertent or unauthorized use or disclosure, or other compromise of data that we store or handle as part of operating our business. Any of these events could adversely affect our reputation, business, or financial condition, including but not limited to: interruptions or stoppages in our business operations (including clinical trials and the development of product candidates); inability to process personal information or to operate in certain jurisdictions; 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.

We cannot assure you that our CROs, CMOs or other third-party service providers with access to our or our suppliers', manufacturers', trial participants', employees' and others' sensitive data in relation to which we are responsible will not breach contractual obligations imposed by us, or that they will not experience data security incidents, which could have a corresponding effect on our business, including putting us in breach of our obligations including under privacy laws and regulations and/or which could in turn adversely affect our business, financial condition, results of operations and prospects. We cannot assure you that our contractual measures and our own privacy and security-related safeguards will protect us from the risks associated with the third-party processing of such information. Any of the foregoing could adversely affect our business, financial condition, results of operations and prospects.

We also publicly post our privacy policies and practices concerning our collection, use, disclosure and other processing of the personal information provided to us or that we collect. Although we endeavor to comply with our public statements and documentation, we may at times fail to do so or be perceived to have failed to do so. Our publication of our privacy policies and other statements we publish that provide promises and assurances about data privacy and security can subject us to potential claims if they are found to be deceptive, unfair or misrepresentative of our actual practices. Any actual or perceived failure by us to comply with federal, state or foreign laws, rules or regulations, industry standards, contractual or other legal obligations, or any actual, perceived or suspected cybersecurity incident, whether or not resulting in unauthorized access to, or acquisition, release, transfer or other compromise of personal information or other sensitive data, may result in enforcement actions and prosecutions, private litigation (including class claims), significant fines, penalties (including bans on processing personal data or orders to destroy or not use personal data) and censure, claims for damages by affected individuals, regulatory inquiries and investigations or adverse publicity and could cause reputational harm, any of which could adversely affect our business, financial condition, results of operations and prospects.

The successful assertion of one or more large data privacy or security claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim.

**Risks Related to Our Reliance on Third Parties**

*We may have conflicts with any future licensors or collaborators that could delay or prevent the development or commercialization of our product candidates.*

We may enter into strategic transactions in the future, and we may have conflicts with any potential licensors or collaborators, such as conflicts concerning the interpretation of preclinical or clinical data, the achievement of milestones, the interpretation of contractual obligations, payments for services, development obligations or the ownership of intellectual property developed during our collaboration. If any conflicts arise with any of our future collaborators, such collaborator may act in a manner that is adverse to our best interests. Any such disagreement could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidates, and in turn prevent us from generating revenue: disputes regarding milestone payments or royalties; uncertainty regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into future additional collaborations; unwillingness by such collaborator to cooperate in the development or manufacture of a product candidate, including providing us with data or materials; unwillingness on the part of a collaborator to keep us informed regarding the progress of its development and commercialization activities or to permit

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public disclosure of the results of those activities; initiating of litigation or alternative dispute resolution options by either party to resolve the dispute; or attempts by either party to terminate the agreement.

***We have relied and expect to continue to rely on third parties to conduct our preclinical studies and clinical trials. If those third parties do not perform as contractually required, fail to satisfy legal or regulatory requirements, miss expected deadlines or terminate the relationship, our development programs could be delayed, more costly or unsuccessful, and we may never be able to seek or obtain regulatory approval for or commercialize our product candidates.***

We rely and intend to rely in the future on third-party clinical investigators, CROs and clinical data management organizations to conduct, supervise and monitor preclinical studies and clinical trials of our current or future product candidates. Because we currently rely and intend to continue to rely on these third parties, we will have less control over the timing, quality and other aspects of preclinical studies and clinical trials than we would have had we conducted them independently. These parties are not, and will not be, our employees and we will have limited control over the amount of time and resources that they dedicate to our programs. Additionally, such parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs.

We have no experience as a company in submitting and supporting the applications necessary to gain regulatory approvals. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each indication to establish the product candidate's safety or efficacy for that indication. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities and clinical trial sites by, applicable regulatory authorities.

Large-scale clinical trials require significant financial and management resources, and reliance on third-party clinical investigators, CROs, partners or consultants. Relying on third-party clinical investigators or CROs may force us to encounter delays and challenges that are outside of our control. We may not be able to demonstrate sufficient comparability between products manufactured at different facilities to allow for inclusion of the clinical results from participants treated with products from these different facilities, in our product registrations. Further, our third-party clinical manufacturers may not be able to manufacture our product candidates or otherwise fulfill their obligations to us because of interruptions to their business, including the loss of their key staff or interruptions to their raw material supply.

Our reliance on these third parties for development activities will reduce our control over these activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable trial protocol and legal, regulatory and scientific standards, and our reliance on the CROs, clinical trial sites, and other third parties does not relieve us of these responsibilities. For example, we will remain responsible for ensuring that each of our preclinical studies are conducted in accordance with good laboratory practices, where applicable, and clinical trials are conducted in accordance with GCPs. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with GCP for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections (including through inspections that may be conducted once we submit an NDA to the FDA) of trial sponsors, clinical investigators, trial sites and certain third parties including CROs. If we, our CROs, clinical trial sites, or other third parties fail to comply with applicable GCP or other regulatory requirements, we or they may be subject to enforcement or other legal actions, 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. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. Moreover, our business may be significantly impacted if our CROs, clinical investigators or other third parties violate federal or state healthcare fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

In the event we need to repeat, extend, delay or terminate our clinical trials because these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, our clinical trials may need to be repeated, extended, delayed or terminated and we may not be able to obtain, or may be delayed in obtaining, regulatory

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approvals for our product candidates, and we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates or we or they may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business may be materially and adversely affected.

If any of our relationships with these third parties terminate, we may not be able to enter into alternative arrangements or do so on commercially reasonable terms. Switching or adding additional contractors involves additional cost and time and requires management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines. In addition, if an agreement with any of our future collaborators terminates, our access to technology and intellectual property licensed to us by that collaborator may be restricted or terminate entirely, which may delay our continued development of our product candidates utilizing the collaborator's technology or intellectual property or require us to stop development of those product candidates completely.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and/or a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA 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 and may ultimately lead to the denial of regulatory approval of one or more of our product candidates.

***We rely on third-party manufacturers and suppliers to supply our product candidates. The loss of our third-party manufacturers or suppliers, or their failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, within acceptable timeframes, or at all, would materially and adversely affect our business.***

We do not own or operate, and currently have no plans to establish, any manufacturing facilities for drug manufacturing, storage, distribution or quality testing. We currently rely, and expect to continue to rely, on third parties for the manufacture of active pharmaceutical ingredients (API), bulk drug substances, raw materials, samples, components and other materials for our product candidates for clinical testing, as well as for the manufacture of any products candidates that we commercialize, if approved. Reliance on third-party manufacturers may expose us to different risks than if we were to manufacture product candidates ourselves. There can be no assurance that our preclinical and clinical development product supplies will not be limited, interrupted, terminated or will be of satisfactory quality or be available at acceptable prices. In addition, any replacement of our manufacturer could require significant effort and time because there may be a limited number of qualified replacements.

We obtain our preclinical and clinical supplies from our manufacturers on a purchase order basis, and currently do not have long-term supply arrangements in place. The manufacturing process for our product candidates is subject to the FDA and foreign regulatory authority review. We, and our suppliers and manufacturers, must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMPs. If our CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities, we may not be able to rely on their facilities for the manufacture of elements of our product candidates. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the FDA, and foreign regulatory authorities. If the FDA or any comparable foreign regulatory authority determines that our third-party manufacturers' facilities are not in compliance with applicable laws and regulations, including those governing cGMPs, they may deny any NDA or marketing application we submit until the deficiencies are corrected or we replace the manufacturer in our application with a manufacturer that is able to demonstrate a compliance status acceptable to the FDA or foreign regulatory authority. Moreover, we are dependent on our CMOs for manufacturing in compliance with cGMPs and

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other regulatory requirements. In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations in relation to quality, timing or otherwise, or if our projected manufacturing capacity or supply of materials becomes limited, interrupted, or more costly than anticipated, we may be forced to enter into an agreement with another third party, which we may not be able to do timely or on reasonable terms, if at all. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such to another third party. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to enable us, or to have another third party, manufacture our product candidates. We will be required to verify that the new manufacturer maintains facilities and procedures that comply with applicable quality standards and regulations and guidelines; and we may be required to repeat some of the development program. If we are required to change manufacturers, the delays and costs associated with the verification of a new manufacturer, whether due to failure to comply with regulatory requirements, or quality, timing and supply issues, or other reason, could negatively affect our ability to develop product candidates in a timely manner or within budget.

For example, as part of our process development efforts, we also may make changes to the manufacturing processes at various points during development, for various reasons, such as controlling costs, achieving scale, decreasing processing time, improving product formulations, increasing manufacturing success rate or other reasons. For example, we plan to implement certain manufacturing process changes for ESK-001 to increase scalability with respect to our planned Phase 3 clinical trials. Such changes carry the risk that they will not achieve their intended objectives, and any of these changes could cause our current or future product candidates to perform differently and affect the results of our future clinical trials. In some circumstances, changes in the manufacturing process may require us to perform *ex vivo* comparability studies or clinical bridging studies, and we may be required to collect additional data from participants prior to undertaking more advanced clinical trials. For instance, changes in our process during the course of clinical development may require us to show the comparability of the product used in earlier clinical phases or at earlier portions of a trial to the product used in later clinical phases or later portions of the trial.

We expect to continue to rely on third-party manufacturers if we receive regulatory approval for any product candidate. To the extent that we enter into future long-term manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. Any manufacturing facilities used to produce our product candidates will be subject to periodic review and inspection by the FDA and foreign regulatory authorities, including for continued compliance with cGMP requirements, quality control, quality assurance and corresponding maintenance of records and documents. If we are unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Our or a third party's failure to execute on our manufacturing requirements, comply with cGMPs or maintain a compliance status acceptable to the FDA or foreign regulatory authorities could adversely affect our business in a number of ways, including:

- an inability to initiate or continue preclinical studies or clinical trials of product candidates;
- delay in submitting regulatory applications, or receiving regulatory approvals, for product candidates;
- loss of the cooperation of future collaborators;
- requirements to cease distribution or to recall batches of our product candidates; and
- in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our products.

Additionally, our CMOs may experience difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our CMOs were to encounter any of these difficulties, our ability to provide our product candidates to participants in preclinical and clinical trials, or to provide product for treatment of participants once approved, would be jeopardized.

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***We depend on limited source suppliers for certain raw materials used in our product candidates. If we are unable to source these supplies on a timely basis or establish redundancy in our manufacturing process or longer-term contracts with our CMOs, we will not be able to complete our clinical trials on time and the development of our product candidates may be delayed.***

Certain of the raw materials necessary to produce ESK-001 and A-005 are in limited supply, and we generally rely on one CMO for each manufacturing stage. While we intend to identify and qualify additional suppliers and redundant manufacturers provide the API, drug product and critical raw material prior to submission of an NDA to the FDA and/or a comparable marketing application outside the United States, there can be no assurance that we will be successful in doing so. Furthermore, any of the limited source suppliers upon whom we rely could stop producing our supplies, cease operations or be acquired by, or enter into exclusive arrangements with, our competitors. Establishing redundancy in CMOs and additional or replacement suppliers for these supplies, and obtaining regulatory authorizations that may result from adding or replacing CMOs and suppliers, could take a substantial amount of time, result in increased costs and impair our ability to produce our products, which would adversely impact our business, financial condition, results of operations and prospects. Any such interruption or delay may force us to seek similar supplies from alternative sources, which may not be available at reasonable prices, or at all. Any interruption in the supply of limited source components for our product candidates would adversely affect our ability to meet scheduled timelines and budget for the development and commercialization of our product candidates, could result in higher expenses and would harm our business. Although we have not experienced any significant disruption as a result of our reliance on limited source suppliers, we have a limited operating history and cannot assure you that we will not experience disruptions in our supply chain in the future as a result of such reliance or otherwise.

In addition, we do not currently have long-term supply contracts with our CMOs, and they are not obligated to supply drug products to us for any period, in any specified quantity or at any certain price beyond the delivery contemplated by the relevant purchase orders. As a result, our suppliers could stop selling to us at commercially reasonable prices, or at all. While we intend to enter into long-term master supply agreements with certain of our CMOs prior to any potential NDA submission, we may not be successful in negotiating such agreements on favorable terms or at all. If we do enter into such long-term master supply agreements, or enter into such agreements on less favorable terms than we currently have with such manufacturers, we could be subject to binding long-term purchase obligations that may be harmful to our business, including in the event that we do not conduct our trials on planned timelines or utilize the drug products that we are required to purchase. Any change in our relationships with our CMOs or changes to the contractual terms of our agreements with them could adversely affect our business, financial condition, results of operations and prospects.

***The operations of our suppliers, most of which are located outside of the United States, are subject to additional risks that are beyond our control and that could harm our business, financial condition, results of operations and prospects.***

Currently, most of our suppliers are located outside of the United States. As a result of our global suppliers, we are subject to risks associated with doing business abroad, including:

- political unrest, terrorism, labor disputes, and economic instability resulting in the disruption of trade from foreign countries in which our products are manufactured;
- the imposition of new laws and regulations, including those relating to labor conditions, quality, and safety standards, imports, duties, taxes, and other charges on imports, as well as trade restrictions and restrictions on currency exchange or the transfer of funds, particularly new or increased tariffs imposed on imports from countries where our suppliers operate;
- greater challenges and increased costs with enforcing and periodically auditing or reviewing our suppliers' and manufacturers' compliance with cGMPs or status acceptable to the FDA or foreign regulatory authorities;
- reduced protection for intellectual property rights, including trademark protection, in some countries particularly China;
- disruptions in operations due to global, regional, or local public health crises or other emergencies or natural disasters, including, for example, disruptions experienced during the COVID-19 pandemic;

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- disruptions or delays in shipments; and
- changes in local economic conditions in countries where our manufacturers or suppliers are located.

These and other factors beyond our control could interrupt our suppliers' production, influence the ability of our suppliers to export our clinical supplies cost-effectively or at all, and inhibit our suppliers' ability to procure certain materials, any of which could harm our business, financial condition, results of operations and prospects.

**Risks Related to this Offering and Ownership of Our Common Stock**

***As a result of our history of losses and negative cash flows from operations, our consolidated financial statements contain a statement regarding a substantial doubt about our ability to continue as a going concern.***

A history of operating losses and negative cash flows from operations combined with our anticipated use of cash to fund operations raises substantial doubt about our ability to continue as a going concern beyond the 12-month period from the issuance date of our consolidated financial statements as of and for the year ended December 31, 2023. Our future viability as an ongoing business is dependent on our ability to generate cash from our operating activities or to raise additional capital to finance our operations.

If we are unable to raise additional capital as and when needed, our business, financial condition and results of operations will be materially and adversely affected, and we may be forced to delay our development efforts, limit our activities and reduce research and development costs. If we are unable to continue as a going concern, we may have to liquidate our assets, and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements. The inclusion of a going concern explanatory paragraph by our independent registered public accounting firm, our lack of cash resources and our potential inability to continue as a going concern may materially adversely affect our share price and our ability to raise new capital, enter into licensing and collaboration arrangements or other contractual relationships with third parties and otherwise execute our development strategy.

***An active and liquid trading market for our common stock may not develop and you may not be able to resell your shares of common stock at or above the public offering price, if at all.***

Prior to this offering, no market for shares of our common stock existed. We intend to apply to list our common stock on Nasdaq under the symbol "ALMS." Assuming that our common stock is listed and after the consummation of this offering, an active or liquid trading market for our common stock may never develop or be sustained following this offering. To the extent certain of our existing stockholders and their affiliated entities participate in this offering, such purchases would reduce the non-affiliated public float of our shares, meaning the number of shares of our common stock that are not held by officers, directors and affiliated stockholders. A reduction in the public float could reduce the number of shares that are available to be traded at any given time, thereby adversely impacting the liquidity of our common stock and depressing the price at which you may be able to sell your shares. Moreover, the initial public offering price for our common stock will be determined through negotiations with the underwriters and may vary from the market price of our common stock following this offering. As a result of these and other factors, you may be unable to resell your shares of our common stock at or above the initial public offering price, at the time you wish to sell them, or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. Furthermore, an inactive market may also impair our ability to raise capital by selling shares of our common stock in the future and may impair our ability to enter into strategic collaborations or acquire companies or products by using our shares of common stock as consideration.

***Our quarterly and annual operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts or any guidance we may publicly provide, each of which may cause our stock price to fluctuate or decline.***

We expect our operating results to be subject to quarterly and annual fluctuations which may, in turn, cause the price of our common stock to fluctuate substantially. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expense related to the ongoing development of our most advanced product candidate ESK-001, A-005 and other development programs;



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- results and timing of preclinical studies and ongoing and future clinical trials, or the addition or termination of any such clinical trials;
- the timing of payments we may make or receive under future license and future collaboration arrangements or the termination or modification thereof;
- our execution of any strategic transactions, including acquisitions, collaborations, licenses or similar arrangements, and the timing and amount of payments we may make or receive in connection with such transactions;
- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- recruitment and departures of key personnel;
- if our product candidates receive regulatory approval, the terms of such approval and market acceptance and demand for such products;
- regulatory developments affecting our product candidates or those of our competitors;
- fluctuations in stock-based compensation expense;
- the impacts of inflation and rising interest rates on our business and operations; and
- changes in general market and economic conditions.

If our quarterly or annual operating results fall below the expectations of investors or securities analysts or any forecasts or guidance we may provide to the market, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide. We believe that quarterly or annual comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

***Our stock price may be volatile, which could result in substantial losses for investors purchasing shares in this offering.***

The market price of our common stock is likely to be volatile and could fluctuate widely in response to many factors, including but not limited to:

- volatility and instability in the financial and capital markets;
- announcements relating to our product candidates, including the results of clinical trials by us or any future collaborators;
- announcements by competitors that impact our competitive outlook;
- negative developments with respect to our product candidates, or similar products or product candidates with which we compete;
- developments with respect to patents or intellectual property rights;
- announcements of technological innovations, new product candidates, new products or new contracts by us or our competitors;
- announcements relating to strategic transactions, including acquisitions, collaborations, licenses or similar arrangements;
- actual or anticipated variations in our operating results due to the level of development expenses and other factors;
- changes in financial estimates by equities research analysts and whether our earnings (or losses) meet or exceed such estimates;
- announcement or expectation of additional financing efforts and receipt, or lack of receipt, of funding in support of conducting our business;
- sales of our common stock by us, our insiders, or other stockholders, or issuances by us of shares of our common stock in connection with strategic transactions;

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- expiration of market standoff or lock-up agreements described in the section titled “Underwriting;”
- conditions and trends in the pharmaceutical, biotechnology and other industries;
- regulatory developments within, and outside of, the United States, including changes in the structure of health care payment systems;
- litigation or arbitration;
- COVID-19 or other pandemics, natural disasters, or major catastrophic events;
- general economic, political and market conditions and other factors; and
- the occurrence of any of the risks described in this section titled “Risk Factors.”

In recent years, the stock market in general, and the market for pharmaceutical and biotechnology companies in particular, has experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. These fluctuations may be even more pronounced in the trading market for our stock shortly following this offering.

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

You will suffer immediate and substantial dilution with respect to the common stock you purchase in this offering. Specifically, assuming an initial public offering price of \$ \_\_\_\_\_ per share, and assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and that the underwriters do not exercise their option to purchase additional shares of common stock in this offering, you will incur immediate dilution of \$ \_\_\_\_\_ per share. That number represents the difference between the assumed initial public offering price of \$ \_\_\_\_\_ per share and our pro forma as adjusted net tangible book value per share as of March 31, 2024, after giving effect to (i) the Preferred Stock Conversion, (ii) the Common Stock Reclassification (as if each had occurred as of March 31, 2024) and (iii) the filing and effectiveness of our amended and restated certificate of incorporation to be in effect immediately prior to the closing of this offering.

For a further description of the dilution that you will experience immediately after this offering, see the section titled “Dilution.”

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

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

Based on shares of common stock outstanding as of March 31, 2024 (after giving effect to (i) the Preferred Stock Conversion and (ii) the Common Stock Reclassification), upon the closing of this offering, we will have outstanding a total of \_\_\_\_\_ shares of common stock, assuming no exercise of the underwriters’ option to purchase additional shares and no exercise of outstanding options subsequent to such date. Of these shares, only the shares of common stock sold in this offering by us, plus any shares sold upon exercise of the underwriters’ option to purchase additional shares, will (unless they are purchased by one of our affiliates) be freely tradable, without restriction, in the public market immediately following this offering.

Our directors and executive officers and holders of substantially all of our outstanding securities have entered into lock-up agreements with the underwriters pursuant to which they may not, with certain exceptions, for a period of 180 days from the date of this prospectus, offer, sell or otherwise transfer or dispose of any of our securities, without the prior written consent of Morgan Stanley & Co. LLC. However, the representatives may permit our officers, directors and other security holders who are subject to the lock-up agreements to sell shares prior to the expiration of the lock-up agreements at any time in their sole discretion. See the section titled “Underwriting.” Sales of these shares, or perceptions that they will be sold, could cause the trading price

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of our common stock to decline. After the lock-up agreements expire, an additional \_\_\_\_\_ shares of common stock will be eligible for sale in the public market, of which \_\_\_\_\_ shares are held by directors, executive officers and other affiliates and will be subject to volume limitations under Rule 144 under the Securities Act.

In addition, as of March 31, 2024, \_\_\_\_\_ shares of common stock that are subject to outstanding options under our employee benefit plan will become eligible for sale in the public market after this offering, to the extent permitted by the provisions of various vesting schedules, the lock-up agreements (and the exceptions thereto) and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

After this offering, the holders of \_\_\_\_\_ shares of our outstanding common stock, or approximately \_\_\_\_\_ % of our total outstanding common stock and non-voting stock based on shares outstanding as of March 31, 2024, will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the lock-up agreements described above. See “Description of Capital Stock—Registration Rights.” Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could adversely affect the trading price of our common stock.

***We have broad discretion in how we use the net proceeds of this offering and may not use these proceeds effectively, which could affect our results of operations and cause our stock price to decline.***

We will have considerable discretion in the application of the net proceeds of this offering, including for any of the purposes described in the section of this prospectus titled “Use of Proceeds,” and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. As a result, investors will be relying upon management’s judgment with only limited information about our specific intentions for the use of the balance of the net proceeds of this offering. We may use the net proceeds for purposes that do not yield a significant return or any return at all for our stockholders. In addition, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

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

Based on \_\_\_\_\_ shares of our common stock outstanding as of March 31, 2024, prior to this offering, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately \_\_\_\_\_ % of our voting common stock and \_\_\_\_\_ % of our non-voting common stock and, upon the completion of this offering, that same group will hold approximately \_\_\_\_\_ % of our outstanding voting common stock and \_\_\_\_\_ % of our outstanding non-voting common stock (assuming no exercise of the underwriters’ option to purchase additional shares of common stock, no exercise of outstanding options and no purchases of shares of common stock in this offering by anyone of this group). The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock. The significant concentration of stock ownership may adversely affect the trading price of our 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 the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.***

We are an “emerging growth company” as defined in Section 2(a) of the Securities Act, as modified by the JOBS Act. As an emerging growth company, we are only required to provide two years of audited financial statements (in addition to any required unaudited interim financial statements) and correspondingly reduced management discussion and analysis of financial condition and results of operations disclosure. In addition,

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we are not required to obtain auditor attestation of reporting on internal control over financial reporting, we have reduced disclosure obligations regarding executive compensation and we are not required to hold non-binding advisory votes on executive compensation or obtain stockholder approval of any golden parachute payments not previously approved. We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of reduced reporting obligations in this prospectus. In particular, in this prospectus, we have not included all of the executive compensation related information that would be required if we were not an emerging growth company. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. These provisions allow an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have elected to take advantage of such extended transition period. We cannot predict whether investors will find our common stock less attractive as a result of its reliance on these exemptions. If some investors find our common stock to be less attractive as a result, there may be a less active trading market for our common stock and the price of our common stock may be more volatile than the current trading market and price of our common stock.

Further, there is no guarantee that the exemptions available under the JOBS Act will result in significant savings. To the extent that we choose not to use exemptions from various reporting requirements under the JOBS Act, we will incur additional compliance costs, which may impact our financial condition.

We will remain an emerging growth company until the earliest of: (i) the end of the fiscal year in which we have a total annual gross revenue of \$1.235 billion; (ii) the last day of our fiscal year following the fifth anniversary of the completion of this offering; (iii) the date on which we have, during the previous three-year period, issued more than \$1.0 billion in non-convertible debt; or (iv) the end of the fiscal year in which the market value of common stock held by non-affiliates exceeds \$700 million as of the prior June 30. Even after we no longer qualify as an emerging growth company, we may continue to qualify as a smaller reporting company, which would allow us to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation. In addition, if we are a smaller reporting company with less than \$100 million in annual revenue, we would not be required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act.

***Anti-takeover provisions in our charter documents and under Delaware law could prevent or delay an acquisition of us that may be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management.***

Our amended and restated certificate of incorporation and our amended and restated bylaws that will be in effect upon completion of this offering contain provisions that could delay or prevent a change in control of our company. These provisions could also make it difficult for stockholders to elect directors who are not nominated by current members of our board of directors or take other corporate actions, including effecting changes in our management. These provisions:

- establish a classified board of directors so that not all members of our board are elected at one time;
- permit only the board of directors to establish the number of directors and fill vacancies on the board;
- provide that directors may only be removed “for cause” and only with the approval of two-thirds of our stockholders;
- require super-majority voting to amend some provisions in our amended and restated certificate of incorporation and amended and restated bylaws;
- authorize the issuance of “blank check” preferred stock that our board could use to implement a stockholder rights plan;
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- prohibit cumulative voting; and
- establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings.

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In addition, Section 203 of the Delaware General Corporation Law (DGCL) may discourage, delay or prevent a change in control of our company. Section 203 imposes certain restrictions on mergers, business combinations and other transactions between us and holders of 15% or more of our common stock.

***The exclusive forum provisions in our organizational documents may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers or employees, or the underwriters of any offering giving rise to such claim, which may discourage lawsuits with respect to such claims.***

Our amended and restated certificate of incorporation that will be in effect upon completion of this offering, to the fullest extent permitted by law, will provide that the Court of Chancery of the State of Delaware is the exclusive forum for: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the DGCL, our amended and restated certificate of incorporation, or our amended and restated bylaws; or any action asserting a claim that is governed by the internal affairs doctrine. This exclusive forum provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, or the underwriters of any offering giving rise to such claims, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, financial condition, results of operations and prospects.

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. Our amended and restated bylaws will provide that the federal district courts of the United States of America will, to the fullest extent permitted by law, be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act (the Federal Forum Provision), including for all causes of action asserted against any defendant named in such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. Our decision to adopt a Federal Forum Provision followed a decision by the Supreme Court of the State of Delaware holding that such provisions are facially valid under Delaware law. While federal or other state courts may not follow the holding of the Delaware Supreme Court or may determine that the Federal Forum Provision should be enforced in a particular case, application of the Federal Forum Provision means that suits brought by our stockholders to enforce any duty or liability created by the Securities Act must be brought in federal court and cannot be brought in state court, and our stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder. 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. In addition, neither the exclusive forum provision nor the Federal Forum Provision applies to suits brought to enforce any duty or liability created by the Exchange Act. Accordingly, actions by our stockholders to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder must be brought in federal court, and our stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Any person or entity purchasing or otherwise acquiring or holding any interest in any of our securities shall be deemed to have notice of and consented to our exclusive forum provisions in our amended and restated bylaws, including the Federal Forum Provision. These provisions may limit a stockholders' ability to bring a claim, and may result in increased costs for a stockholder to bring such a claim, in a judicial forum of their choosing for disputes with us or our directors, officers, other employees or agents, which may discourage lawsuits against us and our directors, officers, other employees or agents.

***Our board of directors will be authorized to issue and designate shares of our preferred stock without stockholder approval.***

Our amended and restated certificate of incorporation will authorize our board of directors, without the approval of our stockholders, to issue shares of preferred stock, subject to limitations prescribed by applicable

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law, rules and regulations and the provisions of our amended and restated certificate of incorporation, and to establish from time to time the number of shares of preferred stock to be included in each such series and to fix the designation, powers, preferences and rights of the shares of each such series and the qualifications, limitations or restrictions thereof. The powers, preferences and rights of these additional series of convertible preferred stock may be senior to or on parity with our common stock, which may reduce our common stock's value.

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

We have never declared nor paid dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development, operation and expansion of our business and we do not anticipate declaring or paying any dividends in the foreseeable future. As a result, capital appreciation of our common stock, which may never occur, will be your sole source of gain on your investment for the foreseeable future.

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

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

#### **General Risk Factors**

***Unstable economic and market conditions may have serious adverse consequences on our business, financial condition and stock price.***

Global economic and business activities continue to face widespread uncertainties, and global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, rising inflation and monetary supply shifts, rising interest rates, labor shortages, declines in consumer confidence, declines in economic growth, increases in unemployment rates, recession risks, and uncertainty about economic and geopolitical stability (for example, related to the ongoing Russia-Ukraine conflict). The extent of the impact of these conditions on our operational and financial performance, including our ability to execute our business strategies and initiatives in the expected timeframe, as well as that of third parties upon whom we rely, will depend on future developments which are uncertain and cannot be predicted. There can be no assurance that further deterioration in economic or market conditions will not occur, or how long these challenges will persist. If the current equity and credit markets further deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

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

The trading market for our common stock will be influenced in part by the research and reports that industry or securities analysts publish about us or our business. We do not have any control over the industry or

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securities analysts, or the content and opinions included in their reports and may never obtain research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, or if analysts cease coverage of us, we could lose visibility in the financial markets, and the trading price for our common stock could be impacted negatively. If any of the analysts who cover us publish inaccurate or unfavorable research or opinions regarding us, our business model, our intellectual property or our stock performance, or if our preclinical studies and clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline.

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

After the completion of this offering, as a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Securities Act, the Exchange Act, Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain sufficient coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. The increased costs may require us to reduce costs in other areas of our business. Moreover, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

***Failure to establish and maintain effective internal control over financial reporting could adversely affect our business and if investors lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could be negatively affected.***

We are not currently required to comply with the rules of the SEC implementing Section 404 of the Sarbanes-Oxley Act and are therefore not required to make a formal assessment of the effectiveness of our internal control over financial reporting for that purpose. Upon becoming a public company, we will be required to comply with the SEC's rules implementing Sections 302 and 404 of the Sarbanes-Oxley Act, which will require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of internal control over financial reporting. Although we will be required to disclose changes made in our internal control over financial reporting on a quarterly basis, we will not be required to make our first annual assessment of our internal control over financial reporting until our second annual report on Form 10-K. However, as an emerging growth company, our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting until the later of the year following our first annual report required to be filed with the SEC or the date we are no longer an emerging growth company. At such time, our independent registered public accounting firm would need to issue a report that is adverse in the event that there are material weaknesses in our internal control over financial reporting.

As a private company, we do not currently have any internal audit function. To comply with the requirements of being a public company, we have undertaken various actions, and will need to take additional actions, such as implementing numerous internal controls and procedures and hiring additional accounting or internal audit staff or consultants. Testing and maintaining internal controls can divert our management's attention from other matters that are important to the operation of our business. Additionally, when evaluating our internal control over financial reporting, we may identify material weaknesses that we may not be able to remediate in time to meet the applicable deadline imposed upon us for compliance with the requirements of

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Section 404. If we identify any material weaknesses in our internal control over financial reporting or are unable to comply with the requirements of Section 404 in a timely manner or assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting once we are no longer an emerging growth company, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be negatively affected, and we could become subject to investigations by the stock exchange on which our securities are listed, the SEC or other regulatory authorities, which could require additional financial and management resources. In addition, if we fail to remedy any material weakness, our financial statements could be inaccurate, and we could face restricted access to capital markets.

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

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

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make any related party transaction disclosures. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. In addition, we do not have a formal risk management program for identifying and addressing risks to our business in other areas.

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

The market price of our common stock is likely to be volatile. The stock market in general, and Nasdaq and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation (including the cost to defend against, and any potential adverse outcome resulting from any such proceeding) can be expensive, time-consuming, damage our reputation and divert our management's attention from other business concerns, which could seriously harm our business.



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**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus contains forward-looking statements that are based on our management's beliefs and assumptions and on information currently available to our management. Some of the statements under the sections titled "Prospectus Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business" and elsewhere in this prospectus contain forward-looking statements. In some cases, you can identify forward-looking statements by the following words: "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "ongoing," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words.

These forward-looking statements involve risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this prospectus, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain. Forward-looking statements in this prospectus include, but are not limited to, statements about:

- our expectations regarding the potential benefits of our strategy;
- our expectations regarding the operation of our product candidates and related benefits;
- the success of competing therapies that are, or may become, available;
- developments relating to our competitors and our industry, including competing product candidates and therapies;
- details regarding our strategic vision and planned product candidate pipeline;
- our beliefs regarding the success, cost and timing of our product candidate development activities and current and future clinical trials and studies, including study design
- the timing or likelihood of regulatory filings or other actions and related regulatory authority responses;
- the ability and willingness of various third parties to engage in research and development activities involving our product candidates, and our ability to leverage those activities;
- our expectations regarding the ease of administration associated with our product candidates;
- our expectations regarding the patient compatibility associated with our product candidates;
- our beliefs regarding the potential markets for our product candidates and our ability to serve those markets;
- the ability to obtain and maintain regulatory approval of any of our product candidates, and any related restrictions, limitations and/or warnings in the label of any approved product candidate;
- our ability to commercialize any approved products;
- the rate and degree of market acceptance of any approved products;
- our ability to attract and retain key personnel;
- the accuracy of our estimates regarding our future revenue, as well as our future operating expenses, capital requirements and needs for additional financing;
- our ability to obtain funding for our operations, including funding necessary to complete further development and any commercialization of our product candidates;
- our ability to obtain, maintain, protect and enforce intellectual property protection for our product candidates and technology and not infringe, misappropriate or otherwise violate the intellectual property of others;
- regulatory developments in the United States and foreign countries;

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- our expected use of the net proceeds to us from this offering; and
- our expectations regarding the period during which we qualify as an “emerging growth company” under the JOBS Act, and a “smaller reporting company,” as defined in Rule 12b-2 of the Exchange Act.

You should refer to the section titled “Risk Factors” for a discussion of other important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this prospectus will prove to be accurate.

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 although 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 a thorough inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely upon these statements.

Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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**MARKET, INDUSTRY AND OTHER DATA**

We obtained the industry, market and competitive position data used throughout this prospectus from our own internal estimates and research, as well as from market research, industry and general publications and surveys, governmental agencies, research, surveys and studies conducted by third parties and publicly available information.

In presenting this data, we have made certain assumptions based on our knowledge of our industry and market, which we believe to be reasonable. Internal estimates are derived from publicly available information released by industry analysts and third-party sources, our internal research and our industry experience. 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. In addition, while we believe the industry, market and competitive position data included in this prospectus is reliable and based on reasonable assumptions, such data involve risks and uncertainties and are subject to change based on various factors, including those discussed in the sections titled "Risk Factors" and "Special Note Regarding Forward-Looking Statements." These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties or by us.

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**USE OF PROCEEDS**

We estimate that we will receive net proceeds from this offering of approximately \$            million (or approximately \$            million if the underwriters' over-allotment option is exercised in full) based on the assumed initial public offering price of \$            per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

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

The principal purposes of this offering are to obtain additional capital to support our operations, establish a public market for our common stock and facilitate our future access to the public capital markets. We expect to use a substantial majority of the net proceeds from this offering to fund clinical development and related studies for our product candidates as well as our activities in preparation for such clinical development. We also expect to use a portion of the net proceeds from this offering to fund our in-house research activities as well as for general corporate purposes, general and administrative expenses, capital expenditures, working capital and prosecution and maintenance of our intellectual property.

We may also use a portion of the net proceeds and our existing cash, cash equivalents and marketable securities to in-license, acquire, or invest in complementary businesses, technology platforms, products or assets, although we have no current agreements, commitments or understandings to do so.

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 proceeds to be received upon the closing of this offering or the actual amounts that we will spend on the uses set forth above.

The amounts and timing of our actual expenditures will depend on numerous factors, including the time and cost necessary to conduct our ongoing and planned preclinical studies and clinical trials, the results of our preclinical studies and clinical trials and other factors described in the section titled "Risk Factors" in this prospectus, as well as the amount of cash used in our operations and any unforeseen cash needs. Therefore, our actual expenditures may differ materially from the estimates described above. We may find it necessary or advisable to use the net proceeds for other purposes.

We expect that the funds raised in connection with this offering and our cash, cash equivalents and marketable securities on hand will be sufficient to fund our operating expenses and capital expenditure requirements for at least the next 12 months. We have based this estimate on our current assumptions, which may prove to be wrong, and we may exhaust our available capital resources sooner than we expect. Such amount will not be sufficient for us to fund our programs through regulatory approval and commercialization, and we will need to raise substantial additional capital in order to do so. To obtain the capital necessary to fund our programs through regulatory approval and commercialization, we may need to enter into additional public or private equity offerings, debt financings, or collaborations and licensing arrangements, or seek out other sources of capital. We also may elect to raise additional capital opportunistically.

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 this offering that are not used as described above in short-term, investment-grade, interest-bearing instruments.

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**DIVIDEND POLICY**

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. 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.

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**CAPITALIZATION**

The following table sets forth our cash and cash equivalents, marketable securities, and total capitalization as of March 31, 2024:

- on an actual basis;
- on a pro forma basis, giving effect to the (i) the Preferred Stock Conversion; (ii) the Common Stock Reclassification (as if each had occurred as of March 31, 2024), and (iii) the filing and effectiveness of our amended and restated certificate of incorporation, each of which will occur immediately prior to the closing of the offering; and
- on a pro forma as adjusted basis to give further effect to our issuance and sale of shares of our common stock in this offering at the assumed initial public offering price of \$ \_\_\_\_\_ per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this table together with the sections titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Description of Capital Stock,” and our consolidated financial statements and the related notes included elsewhere in this prospectus.

	As of March 31, 2024		
	Actual	Pro Forma	Pro Forma As Adjusted <sup>(1)(2)</sup>
	(in thousands except share and per share amounts)		
Cash and cash equivalents	\$	\$	\$
Marketable securities			
<b>Total cash, cash equivalents and marketable securities</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>
Redeemable convertible preferred stock, \$0.0001 par value per share; _____ shares authorized, issued and outstanding, actual; and no shares authorized, issued and outstanding, pro forma and pro forma as adjusted		—	—
<b>Stockholders’ equity (deficit):</b>			
Preferred stock, \$0.0001 par value; no shares authorized, issued and outstanding, actual; _____ shares authorized, no shares issued and outstanding, pro forma and pro forma as adjusted		—	—
Common stock, \$0.0001 par value per share; Class A common stock; _____ shares authorized, _____ shares issued and outstanding, actual; no shares authorized, issued and outstanding, pro forma and pro forma as adjusted; Class B common stock; _____ shares authorized, no shares issued and outstanding, actual; no shares authorized, issued and outstanding, pro forma and pro forma as adjusted			
Common stock, \$0.0001 par value per share; no shares authorized, issued and outstanding, actual; _____ shares authorized, _____ shares issued and outstanding, pro forma; _____ shares authorized, _____ shares issued and outstanding, pro forma as adjusted		—	
Non-voting common stock, \$0.0001 par value per share; no shares authorized, issued and outstanding, actual; _____ shares authorized, _____ issued and outstanding, pro forma and pro forma as adjusted		—	
Additional paid-in capital			
Accumulated other comprehensive (loss) income			
Accumulated deficit			
<b>Total stockholders’ equity (deficit)</b>			
<b>Total capitalization</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>

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- (1) Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ \_\_\_\_\_ per share would increase (decrease) each of our pro forma as adjusted cash and cash equivalents, additional paid-in capital, total stockholders' equity (deficit) and total capitalization by approximately \$ \_\_\_\_\_ million, assuming that the number of shares offered, as set forth on the cover of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Each increase (decrease) of 1,000,000 shares in the number of shares offered by us would increase (decrease) each of our pro forma as adjusted cash and cash equivalents, additional paid-in capital, total stockholders' equity (deficit) and total capitalization by approximately \$ \_\_\_\_\_ million, assuming the assumed initial public offering price per share remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.
- (2) This pro forma as adjusted information is illustrative only and will depend on the actual initial public offering price and other terms of this offering determined at pricing.

The number of shares of our common stock and non-voting common stock to be outstanding immediately after this offering, pro forma and pro forma as adjusted in the table above, is based on an aggregate of \_\_\_\_\_ shares of common stock and nonvoting common stock (which include \_\_\_\_\_ shares of unvested restricted stock awards subject to repurchase as of such date) outstanding as of March 31, 2024 after giving effect to the Preferred Stock Conversion and the Common Stock Reclassification, as if each had occurred as of March 31, 2024, and excludes:

- \_\_\_\_\_ shares of our common stock issuable upon the exercise of outstanding stock options as of March 31, 2024, with a weighted-average exercise price of \$ \_\_\_\_\_ per share;
- \_\_\_\_\_ shares of our common stock issuable upon the exercise of outstanding stock options granted subsequent to March 31, 2024, with a weighted-average exercise price of \$ \_\_\_\_\_ per share;
- \_\_\_\_\_ shares of our common stock reserved for future issuance under our 2024 Plan, which will become effective once the registration statement of which this prospectus forms a part is declared effective, including \_\_\_\_\_ new shares plus the number of shares (not to exceed \_\_\_\_\_ shares) that (i) remain available for grant of future awards under the 2021 Plan and will cease to be available for issuance under the 2021 Plan at the time our 2024 Plan becomes effective in connection with this offering, and (ii) are underlying outstanding stock awards granted under our 2021 Plan, that expire or are repurchased, forfeited, cancelled or withheld, as well as any future automatic annual increases in the number of shares of common stock reserved for issuance under our 2024 Plan and, as more fully described in the section titled "Executive Compensation—Equity Benefit Plans;" and
- \_\_\_\_\_ shares of our common stock reserved for issuance under our ESPP, which will become effective once the registration statement of which this prospectus forms a part is declared effective, as well as any future automatic annual increases in the number of shares of common stock reserved for future issuance under our ESPP, as more fully described in the section titled "Executive Compensation—Equity Benefit Plans."

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**DILUTION**

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

As of March 31, 2024, our historical net tangible book value (deficit) was \$ \_\_\_\_\_ million, or \$ \_\_\_\_\_ per share based on \_\_\_\_\_ shares of our common stock (including \_\_\_\_\_ shares subject to repurchase as of such date) outstanding as of such date. Our historical net tangible book value (deficit) per share represents the amount of our total tangible assets less our total liabilities and our redeemable convertible preferred stock, divided by the total number of shares of Class A and Class B common stock outstanding as of March 31, 2024 (including \_\_\_\_\_ shares subject to repurchase as of such date).

Our pro forma net tangible book value as of March 31, 2024 was \$ \_\_\_\_\_ million, or \$ \_\_\_\_\_ per share of common stock and non-voting common stock. Pro forma net tangible book value per share represents the amount of our total tangible assets less our total liabilities after giving effect to (i) the Preferred Stock Conversion, (ii) the Common Stock Reclassification (as if each had occurred as of March 31, 2024) and (iii) the filing and effectiveness of our amended and restated certificate of incorporation, each of which will occur immediately prior to the closing of the offering. Pro forma net tangible book value per share represents pro forma net tangible book value divided by the total number of shares of our common stock and nonvoting common stock outstanding as of March 31, 2024 (including \_\_\_\_\_ shares of common stock subject to repurchase as of such date), after giving effect to the pro forma adjustments described above.

After giving effect to our issuance and sale of \_\_\_\_\_ shares of common stock in this offering at the assumed initial public offering price of \$ \_\_\_\_\_ per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of March 31, 2024 would have been \$ \_\_\_\_\_ million, or \$ \_\_\_\_\_ per share. This amount represents an immediate increase in pro forma as adjusted net tangible book value of \$ \_\_\_\_\_ per share to our existing stockholders and an immediate dilution in pro forma as adjusted net tangible book value of \$ \_\_\_\_\_ per share to new investors purchasing common stock in this offering. We determine dilution by subtracting the pro forma as adjusted net tangible book value per share after this offering from the initial public offering price per share paid by new investors. The following table illustrates this dilution on a per share basis:

Assumed initial public offering price per share	\$ _____
Historical net tangible book value (deficit) per share as of March 31, 2024	\$ _____
Increase per share attributable to the pro forma adjustments described above	_____
Pro forma net tangible book value per share as of March 31, 2024	_____
Increase in pro forma as adjusted net tangible book value per share attributable to new investors purchasing shares of common stock in this offering	_____
Pro forma as adjusted net tangible book value per share immediately after this offering	_____
Dilution per share to new investors purchasing shares in this offering	\$ _____

The dilution information discussed above is illustrative only and may change based on the actual initial public offering price and other terms of this offering. Each \$1.00 increase or decrease in the assumed initial public offering price of \$ \_\_\_\_\_ per share, would increase or decrease, as applicable, our pro forma as adjusted net tangible book value per share after this offering by \$ \_\_\_\_\_ per share and increase or decrease, as applicable, the dilution to new investors purchasing shares of common stock in this offering by \$ \_\_\_\_\_ per share, in each case assuming the number of shares of 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 of 1.0 million shares in the number of shares of common stock offered by us would increase or decrease our pro forma as adjusted net tangible book value by approximately \$ \_\_\_\_\_ per share and decrease or increase, as applicable, the dilution to investors purchasing shares in this offering by approximately \$ \_\_\_\_\_ per share, in each case assuming the assumed initial public offering price of \$ \_\_\_\_\_ per share remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.



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If the underwriters exercise their over-allotment option in full, the pro forma net tangible book value per share, as adjusted to give effect to this offering, would be \$ \_\_\_\_\_ per share, and the dilution in pro forma net tangible book value per share to new investors in this offering would be \$ \_\_\_\_\_ per share.

The following table summarizes on the pro forma as adjusted basis as of March 31, 2024, the total number of shares of common stock and non-voting common stock purchased from us on an as converted to common stock and nonvoting common stock basis, the total consideration paid or to be paid and the weighted-average price per share paid or to be paid by existing stockholders and by new investors in this offering at an assumed initial public offering price of \$ \_\_\_\_\_ per share, before deducting underwriting discounts and commissions and estimated offering expenses payable by us. As the table shows, new investors purchasing common stock in this offering will pay an average price per share substantially higher than our existing stockholders paid.

	Shares Purchased		Total Consideration		Weighted-Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders		%	\$	%	\$
New investors					\$
<b>Totals</b>		<b>100.0%</b>	<b>\$</b>	<b>100.0%</b>	

The table above assumes no exercise of the underwriters' over-allotment option in this offering. If the underwriters' over-allotment option is exercised in full, the number of shares of our common stock held by existing stockholders would be reduced to \_\_\_\_\_ % of the total number of shares of our common stock and non-voting common stock outstanding after this offering, and the number of shares of common stock held by new investors purchasing common stock in this offering would be increased to \_\_\_\_\_ % of the total number of shares of our common stock and non-voting common stock outstanding after this offering.

The foregoing discussion and tables above (other than the historical net tangible book value (deficit) calculation) are based on an aggregate of number of shares of our common stock and non-voting common stock to be outstanding immediately after this offering is based on an aggregate of \_\_\_\_\_ shares of common stock and non-voting common stock (which include \_\_\_\_\_ shares of unvested restricted stock awards subject to a repurchase option by us) outstanding as of March 31, 2024, after giving effect to the Preferred Stock Conversion and the Common Stock Reclassification, as if each had occurred as of March 31, 2024, and excludes:

- \_\_\_\_\_ shares of our common stock issuable upon the exercise of outstanding stock options as of March 31, 2024, with a weighted-average exercise price of \$ \_\_\_\_\_ per share;
- \_\_\_\_\_ shares of our common stock issuable upon the exercise of outstanding stock options granted subsequent to March 31, 2024, with a weighted-average exercise price of \$ \_\_\_\_\_ per share;
- \_\_\_\_\_ shares of our common stock reserved for future issuance under our 2024 Plan, which will become effective once the registration statement of which this prospectus forms a part is declared effective, including \_\_\_\_\_ new shares plus the number of shares (not to exceed \_\_\_\_\_ shares) that (i) remain available for grant of future awards under the 2021 Plan and will cease to be available for issuance under the 2021 Plan at the time our 2024 Plan becomes effective in connection with this offering, and (ii) are underlying outstanding stock awards granted under our 2021 Plan, that expire or are repurchased, forfeited, cancelled or withheld, as well as any future automatic annual increases in the number of shares of common stock reserved for issuance under our 2024 Plan and, as more fully described in the section titled "Executive Compensation—Equity Benefit Plans;" and
- \_\_\_\_\_ shares of our common stock reserved for issuance under our ESPP, which will become effective once the registration statement of which this prospectus forms a part is declared effective, as well as any future automatic annual increases in the number of shares of common stock reserved for future issuance under our ESPP, as more fully described in the section titled "Executive Compensation—Equity Benefit Plans."

To the extent that any outstanding options are exercised or new options are issued under our stock-based compensation plans, or we issue additional shares of common stock in the future, there will be further dilution to new investors participating in this offering.

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

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

**Overview**

Our mission is to significantly improve the lives of patients by replacing broad immunosuppression with targeted therapies. Our name, Alumis, captures our mission to enlighten immunology, and is inspired by the words "allumer"—French for illuminate—and "immunis"—Latin for the immune system.

We are a clinical stage biopharmaceutical company and our initial focus is to develop our two Tyrosine Kinase 2 (TYK2) inhibitors: ESK-001, a second-generation inhibitor that can safely achieve maximum target inhibition and A-005, a central nervous system (CNS) penetrant molecule. ESK-001 has demonstrated significant therapeutic effect in our Phase 2 program in patients with PsO, which we define as moderate-to-severe plaque psoriasis (PsO), and is currently being evaluated in additional Phase 2 clinical trials in patients with systemic lupus erythematosus (SLE) and non-infectious uveitis (Uveitis), for which we expect to report results in [redacted] and [redacted], respectively. With the favorable results in our Phase 2 clinical trial in PsO, we intend to initiate multiple Phase 3 trials of ESK-001 in [redacted] in this indication. TYK2 genetic mutations are associated with a strong protective effect in multiple sclerosis, motivating us to develop our second product candidate, A-005, a CNS penetrant, allosteric TYK2 inhibitor for neuroinflammatory and neurodegenerative diseases. In [redacted] 2024, we initiated our Phase 1 program of A-005 in healthy volunteers and expect to report results in [redacted].

Alumis was incubated by Foresite Labs, LLC (Foresite Labs) and incorporated on January 29, 2021 as a Delaware corporation under the name FL2021-001, Inc. FL2021-001, Inc.'s name was changed to Esker Therapeutics, Inc. in March 2021 and to Alumis Inc. in January 2022.

Since our inception, we have devoted substantially all of our efforts to organizing our company, hiring personnel, business planning, acquiring and developing our product candidates, performing research and development, conducting preclinical studies and clinical trials, establishing and protecting our intellectual property portfolio, raising capital and providing general and administrative support for these activities. We do not have any products approved for sale and have not generated any revenue from product sales. We expect to continue to incur significant and increasing expenses and increasing substantial losses for the foreseeable future as we continue our development of [redacted] and seek regulatory approvals for our product candidates and commercialize any approved products, seek to expand our product pipeline and invest in our organization. Our ability to achieve and sustain profitability will depend on our ability to successfully develop, obtain regulatory approval for and commercialize our product candidates. There can be no assurance that we will ever earn revenue or achieve profitability, or if achieved, that the revenue or profitability will be sustained on a continuing basis.

To date, we have primarily funded our operations with proceeds from sales of shares of our redeemable convertible preferred stock and the issuance of convertible promissory notes in private placements. As of December 31, 2023, we had \$49.0 million in cash, cash equivalents and marketable securities. In March 2024, we received aggregate gross proceeds of \$129.5 million from the issuance and sale of 41,264,891 shares of Series C redeemable convertible preferred stock at a purchase price of \$3.13826 per share (the "First Tranche Series C Closing").

We have incurred significant operating losses and negative cash flows since our inception. Our net loss for the years ended December 31, 2022 and 2023 was \$111.9 million and \$155.0 million, respectively. As of

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December 31, 2023, we had an accumulated deficit of \$364.3 million. Substantially all of our net losses have resulted from costs incurred in connection with our research and development efforts, including acquisitions of in-process research and development assets, and, to a lesser extent, from general and administrative costs associated with our operations. Our net losses and operating losses may fluctuate from quarter to quarter and year to year depending primarily on the timing of acquisition of any new product candidates, the timing of our preclinical studies and clinical trials, our other research and development expenses, and the timing and amount of any milestone or royalty payments due under our existing or future license agreements. In addition, following the closing of this offering, we expect to incur additional costs associated with operating as a public company, including significant legal, audit, accounting, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer liability insurance costs, investor and public relations costs, and other expenses that we did not incur as a private company.

We anticipate that our expense will increase significantly in connection with our ongoing activities, particularly if and as we:

- continue to progress the development of our product candidates in multiple clinical trials in parallel;
- explore additional indications for our existing product candidates;
- hire additional clinical and scientific personnel;
- obtain, maintain, expand and protect our intellectual property rights;
- make royalty, milestone, or other payments under our existing acquisition agreements and any future license or collaboration agreements;
- seek to identify, acquire or in-license new technologies or product candidates;
- seek regulatory and marketing approvals for any of our product candidates that successfully complete clinical trials, if any;
- procure manufacturing and supply chain capacity for our product candidates, including commercial manufacturing readiness and scale-up;
- experience any delays, challenges or other issues associated with the clinical development and regulatory approvals of our product candidates;
- add operational, legal, financial and management information systems and personnel to support our product development, clinical execution and planned future commercialization efforts, as well as to support our transition to a public company;
- establish a sales, marketing and distribution infrastructure to commercialize any product candidates for which we obtain marketing approval; and
- operate as a public company.

We do not have any products approved for sale and have not generated any revenue from product sales since our inception. We do not expect to generate revenue from any product candidates that we develop until we obtain regulatory approval for one or more of such product candidates and commercialize our products or enter into collaboration agreements with third parties. Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we may never achieve or sustain profitability and, unless and until we are able to develop and commercialize our product candidates, we will need to continue to raise additional capital. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through public or private equity or debt financings, or potentially other capital sources, such as collaboration or licensing arrangements with third parties or other strategic transactions. There are no assurances that we will be successful in obtaining an adequate level of financing to support our business plans when needed on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration or licensing arrangements with third parties or other strategic transactions, we may

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have to relinquish rights to our intellectual property, future revenue streams, research programs, or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise capital as and when needed, or on attractive terms, we may have to significantly delay, reduce, or discontinue the development and commercialization of our product candidates or scale back or terminate our pursuit of new in-licenses and acquisitions.

We do not currently own or operate any manufacturing facility. We rely on contract manufacturing organizations (CMOs) to produce our product candidates in accordance with the FDA's current cGMP regulations for use in our clinical studies. We have entered into development and manufacturing agreements with various CMOs relating to process development, manufacturing of drug substance and drug product, and quality testing of our product candidates. We expect to rely on our CMOs in the future for the manufacturing of our product candidates in order to expedite readiness for future clinical trials. Most of these CMOs have demonstrated capability in preparation of materials for commercialization. Additionally, we may decide to build our own manufacturing facility in the future to provide us greater flexibility and control over our clinical or commercial manufacturing needs.

Given our stage of development, we do not yet have a marketing or sales organization or commercial infrastructure; however, we intend to build the necessary sales, marketing and commercialization capabilities and infrastructure over time as our product candidates advance through clinical development. We expect to spend a significant amount in commercial development and marketing costs prior to obtaining regulatory and marketing approval of one or more of our product candidates.

### ***Macroeconomic Trends***

Unfavorable conditions in the economy in the United States and abroad may negatively affect the growth of our business and our results of operations. For example, macroeconomic events, including, rising inflation, tensions in U.S.-China relations, the U.S. Federal Reserve raising interest rates, recent and potential future disruptions in access to bank deposits and lending commitments due to bank failures and the effects of the ongoing geopolitical conflicts in Ukraine and Israel and the surrounding areas, have led to economic uncertainty and volatility globally. The effect of macroeconomic conditions may not be fully reflected in our results of operations until future periods. Moreover, negative macroeconomic conditions could adversely impact our ability to obtain financing in the future on terms acceptable to us, or at all. In addition, the geopolitical instability and related sanctions could continue to have significant ramifications on global financial markets, including volatility in the U.S. and global financial markets. To date, the macroeconomic trends discussed above have not had a material adverse impact on our business, financial condition or results of operations. If, however, economic uncertainty increases or the global economy worsens, our business, financial condition and results of operations may be harmed.

### **Components of Results of Operations**

#### **Operating Expenses**

Our operating expenses consist of (i) research and development expenses and (ii) general and administrative expenses.

#### *Research and Development Expenses*

Research and development expenses consist of external and internal costs primarily related to acquiring and developing our research pipeline and technologies and clinical development of our product candidates.

External costs include:

- costs associated with acquiring technology and intellectual property licenses that have no alternative future uses and costs incurred under in-license or assignment agreements, including milestone payments;
- expenses incurred in connection with the discovery and preclinical development of our pipeline programs;

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- costs incurred in connection with the clinical development of our product candidates, including under agreements with clinical research organizations (CROs), CMOs and other third parties that conduct clinical trials and manufacture clinical supplies, product candidates and components on our behalf; and
- costs for third-party professional research and development consulting services.

Internal costs include:

- research and development personnel-related costs, including salaries, annual bonuses, benefits, travel and meals expenses and stock-based compensation expense; and
- allocated facilities and other overhead costs, including software licenses, computer supplies and accessories and other miscellaneous expenses.

We have acquired and may continue to acquire the rights to develop and commercialize new product candidates. Upfront and milestone payments are accrued for and expensed as in process research and development (IPRD) assets expense when the achievement of the milestone is probable up to the point of regulatory approval and, absent obtaining such approval, have no alternative future use. Milestone payments made after a product's regulatory approval will be capitalized and amortized over the remaining useful life of the related product.

We expense research and development costs as incurred. Costs of certain activities are recognized based on an evaluation of the progress to completion of specific tasks. However, payments made prior to the receipt of goods or services that will be used or rendered for future research and development activities are deferred and capitalized as research and development prepaid expenses on our consolidated balance sheets. The capitalized amounts are recognized as expense as the goods are delivered or services are performed. Since our inception and through December 31, 2023, our external research and development expenses were primarily related to the discovery and advancement of programs under our TYK2 platform, including our two most advanced product candidates, ESK-001 and A-005. We use internal resources primarily for managing our research, process development, manufacturing and clinical development activities. In particular, with respect to internal costs, we deploy our personnel across all of our research and development activities as our employees work across multiple programs, and therefore the costs cannot be allocated to a particular product candidate or research program. In 2023, we began tracking external costs by program.

We expect our research and development expenses to increase substantially for the foreseeable future as we advance our product candidates into and through clinical trials, pursue regulatory approval of our product candidates, build our operational and commercial capabilities for marketing our products, if approved, and expand our pipeline of product candidates. The process of conducting the necessary clinical research to obtain regulatory approval is time-consuming, expensive and uncertain. The actual probability of success for our product candidates may be affected by a variety of factors, including the safety and efficacy of our product candidates, clinical data, investment in our clinical programs, competition, manufacturability and commercial viability. It is possible that we may never receive regulatory approval for any of our product candidates. As a result of the uncertainties discussed above, we are unable to determine the duration and completion of 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 product candidates, if approved by the FDA and other applicable regulatory authorities.

Our future research and development costs may vary significantly based on factors such as:

- the timing and progress of our preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- the costs and timing of manufacturing of our product candidates
- the amount and timing of any milestone payment due under our existing asset acquisition agreements and any future license or collaboration agreements;
- the number of patients that participate in our clinical trials, and per participant clinical trial costs;
- the number and duration of clinical trials required for approval of our product candidates;

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- the number of sites included in our clinical trials, and the locations of those sites;
- delays or difficulties in adding trial sites and enrolling participants;
- patient drop-out or discontinuation rates;
- additional safety monitoring if requested by regulatory authorities;
- the phase of development of our product candidates;
- the timing, receipt and terms of any approvals from applicable regulatory authorities including the FDA and non-U.S. regulators;
- maintaining a continued acceptable safety profile of our product candidates following approval, if any, of our product candidates;
- changes in the competitive outlook;
- the extent to which we establish additional strategic collaborations or other arrangements; and
- the impact of any business interruptions to our operations or to those of the third parties with whom we work.

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

*General and Administrative Expenses*

Our general and administrative expenses consist primarily of personnel-related costs, legal and consulting services, including those relating to intellectual property and corporate matters, marketing expenses and allocated facilities and other overhead costs, including software licenses, computer supplies, insurance and other miscellaneous expenses. Personnel-related costs include salaries, annual bonuses, benefits, travel and meal expenses and stock-based compensation expense for our general and administrative personnel.

We expect that our general and administrative expenses will increase substantially in the future as a result of expanding our operations, including hiring personnel, preparing for potential commercialization of our product candidates and facility occupancy costs, as well as various incremental costs associated with operating as a public company. We expect that our costs will increase related to legal, audit, accounting fees, consulting fees, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance costs, investor and public relations costs and other expenses that we did not incur as a private company. We also expect to increase the size of our administrative function to support the growth of our business.

**Other Income (Expense)**

Other income (expense) consists primarily of interest income, including amortization of premiums and accretion of discounts on marketable securities and change in fair value of derivative liability.

In May 2023, in connection with the Series B-2 and Series B-2A financing, we issued a call option to purchase additional shares at the same price as the initial closing price per share in the second tranche closing in October 2023, which was accounted for as a derivative liability. Changes in fair value of the derivative liability from the issuance date to the settlement date in October 2023 were included in the other income (loss) in the consolidated statement of operations and comprehensive loss.

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**Results of Operations**

**Comparison of the Periods for the Years Ended December 31, 2022 and 2023**

The following table summarizes our results of operations for the years ended December 31, 2022 and 2023 (dollars in thousands):

	Year ended December 31, 2022	Year ended December 31, 2023	Change	
			\$	%
<b>Operating expenses:</b>				
Research and development expenses, including related party expenses of \$1,570 and \$1,519 for the years ended December 31, 2022 and 2023, respectively	\$ 101,304	\$ 137,676	\$ 36,372	36%
General and administrative expenses	12,546	20,498	7,952	63%
Total operating expenses	113,850	158,174	44,324	39%
Loss from operations	(113,850)	(158,174)	(44,324)	39%
<b>Other income (expense):</b>				
Interest income	1,992	3,368	1,376	69%
Change in fair value of derivative liability	—	(119)	(119)	100%
Other income (expense), net	(72)	(68)	4	*
Total other income (expense), net	1,920	3,181	1,261	*
Net loss	\$(111,930)	\$(154,993)	\$(43,063)	38%

\* not meaningful

*Research and Development Expenses*

The following table summarizes our external and internal research and development expenses for the years ended December 31, 2022 and 2023 (dollars in thousands):

	Year ended December 31, 2022	Year ended December 31, 2023	Change	
			\$	%
<b>External costs:</b>				
Milestones related to previously acquired IPR&D assets	\$ 37,000	\$ —	\$(37,000)	(100)%
CRO, CMO and clinical trials	28,570	68,967	40,397	141%
Professional consulting services	10,208	13,155	2,947	29%
Other research and development costs	3,999	11,463	7,464	187%
<b>Internal costs:</b>				
Personnel-related costs	17,985	32,068	14,083	78%
Facilities and overhead costs	3,542	12,023	8,481	239%
Total research and development expense	\$101,304	\$137,676	\$ 36,372	36%

Research and development expenses increased by \$36.4 million, from \$101.3 million for the year ended December 31, 2022 to \$137.7 million for the year ended December 31, 2023.

During the year ended December 31, 2022, milestones related to previously acquired IPR&D assets include a \$37.0 million clinical milestone payment in connection with a March 2021 asset acquisition. No milestones were achieved or probable during the year ended December 31, 2023. CRO, CMO and clinical trials expenses increased by \$40.4 million for the year ended December 31, 2023 compared to the year ended December 31, 2022, primarily due to increased CRO and CMO activities related to ESK-001 development. Professional research and development consulting service expense increased by \$2.9 million and other research and

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development costs increased by \$7.5 million to support clinical trials for ESK-001, preclinical advancement of A-005 and other research programs.

Personnel-related costs increased by \$14.1 million, from \$18.0 million for the year ended December 31, 2022 to \$32.1 million for the year ended December 31, 2023, as a result of increased research and development headcount from 63 to 90 employees as of December 31, 2022 and 2023, respectively. The increase in personnel-related costs includes an increase in stock-based compensation expense of \$1.6 million as a result of additional options granted and an increase in the fair value of our common stock. Facilities and allocated overhead costs increased by \$8.5 million primarily as a result of facilities and IT related expenses.

During the year ended December 31, 2023, our external research and development expenses were primarily related to the clinical development of our ESK-001 program and, to a lesser extent, advancing our A-005 product candidate and research pipeline. The following table summarizes our external costs by program for the year ended December 31, 2023 (dollars in thousands):

	<u>Year ended December 31, 2023</u>
ESK-001	\$70,414
A-005	7,161
Other programs and research and development activities	<u>16,010</u>
Total external research and development expenses	<u><u>\$93,585</u></u>

*General and Administrative Expenses*

General and administrative expenses increased by \$8.0 million, from \$12.5 million for the year ended December 31, 2022 to \$20.5 million for the year ended December 31, 2023. Personnel-related expenses increased by \$3.6 million from \$7.4 million for the year ended December 31, 2022 to \$11.0 million for the year ended December 31, 2023 as a result of increase in headcount from 16 to 20 employees as of December 31, 2022 and 2023, respectively. The increase in personnel-related costs includes an increase in stock-based compensation expense of \$1.0 million as a result of additional options granted and an increase in the fair value of our common stock. Expenses related to professional consulting services increased by \$4.0 million, from \$3.9 million for the year ended December 31, 2022 to \$7.9 million for the year ended December 31, 2023 primarily due to an increase in consulting, legal and accounting services to support our growth and business development.

*Total Other Income (Expense), Net*

Total other income (expense), net increased by \$1.3 million, from other income of \$1.9 million for the year ended December 31, 2022 to other income of \$3.2 million for the year ended December 31, 2023.

Interest income increased by \$1.4 million from \$2.0 million for the year ended December 31, 2022 to \$3.4 million for the year ended December 31, 2023 as a result of higher interest rates and higher investments balances during the year ended December 31, 2023 compared to the year ended December 31, 2022.

We recognized a loss of \$0.1 million for the year ended December 31, 2023 related to the change in fair value of a derivative liability. We did not have a derivative liability for the year ended December 31, 2022 and therefore no such loss was recognized.

**Liquidity, Capital Resources and Capital Requirements**

**Sources of Liquidity**

Since our inception, we have not generated any revenue from product sales and have incurred significant operating losses and negative cash flows from our operations. To date, we have primarily funded our operations with proceeds from sales of shares of our redeemable convertible preferred stock and the issuance of convertible promissory notes in private placements. From inception through December 31, 2023, we received aggregate gross proceeds of \$329.6 million from sales of shares of our redeemable convertible preferred stock



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and \$37.5 million from the issuance of convertible promissory notes to related parties. As of December 31, 2023, we had \$49.0 million in cash, cash equivalents and marketable securities.

In March 2024, we entered into a Series C preferred stock purchase agreement and received \$129.5 million gross cash proceeds from the issuance of 41,264,891 shares at a purchase price of \$3.13826 per share in the First Tranche Series C Closing.

Anytime prior to December 31, 2024, the execution of a letter of intent for the sale of our company, or the closing date of our initial public offering and at the discretion of our board of directors, we are obligated to sell, and each Series C purchaser is obligated to purchase additional shares of our Series C redeemable convertible preferred stock, with the amount equal to the purchaser's aggregate purchase price in the First Tranche Series C Closing less any previous payments by the purchaser as part of a purchase right exercisable no later than December 31, 2024. See Note 14 to our consolidated financial statements included elsewhere in this prospectus for more information.

We expect to incur additional losses and negative cash flows from operations for the next 12 months. Given our recurring losses from operations and negative cash flows, and based on our current operating plan, there is substantial doubt about our ability to continue as a going concern.

We expect that the funds raised in connection with this offering and our cash, cash equivalents and marketable securities on hand will be sufficient to fund our operating expenses and capital expenditure requirements for at least the next 12 months. We have based this estimate on our current assumptions, which may prove to be wrong, and we may exhaust our available capital resources sooner than we expect.

#### **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 and increasing expenses for the foreseeable future as we continue to advance our product candidates, expand our corporate infrastructure, including the costs associated with being a public company, further our research and development initiatives for our product candidates, and incur costs associated with potential commercialization. We are subject to all of the risks typically related to the development of new drug candidates, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We anticipate that we will need substantial additional funding in connection with our continuing operations.

We do not have any products approved for sale and have not generated any revenue from product sales since our inception. We do not expect to generate revenue from any product candidates that we develop until we obtain regulatory approval for one or more of such product candidates and commercialize our products or enter into collaboration agreements with third parties. Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we may never achieve or sustain profitability and, unless and until we are able to develop and commercialize our product candidates, we will need to continue to raise additional capital. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through public or private equity or debt financings, or potentially other capital sources, such as collaboration or licensing arrangements with third parties or other strategic transactions. There are no assurances that we will be successful in obtaining an adequate level of financing to support our business plans when needed on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration or licensing arrangements with third parties or other strategic transactions, we may have to relinquish rights to our intellectual property, future revenue streams, research programs, or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise capital as and when needed, or on attractive terms, we may have to significantly delay, reduce, or discontinue the development and commercialization of our product candidates or scale back or terminate our pursuit of new in-licenses and acquisitions.

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Because of the numerous risks and uncertainties associated with research, development and commercialization of our products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including the following:

- the timing, scope, progress and results of our preclinical studies and clinical trials for our current and future product candidates;
- the number, scope and duration of clinical trials required for regulatory approval of our current and future product candidates;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities for our product candidates;
- the cost of manufacturing clinical and commercial supplies as well as scale up of our current and future product candidates;
- the increase in the number of our employees and expansion of our physical facilities to support growth initiatives;
- our ability to establish new, strategic collaborations, licensing or other arrangements;
- the cost of filing and prosecuting our patent applications, and maintaining and enforcing our patents and other intellectual property rights;
- the extent to which we acquire or in-license other product candidates and technologies;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against our product candidates;
- the timing of when we pay our operating expenses;
- the effect of competing technological and market developments;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- our implementation of various computerized informational systems and efforts to enhance operational systems;
- the costs associated with being a public company; and
- other factors, including economic uncertainty and geopolitical tensions, which may exacerbate the magnitude of the factors discussed above.

### **Cash Flows**

The following summarizes our cash flows for the periods indicated (in thousands):

	<b>Year ended December 31, 2022</b>	<b>Year ended December 31, 2023</b>
Net cash used in operating activities	\$(107,722)	\$(129,975)
Net cash (used in) provided by investing activities	(68,751)	60,472
Net cash provided by financing activities	101,627	89,682
Net (decrease) increase in cash, cash equivalents and restricted cash	<u>\$ (74,846)</u>	<u>\$ 20,179</u>

#### *Operating Activities*

Net cash used in operating activities was \$107.7 million and \$130.0 million for the years ended December 31, 2022 and 2023, respectively.

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Net cash used in operating activities in the year ended December 31, 2022 was primarily due to our net loss for the period of \$111.9 million and changes in operating assets and liabilities of \$1.9 million. The cash used in operating activities was partially offset by non-cash items of \$6.1 million, of which \$6.0 million is related to stock-based compensation expense. The changes in operating assets and liabilities primarily include an increase of \$7.3 million in research and development prepaid expenses and an increase of \$1.0 million in other prepaid expense and current assets, partially offset by an increase of \$3.6 million in other accrued expenses and current liabilities, an increase of \$2.4 million in research and development accrued expenses and an increase of \$1.3 million in accounts payable. The increase in research and development prepaid expenses was primarily due to advance payments to CROs related to the ongoing clinical trials. The increase in other accrued expenses and current liabilities was primarily due to an increase in accrued bonuses expense, driven by an increase in headcount.

Net cash used in operating activities for the year ended December 31, 2023 was due to our net loss for the period of \$155.0 million, offset by non-cash items of \$13.0 million and changes in operating assets and liabilities of \$12.0 million. Non-cash items primarily include \$8.6 million of stock-based compensation expense, \$2.0 million of non-cash lease expense and \$1.3 million of depreciation and amortization. The changes in operating assets and liabilities primarily include a decrease of \$5.5 million in research and development prepaid expenses, an increase of \$5.2 million in research and development accrued expenses and an increase \$2.5 million in other accrued expenses and current liabilities.

*Investing Activities*

Net cash used in investing activities for the year ended December 31, 2022 of \$68.8 million was related to purchases of marketable securities of \$209.1 million and purchases of property and equipment of \$2.4 million, partially offset by proceeds from maturities of marketable securities of \$142.7 million.

Net cash provided by investing activities for the year ended December 31, 2023 of \$60.5 million was related to proceeds from maturities of marketable securities of \$76.3 million, partially offset by purchases of marketable securities of \$11.3 million and purchases of property and equipment of \$4.5 million.

*Financing Activities*

Net cash provided by financing activities for the year ended December 31, 2022 of \$101.6 million was related to net proceeds from the issuance of our Series B redeemable convertible preferred stock financing of \$99.9 million and proceeds of \$1.7 million from issuance of common stock upon exercise of stock options.

Net cash provided by financing activities for the year ended December 31, 2023 of \$89.7 million was primarily related to net proceeds from the issuance of our Series B-2 and Series B-2A redeemable convertible preferred stock financing.

**Contractual Obligations and Commitments**

We enter into contracts in the normal course of business with suppliers, CROs, CMOs and clinical trial sites. These agreements provide for termination at the request of either party generally with less than one-year notice and are therefore cancellable contracts. We do not currently expect any of these agreements to be terminated and did not have any non-cancelable obligations under these agreements as of December 31, 2023.

On March 5, 2021, we entered into a stock purchase agreement to acquire FronThera U.S. Holdings, Inc. and its wholly owned subsidiary, FronThera U.S. Pharmaceuticals LLC. The transaction was accounted for as an asset acquisition. Under the agreement, we are obligated to pay contingent consideration of up to \$120.0 million based on the achievement of specified clinical and commercialization milestones related to technology acquired under the agreement. We incurred and paid a milestone of \$37.0 million during the year ended December 31, 2022. No milestones were reached or probable for the year ended December 31, 2023. We cannot estimate when or if the remaining milestone payments will be incurred. None of the future milestones events were probable to occur as of December 31, 2023.

**Leases**

We have operating lease arrangements for office and laboratory space in South San Francisco, California. As of December 31, 2023, we had total lease payment obligations under non-cancelable leases of \$53.7 million,

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including \$5.3 million payable within 12 months. See Note 7 to our consolidated financial statements included elsewhere in this prospectus.

**Recently Issued Accounting Pronouncements**

A description of recently issued accounting pronouncements that may potentially impact our financial position, results of operations or cash flows is disclosed in Note 2 to our audited consolidated financial statements included elsewhere in this prospectus.

**Critical Accounting Policies and Significant Judgments and Estimates**

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported expenses during the reporting period. These estimates and assumptions are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates and assumptions could occur in the future. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ from these estimates under different assumptions or conditions.

Although our significant accounting policies are described in more detail in Note 2 to our audited consolidated financial statements included in this prospectus, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

**Research and Development Accrued Expenses**

Research and development costs are expensed as incurred. As part of the process of preparing our financial statements, we are required to estimate our research and development accrued expenses, including those related to clinical trials and manufacturing clinical and preclinical materials. This process involves reviewing open contracts and purchase orders communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the services when we have not yet been invoiced or otherwise notified of actual costs. Our service providers invoice us in arrears, as well as on a pre-determined schedule or when contractual milestones are met. We make estimates of our research and development accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of the estimates with the service providers and make adjustments if necessary. Examples of estimated research and development accrued expenses include fees paid to:

- vendors in connection with preclinical and clinical development activities;
- CROs in connection with clinical trials; and
- CMOs in connection with the process development and scale-up activities and the production of preclinical and clinical trial materials.

Costs for clinical trials and manufacturing activities are recognized based on an evaluation of our vendors' progress towards completion of specific tasks, using data such as participant enrollment, clinical site activations or information provided to us by our vendors regarding their actual costs incurred. Payments for these activities are based on the terms of individual contracts and payment timing may differ significantly from the period in which the services were performed. We determine accrual estimates through reports from and discussions with applicable personnel and outside service providers as to the progress or state of completion of studies, or the services completed. Our estimates of research and development accrued expenses as of each balance sheet date are based on the facts and circumstances known at the time. Costs that are paid in advance of performance are deferred as a prepaid expense and amortized over the service period as the services are provided.

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Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of research and development accrued expenses. However, due to the nature of estimates, we cannot assure that we will not make changes to our estimates in the future as we become aware of additional information about the status or conduct of our clinical trials and other research activities.

**Asset Acquisitions and Acquired In-Process Research and Development Expenses**

We measure and recognize asset acquisitions that are not deemed to be business combinations based on the cost to acquire the asset or group of assets, which includes transaction costs. We determine if the acquisition should be accounted for as an asset acquisition after considering whether substantially all of the fair value of the gross assets acquired was concentrated in a single asset or group of assets and whether we acquired a substantive process capable of significantly contributing to our ability to create outputs. Goodwill is not recognized in asset acquisitions. If acquired in-process technology assets, including licenses, know-how and patents are determined to not have an alternative future use, the cost is charged to research and development expenses at the acquisition date.

Contingent consideration in asset acquisitions payable in the form of cash is recognized in the period the triggering event is determined to be probable of occurrence and the related amount is reasonably estimable. Such amounts are expensed or capitalized based on the nature of the associated asset at the date the related contingency is probable and reasonably estimable.

**Derivative Liability**

We determined that the obligation to issue additional shares of redeemable convertible preferred stock upon the occurrence of certain events, including our board of directors' consent, represents a freestanding financial instrument. The instrument is classified as a liability on the consolidated balance sheets and is subject to re-measurement at each balance sheet date and at the settlement date. Any change in fair value is recognized in the statements of operations and comprehensive loss.

We utilize the Black-Scholes option-pricing model, which incorporates assumptions and estimates, to value derivative liability. On a quarterly basis, we assess these assumptions and estimates as additional information impacting the assumptions is obtained. Significant estimates and assumptions impacting fair value include the estimated time and probability of closing of the second tranche financing, preferred stock fair value and estimated stock volatility.

We determine the fair value per share of the underlying redeemable convertible preferred stock by taking into consideration our most recent sales of our preferred stock as well as additional factors that we deem relevant. We are a private company and lack company-specific historical and implied volatility information of our stock. Therefore, we determine expected stock volatility based on the historical volatility of the prices of shares of common stock of publicly traded peer companies. We estimate the risk-free interest rate by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the outstanding tranche liability. We have assumed a 0% dividend considering that our board of directors has no history of declaring dividends and does not intend to declare any.

In May 2023, we estimated the fair value of the derivative liability of \$2.1 million at the issuance date. We recognized changes in fair value of \$0.1 million as other expense in the consolidated statement of operations and comprehensive loss during the year ended December 31, 2023. The derivative liability was settled in October 2023, when investors purchased shares of Series B-2 and Series B-2A redeemable convertible preferred stock in a second tranche closing.

**Stock-Based Compensation Expense**

Stock-based compensation expense related to the stock-based awards granted to employees, consultants and directors is measured at the grant date based on the fair value of the award. Compensation expense for those

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awards is recognized over the requisite service period, which is generally the vesting period. We use the straight-line method to record the expense of awards with service-based vesting conditions. We account for forfeitures of stock-based awards as they occur rather than applying an estimated forfeiture rate to stock-based compensation expense.

We estimate the fair value of each award on the date of grant using the Black-Scholes option pricing model. This model requires the use of highly subject assumptions to determine the fair value of each stock-based award, including:

- *Fair value of common stock.* See the subsection titled “—Determination of Fair Value of Common Stock” below.
- *Expected term.* The expected term represents the weighted-average period the stock options are expected to remain outstanding and is based on the options’ vesting terms and contractual terms, as we did not have sufficient historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior.
- *Expected volatility.* Since we are not yet a public company and do not have any trading history for our common stock, the expected volatility was estimated based on the average historical volatilities of common stock of comparable publicly traded entities over a period equal to the expected term of the stock option grants. The comparable industry peers were chosen based on their size, stage of their life cycle or area of specialty. We will continue to apply this process until enough historical information regarding the volatility of our stock price becomes available.
- *Risk-free interest rate.* The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero-coupon U.S. Treasury notes with maturities approximately equal to the expected term of the awards.
- *Expected dividend yield.* We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.

See Note 10 to our audited consolidated financial statements included elsewhere in this prospectus for information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options granted in the periods presented.

As of December 31, 2023, there was \$29.6 million of total unrecognized stock-based compensation expense related to our granted options, which we expect to recognize over a remaining weighted-average period of 3.14 years. We expect to continue to grant equity-based awards in the future, and to the extent that we do, our stock-based compensations expense recognized in future periods will likely increase.

The intrinsic value of all outstanding stock options as of December 31, 2023 was approximately \$ million, based on the assumed initial public offering price of \$ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, of which approximately \$ million related to vested stock options and approximately \$ million related to unvested stock options.

#### **Determination of Fair Value of Common Stock**

As there has been no public market for our common stock to date, the estimated fair value of our common stock underlying our share-based awards was estimated on each grant date by our management and approved by our board of directors. Our board of directors exercised reasonable judgment and considered a number of objective and subjective factor, as well as valuations prepared by independent third party valuation firms. The methodologies used to estimate the enterprise value are performed using methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation (*the Practice Aid*).

In addition to considering the results of independent third-party valuations, we considered various objective and subjective factors to determine the fair value of common stock as of each grant date, including:

- the prices at which we sold shares of our preferred stock and the superior rights, preferences and privileges of our preferred stock relative to those of our common stock at the time of each grant;

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- the progress of our research and development programs, including the status of preclinical studies and clinical trials for our product candidates;
- our stage of development and our business strategy, and material risks related to our business;
- external market conditions affecting the biotechnology industry and trends within the biotechnology industry;
- the competitive landscape for our product candidates;
- our financial position, including cash on hand, and our historical and forecasted performance and operating results;
- the lack of an active public market for our common stock and our preferred stock;
- the likelihood of achieving a liquidity event, such as an IPO or a sale of our company, given prevailing market conditions; and
- the economy in general.

Prior to May 2023, we utilized an Option Pricing Method (OPM) based analysis, primarily the OPM backsolve methodology, to determine the estimated fair value of our common stock and redeemable convertible preferred stock. Within the OPM framework, we determined the backsolve method was the most appropriate method for determining the fair value of our common stock. The backsolve method is used for inferring the total equity value implied by a recent financing transaction, or by an estimated equity value of our pipeline product candidates, involves the construction of an allocation model that takes into account our capital structure and the rights, preferences and privileges of each class of stock, then assumes reasonable inputs for the other OPM variables (expected time to liquidity, volatility and risk-free rate). The total equity value is then iterated in the model until the model output value for the equity class sold in a recent financing round equals the price paid in that round. The OPM is generally utilized when specific future liquidity events are difficult to forecast (i.e., the enterprise has many choices and options available), and the enterprise's value depends on how well it follows an uncharted path through the various possible opportunities and challenges. The resulting equity value was then assigned to each class of equity securities using the OPM, which treats ordinary shares and preferred shares as call options on the equity value, with exercise prices based on the liquidation preference of our preferred stock. The shares of common stock are modeled as a call option with a claim on the equity value at an exercise price equal to the remaining value immediately after our preferred stock is liquidated. After the equity value is determined and allocated to the various classes of equity securities, we applied discounts to reflect the lack of marketability of our common stock based on the weighted-average expected time to liquidity. The estimated fair value of the common stock at each grant date reflected a non-marketability discount partially based on the anticipated likelihood and timing of a future liquidity event.

For our valuations performed on and after May 2023, we utilized a hybrid method that combines the Probability-Weighted Expected Return Method (PWERM), an accepted valuation method described in the Practice Aid, and the OPM. We determined this was the most appropriate method for determining the fair value of our common stock based on our stage of development and other relevant factors. The PWERM is a scenario-based analysis that estimates the value per share of common stock based on the probability-weighted present value of expected future equity values for the common stock, under various possible future liquidity event scenarios, considering the rights and preferences of each class of shares, discounted for a lack of marketability. Under the hybrid method, an OPM was utilized to determine the fair value of our common stock and our redeemable convertible preferred stock in certain of the PWERM scenarios (capturing situations where our development path and future liquidity events were difficult to forecast), potential exit events were explicitly modeled in the other PWERM scenarios. A discount for lack of marketability was applied to the value derived under each scenario to account for a lack of access to an active public market to estimate our common stock fair value. The assumptions underlying these valuations represented our management's best estimates, which involved inherent uncertainties and the application of management's judgment. As a result, if we had used significantly different assumptions or estimates, the fair value of our common stock and our stock-based compensation expense could have been materially different.

The assumptions underlying these valuations represented management's best estimate, which involved inherent uncertainties and the application of management's judgment. As a result, if we had used significantly different

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assumptions or estimates, the fair value of our common stock and our stock-based compensation expense could be materially different.

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

**Off-Balance Sheet Arrangements**

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

**Quantitative and Qualitative Disclosures About Market Risks**

**Interest Rate Risk**

The primary objectives of our investment activities are to ensure liquidity and to preserve capital. We are exposed to market risks related to changes in interest rates of our cash equivalents and marketable securities. However, due to the nature of these cash equivalents and marketable securities, we do not believe that a hypothetical 10% increase or decrease in interest rates during any of the periods presented would have had a material effect on our consolidated financial statements included elsewhere in this prospectus.

**Foreign Currency Exchange Risk**

All of our employees and our operations are currently located in the United States, and our expenses are generally denominated in U.S. dollars. However, we do utilize certain CRO and CMO vendors outside of the United States for our clinical trials and product development and manufacturing. As such, our expenses are denominated in both U.S. dollars and foreign currencies. Therefore, our operations are and will continue to be subject to fluctuations in foreign currency exchange rates. To date, foreign currency transaction gains and losses have not been material to our consolidated financial statements, and we have not had a formal hedging program with respect to foreign currency. We do not believe that a hypothetical 10% increase or decrease in exchange rates during any of the periods presented would have had a material effect on our consolidated financial statements included elsewhere in this prospectus.

**Effects of Inflation**

Inflation generally affects us by increasing our cost of labor and research and development costs. We do not believe that inflation had a material effect on our business, results of operations, or financial condition, or on our consolidated financial statements included elsewhere in this prospectus.

**JOBS Act Transition Period and Smaller Reporting Company Status**

We are an “emerging growth company” as defined in the JOBS Act. Under the JOBS Act, an emerging growth company can take advantage of the extended transition period for complying with new or revised accounting standards and delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption from complying with new or revised accounting standards and, therefore, will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements under the JOBS Act. Subject to certain conditions, as an emerging growth company, we may rely on certain of these exemptions, including without limitation exemptions to the requirements for (i) providing an auditor’s attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements, known



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as the auditor discussion and analysis. We will remain an emerging growth company until the earlier to occur of (a) the last day of the fiscal year (A) following the fifth anniversary of the completion of this offering, (B) in which we have total annual gross revenues of at least \$1.235 billion or (C) in which we are deemed to be a “large accelerated filer” under the rules of the SEC, which means the market value of our common stock and non-voting common stock that is held by non-affiliates exceeds \$700.0 million as of the prior June 30th, or (b) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

We are also a “smaller reporting company,” meaning that the market value of our common stock and non-voting common stock held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of this offering is less than \$700.0 million and our annual revenue is less than \$100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company after this offering if either (i) the market value of our common stock and non-voting common stock held by non-affiliates is less than \$250.0 million or (ii) our annual revenue is less than \$100.0 million during the most recently completed fiscal year and the market value of our common stock and non-voting common stock held by non-affiliates is less than \$700.0 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.

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**BUSINESS**

**Overview**

Our mission is to significantly improve the lives of patients by replacing broad immunosuppression with targeted therapies. Our name, Alumis, captures our mission to enlighten immunology, and is inspired by the words “allumer”—French for illuminate—and “immunis”—Latin for the immune system.

We are a clinical stage biopharmaceutical company with an initial focus on developing our two Tyrosine Kinase 2 (TYK2) inhibitors: ESK-001, a second-generation inhibitor that we are developing to safely achieve maximum target inhibition and A-005, a central nervous system (CNS) penetrant molecule. ESK-001 has demonstrated significant therapeutic effect in our Phase 2 program in patients with PsO, which we define as moderate-to-severe plaque psoriasis (PsO), and is currently being evaluated in additional Phase 2 clinical trials in patients with systemic lupus erythematosus (SLE) and non-infectious uveitis (Uveitis), for which we expect to report results in [redacted] and [redacted], respectively. With the favorable results in our Phase 2 trial in PsO, we intend to initiate multiple Phase 3 clinical trials of ESK-001 in [redacted] in this indication. TYK2 genetic mutations are associated with a strong protective effect in multiple sclerosis, motivating us to develop our second product candidate, A-005, as a CNS penetrant, allosteric TYK2 inhibitor for neuroinflammatory and neurodegenerative diseases. In [redacted] 2024, we initiated our Phase 1 program of A-005 in healthy volunteers and expect to report results in [redacted].

We utilize our precision data analytics platform, biological insights and team of experienced research and development experts to deepen our understanding of disease pathologies, accelerate research and development and increase the probability of clinical success. Our collective insights informed our selection of TYK2 as the target for our two lead programs. Beyond TYK2, our precision data analytics platform and drug discovery expertise have led to the identification of additional preclinical programs that exemplify our precision approach.

We recognize that patients living with immune-mediated diseases need alternatives to currently available therapies. Despite recent advances and innovations in the treatment of immune-mediated diseases, many patients continue to suffer, cycling through currently approved therapies while looking for a solution that alleviates the debilitating impact of their disease without life-limiting side effects.

Addressing the needs of these patients is why we exist. We are pioneering a precision approach that leverages insights derived from powerful data analytics to select the right target, right molecule, right indication, right patient, right endpoint and right combination to dramatically improve patient outcomes. We believe that combining our insights with an integrated approach to drug development will produce the next generation of treatments to address immune dysfunction.

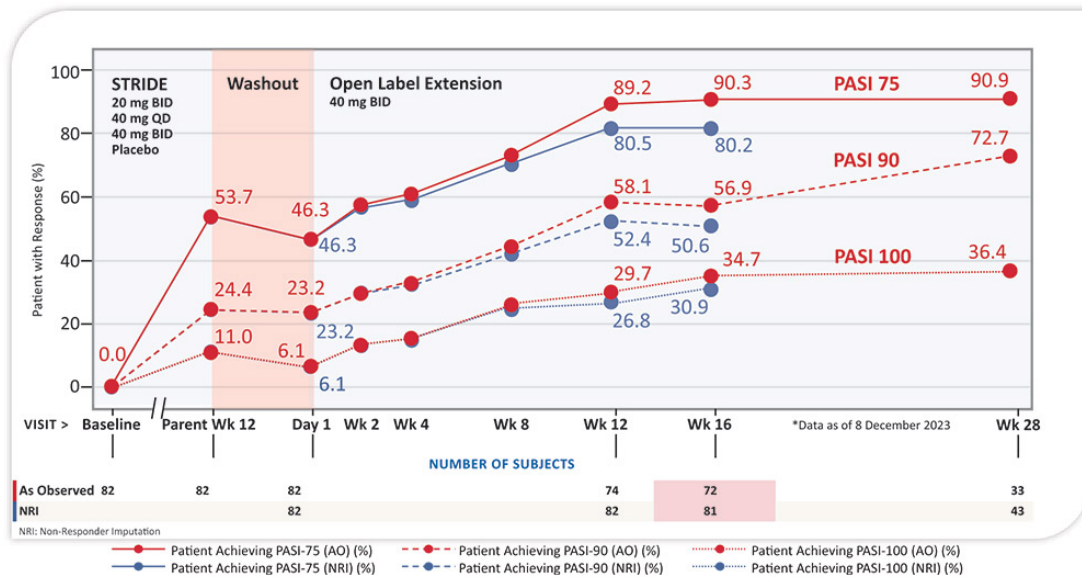
Our most advanced product candidate, ESK-001, is an oral, highly selective, small molecule, allosteric inhibitor of TYK2. At the 2024 American Academy of Dermatology (AAD) Annual Meeting in March 2024, we announced positive data from our Phase 2 clinical program of ESK-001 in patients with PsO, which included the results of our Phase 2 STRIDE trial and interim results of our open label extension (OLE) as of a December 8, 2023 data cut. Our data demonstrated that ESK-001’s ability to maximally inhibit TYK2 translates to the achievement of high rates of response, as measured by the Psoriasis Area and Severity Index (PASI), in patients, with response rates in the range observed with existing biologic therapies. Our Phase 2 STRIDE trial, in which 228 patients with PsO were randomized to one of five ESK-001 dose cohorts or placebo, met its primary endpoint, the proportion of patients achieving a 75% improvement in the PASI Score (PASI 75) at week 12 compared to placebo, and key secondary efficacy endpoints at all clinically relevant doses tested. Clear dose-dependent responses were observed, with the highest response rates and maximal TYK2 inhibition achieved at the highest dose of 40 mg twice daily (BID). At the 40 mg BID dose and at the 40 mg once daily (QD) dose, 64% and 56% of evaluable patients, respectively, achieved PASI 75 at week 12 compared to 0% for placebo.

Patients who completed the randomized placebo-controlled Phase 2 STRIDE trial were eligible to participate in the open label extension (OLE). In the OLE, 164 patients were assigned to receive either 40 mg BID or 40 mg QD. As shown in the figure below, as of the December 8, 2023 data cut, interim OLE data following 16 weeks of treatment in the extension period showed sustained increases in PASI response rates over time, with

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the majority of patients (90% of evaluable patients, 80% using a conservative non-responder imputation (NRI)) achieving PASI 75 at the 40 mg BID dose, as well as a continued favorable tolerability profile. Maximal target inhibition at the 40 mg BID dose, confirmed by blood and skin biopsy biomarkers, translated into the highest response rates, as compared with substantially lower response rates at the 40 mg QD dose. Given the tolerability profile we observed at the highest dose in our Phase 2 program, we intend to advance that dose into Phase 3 pivotal clinical trials. We are also developing a once-a-day modified release formulation that we plan to have available at the time of market launch, if approved, or within the first year post approval. Data in the table below are presented both “as observed” (AO) and applying an NRI where patients who dropped out during the trial were assumed to be non-responders for all time points after dropping out.

*OLE ESK-001 40 mg BID Cohort  
As Observed (AO) and Non-Responder Imputation (NRI) Analyses*



NOTE: The shaded column in the figure above represents a four-week period during which no treatment was administered (the washout period).

These data suggest a differentiated profile of ESK-001 relative to first-generation TYK2 inhibitors. We plan to initiate our Phase 3 pivotal clinical trials in PsO in . We are also evaluating ESK-001 in LUMUS, a Phase 2b clinical trial of ESK-001 for the treatment of patients with SLE, and in OPTYK-1, a proof-of-concept Phase 2a clinical trial in patients with Uveitis. We expect to report results for these trials in and , respectively.

Beyond our initial three ongoing clinical indications of ESK-001, we plan to leverage our large clinical and genetic datasets to prioritize future indications, such as psoriatic arthritis and gastrointestinal and other indications where we believe ESK-001 could be differentiated from existing therapies. We believe ESK-001 has the potential to address a broad range of immune-mediated diseases and unmet patient needs that represent substantial commercial opportunities.

We have incorporated our learnings from ESK-001 to develop A-005, as a CNS penetrant, allosteric TYK2 inhibitor with potential application in multiple sclerosis (MS) and other neuroinflammatory and neurodegenerative diseases. Our large proprietary genetic data set as well as scientific literature have shown that the naturally occurring TYK2 loss of function genetic variant has a protective effect in MS. In our preclinical studies, A-005 has demonstrated protective effects in multiple *in vivo* disease models of neuroinflammation. In 2024, we initiated the first Phase 1 study of A-005 in healthy volunteers and expect to report results in .

We apply our precision approach to immunology by focusing on the key drivers of immune dysfunction. We have established and continue to uncover key genetic and translational insights to significantly impact clinical

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outcomes. Foundational to our approach is our precision data analytics platform that allows us to leverage genetic, genomic, proteomic, and biological and clinical disease insights to potentially increase speed of development, probability of success and precision of therapy. We employ our insights and capabilities through every stage of development, always aiming to improve the likelihood of clinical success while achieving the best outcomes for patients. We believe our precision approach can bring forth paradigm-shifting advances in each of the following key areas:

- **Right target:** We select drug targets based on our understanding of their role in immune-mediated diseases in an effort to maximize clinical benefit and probability of success.
- **Right molecule:** We design our molecules to achieve maximal target engagement and a safe pharmacological profile.
- **Right indication:** We select indications based on weight of evidence and biological insights from our precision data analytics platform.
- **Right endpoint:** We seek to accelerate drug development and improve the clinical probability of success through selection of optimal clinical endpoints for our trials.
- **Right patient:** We gain insights from our proprietary clinical samples to identify patients that we believe are most likely to benefit from our therapies.
- **Right combinations:** We identify future combination strategies with the potential to break through efficacy limitations of existing therapies without broadly suppressing the immune system.

### Our Pipeline

We are building a pipeline of molecules with the potential to address a broad range of immune-mediated diseases as monotherapy or combination therapies. Within our TYK2 franchise, we are developing our most advanced product candidate, ESK-001, to be a potential best-in-class allosteric TYK2 inhibitor for the treatment of PsO, SLE and Uveitis. We are developing our second TYK2 product candidate, A-005, as a CNS penetrant allosteric TYK2 inhibitor, to offer the therapeutic benefit of TYK2 inhibition within the CNS for a broad range of neuroinflammatory and neurodegenerative diseases.

TYK2 MODULATION	INDICATION	DEVELOPMENT				ANTICIPATED MILESTONE	GLOBAL RIGHTS
		DISCOVERY/PRECLINICAL	PHASE 1	PHASE 2	PHASE 3		
ESK-001 (TYK2)	PsO						alumis
	Systemic Lupus Erythematosus						
	Non-infectious Uveitis						
A-005 (TYK2)	Neuroinflammation						alumis

### Our Team

We have assembled an executive team of industry veterans experienced in small-molecule compound drug development for immune-mediated diseases. Our senior leaders bring together a wealth of scientific, clinical, business and commercial expertise in the biopharmaceutical industry. Many of our employees and executives previously worked together at Genentech, Roche, Principia and MyoKardia and have united to work together again. Collectively, our executives have contributed to the research, development, approval and commercial launch of multiple drugs across several therapeutic areas, including Adbry, Avastin, Camzyos, Fasenra, Lucentis, Ocrevus, Rituxan, Saphnelo, Siliq, Tarceva, Tezspire, Uplizna, Xeljanz and Xolair. To date, we have raised more than \$600 million and are backed by established blue-chip life science investors.

### Our Strategy

Our mission is to significantly improve the lives of patients by replacing broad immunosuppression with targeted therapies. As our driving principle, we are using our precision approach focused on the important

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drivers of immune dysfunction. We use our key insights to pursue our mission of significantly improving outcomes for patients. We select drug targets that have been previously validated by strong human genetic evidence and human clinical data.

The core components of our business strategy include:

- **Maximize the opportunity by developing a best-in-class profile for ESK-001.** We believe that ESK-001 is a foundational asset that exemplifies our approach. Our Phase 2 clinical data in PsO provided strong clinical validation of our approach and set the stage for developing ESK-001 into a leading oral therapy in PsO. Beyond PsO we continue to expand into additional indications. Genetic and biologic data generated to date highlight the important role of TYK2 inhibition across multiple diseases where we have current clinical programs (PsO, SLE, Uveitis) and future clinical ambitions. We intend to expand clinical development of ESK-001 to additional therapeutic areas and indications where TYK2 inhibition and our differentiated profile have the potential to deliver significant improvements for patients.
- **Expand our TYK2 franchise with A-005, our potential first-in-class allosteric TYK2 inhibitor designed to penetrate the CNS to treat neuroinflammation.** There is strong biological rationale for the involvement of TYK2 in neuroinflammatory and neurodegenerative diseases, as well as compelling genetic evidence for the role of TYK2 in MS. As a result, we believe TYK2 inhibition has potential utility in various neuroinflammatory and neurodegenerative diseases, including MS, Alzheimer’s disease, amyotrophic lateral sclerosis (ALS), optic neuritis, neuromyelitis optica and Parkinson’s disease. Given the results of our preclinical data, which support the protective effect in multiple *in vivo* disease models of neuroinflammation, we initiated the first-in-human trials of A-005 in 2024.
- **Discover and advance earlier-stage product candidates into clinical development.** We intend to expand our pipeline of clinical-stage product candidates by identifying and developing earlier-stage assets. Utilizing our precision approach to address immune dysfunction, we have selected multiple additional targets to date, including interferon regulatory factor 5 (IRF5), across indications that are in various stages of development, from lead identification to lead optimization. These targets may enable development in a broad range of indications, either as a monotherapy or using a combination therapy approach with our TYK2 franchise.
- **Leverage our precision approach to increase speed of development, probability of success and precision of therapy.** We are using our precision data analytics platform that integrates key genetic and translational insights to optimize clinical outcomes. We leverage and implement these capabilities to design efficient and effective development paths at every stage of our pipeline. We believe this approach can bring forth paradigm-shifting medications by following the science to inform the right target, right molecule, right indication, right patient, right endpoint and right combinations.
- **Evaluate strategic collaborations to maximize the global impact of our product candidates.** We plan to strategically evaluate potential partnerships to maximize the value of our lead programs and broader portfolio. We believe that our product candidates, indications, clinical data and data analytics make our company an attractive partner. Given our scientific expertise and significant therapeutic depth, and the broad addressable populations of our product candidates, the right partner could help us expand the breadth of indications we pursue and increase our commercial reach.

### **Our Precision Approach and Capabilities**

Our driving principle is to deliver the right medicine to achieve the best possible clinical outcome. To realize that goal, we are using our precision approach to immunology focused on the important drivers of immune dysfunction while relying on key genetic and translational insights, all with the aim of optimizing therapeutic outcomes for patients. We were incubated by Foresite Labs, LLC (Foresite Labs) and benefited from its data platform, which includes large, multi-modal data sets and mature, scalable, and proprietary tools from the world of statistical genetics and causal inference. With Foresite Labs’ capabilities as a foundation, we have established a precision data analytics platform focused on immune-mediated diseases and enhanced with data from our own clinical studies. We believe that the application of insights from our internal efforts, combined with our Foresite Labs collaboration, may ultimately bring forth the most effective, paradigm-shifting medications by optimizing the following design elements:

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**Right Target:** *We select drug targets based on our understanding of their role in immune-mediated diseases in an effort to maximize clinical benefit and probability of success.*

We identify and select drug targets with strong human genetic evidence, utilizing a comprehensive proprietary genetic database for immune-mediated diseases or with human clinical validation. We believe that drugs with indications supported by human genetics have twice the likelihood of success in Phase 2 and Phase 3 clinical development.

- Our analysis of over 350 immune-relevant genome-wide association study (GWAS) results from both the public domain and the UK Biobank biomedical resource identified TYK2 as the right therapeutic target. These studies include GWAS of susceptibility to immune-mediated diseases and immunologically relevant laboratory values and biomarkers

For example, the identification of a loss-of-function mutation in the TYK2 gene appears to be protective against an array of immune-mediated disorders. Loss of kinase function, as consistent with the mode of action of ESK-001 and A-005, does not appear to significantly increase susceptibility to serious infections or malignancy. In contrast, mutations that lead to complete loss of TYK2 protein expression have been associated with severe immunodeficiency. Our insights regarding the role of TYK2 in disease, as well as the effectiveness of TYK2 inhibition in preventing inducible disease and ameliorating established disease in various models, led to our selection of TYK2 as the foundational program in our efforts to treat immune-mediated diseases.

**Right Molecule:** *We design our molecules to achieve maximal target engagement and a safe pharmacological profile.*

- Our lead generation efforts are enabled via a combination of high throughput screening technologies and in-house *in-silico* screens. We utilize our robust informatics platform and modern Artificial Intelligence (AI)- and Machine Learning (ML)-based methods to guide molecular designs.
- We further refine our molecular designs using a combination of traditional structure-guided approaches from proprietary crystallographic structures and advanced computational methods.
- Early in our development efforts, we apply medicinal chemistry, biochemistry, cellular biology and pharmacology to define the pharmacokinetic (PK) and pharmacodynamic (PD) relationship, to maximize target inhibition, and to reach the relevant compartments of the body.

For example, we designed A-005 to maximize target coverage within the CNS by crossing the blood brain barrier, and to directly interrupt the neuroinflammatory and neurodegenerative processes where they occur, with the aim of providing maximal benefit to patients.

**Right Indication:** *We select indications based on weight of evidence and biological insights from our precision data analytics platform.*

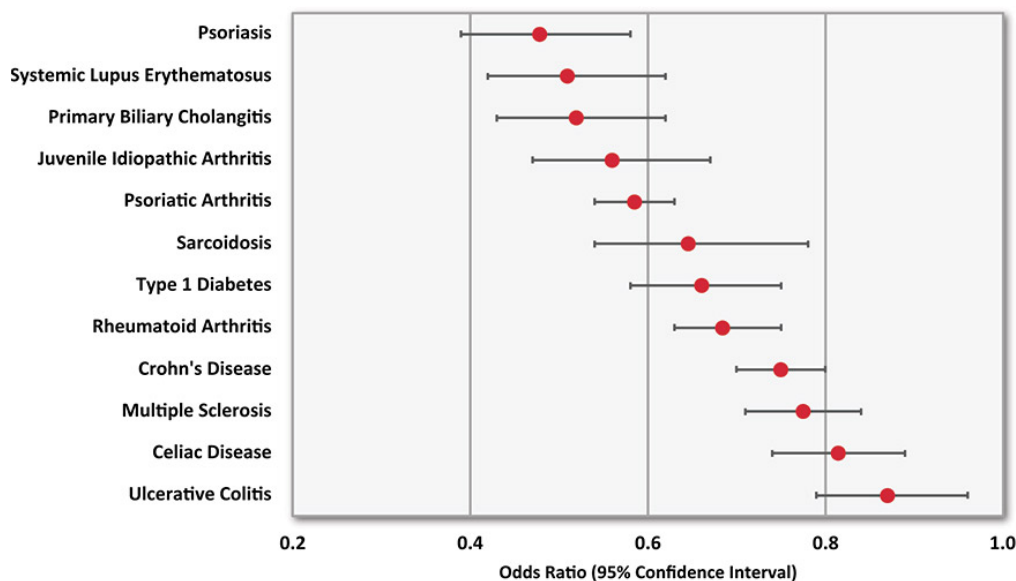
We utilize our comprehensive immune-focused database and advanced multi-trait statistical methods to evaluate and establish the strength of genetic associations across identified indications of interest.

- We apply proprietary statistical methods to establish the causality of genetic variants with complex phenotypes via novel adaptations of the Mendelian Randomization method.
- We implement advanced multi-trait statistical methods to simultaneously evaluate the strength of genetic associations across multiple indications with a target of interest and to identify therapeutic opportunities based on novel associations.

For example, as illustrated in the figure below, we are pursuing indications for our TYK2 franchise that are underpinned by phenotypic-genotypic links or known clinical proof-of-concept data in adjacent pathways

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*Association of TYK2 P1104A Loss of Function Variant with Immune Mediated Diseases*



Forest plot of immune-mediated indications associated with TYK2 loss-of-function variant P1104A. Point estimates below 1 suggest protection against disease while point estimates above 1 suggest susceptibility to disease, with points furthest away from “1.0” indicating highest level of association.

**Right Endpoint:** *We seek to accelerate drug development and improve the clinical probability of success through selection of optimal clinical endpoints for our trials.*

- We survey external data to help us select optimal clinical endpoints for our trials. For example, we carefully analyzed data from recent pivotal trials in SLE to support selection of the primary endpoint for our LUMUS trial and to minimize the variability and high placebo response rates that have been common causes of failure in SLE trials.
- We select endpoints that are clinically meaningful, that are appropriate to the stage of development and that enable expeditious advancement into the next stage of development.
- We aim to link genetic and biological markers to clinical outcome measures to help identify those patients most likely to respond to our medicines in subsequent stages of development.

For example, we selected a 12-week primary endpoint in our Phase 2 STRIDE trial, which enabled us to benchmark against competitors and make a rapid Go-to-Phase 3 decision. We also included an OLE to better define peak efficacy and long-term safety.

**Right Patient:** *We gain insights from our proprietary clinical samples to identify patients that we believe are most likely to benefit from our therapies.*

- In our interventional studies, we seek to uncover patient selection and stratification criteria by pairing advanced data analytics and ML methods with extensive biomarker profiling across multiple timepoints, including high-dimensional genetics, genomics and proteomics together with functional immune-cell-profiling techniques.

For example, in our Phase 1 clinical trial of ESK-001, we identified a novel biomarker of TYK2 activity. Taking this insight into our Phase 2 STRIDE trial, we have demonstrated a clear dose-dependent inhibition of this novel biomarker, achieving maximal inhibition at the higher doses, and a profile closely aligned with our Phase 1 and preclinical datasets. We plan to further test this novel biomarker’s ability to differentiate patient responses in PsO, SLE and Uveitis.

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**Right Combinations:** *We identify future combination strategies with the potential to break through efficacy limitations of existing therapies without broadly suppressing the immune system.*

- Existing immunological therapeutics continue to confront limitations of their efficacy in some diseases, such as rheumatoid arthritis and Crohn's disease. One potentially promising path to breaking through these efficacy barriers is to utilize the right combinations of precise agents that separately target specific immune pathways and can be safely administered together without broadly suppressing the immune system.
- We developed an internal biology platform using multiplexed immune cell assays and *in vivo* models. We utilize *in-silico* techniques for predicting genetic signatures of drug response using advanced polygenic risk score methodologies. We utilize *in-silico* interaction modelling to predict therapeutic combinations that are likely to be complimentary and/or synergistic with respect to efficacy.

For example, we believe ESK-001 has significant potential as a future combination therapy due to the inherent safety of allosterically targeting the TYK2 pathway together with ESK-001's therapeutic profile as mono-therapy, low risk of drug interactions and highly predictable PK profile in humans. We aim to develop additional therapeutics that may be complimentary to our TYK2 inhibitors and to each other, opening up the future potential of combination therapy.

### **Immune Dysfunction Overview**

The immune system is a highly regulated and balanced system that has evolved to protect us from infection, recognize and neutralize harmful agents from the environment and fight disease. Dysfunctional immune responses, whether directed towards self or non-self or through unbalanced activation or regulation, can lead to inflammation, allergy, autoimmunity and development of chronic immune-mediated diseases. We are building immune insights from patient samples, incorporating genetic, genomic and proteomic learnings, and translating preclinical findings in an effort to therapeutically target dysfunctional immune mechanisms to improve outcomes for patients with immune-mediated diseases.

### **Role of TYK2 in Immunology**

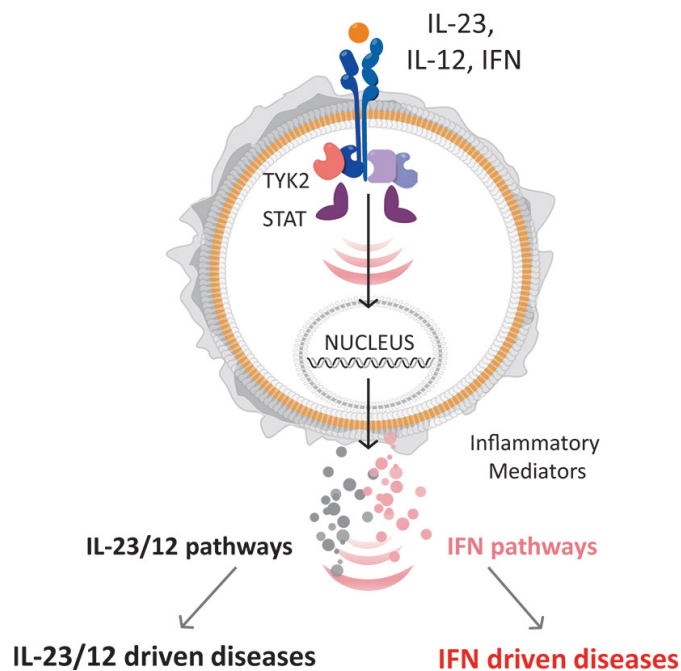
TYK2 is an intracellular tyrosine kinase protein within the broader Janus kinase (JAK) family shown to play an essential role in mediating cytokine receptor signaling pathways in both innate and adaptive immunity, as shown in the figure below. Cytokines are a group of proteins in the body that play an important role in boosting the immune system. TYK2 associates with a defined set of cytokine receptors expressed primarily on immune cells, such as IL-23, IL-12 and type I interferon (IFN) receptors, distinct from other JAK family members. TYK2 functions to relay signals into the cell through phosphorylation of signal transducing and activators of transcription (STATs), to initiate a cascade of protein-signaling interactions resulting in cytokine-responsive gene transcription and cell activation, which drives downstream immune responses including Th17, IL-17 pathways, and type I IFN responsive genes that are known drivers of inflammation and immune mediated disease. Therapeutic inhibition of TYK2 and associated cytokine pathways, in particular IL-23/ IL-17 and type I IFN, have been broadly validated to address immune dysfunction in immune-mediated diseases, such as psoriasis, psoriatic arthritis and SLE. TYK2 is expressed in circulating and tissue-resident immune cells, and is also active in CNS-resident immune cells, such as microglia, which are thought to play a key role in neuroinflammation.

Human genetic studies of TYK2 strongly validated it as a therapeutic target. An identified loss-of-function mutation (P1104A) in the TYK2 gene, present in approximately 3% to 5% of European populations, is protective against an array of immune-mediated disorders, including SLE, psoriasis, sarcoidosis, psoriatic arthritis, inflammatory bowel disease and neuroinflammatory and neurodegenerative conditions, such as MS. Importantly, this TYK2 variant does not appear to significantly increase susceptibility to serious infections, suggesting that TYK2 inhibition may be associated with an optimal balance between efficacy and safety.



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*TYK2 Receptor, pathway, downstream cytokines*



***Overview of the TYK2 Landscape***

TYK2 inhibition has the potential to be a highly efficacious oral treatment for multiple immune-mediated diseases. The FDA's approval of deucravacitinib (marketed as Sotyktu) in 2022, with labeling enabling its use as first-line therapy without any boxed warnings, highlights the appeal of TYK2 inhibition for the treatment of immune-mediated indications driven by IL23 and IFN. Current first-generation allosteric TYK2 inhibitors include Sotyktu and TAK-279. However, first-generation allosteric TYK2 inhibitors have not been able to achieve complete TYK2 inhibition to date, limiting their otherwise promising therapeutic potential. The approved dose of Sotyktu of 6 mg QD, while safe and effective in psoriasis, provides only partial target coverage. In Phase 2 clinical trials of Sotyktu, higher doses, such as 6 mg BID or 12 mg QD, showed incremental improvements in several outcome measures of psoriasis and psoriatic arthritis. However, these higher doses were associated with the occurrence of skin rashes in up to 9% of patients.

Similar results were observed with TAK-279, where cutaneous adverse events (AEs) (e.g., acne and acneiform dermatitis) were reported at higher dose levels. The mechanisms causing these skin rashes are not known.

TYK2 inhibition represents a breadth of opportunity, and there have been or are ongoing clinical trials of TYK2 inhibitors in multiple indications such as psoriatic arthritis, SLE, cutaneous lupus, alopecia areata, Sjogren's disease, vitiligo, Crohn's disease (CD) and ulcerative colitis.

**Our TYK2 Franchise**

***ESK-001: Our Allosteric TYK2 Inhibitor***

ESK-001 is a potent, highly selective, allosteric TYK2 inhibitor. We believe that ESK-001 may potentially overcome the limitations of first-generation allosteric TYK2 inhibitors by achieving maximal target inhibition without causing dose limiting safety or tolerability issues. We believe this will result from optimized physicochemical properties, favorable and highly predictable PK, and lack of significant drug interactions.

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### *Key Differentiating Features*

We believe ESK-001 is differentiated from first-generation TYK2 inhibitors for the following reasons:

- **Intrinsic Selectivity and Preclinical Pharmacology.** Due to ESK-001's design as an allosteric inhibitor, the molecule is both potent and intrinsically selective for TYK2 over other protein kinases, including the related JAK family members. No JAK-related pharmacology has been observed with ESK-001 to date. ESK-001 is supported by a preclinical safety package in which no clinically limiting findings were observed. By contrast, skin rashes requiring treatment were observed in preclinical toxicology studies of Sotyktu.
- **Optimized Molecular Properties and PK.** At the core of ESK-001's differentiation from other clinical-stage allosteric inhibitors of TYK2 are its physicochemical properties that we believe impart highly desirable drug-like features. ESK-001 is highly permeable with low efflux resulting in high and rapid systemic absorption and favorable tissue distribution *in-vivo*. These properties result in its highly predictable, linear PK profile in humans with low variability. In addition, ESK-001 has a desirable half-life in humans of approximately 8 to 12 hours and we have not observed any concerns for drug-drug interactions with other therapies.
- **Maximal Target Inhibition.** ESK-001 demonstrated a robust and predictable PK/PD relationship in Phase 1 studies, enabling the identification of a dose level that achieved maximal TYK2 inhibition for 24 hours a day to take into Phase 2 clinical trials. A clear dose dependent inhibition of TYK2 markers was observed across the dose range. At the 40mg BID dose, maximal TYK2 inhibition confirmed in healthy volunteer PsO patient blood samples by RNA-seq analysis, and a return to non-lesional baseline levels of TYK2 pathway (including IFN signature, IL-23, IL-17) and PsO-relevant disease biomarkers confirmed in PsO patient skin biopsies.
- **Clinical Tolerability.** There have been no clinically limiting findings across our clinical trials to date that prevent ESK-001 from being dosed to achieve maximal target inhibition. In contrast to what has been reported with first-generation allosteric TYK2 inhibitors, skin rashes have been observed at much lower frequency with ESK-001 to date, even at very high and sustained levels of target inhibition, suggesting that skin toxicities may not be an on-target, class effect of TYK2 inhibitors.

### *Strategic Indication Selection*

TYK2-mediated cytokine signaling is involved in a broad range of immune-mediated diseases. TYK2 loss of function mutations have been shown to be protective for several conditions including psoriasis, psoriatic arthritis, Crohn's disease, ulcerative colitis and multiple sclerosis. Therefore, ESK-001 has the potential to provide benefit in a large number of indications. We have selected PsO, SLE and Uveitis as our initial indications. TYK2 has strong validation as a therapeutic target in PsO, and it provides an opportunity for ESK-001 to be benchmarked against in-class competitors, testing the hypothesis that higher degrees of target inhibition result in improved clinical outcomes. The evidence that TYK2-mediated pathways play a key role in disease pathogenesis is similarly strong in SLE: a biologic targeting the type I IFN receptor is approved in SLE, the protective effect of certain loss of function mutations of TYK2 is of similar magnitude as in PsO, and a third-party Phase 2 clinical trial of Sotyktu in patients with active SLE met its primary and secondary endpoints. The unmet need for safe and efficacious oral therapies remains high in SLE. Uveitis is a common manifestation of several immune-mediated diseases associated with dysregulation of TYK2 mediated cytokine pathways, including psoriatic arthritis, sarcoidosis, and inflammatory bowel disease. There is an unmet need for safe and effective systemic therapies in patients with Uveitis not responding to topical therapies.

### *Combination Potential*

Despite significant advances in the treatment of immune-mediated disease, in many diseases, only a minority of patients achieve disease remission or nearly complete response with current therapies. Because of the complexity, overlap and redundancy of inflammatory pathways, combination approaches targeting complementary pathways may be needed to achieve high-hurdle endpoints such as remission. We believe that

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ESK-001's pharmacological properties, including its lack of drug-drug interaction potential and its clinical profile positions it well as a partner for future combination therapies.

ESK-001 for the treatment of PsO

*Psoriasis Overview*

Psoriasis is a chronic immune-mediated skin disease characterized by abnormal epidermal growth, usually presenting as red, scaly patches, papules or plaques (plaque psoriasis). Patients with psoriasis are also at increased risk of developing other co-morbid conditions, such as cardiovascular disease, obesity, insulin resistance, uveitis and thyroid dysfunction. Up to 40% of psoriasis patients develop inflammatory arthritis (psoriatic arthritis) that leads to joint destruction and disability. According to the World Health Organization, psoriasis significantly impacts quality of life—physical and emotional challenges of disfigurement, low self-esteem, loss of productivity and depression.

Plaque psoriasis impacts over 7.7 million people in the United States (and over 16 million people globally), with an annual growth rate of ~1%. Over 60% of these people have PsO, and over 97% of PsO patients are drug treated.

The pharmaceutical drug market for plaque psoriasis is approximately \$14 billion in the United States in 2023 (and over \$17 billion globally), and is forecasted to increase substantially, to over \$20 billion in United States in 2030 (and over \$25 billion globally) due to the increase in the psoriasis patient population and the development of new therapies.

Targeted biologic therapies have demonstrated robust efficacy in PsO. Biologics targeting the IL-23/IL-17 inflammatory pathways have achieved PASI-75 in more than 80% of treated patients. There are currently only two approved advanced oral therapies for PsO in the United States, Otezla (apremilast) and Sotyktu (deucravacitinib). PASI-75 response rates for either oral agent have been lower than those observed with biologic treatments targeting IL-23 or IL-17.

Sotyktu, an oral TYK2 inhibitor, was approved by the FDA in 2022 for the treatment of PsO. In the two Sotyktu placebo-controlled Phase 3 studies, POETYK PSO-1 and POETYK PSO-2, the efficacy of Sotyktu at Week 16 was found to be superior to apremilast, with a 75% reduction in PASI score (PASI 75) achieved in 58% and 53% of patients, respectively, in the Sotyktu arm and 35.1% and 39.8%, respectively, in the apremilast arm. Sotyktu response was maintained through 52 weeks (82% of patients who achieved PASI-75 at Week 24 maintained it through 52 weeks). Sotyktu was well-tolerated and had a similar safety profile in both studies, with no evidence of AEs associated with JAK inhibition. Notwithstanding these results, Sotyktu did not achieve complete inhibition of TYK2 throughout the dose interval. As a result, we believe there is an unmet medical need for an oral therapy that is safe and can provide biologic level efficacy for patients with PsO.

*Rationale for Targeting TYK2 in the Treatment of PsO*

As discussed above, the loss-of-function mutations of TYK2 confer strong protection from the development of PsO. Our internal analyses estimate that carriers of the TYK2 P1104A variant have a two-fold reduced risk of developing disease throughout the course of their lifetime.

The TYK2 inhibitors class emerged as a potentially safe and effective option for the treatment of PsO. Recent data from a Phase 2 dose-ranging placebo-controlled clinical trial of TAK-279, an allosteric TYK2 inhibitor, demonstrated safety and efficacy profile similar to Sotyktu, with a greater proportion of patients achieving PASI 100 or sPGA0 at the 30 mg (highest) dose of TAK-279. Neither Sotyktu nor TAK-279 achieved complete inhibition of TYK2 throughout the dose interval in their Phase 2 PsO trials. Our Phase 2 STRIDE trial of ESK-001 is the first trial to test the hypothesis that higher degrees of target inhibition result in improved clinical outcomes without incurring safety or tolerability liabilities.

*Our Phase 2 Program of ESK-001 in PsO*

Our Phase 2 program is composed of STRIDE, a randomized, double-blind, placebo-controlled Phase 2 clinical trial in patients with PsO and an open-label extension (OLE) trial in patients who completed our

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STRIDE trial. For our Phase 2 STRIDE trial, we selected a 12-week primary endpoint, which enabled us to benchmark against competitors and make a rapid Go-to-Phase 3 decision. We also included the OLE to help better define peak efficacy and long-term safety. The doses were selected to evaluate the safety, tolerability and efficacy of the full range of target inhibition.

Our Phase 2 STRIDE trial assessed the clinical efficacy, safety, PK and PD of ESK-001 compared to placebo. The trial enrolled 228 patients with PsO. Male and female patients were randomized equally across six trial arms (approximately 35 patients per arm) to receive oral doses of ESK-001 at one of five dose levels (10 mg QD, 20 mg QD, 40 mg QD, 20 mg BID or 40 mg BID) or placebo. Key inclusion criteria were a baseline Psoriasis Area and Severity Index (PASI) score of at least 12, static Physician Global Assessment (sPGA) of at least 3, and body surface area (BSA) of at least 10%. Randomization was stratified by prior use of biologics and geographic region.

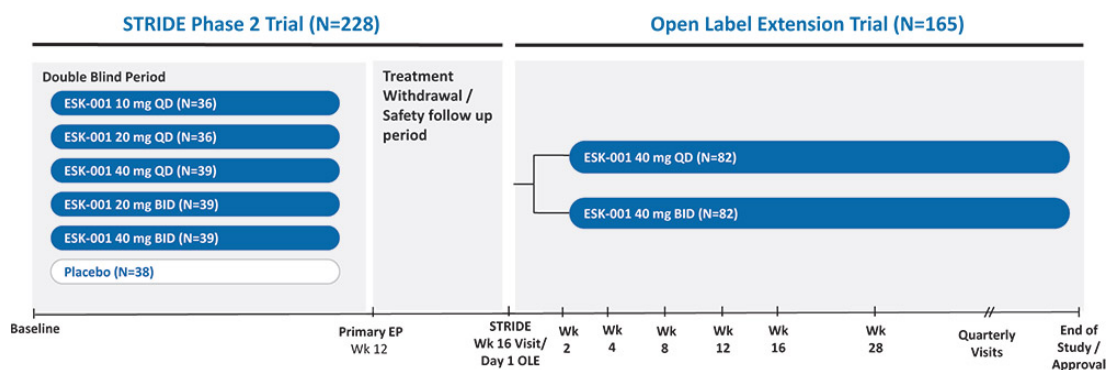
The primary endpoint of the trial was the proportion of patients achieving at least 75% improvement in PASI score at 12 weeks compared to placebo. Secondary objectives included additional efficacy evaluations, safety and tolerability and PK characterisation of ESK-001.

Secondary endpoints included the proportion of patients achieving an sPGA score of “0” (“cleared”) or “1” (“minimal”), PASI-50, PASI-90 and PASI-100 after 12 weeks of treatment compared with placebo, the change from baseline in percent body surface area (BSA) and Dermatology Life Quality Index (DLQI) after 12 weeks of treatment compared with placebo, the incidence of Treatment Emergent Adverse Events (TEAEs) and Serious Adverse Events (SAEs), plasma concentrations and PK parameters of ESK-001.

The trial included a screening period of approximately four weeks. The treatment period of 12 weeks was followed by a safety follow-up period, also referred as the washout period, of four weeks during which the patients remained off drug. Eligible patients were then offered the opportunity to participate in the OLE trial following completion of the end-of-trial visit at Week 16. During the OLE trial, patients were assigned to receive ESK-001 at a dose of either 40 mg QD, which provides high but incomplete target inhibition, or 40 mg BID, which provides maximal target inhibition throughout the entire day.

Primary endpoint analyses were based on the intent-to-treat (ITT) approach. The primary endpoint analysis compared the proportion of patients in the active treatment groups with at least 75% improvement in PASI at Week 12 relative to baseline to placebo using the Cochran-Mantel-Haenszel test. A schematic representation of our Phase 2 STRIDE trial and OLE is shown in the figure below.

*STRIDE and OLE Design Schema*



*Results From Our Completed Phase 2 STRIDE Trial*

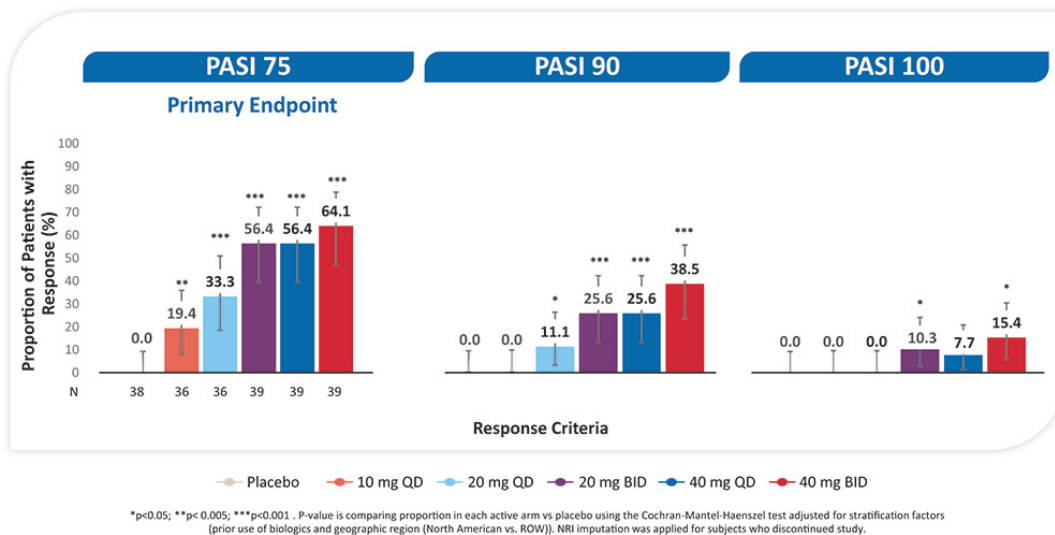
The baseline characteristics of the 228 patients enrolled in the trial were the following: mean age 48 years, 68% male, median disease duration 17.9 years, 40% with prior exposure to biologics or JAK inhibitors, and mean PASI score of 17.8. The proportion of sPGA score 3, 4, or 5 was 59%, 38% and 3%, respectively, and the mean BSA was 21%. Baseline characteristics were generally well balanced among all treatment arms. The baseline skin scores, duration of the disease and percent of patients previously treated with biologics indicated that it

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was a patient population with long-standing active disease. In our Phase 2 STRIDE trial, 90% of patients in the active treatment groups completed the trial, compared to 87% in the placebo group.

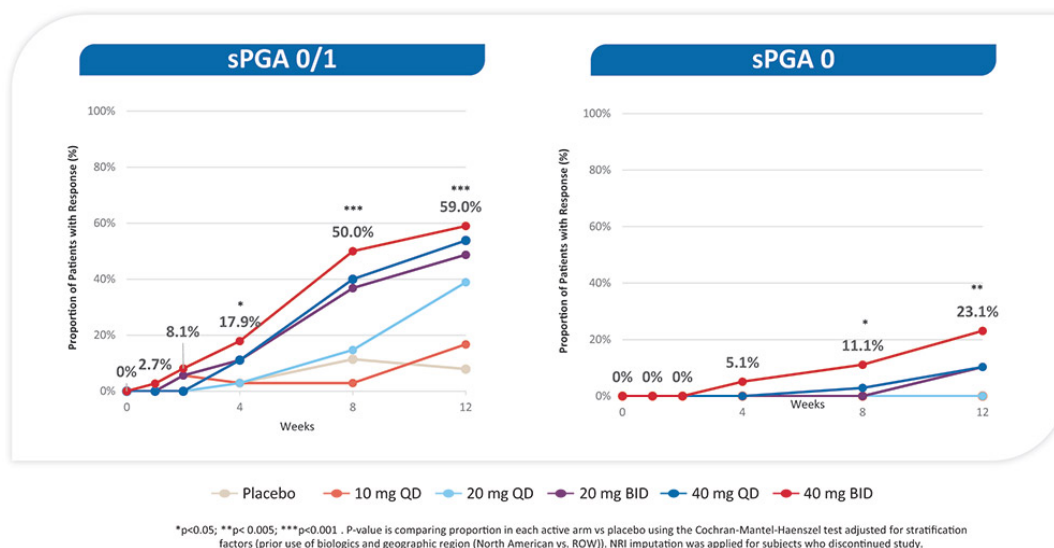
Our Phase 2 STRIDE trial achieved its primary endpoint at all dose levels with a clear dose response. A meaningfully greater proportion of patients treated with ESK-001 at all doses showed significantly greater PASI 75 response rates compared to placebo at Week 12. All secondary endpoints were met at the higher dose levels. PASI 90 responses were significantly higher than placebo at doses of 20 mg QD and above, and PASI 100 response rates were significantly higher than placebo at doses of 20 mg BID, 40 mg QD and 40 mg BID. For the highest dose of 40 mg BID, PASI 75, PASI 90 and PASI 100 response rates were 64%, 39% and 15% respectively, compared to 0% in the placebo group. PASI responses at Week 12 are shown in the first figure below. There were statistically significant differences at Week 12 among patients treated with ESK-001 at dose 40 mg QD and above relative to placebo in achieving sPGA 0/1, PASI 90 and sPGA 0 (nominal  $p < 0.05$ ), with the highest response observed in the ESK-001 40 mg BID arm. sPGA responses over time are shown in the second figure below. PASI response did not appear to reach a plateau at week 12 and remained on an upward trajectory. PASI response was similar in biologic-naïve and biologic-experienced patients. Treatment with ESK-001 resulted in more patients achieving improvement in quality of life (measured by Dermatology Life Quality Index, DLQI) relative to placebo treated patients. As shown in the table below, 64% of patients achieved DLQI 0/1 (indicating no or minimal impact on quality of life) at 40 mg BID ESK-001 compared to 18% in the placebo arm. Pruritus (itch) as assessed by the Pruritus Numerical Rating Scale (NRS) also showed significant improvement in a dose dependent manner.

*STRIDE Trial PASI responses at Week 12*



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*STRIDE Trial sPGA Responses Over Time*



*STRIDE Trial Patient Reported Outcomes: DLQI and Pruritus NRS at Week 12*

	DLQI-0/1* (% patients)	Pruritus NRS, On Average**	Pruritus NRS, At Worst**
<b>Placebo</b>	18.4	-0.8	-0.97
<b>40 mg BID</b>	64.1	-4.9	-5.09
<b>40 mg QD</b>	48.7	-4.3	-4.58
<b>20 mg BID</b>	51.3	-3.7	-4.05
<b>20 mg QD</b>	33.3	-2.9	-2.62
<b>10mg QD</b>	27.8	-2.3	-2.69

\* Proportion of patients achieving DLQI-0/1 at Week 12 primary endpoint

\*\* Mean change from Baseline to Week 12 in pruritus NRS (scored 0-10: severity of itch, on average or at worst, within the past 24 hours)

ESK-001 was generally well-tolerated. During the randomized, placebo-controlled portion of the trial, 40% of patients in the placebo group and 50% of patients in the combined active treatment groups reported AEs, the majority of which were mild to moderate. One patient experienced a SAE in the 10 mg QD group (lower limb fracture). No SAEs were considered related to ESK-001. No AEs typically associated with JAK inhibition (e.g., Major Adverse Cardiovascular Events, cytopenias, treatment related thromboses) were observed. The most common AEs reported by patients across the active arms were headaches, upper respiratory tract infections, and nasopharyngitis. Five patients (3%) treated with ESK-001 discontinued treatment due to AEs. Treatment with ESK-001 resulted in no clinically significant changes from baseline in mean values of lipid levels, blood counts, serum levels of liver enzymes, creatinine, ECG results or vital signs. AEs collected through the end of the study (Week 16) are summarized in the table below.

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*Summary of adverse events in our Phase 2 STRIDE trial*

	Placebo (N=38)	10 mg QD (N=36)	20 mg QD (N=36)	20 mg BID (N=39)	40 mg QD (N=39)	40 mg BID (N=39)	Overall (N=227)
Subjects with ≥1 TEAE	15 (39.5)	19 (52.8)	14 (38.9)	18 (46.2)	19 ( 48.7)	25 (64.1)	110 (48.5)
Subjects with ≥1 SAE	0	1 (2.8)	0	3 (7.7)	1 (2.6)	0	5 (2.2)
Subjects with treatment related SAEs	0	0	0	0	0	0	0
Deaths	0	0	0	0	0	0	0
Subjects with TEAE leading to treatment discontinuation	0	0	2 (5.6)	0	2 (5.1)	1 (2.6)	5 (2.2)
Most frequent TEAEs*							
Headache	2 (5.3)	0	2 (5.6)	3 (7.7)	4 (10.3)	3 (7.7)	14 (6.2)
Upper resp. tract infection	0	2 (5.6)	2 (5.6)	1 (2.6)	2 (5.1)	3 (7.7)	10 (4.4)
Nasopharyngitis	3 (7.9)	2 (5.6)	0	1 (2.6)	1 (2.6)	3 (7.7)	10 (4.4)

*Preliminary Results from the Ongoing OLE Trial*

The randomized, placebo-controlled portion of our Phase 2 program was followed by an ongoing OLE, which we designed to evaluate the safety and efficacy of long-term treatment with ESK-001 in patients with PsO. Patients who completed the randomized placebo-controlled part of the trial were eligible to participate in the OLE, and 94% of all eligible patients opted to participate. Treatment relevant baseline characteristics and clinical response rates at week 12 were similar between the overall STRIDE population and the subset enrolled in the OLE. Patients in the Czech Republic (31) were not eligible to participate in the OLE because local regulatory requirements would not have been consistent with the global protocol.

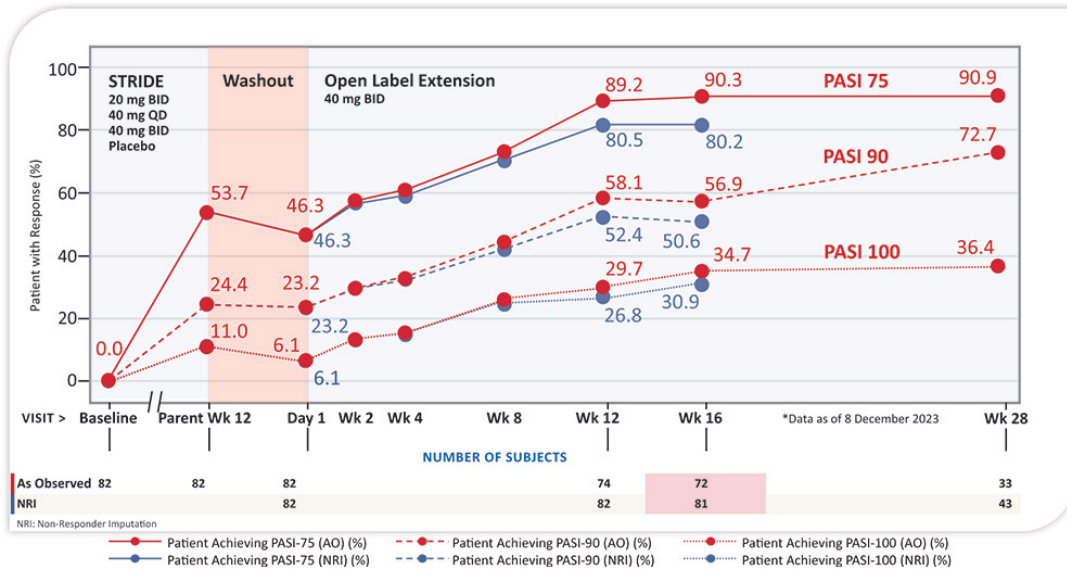
Patients were assigned to receive oral doses of ESK-001 at one of two open-label dose levels (40 mg QD or 40 mg BID). Patients, investigators and site staff remained blinded to the treatment assignment in the parent trial. As of March 2024, we amended the protocol to provide that all patients are to receive the 40 mg BID dose going forward as we determined this dose to represent the optimal risk benefit.

Interim results from the OLE are presented below and represent a data cut as of December 8, 2023. Data are presented both “as observed” (AO) and applying a non-responder imputation (NRI) where patients who discontinued study were assumed to be non-responders for all time points after study drug discontinuation. NRI analysis is performed only for those time points where all patients on study have reached at the time of the data cut. Additional data cuts will be generated in the future as the study progresses.

As shown in the figure below, as of the December 8, 2023 data cut, PASI 75, PASI 90 and PASI 100 responses continued to increase over time such that by Week 28 of the OLE, in the AO group over 90% of patients had achieved PASI 75, over 70% had achieved PASI 90 response, and 36% had achieved PASI 100 based on AO data. This data confirms the dose-dependence relationship observed in our Phase 2 STRIDE trial, with the highest response rates and maximal TYK2 inhibition achieved at the highest dose of 40 mg BID.

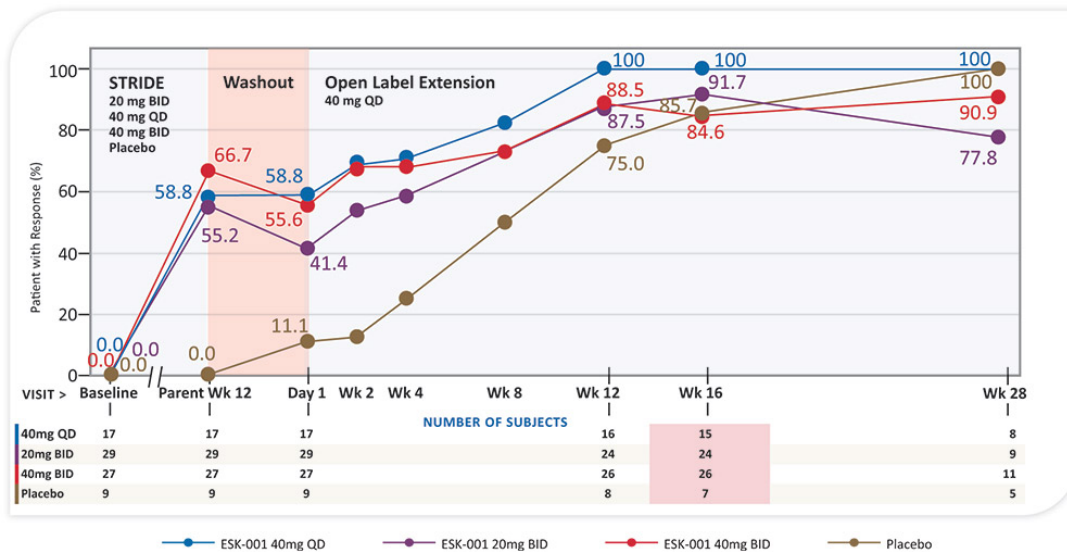
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*OLE ESK-001 40 mg BID Cohort  
As Observed (AO) and Non-Responder Imputation (NRI) Analyses*



In order to better assess the potential impact of ESK-001, excluding the washout period, we analyzed the PASI 75 response rates by parent study dose for patients rolling into the 40mg BID OLE cohort (see figure below). This analysis revealed that patients reached very high proportions of PASI 75 responses irrespective of which dose they were assigned to in the randomized controlled parent study. Focusing on the PASI 75 response rates of patients who initially received placebo in the parent study treatment cohort demonstrates that these patients were able to achieve PASI 75 score of 75% by week 12 and 86% by week 16 of the OLE trial. This demonstrates ESK-001’s ability to deliver sustained increases in PASI responses over time, particularly beyond week 12.

*As Observed PASI-75 responses for the 40 mg BID Cohort in the OLE by Parent Study Dose*



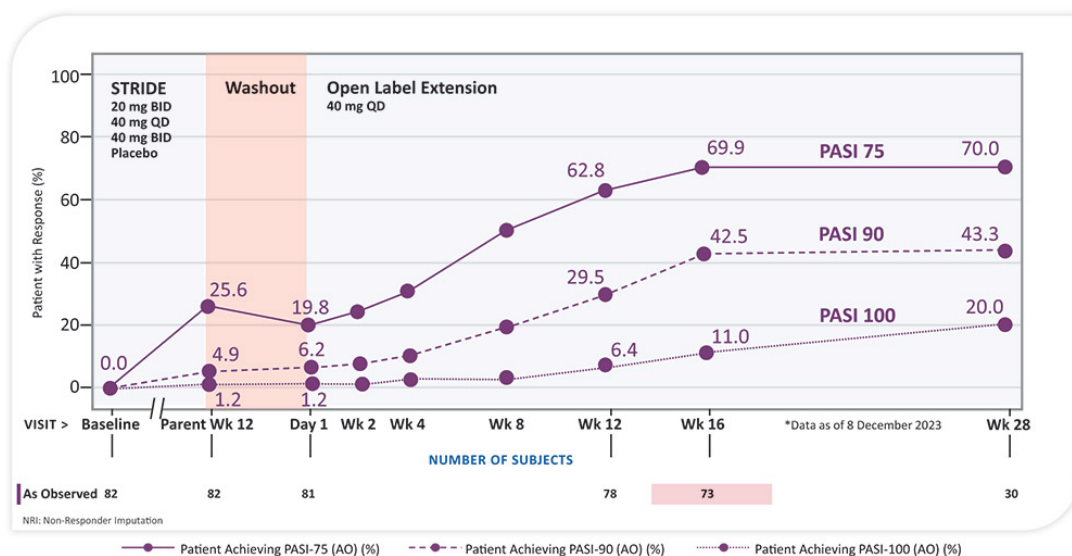
To compare the clinical outcome of maximal vs. incomplete TYK2 inhibition, patients in the second cohort in the OLE trial were assigned to receive a lower dose (40 mg QD), which provides high but incomplete TYK2



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inhibition. Patients who received this lower dose also had increasing response rates over time, up to 70% at week 16 of the OLE trial. However, peak response rates were substantially below those observed with the 40 mg BID dose, demonstrating that maximal inhibition of TYK2 throughout the entire dose interval is essential to achieve optimal efficacy.

*As Observed PASI responses in the OLE 40 mg QD Cohort*



ESK-001 continued to be well tolerated at both doses in the OLE. As of the December 8, 2023 data cut, the proportion of patients reporting any AE was 43% in the 40 mg QD group, and 46% in the 40 mg BID group. As of March 31, 2024, there have been five SAEs in the OLE trial, two of which we have assessed to be possibly related to study drug; one case of arthritis and one case of peritonsillar abscess. Two patients in the 40 mg BID group discontinued due to AE. The most common AEs were upper respiratory tract infections, nasopharyngitis and headaches. A summary of the safety data as of the December 8, 2023 data cut is shown in the table below.

*Summary of adverse events in OLE as of December 8, 2023 data cut*

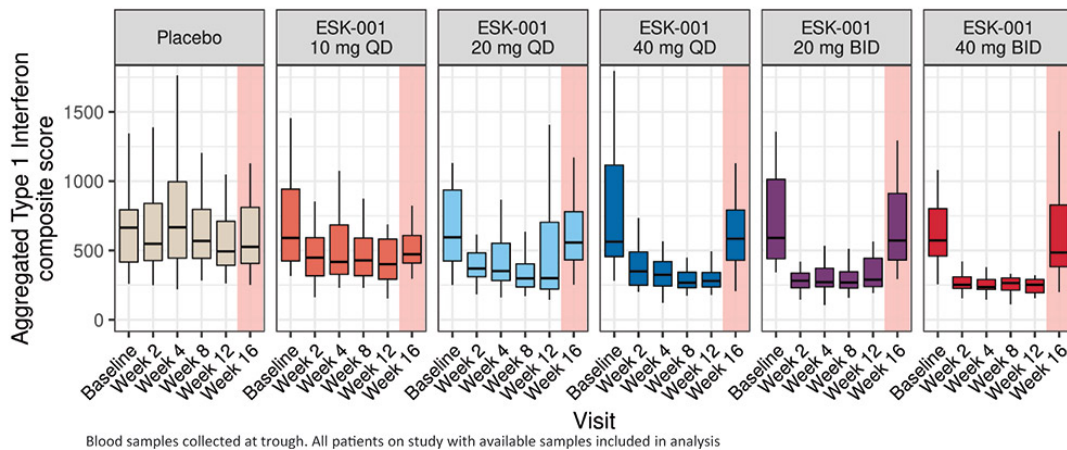
	ESK-001 40 mg QD (N=82)	ESK-001 40 mg BID (N=82)	Overall (N=164)
Subjects with $\geq 1$ TEAE	35 (42.7)	38 (46.3)	73 (44.5)
Subjects with $\geq 1$ SAE <sup>1</sup>	1 (1.2)	1 (1.2)	2 (1.2)
Deaths	0	0	0
Subjects with TEAE leading to treatment discontinuation <sup>2</sup>	0	2 (2.4)	2 (1.2)
Subjects with TEAE $\geq$ Grade 3 <sup>3</sup>	0	2 (2.4)	2 (1.2)
Most frequent TEAEs <sup>4</sup>			
Nasopharyngitis	9 (11.0)	2 (2.4)	11 (6.7)
Upper Respiratory Tract Infection	1 (1.2)	4 (4.9)	5 (3.0)
Folliculitis	0	3 (3.7)	3 (1.8)
Urinary tract infection	0	3 (3.7)	3 (1.8)
Acne	2 (2.4)	3 (3.7)	5 (3.0)
Headache	5 (6.1)	3 (3.7)	8 (4.9)

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In summary, our STRIDE Phase 2 clinical trial and open label extension trial in PsO demonstrated that ESK-001 at a dose of 40 mg BID was well tolerated and highly efficacious. The PASI response was closely linked to the degree of TYK2 inhibition achieved such that maximal target inhibition, whereas incomplete target inhibition led to a significant step down in PASI response. We believe this data supports advancement of ESK-001 into Phase 3 trials in PsO.

We further assessed the degree of TYK2 inhibition utilizing blood and skin biomarkers. We measured the type I IFN signature in whole blood using RNA Sequencing, and within skin biopsies obtained from a subset of STRIDE patients before treatment with ESK-001 (baseline) and at various time points after the treatment with ESK-001 or placebo. The figure below shows increasingly deep suppression of the type I IFN signature with increasing doses of ESK-001. This inhibition occurred within 2 weeks of initiating treatment and was reversed when treatment was discontinued during the washout period (reflected in the pink bars in the figure below). These blood and skin biopsy biomarker data confirm the maximal target inhibition at the 40 mg BID dose.

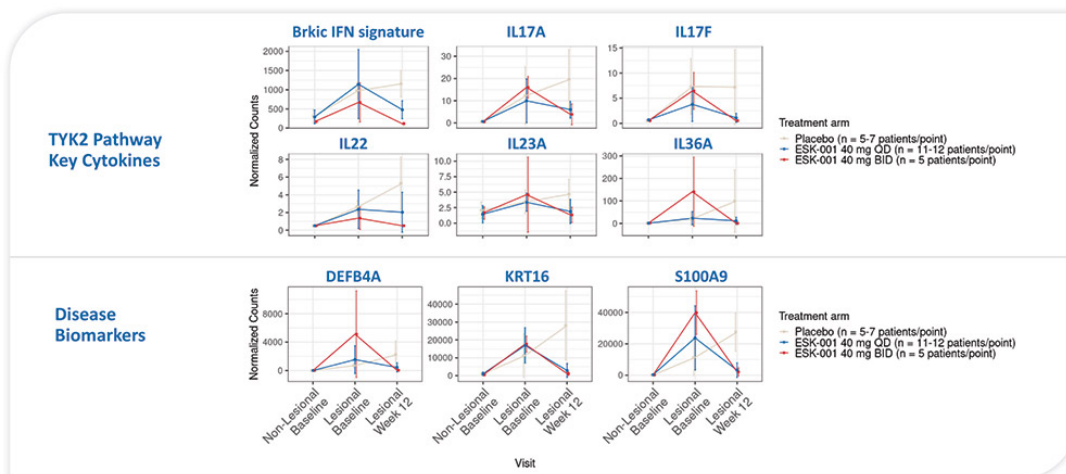
*STRIDE Trial: Inhibition of the type I IFN signature at trough in patient Whole Blood*



We also wanted to characterize the target inhibition in the relevant tissue, the skin. We obtained skin biopsies from a subset of the patients in the STRIDE study and measured the mRNA in various key TYK2 pathways as well as in known disease biomarkers of PsO (see figure below). Lesional and non-lesional skin biopsy samples were probed for the expression of certain cytokines and disease related biomarkers using RNA Sequencing. Paired lesional and non-lesional biopsy samples were obtained at baseline (shown in the middle and on the left of each plot chart on the figure below) and a lesional sample was obtained after 12 weeks of treatment with ESK-001 (shown on the right of the plot chart). This analysis demonstrated that for most analytes, increased expression of inflammatory cytokines and disease biomarkers returned to non-lesional levels after treatment with ESK-001, except for patients who received the placebo.

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*STRIDE Trial: Expression of inflammatory cytokines and disease biomarkers in PsO skin biopsies*



ESK-001 Psoriasis Phase 2 Skin biopsy RNA-seq.

Skin biopsies collected in subset of patients, all available skin biopsy samples with valid RNAseq data included in analysis.

*Proposed Phase 3 Clinical Trials of ESK-001 in PsO*

Our Phase 3 development program includes two identical, global, randomized, double-blind, placebo-controlled studies to evaluate the efficacy and safety of ESK-001 in adult patients with PsO. Comparators will include placebo (though Week 16) and Otezla (through Week 24). The co-primary endpoints will be PASI-75 and sPGA 0/1 at Week 16. Key secondary endpoints will include PASI-90, PASI-100, and sPGA 0 measured at Weeks 16 and Week 24. In addition, patient-reported outcomes including quality of life measures and pruritus will be captured. Patients completing Week 24 will have the opportunity to participate in a long-term extension (LTE) trial that will evaluate durability and maintenance of response and long-term safety. In addition, we are considering conducting other active comparator trials. These trials are not expected to be part of the NDA submission in the United States.

We have received and incorporated feedback from the FDA and the Committee for Medicinal Products for Human Use (CHMP) in Europe in our proposed Phase 3 program in PsO, and regulatory feedback from the PMDA in Japan has been requested.

Enrollment in our two Phase 3 pivotal trials is expected to commence in \_\_\_\_\_, and top line results are expected in \_\_\_\_\_.

ESK-001 for the treatment of Systemic Lupus Erythematosus (SLE)

*SLE Overview*

SLE is a chronic autoimmune disease predominantly affecting women at childbearing age. Clinical manifestations are highly heterogeneous, and the disease typically waxes and wanes, with flares and periods of relative remission. Certain loss-of-function variants of TYK2 significantly decrease the risk of SLE.

While mortality in SLE has decreased since the mid-20th century as a result of improved treatments, the disease remains associated with increased disability and loss of social and occupational functioning and high utilization of health care resources.

Treatment for SLE varies and, in general, is proportional to the severity of the disease manifestations. Hydroxychloroquine or other antimalarials are widely used along with corticosteroids and immunosuppressives/immunomodulators for moderate to severe SLE and are responsible for significant long-term toxicity and excess mortality. Causes of death in SLE patients are primarily related to infection, as well as accelerated cardiovascular disease or end organ failure.

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*Overview of the SLE Market*

Over \_\_\_\_\_ people have SLE in the United States (and over \_\_\_\_\_ people globally), with an annual growth rate of \_\_\_\_%. \_\_\_\_% of these U.S. SLE patients have moderate-to-severe SLE, and over \_\_\_\_% of moderate-to-severe SLE patients are drug treated in the United States. An additional \_\_\_\_\_ people in the United States have SLE with lupus nephritis, a serious complication of SLE. Over \_\_\_\_% of lupus nephritis patients with Class III and above disease are drug treated in the United States.

The pharmaceutical drug market for SLE is \$ \_\_\_\_\_ in the United States in 2023 (and \$ \_\_\_\_\_ globally), and is forecasted to increase to \$ \_\_\_\_\_ in 2030 (and \$ \_\_\_\_\_ globally) due to the increase in SLE patient population and the development of new therapies for SLE.

The therapies available for the treatment of SLE include anti-malarial therapies, corticosteroids, immunosuppressive agents and biologic therapies. There are currently only two advanced targeted therapies approved for SLE in the United States—Benlysta and Saphnelo. There remains a strong unmet need for more effective and safe therapies to treat SLE, as these are the only two therapies approved since the 1950s and oral corticosteroids with or without broad immunosuppressants are still widely used.

*Rationale for Targeting TYK2 in the Treatment of SLE*

The importance of the type I IFN pathway is well established in SLE. Type I IFN regulated genes and proteins are elevated in SLE patient serum, skin, joints, and kidneys, driving disease activity and flares. The type I IFN receptor signals through TYK2 to drive T-cell activation, enhanced natural killer (NK) cell activity, dendritic cell maturation and neutrophil extracellular traps formation. The IL-23/IL-12 pathways are less well characterized in SLE compared to psoriasis. IL-23 levels have been shown to be higher in active as compared to inactive SLE biopsy samples, and glomerular IL-23 appears to correlate with severity of kidney inflammation.

Sotyktu has been studied in a 48-week Phase 2 clinical trial in adults (n=363) with active SLE. The primary endpoint was the SLE Responder Index 4 (SRI-4) at Week 32 across four groups randomized 1:1:1:1 to receive Sotyktu 3 mg twice daily, 6 mg twice daily, 12 mg once daily, or placebo. This study met its primary and several secondary and exploratory endpoints. Sotyktu showed higher response rates relative to placebo at all dose levels, but there did not appear to be a clear dose response relationship. Overall rates of AEs were similar across groups, except for higher rates of infections and cutaneous events, including rash and acne, with Sotyktu treatment. Patient drop-out rates were higher at higher doses. Rates of SAEs were comparable across dose cohorts, with no deaths, opportunistic infections, tuberculosis infections, major adverse cardiovascular events or thrombotic events reported.

*Ongoing Phase 2b LUMUS trial of ESK-001 in SLE*

We are currently conducting LUMUS, a Phase 2b, 48-week, global, placebo-controlled, double-blind, randomized, clinical trial evaluating ESK-001 in patients with moderate-to-severe active SLE.

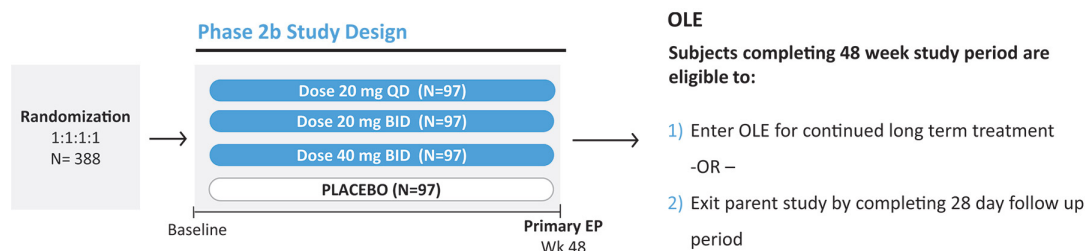
The trial is enrolling patients with autoantibody positive SLE diagnosed per the 2019 EULAR/ACR criteria more than six months prior to screening, and with evidence of active disease per both Systemic Lupus Erythematosus Disease Activity Index—2K (SLEDAI-2K) and British Isles Lupus Assessment Group index (BILAG) (both validated composite outcome measures of lupus disease activity), despite current treatment with corticosteroids and/or any of the following: antimalarials, methotrexate, azathioprine, or a combination of these treatments

We plan to enroll 338 patients in three active dose arms and a placebo arm with randomization ratio of 1:1:1:1. The trial is designed to test the efficacy, safety and optimal dose regimen of ESK-001 in patients with active SLE. The primary endpoint is BICLA response (a validated composite measure of lupus disease activity) at Week 48. The trial is designed to potentially serve as the first of two pivotal trials. It is accompanied by an open label extension trial. An extensive array of biomarker samples is being collected in order to help identify biomarkers associated with response or non-response, potentially enabling future stratification and/or selection of patients most likely to respond. A schematic of the trial design is shown in the figure below.

We expect to report data in \_\_\_\_\_.

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*LUMUS Phase 2b Trial Design in SLE*



ESK-001 for the Treatment of Active Non-Infectious Intermediate, Posterior or Pan Uveitis

*Overview of Uveitis*

Uveitis refers to eye inflammation involving the uvea (iris, ciliary body and choroid) and adjacent structures. It is a very serious disease that can have a sudden onset with rapid progression resulting in blindness. It is one of the leading causes of preventable blindness in the United States and accounts for 15% of the causes of total blindness in western countries. Uveitis is divided into infectious and non-infectious uveitis, with non-infectious uveitis accounting for approximately half of all uveitis cases. Non-infectious uveitis can further be classified further into uveitis associated with underlying systemic disease such as juvenile idiopathic arthritis, sarcoidosis, psoriasis or psoriatic arthritis, or without an underlying systemic disease, such as associated with drugs, injury, post-surgery or idiopathic.

*Overview of the Uveitis Market*

Over \_\_\_\_\_ in the United States have Uveitis (and over \_\_\_\_\_ globally), with an annual growth rate of \_\_\_\_\_%. \_\_\_\_\_% of U.S. Uveitis patients have anterior uveitis, and \_\_\_\_\_% have intermediate, posterior or panuveitis. \_\_\_\_\_ to \_\_\_\_\_% (depending on the disease severity and subtype) of Uveitis patients are drug treated in the United States.

The pharmaceutical drug market for Uveitis is \$ \_\_\_\_\_ in the United States in 2023 (and \$ \_\_\_\_\_ globally), and is forecasted to increase to \$ \_\_\_\_\_ in 2029 (and \$ \_\_\_\_\_ globally) due to the increase in Uveitis patient population and the development of new therapies for Uveitis.

The therapies available for the treatment of Uveitis include steroid therapies and implants, antimetabolites, alkylating agents, calcineurin inhibitors and biologic therapies. Humira is the only FDA-approved biologic for the treatment of Uveitis and a significant proportion of patients are refractory to treatment with Humira. Other therapies are used off-label. There is an unmet need for effective and safe therapies to achieve sustained control of inflammation in patients.

*Rationale for Targeting TYK2 in the Treatment of Uveitis*

Uveitis is a common manifestation of systemic autoimmune diseases believed to be driven by dysregulation of TYK2-mediated cytokine pathways. Uveitis is predominantly a T-cell mediated disease, mainly driven by Th1 and Th17 pathways. The IL-12 family of cytokines, including IL-12, IL-23, IL-27, and IL-35, are vital for the regulation of T-cells. Although Uveitis due to autoimmune and autoinflammatory mechanisms may be heterogeneous in clinical manifestations and includes a range of immune-mediated diseases, many studies now show that these entities share the dysregulation of the IL-23/IL-17 signaling pathway.

*Ongoing Phase 2a Proof-of-Concept OPTYK-1 Trial*

We are currently conducting OPTYK-1, a Phase 2a, proof-of-concept, double-blinded, randomized, clinical trial evaluating ESK-001 in patients with Uveitis in United States.

The trial aims to investigate the safety and efficacy of ESK-001 in patients with active non-infectious, intermediate, posterior and pan Uveitis in at least one eye. We enrolled 36 patients in two active dose arms of



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United States in 2023 (and \$ globally), and is forecasted to increase substantially to over \$ in 2028 (and over \$ globally) due to the increase in PsA patient population and the development of new therapies for PsA. There are a number of therapies available for the treatment of PsA, including TNF inhibitors, interleukin inhibitors, biologic therapies, JAK inhibitors and other systemic therapies. Humira is the most used TNF inhibitor among moderate-to-severe PsA patients. Stelara is the most used biologic in the anti-IL-12/23 category. There are three advanced oral therapies for PsA approved in the United States—Xeljanz, Rinvoq and Otezla. Xeljanz and Rinvoq are oral JAK inhibitors, which carry a black box warning for JAK-related AEs, and are advised for use after a TNF inhibitor.

#### Once daily oral formulation of ESK-001

We are currently developing a once daily modified release (MR) oral formulation of ESK-001 that can replace our current immediate release (IR) oral formulation that is dosed twice daily. Our target profile is an MR product that has comparable pharmacokinetic (PK) and pharmacodynamic (PD) behavior to the 40 mg IR twice daily dose utilized in our Phase 2 clinical trials to date. We plan to initiate human studies in to identify the best MR formulation. We plan to use this formulation to advance our clinical programs and to introduce it between the time of PsO approval or via a supplemental NDA within the first year post approval.

#### A-005: Our CNS Penetrant Allosteric TYK2 Inhibitor

The second clinical product candidate in our TYK2 franchise, A-005, is a highly differentiated, CNS penetrant, allosteric TYK2 inhibitor that has potential applications in multiple sclerosis (MS) and other neurological diseases. A loss-of-function mutation in the TYK2 gene has been shown to have a protective effect in MS. In preclinical studies, A-005 has recapitulated the protective effects reported with the TYK2 genetic loss-of-function in multiple *in vivo* disease models of neuroinflammation. We have completed investigational new drug (IND) enabling studies of A-005. In 2024, we initiated a randomized, double-blind, placebo-controlled, multi-cohort investigation to assess the safety, PK, and PD of single ascending doses (SAD) and multiple ascending doses (MAD) of orally-administered A-005. As part of the study, we intend to include an open-label, one-cohort, single dose study to assess the penetration of orally-administered A-005 into the cerebrospinal fluid (CSF). We intend to pursue MS as our initial indication.

#### *Role of TYK2 in neuroinflammatory and neurodegenerative diseases.*

TYK2 pathways are active in CNS resident immune cells and may play a localized role in the CNS contributing to the pathology of several CNS inflammatory disorders including MS. Genome-wide association studies have shown the loss-of function TYK2 genetic variant, P1104A, has a protective effect for the development of MS. An additional missense variant in TYK2, Rs35018800, has the largest effect on MS risk of any variant outside the MHC/HLA region discovered to date. In addition to its genetic association with MS, TYK2 is known to be expressed and functionally active in CNS-resident microglia. Microglia express IL-23 and interferon receptors and IL-23/IL-12 cytokines have been shown to localize to MS lesions. Activated microglia are associated with disease worsening in MS, and TYK2 inhibitors with adequate CNS exposure provide an opportunity to target neuroinflammation and neurodegeneration. We believe TYK2 inhibition has the potential to treat the neuroinflammatory component of other neurological diseases where activated microglia and/or TYK2 proinflammatory cytokines including interferon are implicated such as Alzheimer's disease, ALS, optic neuritis, neuromyelitis optica, and Parkinson's disease.

#### A-005 for the treatment of Multiple Sclerosis.

MS is a chronic immune-mediated disease of the central nervous system. This condition causes a wide range of physical and cognitive challenges for those afflicted, often resulting in neurological symptoms and disabilities. Despite available treatments to manage symptoms and slow diseases progression, treatments are limited for progressive disease and a definitive cure remains elusive. Agents directly targeting the CNS pathology and CNS resident cells, including activated microglia, are of increasing interest as these are thought to impact progressive neurological impairment. The unmet need lies in finding safe and more effective targeted therapies that can halt or reverse the disease progression, alleviating the burden on patients and their families and improving their overall quality of life.

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MS afflicts approximately            patients in the United States and more than            people worldwide, with an annual growth rate of            %.

The global market size for MS is approximately \$            and is forecasted to increase substantially to over \$            by 2030 due to the increase in MS patient population, the development of new therapies for MS and projected increase in treatment rate.

There are several therapies available for the treatment of relapsing forms of MS, including interferon beta regulators, monoclonal antibodies, synthetic immunomodulatory drugs and S1P receptor modulators. Few therapies exist for the progressive form of MS. Ocrevus (ocrelizumab), a CD20 antibody, is the most used injectable therapy in the United States for relapsing MS and is the only approved treatment option shown to slow progression of primary progressive multiple sclerosis (PPMS). There continues to be a high unmet need for a safe and efficacious oral therapies for progressive forms of MS.

#### *A-005 Preclinical Validation*

In our preclinical studies, A-005 was shown to bind to the TYK2 allosteric domain (JH2 domain) with picomolar binding affinity and potently inhibits receptor-mediated activation of pSTAT pathways downstream of IL-23, IL-12 and type I IFN receptor signaling in whole blood, PBMCs and microglial cells. As shown in the figure below, A-005 is highly potent and intrinsically selective for TYK2 over other protein kinases, including the JAK family members and is devoid of JAK pharmacology in immune cell assays.

*Profile of A-005 inhibition in biochemical and immune cell assays demonstrates potent and selective inhibition of TYK2 with no JAK-related pharmacology*

Target	Kd (nM)	Selectivity
TYK2 JH2*	0.017	-
JAK1 JH2*	2.5	149-fold
JAK1 JH1	>10,000	>595,000
JAK2 JH1	737	43,869
JAK3 JH1	737	43,869
TYK2 JH1	>30,000	>1,786,000
BMPR2*	80	4,762
GCN2*	88	5,238
RSK3*	1,700	>100,000

\*Eurofins kinase panel hits >90% at 1  $\mu$ M A-005

Stimulus	Readout	Pathway	Human whole blood IC <sub>50</sub> (nM)	Human PBMC IC <sub>50</sub> (nM)	HMC3 microglia IC <sub>50</sub> (nM)
IFN $\alpha$	pSTAT3	TYK2	30	3.7	5.4
IFN $\alpha$	pSTAT5		31	3.3	4.8
IL-12	pSTAT4		56	8.1	N/A
IL-2	pSTAT5	JAK1/JAK3	>1,000	>1000	N/A
TPO	pSTAT5	JAK1/JAK2	>1,000	N/A	N/A

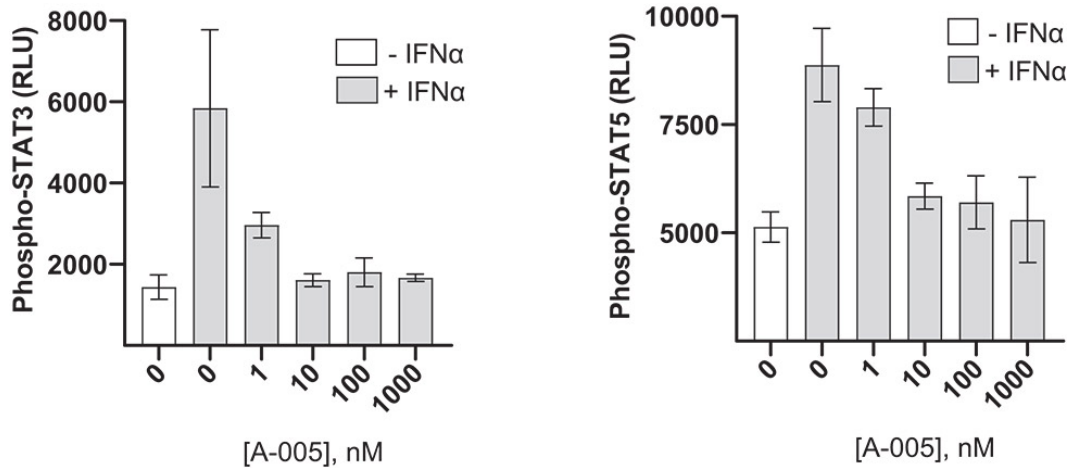
TPO, thrombopoietin; pSTAT, phosphorylated signal transducer and activator of transcription

We believe A-005 can potently target neuroinflammatory processes systemically and within the CNS. Our preclinical studies have shown that microglia express TYK2 and respond to TYK2 signaling cytokines such as IFN $\alpha$  and IL-23. A-005 can effectively inhibit TYK2 microglial responses in primary microglia derived from human induced pluripotent stem cell (iPSC) (see figure below). These results are similar to those observed with immune PBMCs.



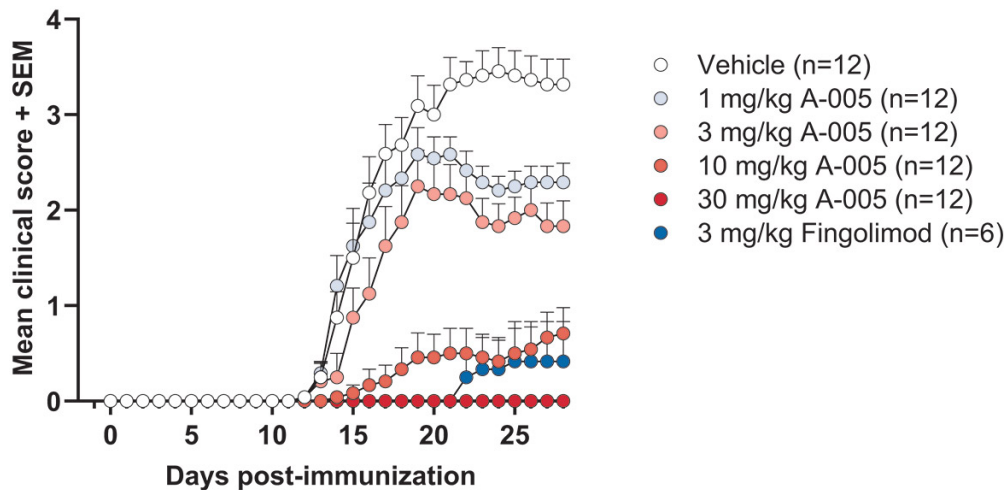
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*A-005 maximally inhibits activation of human iPSC-derived microglia*



When administered orally once a day, A-005 was protective in rodent models of experimental autoimmune encephalitis (EAE), which are commonly used to evaluate mechanisms of neuroinflammation. When administered prophylactically in an EAE model, A-005 showed a significant dose response and prevented disease at higher doses. A-005 disease reduction surpassed that of fingolimod, which is commonly used as a positive control in this model. In a therapeutic dosing EAE model, A-005 administered after disease onset resulted in significant suppression of established disease with once daily treatments again exceeding the benefit observed with fingolimod.

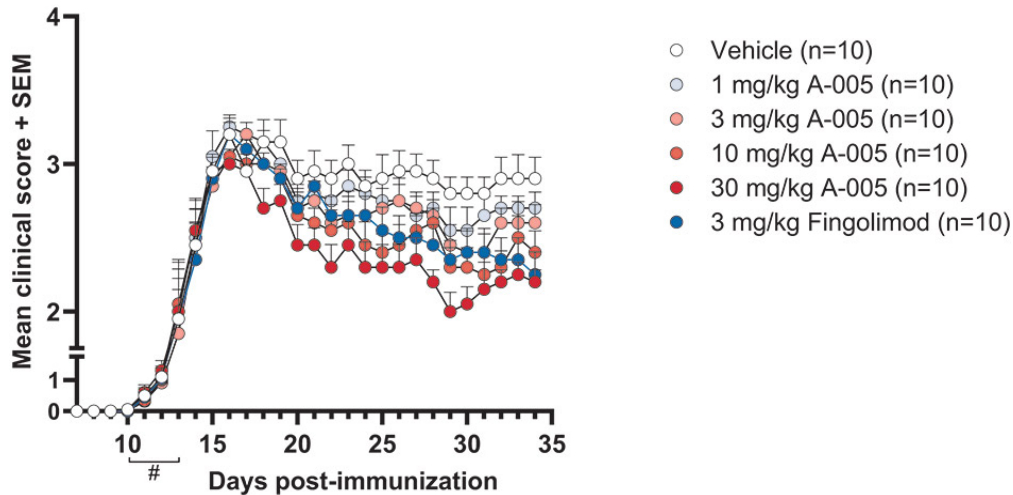
*Prophylactic CNS EAE model: complete suppression achieved with once daily A-005 treatment*



One daily oral dosing initiated 1 day prior to EAE induction. Mann-Whitney U-test vs vehicle,  $p < 0.05$  for 1mg/kg (day 20-28); 3mg/kg (day 20-28); 10mg/kg (day 14-28); 30mg/kg (day 14-28)

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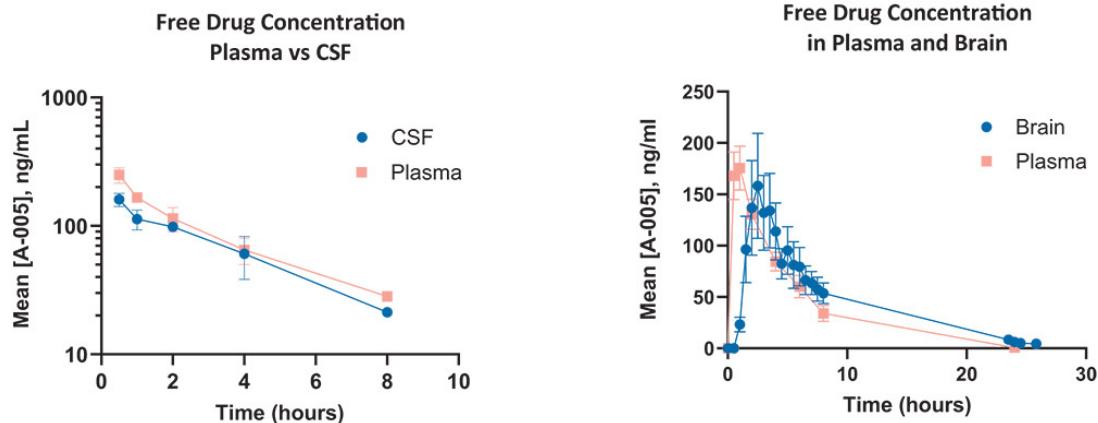
*Therapeutic CNS EAE model: dose dependent suppression of established disease with once daily A-005 treatment initiated after onset*



One daily oral dosing initiated at the onset of EAE clinical signs (# enrollment period, days 10-13). Experiment continued until each mouse had been dosed for at least 21 days (day 34). Mann-Whitney U-test vs vehicle,  $p < 0.05$  for 10 mg/kg (day 21, 25-27, 29-32, 34), 30 mg/kg (day 18-34).

We assessed the ability of A-005 to transit across the blood brain barrier in rodents by comparing levels of A-005 present in the plasma with levels in the cerebrospinal fluid (CSF) and within the brain tissues at specified timepoints after oral administration. As shown in the figure below, near equivalent levels of A-005 were confirmed in the CSF and within the brain compared to measured free drug plasma levels adjusted for protein binding.

*High CNS Penetration confirmed with oral dosing of A-005 In Vivo*



### First in human study

In 2024, we initiated a randomized, double-blind, placebo-controlled, multi-cohort investigation to assess the safety, PK, and PD of single ascending doses (SAD) and multiple ascending doses (MAD) of orally-administered A-005 in healthy volunteers. As part of the study we intend to include an open-label, single-dose cohort to assess the penetration of orally-administered A-005 into the human CSF and expect to report preliminary results in

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We are building a pipeline of molecules with the potential to address a broad range of immune-mediated diseases. We pursue drug targets that have been previously validated by strong human genetic evidence or human clinical data. Our drug discovery efforts for our selected targets take advantage of structure-guided approaches built from public or proprietary crystallographic structures to enable use of advanced computational methods. These approaches enable optimization of traditional protein modulators, protein degraders, and targeted covalent inhibitors as appropriate. In addition, we have chosen targets that could be complementary for use in combination with our existing TYK2 franchise and to each other.

For example, interferon regulatory factor 5 (IRF5) is a transcription factor that mediates signaling of several cytokines including type I IFN, IL-6, IL-12, IL-23, and TNF. It is a genetically-supported target across multiple immune indications with known functional roles in both innate and adaptive immunity. IRF5 has been implicated in macrophage polarization, cell growth regulation, and apoptosis. It acts on innate immune responses via recognition of upstream self-nucleic acid-containing immune complexes and pathogens by toll like receptors (TLR), specifically: TLR7, TLR8 and TLR9 in the endosome via MyD88. Translocation of IRF5 to the nucleus following phosphorylation by IKK $\beta$  is critical to the pathogenesis of many immune mediated diseases. Genome-wide association studies have identified several functional genetic variants in IRF5 that predispose patients to immune-mediated diseases including, but not limited to SLE, systemic sclerosis, and primary sclerosing cholangitis.

We are actively engaged in lead generation activities to identify small molecules that can precisely bind and block IRF5 function. These efforts are aided by our proprietary crystal structure of our compounds bound to IRF5, which enables computational approaches to optimize binders for either IRF5 inhibition or degradation. We have developed several proprietary assays including a biochemical dimerization assay that has been used in conjunction with high-throughput screening to identify leads. In addition, we have applied an orthogonal method to identify small-molecule binders that may target allosteric pockets providing inhibition directly or as a component in a PROTAC. We will pursue multiple mechanisms of inhibition and use our extensive pharmacology expertise to guide the final selection of clinical candidates.

**Foresite Labs Collaboration**

Foresite Labs was an original shareholder in, and actively involved in our incubation. We and Foresite Labs have had an ongoing collaboration since our inception, with Foresite Labs originally providing incubation services, development assistance and oversight, and data analytics services; currently, Foresite Labs provides data analytics services related to our TYK2 franchise, our discovery programs and to our business development activities. The original Services Agreement between us and Foresite Labs was entered into in January 2021, was amended and restated in August 2021, was amended and restated for a second time in December 2023, and expires in December 2026, unless terminated earlier by the parties. Work under the Services Agreement is memorialized in a series of Statements of Work and we pay Foresite Labs for the estimated costs of its services in advance on a quarterly basis, with a true-up to actuals at the end of each quarter.

**Intellectual Property**

We strive to protect and enhance the proprietary technology, inventions and improvements that are commercially important to our business, including by seeking, maintaining, enforcing and defending patent rights. Our policy is to seek to protect our proprietary position by, among other methods, filing patent applications in the United States and in jurisdictions outside of the United States related to our proprietary technology, inventions, improvements and product candidates that are important to the development and implementation of our business. We also rely on trade secrets and know-how relating to our proprietary technology and product candidates, and may in the future rely on in-licensing opportunities, to develop, strengthen and maintain our proprietary position in our field. Our commercial success will depend in part on our ability to obtain and maintain patent and other proprietary protection for our technology, inventions and improvements; to preserve the confidentiality of our trade secrets; to obtain and maintain any future licenses to use intellectual property owned by third parties; and to defend and enforce our proprietary rights, including our patent rights.

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As of March 31, 2024, our solely owned patent portfolio included two issued U.S. patents, three pending U.S. provisional patent applications, five pending non-provisional U.S. patent applications, over 40 pending foreign patent applications, and eight pending Patent Cooperation Treaty (PCT) patent applications.

***ESK-001 and A-005***

In regard to ESK-001 and A-005, we own one patent family that includes two issued U.S. patents, three pending U.S. patent applications and over 20 foreign patent applications pending in various jurisdictions, such as Europe, Brazil, Canada, China, Australia, Japan, India, Israel, Singapore and Vietnam. Not accounting for any patent term adjustment or extensions or terminal disclaimers, and assuming that all applicable annuity and/or maintenance fees are paid timely, the issued patents, and, if granted, the pending patent applications in this family, are expected to expire in 2039. The U.S. patent and pending patent applications disclose and/or contain composition-of-matter and method of treatment claims relating to ESK-001 and A-005, and disclose and/or contain claims relating to the production of ESK-001 and A-005. One pending U.S. patent application is directed to the composition of matter claims to A-005.

We also own three patent families which include three pending PCT applications that disclose and/or contain claims directed to crystalline and salt forms of ESK-001. Not accounting for any patent term adjustment or extension and assuming that all applicable annuity and/or maintenance fees are paid timely, any patent applications claiming the benefit of these PCT applications, if issued, will be expected to expire in 2043.

We own another patent family that includes one pending PCT application that discloses and/or contains claims directed to methods of treating a TYK2-mediated disease using ESK-001. Not accounting for any patent term adjustment or extension and assuming that all applicable annuity and/or maintenance fees are paid timely, any patent applications claiming the benefit of this PCT application, if issued, will be expected to expire in 2043.

We own two pending PCT applications and one pending U.S. provisional patent application that disclose and/or contain claims directed to methods of treating various diseases with ESK-001, such as hidradenitis suppurativa, uveitis and autoimmune skin disease. Not accounting for any patent term adjustment or extension and assuming that all annuity and/or maintenance fees are paid timely, any patent applications claiming the benefit of the PCT applications, or patent applications claiming priority to the PCT applications or the provisional patent application, if issued, will be expected to expire in 2044.

We continue to assess the extent to which we may seek additional patent protection for aspects of our product engine. The term of individual patents depends upon the date of filing of the patent application, date of patent issuance and 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 of the first non-provisional application to which priority is claimed. Outside of the United States, the duration of patents varies in accordance with applicable local law, but typically is also 20 years from the earliest non-provisional filing date. In the United States, patent term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the United States Patent and Trademark Office (USPTO) in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier-filed patent. Moreover, in context of approved products, there may be other additional exclusivity for the patents covering such approved product. In the United States, the term of a patent that covers an FDA-approved drug may also be eligible for a patent term extension of up to five years under the Hatch-Waxman Act, which is designed to compensate for the patent term lost during the FDA regulatory review process. The length of the patent term extension is calculated based on the length of time it takes for regulatory review. A patent term extension under the Hatch-Waxman Act cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to an approved drug may be restored and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Moreover, a patent can only be restored once, and thus, if a single patent is applicable to multiple products, it can only be extended based on one product. Similar provisions are available in Europe and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug.

We intend to pursue, in the normal course of business and when possible, composition, method of use, process, dosing and formulation patent protection for the product candidates we develop and commercialize. We may also pursue patent protection with respect to manufacturing and immunotherapy development processes and

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technology. When available to expand market exclusivity, we intend to strategically obtain or license additional intellectual property related to current or contemplated product candidates.

In some instances, we submit patent applications directly to the USPTO as provisional patent applications. Corresponding non-provisional patent applications must be filed within 12 months after the provisional application filing date. The corresponding non-provisional application may be entitled to the benefit of the earlier provisional application filing date(s), and the patent term of the finally issued patent is calculated from the later non-provisional application filing date. Provisional applications for patents were designed to provide a lower-cost first patent filing in the United States. This system allows us to obtain an early priority date, add material to the patent application(s) during the priority period, obtain a later start to the patent term and to delay prosecution costs.

The PCT system allows a single application to be filed within 12 months of the original priority date of the patent application, and to designate all of the PCT member states in which national or regional patent applications can later be pursued based on the international patent application filed under the PCT. The PCT searching authority performs a patentability search and issues a non-binding patentability opinion which can be used to evaluate the chances of success for the national or regional applications prior to having to incur the filing fees and prosecution costs. Although a PCT application does not issue as a patent, it allows the applicant to seek protection in any of the member states through national/regional-phase applications. At the end of the period of two and a half years from the first priority date of the patent application, separate patent applications can be pursued in any of the PCT member states either by direct national filing or, in some cases by filing through a regional patent organization, such as the European Patent Organisation. The PCT system delays expenses, allows a limited evaluation of the chances of success for national/regional patent applications and enables substantial savings where applications are abandoned within the first two and a half years of filing. We intend to file U.S. nonprovisional applications and PCT applications that claim the benefit of the priority date of earlier filed provisional applications, when applicable.

For all patent applications, we determine claiming strategy on a case-by-case basis. Advice of counsel, country-specific patent laws and our business model and needs are always considered. We may file patents containing claims for protection of all useful applications of our proprietary product candidates, as well as all new applications and/or uses we discover for existing product candidates, assuming these are strategically valuable. We continuously reassess the number and type of patent applications in our portfolio, as well as the pending and issued patent claims, to help ensure that maximum coverage and value are obtained for our processes, and compositions, given existing patent office rules and regulations. Further, claims may be modified during patent prosecution, to the extent allowed, to meet our intellectual property and business needs.

There can be no assurance that we will be able to obtain, maintain, enforce and defend all patents and other intellectual property rights necessary to conduct our business. The patents that issue from our patent applications or any that we may in-license in the future, if any, may be challenged by third parties, may not effectively prevent third parties from commercializing competitive technologies or may not otherwise provide us with a competitive advantage.

We may also rely on trade secrets relating to our product candidates and technology, and seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. However, trade secrets are difficult to protect and may provide us with only limited protection. It is our policy and practice to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us, and for employees and consultants to enter into invention assignment agreements with us. These agreements provide that all confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. Where applicable, the agreements provide that all inventions to which the individual contributed as an inventor shall be assigned to us, and as such, will become our property. There can be no assurance, however, that these agreements will provide meaningful protection or adequate remedies for our trade secrets in the event of unauthorized use or disclosure of such information.

For more information regarding the risks related to our intellectual property, see section titled "Risk Factors — Risks Related to Intellectual Property."

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**Sales and Marketing**

Given our stage of development, we have not yet established a full commercial organization or distribution capabilities. We have stage-appropriate commercial capabilities we intend to build a commercial infrastructure to support sales of any approved products and intend to continue evaluating opportunities to work with partners that enhance our capabilities with respect to the development and commercialization of ESK-001 and A-005, if approved. In addition, we intend to commercialize our product candidates, if approved, in key markets in the United States, the European Union, and APAC, either alone or with partners in order to maximize the worldwide commercial potential of our programs.

**Manufacturing**

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for clinical testing, as well as for manufacture of any products that we may commercialize, if approved. To date, we have obtained active pharmaceutical ingredients (API) for ESK-001 and A-005 for our preclinical and clinical testing from different third-party API manufacturers and bulk drug product from other third-party manufacturers. We obtain our preclinical and clinical supplies from these manufacturers on a purchase order basis and currently do not have long-term supply arrangements in place. We are in the process of implementing a redundant supply chain for ESK-001 API, drug product and critical raw material. For all our product candidates, we intend to identify and qualify redundant manufacturers, including entering into long-term agreements, to provide the API and drug product and prior to submission of the NDA to the FDA and/or a marketing authorization application to the European Medicines Agency (EMA) and/or other health authorities. ESK-001 and A-005 are compounds of low molecular weight, generally called small molecules. ESK-001 can be manufactured in reliable and reproducible processes from readily available starting materials. A-005 has been produced in small quantities to support our preclinical studies and is currently being manufactured at larger quantities for clinical testing. The chemistries for ESK-001 and A-005 are amenable to scale-up and do not require unusual equipment in the manufacturing process. Additional contract manufacturers are used to package, label, and distribute investigational drug products. This strategy allows us to maintain a more efficient infrastructure, avoid depending on our own manufacturing facility and equipment while simultaneously enabling us to focus our expertise on developing our products. We expect to continue to develop product candidates that can be produced cost-effectively at contract manufacturing facilities.

**Competition**

The biopharmaceutical industry is characterized by intense competition and rapid innovation. Our potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical companies and generic drug companies. Many of our potential competitors have greater financial and technical human resources than we do, as well as equal or greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products. Accordingly, our potential competitors may be more successful than us in achieving regulatory approvals and commercializing their drugs. We anticipate that we will face intense and increasing competition from existing, approved drugs, as well as new drugs entering the market and emerging technologies that become available. Finally, the development of new treatment methods for the diseases we are targeting could render our product candidates non-competitive or obsolete.

We believe the key competitive factors that will affect the development and commercial success of our product candidates, if approved, will be efficacy, safety, tolerability profile, convenience of dosing, price and coverage by governmental and third-party payors.

We are currently developing ESK-001 for the treatment of PsO, SLE and Uveitis, with multiple other potential indications to follow. Other emerging and established life sciences companies have been focused on similar therapeutics. If approved, ESK-001 would compete with several currently approved or late-stage oral clinical therapeutics, including Sotyktu (marketed by Bristol Myers Squibb Company (BMS)), TAK-279 (in development by Takeda Pharmaceutical Company), VTX-958 (in development by Ventyx Biosciences, Inc.), JNJ-2113 (in development by Johnson & Johnson), DC-806 (in development by Eli Lilly and Company), as well as new early-stage therapeutic companies that may develop competing molecules. Additional TYK2 agents are under development by BMS, Galapagos NV, Innocare, and Priovant Therapeutics, Inc.

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Our second TYK2 product candidate, A-005, is a highly differentiated CNS penetrant allosteric TYK2 inhibitor that has a potential application in multiple sclerosis (MS) and other neuroinflammatory diseases. In MS, there are a large number of therapies available for the treatment of relapsing forms of MS, including interferon beta regulators, monoclonal antibodies, synthetic immunomodulatory drugs, S1P receptor modulators. Ocrevus, a CD20 antibody marketed by Genentech, Inc., is the only current therapy approved for PPMS for slowing disease progression. We are aware that Biohaven is developing a CNS penetrant TYK2/JAK1 inhibitor BHV-8000, for which they expect to initiate Phase 2 clinical trials in 2H 2024 in MS as well as Alzheimer's Disease and Parkinson's Disease. BMS has reported that they have a CNS penetrant TYK2 inhibitor (BMS-986465) positioned for neuroinflammation diseases that will initiate first in human clinical studies soon. Sudo has reported a CNS TYK2 inhibitor (SUDO-550) that is in advanced preclinical studies and Neuron 23 also has disclosed that they have a TYK2 inhibitor program targeting neuroinflammation and MS.

### **Government Regulation**

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

### ***FDA Approval Process***

In the United States, pharmaceutical products are subject to extensive regulation by the U.S. Food and Drug Administration (the FDA). The Federal Food, Drug, and Cosmetic Act (the FDCA) and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as a clinical hold, FDA refusal to approve a pending New Drug Application (NDA), warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

Pharmaceutical product development for a new product or certain changes to an approved product in the United States typically involves preclinical laboratory and animal tests, the submission to the FDA of an investigational new drug application (IND), which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. 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 product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including good laboratory practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls (CMC), and a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin.

Clinical trials involve the administration of the investigational drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practices (GCPs), which are standards meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors; as

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well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an investigational review board (IRB) for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into patients, the drug is tested to assess safety, dosage tolerance, metabolism, pharmacokinetics, pharmacological actions, side effects associated with drug exposure and, if possible, early evidence on effectiveness. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, determine optimal dose and regimen, and to identify common AEs and safety risks. If a drug demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the safety and efficacy of the drug. A single Phase 3 trial may be sufficient in rare instances, including (1) where the study is a large, multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible or (2) when the single trial is supported by other confirmatory evidence.

The manufacturer of an investigational drug in a Phase 2 or Phase 3 clinical trial for a serious or life-threatening disease is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for expanded access to such investigational drug.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing and distribution of the product may begin in the United States. The NDA must include the results of all preclinical, clinical, and other testing and a compilation of data relating to the product's pharmacology and CMC. The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee. Under an approved NDA, the applicant is also subject to an annual program fee. These fees are typically increased annually.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs. Most applications are classified as Standard Review products that are reviewed within ten months of the date the FDA files the NDA; most applications classified as Priority Review are reviewed within six months of the date the FDA files the NDA. An NDA can be classified for Priority Review when the FDA determines the drug has the potential to treat a serious or life-threatening condition and, if approved, would be a significant improvement in safety or effectiveness compared to available therapies. The review process for both standard and priority reviews may be extended by the FDA for three or more additional months to consider certain late-submitted information or information intended to clarify information already provided in the NDA submission.

The FDA may also refer applications for novel drugs, as well as drugs that 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 NDA should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will generally inspect the facility or the facilities at which the drug is



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manufactured. The FDA will not approve the product unless compliance with current Good Manufacturing Practice (cGMP) is satisfactory.

After the FDA evaluates the NDA and completes any clinical and manufacturing site inspections, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the NDA and may require substantial additional testing, or information, in order for the FDA to reconsider the NDA for approval. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

An approval letter authorizes commercial marketing and distribution of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy (REMS) to help ensure that the benefits of the drug outweigh the potential risks. 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 drug. Moreover, the FDA may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy.

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 NDA, including changes in indications, labeling or manufacturing processes or facilities, require submission 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.

#### *Fast Track Designation and Priority Review*

The FDA is required to facilitate the development, and expedite the review, of drugs that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Fast track designation may be granted for products that are intended to treat a serious or life-threatening disease or condition for which there is no effective treatment and preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to both the product and the specific indication for which it is being studied. Any product submitted to FDA for marketing, including under a fast-track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review.

Priority review may be granted for products that are intended to treat a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies. FDA will attempt to direct additional resources to the evaluation of an application designated for priority review in an effort to facilitate the review.

#### *Disclosure of Clinical Trial Information*

Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information on ClinicalTrials.gov. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

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Under the Pediatric Research Equity Act, NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant full or partial waivers or deferrals for submission of data.

The Best Pharmaceuticals for Children Act (BPCA) provides NDA holders a six-month extension of any exclusivity—patent or nonpatent—for a drug if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

*Post-Approval Requirements*

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling.

AE reporting and submission of periodic reports is required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, drug manufacture, packaging and labeling procedures must continue to conform to cGMP after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMP. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality-control to maintain compliance with cGMP. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

The FDA strictly regulates marketing, labeling, advertising and promotion of drugs that are placed on the market. Advertising and promotion of drugs must be in compliance with the FDCA and its implementing regulations and only for the approved indications and in a manner consistent with the approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities.

*The Hatch-Waxman Amendments**Orange Book Listing*

Under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch Waxman Amendments, NDA applicants are required to identify to FDA each patent whose claims cover the applicant's drug or approved method of using the drug. Upon approval of a drug, the applicant must update its listing of patents to the NDA in timely fashion and each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book.

Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application (ANDA). An ANDA provides for marketing of a drug product that

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has the same active ingredient(s), strength, route of administration and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. An approved ANDA product is considered to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, preclinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved under the ANDA pathway are commonly referred to as “generic equivalents” to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug pursuant to each state’s laws on drug substitution.

The ANDA applicant is required to certify to the FDA concerning any patents identified for the reference listed drug in the Orange Book. Specifically, the applicant must certify to each patent in one of the following ways: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. A certification that the new product will not infringe the already approved product’s listed patents, or that such patents are invalid, is called a Paragraph IV certification. For patents listed that claim an approved method of use, under certain circumstances the ANDA applicant may also elect to submit a section viii statement certifying that its proposed ANDA label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the applicant does not challenge the listed patents through a Paragraph IV certification, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA-holder and patentee(s) once the ANDA has been accepted for filing by the FDA (referred to as the “notice letter”). The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice letter. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months from the date the notice letter is received, expiration of the patent, the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed, or a decision in the patent case that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired. In some instances, an ANDA applicant may receive approval prior to expiration of certain non-patent exclusivity if the applicant seeks, and FDA permits, the omission of such exclusivity-protected information from the ANDA prescribing information.

*Exclusivity*

Upon NDA approval of a new chemical entity (NCE), which is a drug that contains no active moiety that has been approved by FDA in any other NDA, that drug receives five years of marketing exclusivity during which FDA cannot receive any ANDA seeking approval of a generic version of that drug unless the application contains a Paragraph IV certification, in which case the application may be submitted one year prior to expiration of the NCE exclusivity. If there is no listed patent in the Orange Book, there may not be a Paragraph IV certification, and, thus, no ANDA for a generic version of the drug may be filed before the expiration of the exclusivity period.

Certain changes to an approved drug, such as the approval of a new indication, the approval of a new strength, and the approval of a new condition of use, are associated with a three-year period of exclusivity from the date of approval during which FDA cannot approve an ANDA for a generic drug that includes the change. In some instances, an ANDA applicant may receive approval prior to expiration of the three-year exclusivity if the applicant seeks, and FDA permits, the omission of such exclusivity-protected information from the ANDA package insert.

*Patent Term Extension*

The Hatch Waxman Amendments permit a patent term extension as compensation for patent term lost during the FDA regulatory review process. Patent term extension, however, cannot extend the remaining term of a

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patent beyond a total of 14 years from the product's approval date. After NDA approval, owners of relevant drug patents may apply for the extension. The allowable patent term extension is calculated as half of the drug's testing phase (the time between IND application and NDA submission) and all of the review phase (the time between NDA submission and approval) up to a maximum of five years. The time can be reduced for any time FDA determines that the applicant did not pursue approval with due diligence.

The United States Patent and Trademark Office (USPTO) in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. However, the USPTO may not grant an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than requested.

The total patent term after the extension may not exceed 14 years, and only one patent can be extended. The application for the extension must be submitted prior to the expiration of the patent, and for patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the USPTO must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted.

***Other U.S. Regulatory Matters***

Manufacturing, sales, promotion and other activities following drug approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including, in the United States, the Centers for Medicare & Medicaid Services, other divisions of the Department of Health and Human Services, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments. In the United States, the activities of pharmaceutical manufacturers are subject to federal and state laws designed to prevent fraud and abuse in the healthcare industry. The laws generally limit financial interactions between manufacturers and health care providers or other participants in the healthcare industry and/or require disclosure to the government and public of such interactions. Many of these laws and regulations contain ambiguous requirements or require administrative guidance for implementation.

Pharmaceutical manufacturers are also required to provide discounts or rebates under government healthcare programs or to certain government and private purchasers in order to obtain coverage under federal healthcare programs such as Medicaid. Participation in such programs may require tracking and reporting of certain drug prices. Manufacturers are subject to fines and other penalties if such prices are not reported accurately. Drugs must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities are also potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of pharmaceutical drugs is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical drugs.

The failure to comply with regulatory requirements subjects manufacturers to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines, civil monetary or other penalties, injunctions, recall or seizure of drugs, total or partial suspension of production, denial or withdrawal of product approvals, additional regulatory oversight and integrity monitoring, exclusion from participation in government healthcare programs or refusal to allow a firm to enter into supply contracts, including government contracts. In addition, even if a firm complies with FDA and other requirements, new information regarding the safety or efficacy of a product could lead the FDA to modify or withdraw product approval. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

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**Other Healthcare Laws*****Other U.S. Healthcare Laws***

We may also be subject to healthcare regulation and enforcement by the U.S. federal government and the states where we may market our drug candidates, if approved. These laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security and transparency laws, such as the following:

- federal Anti-Kickback Statute, which prohibit, among other things, persons from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- federal false claims laws, including the False Claim Act and the Civil Monetary Penalties Law, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, information or claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent. In addition, a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program (including private health plans) or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the Federal Food, Drug, and Cosmetic Act, which among other things, strictly regulates drug product and medical device marketing, prohibits manufacturers from marketing such products prior to approval or for off-label use and regulates the distribution of samples;
- federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services (CMS) information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, imposes obligations, including mandatory contractual terms, on "covered entities," including certain healthcare providers, health plans, healthcare clearinghouses, and their respective "business associates," and their subcontractors that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; and
- state law equivalents of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payer, including private insurers, state transparency laws, state laws limiting interactions between pharmaceutical manufacturers and members of the healthcare industry, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, and often are not preempted by HIPAA.

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**Coverage and Reimbursement**

Successful sales of our drug candidates in the U.S. market, if approved, will depend, in part, on the extent to which our drugs will be covered by third-party payors, such as government health programs or private health insurance (including managed care plans). Patients who are provided with prescriptions as part of their medical treatment generally rely on such third-party payors to reimburse all or part of the costs associated with their prescriptions and therefore adequate coverage and reimbursement from such third-party payors are critical to new and ongoing product acceptance. Coverage and reimbursement policies for drug products can differ significantly from payor to payor as there is no uniform policy of coverage and reimbursement for drug products among third-party payors in the United States. There may be significant delays in obtaining coverage and reimbursement as the process of determining coverage and reimbursement is often time consuming and costly. Further, third-party payors are increasingly reducing reimbursements for medical drugs and services and implementing measures to control utilization of drugs (such as requiring prior authorization for coverage).

Additionally, the containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic drugs. Adoption or expansion of price controls and cost-containment measures could further limit our net revenue and results. Decreases in third-party reimbursement for our drug candidates, if approved, or a decision by a third-party payor to not cover our drug candidates could have a material adverse effect on our sales, results of operations and financial condition.

General legislative cost control measures may also affect reimbursement for our products. If we obtain approval to market a drug candidate in the United States, we may be subject to spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs and/or any significant taxes or fees.

**U.S. Health Care Reform**

The United States government, state legislatures, and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price-controls, restrictions on reimbursement, and requirements for substitution of generic products for branded prescription drugs. For example, in March 2010, the Affordable Care Act (the ACA) was passed which substantially changed the way healthcare is financed by both the government and private insurers and continues to significantly impact the U.S. pharmaceutical industry.

Several healthcare reform proposals recently culminated in the enactment of the Inflation Reduction Act (IRA) in August 2022, which, among other things, allows the Department of Health and Human Services (HHS) to directly negotiate the selling price of a statutorily specified number of drugs and biologics each year that CMS reimburses under Medicare Part B and Part D. Only high-expenditure single-source drugs that have been approved for at least 7 years (11 years for biologics) can be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. Negotiations for Medicare Part D products take place in 2024 with the negotiated price taking effect in 2026, and negotiations for Medicare Part B products will begin in 2026 with the negotiated price taking effect in 2028. In August 2023, HHS announced the ten Medicare Part D drugs and biologics that it selected for negotiations. HHS will announce the negotiated maximum fair prices by September 1, 2024, and this price cap, which cannot exceed a statutory ceiling price, will go into effect on January 1, 2026. A drug or biological product that has an orphan drug designation for only one rare disease or condition will be excluded from the IRA's price negotiation requirements, but will lose that exclusion if it receives designations for more than one rare disease or condition, or if is approved for an indication that is not within that single designated rare disease or condition, unless such additional designation or such disqualifying approvals are withdrawn by the time CMS evaluates the drug for selection for negotiation. The IRA also imposes rebates on Medicare Part B and Part D drugs whose prices have increased at a rate greater than the rate of inflation. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including significant civil monetary penalties. These provisions have been and may continue to be subject to legal challenges. For

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example, the provisions related to the negotiation of selling prices of high-expenditure single-source drugs and biologics have been challenged in multiple lawsuits brought by pharmaceutical manufacturers. Thus, while it is unclear how the IRA will be implemented, it will likely have a significant impact on the biopharmaceutical industry and the pricing of prescription drug products.

#### **Employees and Human Capital Resources**

As of March 31, 2024, we had 107 full-time employees and 2 part-time employees, consisting of clinical, scientific, development, regulatory, finance and operational personnel. None of our employees is subject to a collective bargaining agreement. We consider our relationship with our employees to be good.

We recognize that our culture is central to the productivity, agility, scalability and competitiveness of our operation, and is essential to our success. We are clear and consistent in our company values and we communicate and support an employee value proposition. Our proposition is centered with unique and impactful professional development opportunities within an environment of inclusive representation and diverse thinking as a unifying force and business differentiator. 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:* Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards.
- *Health and safety:* We support the health and safety of our employees by providing comprehensive insurance benefits, an employee assistance program, company-paid holidays, a personal time-off program and other additional benefits which are intended to assist employees to manage their well-being.
- *Inclusion and diversity:* We are committed to efforts to increase diversity and foster an inclusive work environment that supports our workforce.

#### **Facilities**

Our principal executive office is located in South San Francisco, California. We entered into the lease for our principal executive office in August 2022, for approximately 55,000 square feet of combined office and laboratory space in South San Francisco, which will expire in August 2033. We believe our facilities are adequate and suitable for our current needs, and that should it be needed, suitable additional or alternative space will be available to accommodate our operations.

#### **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. 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.

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**MANAGEMENT**

**Executive Officers and Directors**

The following table sets forth information regarding our executive officers and directors as of March 31, 2024.

<u>Name</u>	<u>Age</u>	<u>Position</u>
<i>Executive Officers:</i>		
Martin Babler	59	President and Chief Executive Officer, Chairman
Mark Bradley	59	Chief Development Officer
Jörn Drappa, M.D., Ph.D.	59	Chief Medical Officer
David M. Goldstein, Ph.D.	58	Chief Scientific Officer
Roy Hardiman	64	Chief Business and Legal Officer
John Schroer	58	Chief Financial Officer
Sara Klein	60	General Counsel
Derrick Richardson	53	Senior Vice President of People and Culture
<i>Non-Employee Directors:</i>		
Julian C. Baker	57	Director
Alan B. Colowick, M.D., M.P.H.	61	Director
Sapna Srivastava	53	Director
James B. Tananbaum, M.D.	60	Director
Zhengbin Yao, Ph.D.	58	Director
Srinivas Akkaraju, M.D., Ph.D.	56	Director
Richard Gaster, M.D., Ph.D.	39	Director

**Executive Officers**

**Martin Babler** has served as our President, Chief Executive, and chairman of our board of directors since September 2021. From April 2011 until November 2020, he served as President and Chief Executive Officer at Principia Biopharma Inc., a biotechnology company acquired by Sanofi S.A. in September 2020. From December 2007 to April 2011, Mr. Babler served as President and Chief Executive Officer of Talima Therapeutics, Inc., a pharmaceutical company. From 1998 to 2007, Mr. Babler held several positions at Genentech, Inc., a biopharmaceutical company, most notably as Vice President, Immunology Sales and Marketing. Mr. Babler presently serves on the board of directors of Prelude Therapeutics Inc., a biopharmaceutical company, and Sardona Therapeutics, Inc. Mr. Babler received a Swiss Federal Diploma in pharmacy from the Federal Institute of Technology in Zurich and completed the Executive Development Program at the Kellogg Graduate School of Management at Northwestern University. We believe that Mr. Babler's industry and leadership roles, and his knowledge of our company as Chief Executive Officer, makes him well qualified to serve on our board of directors.

**Mark Bradley** has served as our Chief Development Officer since May 2021. From November 2020 to March 2021, Mr. Bradley served as Senior Vice President and Site Head at The Bristol-Myers Squibb Company, a biopharmaceutical company, after its acquisition of MyoKardia, Inc., a precision medicine company focused on treating cardiovascular diseases, in November 2020. From November 2017 to November 2020, Mr. Bradley held roles of increasing responsibility at MyoKardia, most recently as Senior Vice President, Development. From 2004 to 2017, Mr. Bradley held roles of increasing responsibility at Genentech, Inc., a biopharmaceutical company, most recently as Head, Business Management gRED Clinical Operations. Mr. Bradley began his career at UCSF in public health research. Mr. Bradley received an M.A. and B.A. from University of California, Berkeley.

**Jörn Drappa, M.D., Ph.D.**, has served as our Chief Medical Officer and Head of Research and Development since September 2022. From February 2018 to March 2021, Dr. Drappa served as the Chief Medical Officer



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and Head of Research and Development at Viela Bio, Inc., a biotechnology company. From May 2011 to February 2018, Dr. Drappa served in various roles at MedImmune, the biologics division of AstraZeneca plc, including as Vice President of Clinical Development. From August 2008 to May 2011, Dr. Drappa served as Senior Medical Director for the Inflammation and Autoimmune assets at Genentech, Inc., a biopharmaceutical company. Dr. Drappa received his M.D. and a Ph.D. from the University of Cologne in Germany. He performed his postgraduate studies at Cornell Medical School/Hospital for Special Surgery, followed by residency at New York Hospital and rheumatology fellowship at the Hospital for Special Surgery.

**David M. Goldstein, Ph.D.**, has served as our Chief Scientific Officer since September 2021. From September 2020 to September 2021, Dr. Goldstein served as Site Head and Chief Scientific Officer of Principia Biopharma Inc., a biopharmaceutical company acquired by Sanofi S.A. in September 2020. From March 2016 to September 2020, Dr. Goldstein served in various roles at Principia Biopharma Inc., including as the Chief Scientific Officer from March 2016 to September 2020. From July 1994 to February 2011, Dr. Goldstein held positions of increasing responsibility at Roche Holding AG, a pharmaceutical company, most recently serving as Senior Director, Medicinal Chemistry and Head of Inflammation Chemistry. Dr. Goldstein was also previously a Consulting Assistant Professor at Stanford University. Dr. Goldstein received a Ph.D. in chemistry from the University of Virginia and a B.A. in chemistry from Franklin and Marshall College.

**Roy Hardiman** has served as our Chief Business and Legal Officer since September 2021. From January 2015 to September 2020, Mr. Hardiman served as the Chief Business Officer of Principia Biopharma Inc., a biotechnology company acquired by Sanofi S.A. in 2020. From 2010 to 2012, Mr. Hardiman was a director of Pharmacyclics Inc., a biopharmaceutical company, and chaired the Nominating and Corporate Governance Committee of Pharmacyclics. From 1990 to 2009, Mr. Hardiman held leadership positions at Genentech, Inc., a biopharmaceutical company, including Vice President of Alliance Management, Vice President, Corporate Law and Assistant Secretary, Director and Far East Representative, Business Development. From 1987 to 1990, Mr. Hardiman was an attorney at Morrison & Foerster LLP. Mr. Hardiman received his J.D. from University of California, Los Angeles School of Law, his M.A. in Biology and his B.A. in pharmacology from University of California, Santa Barbara. Mr. Hardiman serves on the Board of Trustees of the University of California, Santa Barbara Foundation.

**John Schroer** has served as our Chief Financial Officer since May 2022. From February 2021 to February 2022, Mr. Schroer served as Chief Financial Officer at ArsenalBio Inc., a biotechnology company. From May 2018 to December 2020, Mr. Schroer served as Chief Financial Officer and Treasurer at Translate Bio, Inc., a biotechnology company acquired by Sanofi S.A. in 2021. From January 2014 to April 2018, Mr. Schroer served as a director and sector head—healthcare at Allianz Global Investors, a global asset management company. From 2009 to December 2013, Mr. Schroer served as President and Chief Investment Officer at Schroer Capital, LP, a financial services company that he founded. Mr. Schroer received a B.S. in History and International Relations and an M.B.A. from the University of Wisconsin-Madison.

**Sara Klein** has served as our General Counsel and Corporate Secretary since January 2022. Prior to joining us, Ms. Klein served in various roles at Principia Biopharma Inc., a biotechnology company acquired by Sanofi S.A. in September 2020, including Head of Legal from January 2021 to July 2021, Senior Vice President, Legal from December 2019 to January 2021, and Vice President, Legal from May 2018 to December 2019. From November 2001 to May 2018, Ms. Klein was in the private practice of law representing life science and technology companies. From 1993 to 1998, Ms. Klein served as corporate counsel and senior corporate counsel at Genentech, Inc., a biopharmaceutical company. From 1990 to 1993, Ms. Klein was an attorney at the law firm of Baker & McKenzie LLP. Ms. Klein holds a J.D. from U.C. Hastings College of the Law and a B.A. in political science and French from Middlebury College.

**Derrick Richardson** has served as our Senior Vice President of People and Culture since June 2023. From April 2023 to June 2023, Mr. Richardson served as our Vice President of People and Culture. From January 2022 to April 2023, Mr. Richardson served as our Vice President and Head of Program and Portfolio Management. From November 2020 to December 2021, Mr. Richardson served as the Head of Cardiovascular Late-Stage Project Management at The Bristol-Myers Squibb Company, a biopharmaceutical company, after its acquisition of MyoKardia, Inc., a precision medicine company focused on treating cardiovascular diseases, in November 2020. From April 2020 to November 2020, Mr. Richardson served as Executive Director and Head of Project Management at MyoKardia, and consulted for MyoKardia from October 2018 to April 2020. From February 2016 to October 2018, Mr. Richardson served as a Consulting Project Manager at Genentech,

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Inc. Mr. Richardson received an M.S. in Mechanical Engineering from Cornell University and a B.S. in Product Design Engineering from Stanford University.

**Non-Employee Directors**

**Srinivas Akkaraju, M.D., Ph.D.** has served as a member of our board of directors since March 2024. Dr. Akkaraju is a founder and managing member of Samsara BioCapital, a venture capital firm, a position he has held since March 2017. From April 2013 to February 2016, Dr. Akkaraju served as a general partner of Sofinnova Ventures, a venture capital firm. From January 2009 to April 2013, Dr. Akkaraju served as managing director of New Leaf Venture Partners, a venture capital firm. Dr. Akkaraju presently serves on the board of directors of vTv Therapeutics Inc., Scholar Rock Holding Corporation, Mineralys Therapeutics, Inc., and Syros Pharmaceuticals, Inc., and numerous private biopharmaceutical companies. During the past five years, he served as a director of Chinook Therapeutics, Inc., Jiya Acquisition Corp., Aravive, Inc. (formerly Versartis, Inc.), Intercept Pharmaceuticals, Inc., Principia Biopharma Inc., and Seattle Genetics, Inc. Dr. Akkaraju received an M.D. and a Ph.D. in Immunology from Stanford University and undergraduate degrees in Biochemistry and Computer Science from Rice University. We believe that Dr. Akkaraju's extensive investment experience in the biopharmaceutical industry, as well as his scientific background and experience on numerous public and private company boards of directors make him well qualified to serve as a member of our board of directors.

**Julian C. Baker** has served as a member of our board of directors since January 2022. Since 2000, Mr. Baker has been a Managing Member of Baker Bros. Advisors LP, a biotechnology-focused investment adviser to fund partnerships whose investors are primarily endowments and foundations, which Mr. Baker founded together with his brother, Felix Baker, in 2000. From 1994 to 1999, Mr. Baker was a portfolio manager at Tisch Financial Management. From 1988 to 1993, Mr. Baker was employed by the private equity investment arm of Credit Suisse First Boston Corporation. Mr. Baker currently serves on the boards of directors of Incyte Corporation, a public pharmaceuticals company, Acadia Pharmaceuticals, Inc., a public biopharmaceutical company, Prelude Therapeutics, Inc., a private biopharmaceutical company, Everyone Medicines Inc., a private biotechnology company, and Madrigal Pharmaceuticals, Inc., a public biopharmaceutical company. Mr. Baker holds an A.B. from Harvard University. We believe that Mr. Baker's extensive experience in the biotechnology industry and experience working with and serving on the boards of directors of numerous biotechnology and pharmaceutical companies make him well qualified to serve as a member of our board of directors.

**Alan B. Colowick, M.D., M.P.H.** has served as a member of our board of directors since January 2022. Since April 2021, Dr. Colowick has served as the Senior Managing Director of Matrix Capital Management Company. From May 2017 to January 2021, Dr. Colowick served as a private equity partner at Sofinnova Ventures. From 2010 to 2017, Dr. Colowick held various positions at Celgene Corporation, a pharmaceutical company, including Executive Vice President. From 2008 to 2010, Dr. Colowick was the Chief Executive Officer at Gloucester Pharmaceuticals, Inc., a pharmaceutical company, until its acquisition by Celgene in 2010. From 2006 to 2008, Dr. Colowick was President of Oncology for Geron Corporation, a biotechnology company, and from 2005 to 2006 was Chief Medical Officer of Threshold Pharmaceuticals, a pharmaceutical company. From 1999 to 2005, Dr. Colowick held various positions at Amgen Inc., a biopharmaceutical company. Dr. Colowick also serves as a member on the board of directors of ACELYRIN, INC. since November 2021 and multiple private companies. Dr. Colowick completed specialty training in Hematology-Oncology at the Dana Farber Cancer Institute/Brigham and Women's Hospital. Dr. Colowick received a M.D. from Stanford University, a M.P.H from Harvard University, and a B.S. in Molecular Biology from the University of Colorado. We believe that Dr. Colowick's extensive professional experience, as well as financial understanding of the biotechnology industry, provide him with the qualifications and skills to serve as a member of our board of directors.

**Richard Gaster, M.D., Ph.D.** has served as a member of our board of directors since March 2024. From April 2017 to the present, Dr. Gaster has served as the Managing Partner of venBio Partners LLC, a venture capital firm. Dr. Gaster serves on the board of directors of NorthSea Therapeutics B.V., since January 2020, Aeovian Pharmaceuticals Inc., since October 2019, Arrakis Therapeutics, Inc., since April 2019, Entact Bio Ltd, since November 2021, and 35 Pharma Inc., since December 2022. Dr. Gaster also served on the board of directors of Pharvaris N.V. from June 2019 to January 2021, Stargazer from April 2020 to March 2022,

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Acelyrin, Inc. from October until December 2022, Elevation Oncology, Inc. from November 2020 to January 2022 and Ventyx Biosciences, Inc. from March 2021 to January 2023. Prior to joining venBio Partners, Dr. Gaster served as the head of translational medicine at Pliant Therapeutics, Inc. from February 2016 to April 2017. Dr. Gaster began his career as a resident physician in Harvard's Plastic and Reconstructive Surgery Program in 2013. Dr. Gaster holds a BSE in Bioengineering from the University of Pennsylvania, where he graduated summa cum laude. Dr. Gaster received his M.D. and Ph.D. in Bioengineering from Stanford University in the Medical Scientist Training Program. We believe that Dr. Gaster's experience in the biopharmaceutical industry as a physician, entrepreneur, and life sciences investor and his service on the boards of directors of other biopharmaceutical companies make him well qualified to serve as a member of our board of directors.

**Sapna Srivastava, Ph.D.** has served as a member of our board of directors since August 2022. From March 2021 to October 2021, Dr. Srivastava served as the interim Chief Financial Officer at eGenesis, Inc., a biopharmaceutical company. From September 2017 to January 2019, Dr. Srivastava served as the Chief Financial and Strategy Officer at Abide Therapeutics, Inc., a biopharmaceutical company acquired by H. Lundbeck A/S in 2019. From April 2015 to December 2016, Dr. Srivastava served as the Chief Financial and Strategy Officer at Intellia Therapeutics, Inc., a gene editing company. Previously, for nearly 15 years, Dr. Srivastava was a senior biotechnology analyst at Goldman Sachs, Morgan Stanley, and ThinkEquity Partners, LLC. Dr. Srivastava began her career as a research associate at JP Morgan. Dr. Srivastava currently serves on the board of directors of Tourmaline Bio, Inc., Aura Biosciences, Inc., a public biotechnology company, Innoviva, Inc. and Nuvalent, Inc., a public biopharmaceutical company. Dr. Srivastava holds a Ph.D. from New York University School of Medicine and a B.Sc. from St. Xavier's College, University of Bombay. We believe that Dr. Srivastava's experience in the pharmaceutical industry makes her well qualified to serve as a member of our board of directors.

**James B. Tananbaum, M.D.** has served as a member of our board of directors since May 2021. Dr. Tananbaum is currently the President, Chief Executive Officer and a director of Foresite Capital Management, a U.S.-focused healthcare investment firm, which he founded in 2010. From 2000 to 2010, Dr. Tananbaum served as Co-Founder and Managing Director of Prospect Venture Partners L.P. II and III, healthcare venture partnerships. Dr. Tananbaum was also the Founder of GelTex, Inc. in 1991, an intestinal medicine pharmaceutical company acquired by Sanofi-Genzyme, and Theravance, Inc. in 1997 (now Theravance Biopharma, Inc., a diversified biopharmaceutical company focused on organ-selective medicines, and Innoviva, Inc., a respiratory-focused healthcare asset management company partnered with Glaxo Group Limited). Dr. Tananbaum presently serves on the board of directors of Kinnate Biopharma Inc., Pardes Biosciences, Inc. and Fabric Genomics, Inc., among other companies. During the past five years, Dr. Tananbaum served on the boards of directors of Quantum-SI Incorporate, Gemini Therapeutics, Inc., 10X Genomics, Inc., among other companies. Dr. Tananbaum received an M.D. and an M.B.A. from Harvard University, and a B.S. and a B.S.E.E. from Yale University in Applied Math and Computer Science. We believe Dr. Tananbaum's significant executive leadership experience and experience in the healthcare industry make him well qualified to serve as a member of our board of directors.

**Zhengbin (Bing) Yao, Ph.D.** has served as a member of our board of directors since June 2021. From May 2021 to the present, Dr. Yao served as the Chief Executive Officer and chairman of the board of directors of ArriVent Biopharma, a biotechnology company. From March 2018 to March 2021, Dr. Yao served as the Chief Executive Officer, President, and from January 2019 to March 2021 also as chairman of the board of directors of Viela Bio, Inc., a biotechnology company, until it was acquired by Horizon Therapeutics in March 2021. From October 2010 to February 2018, Dr. Yao served as Senior Vice President, Head of Respiratory, Inflammation, Autoimmune iMED at MedImmune, the biologics division of AstraZeneca plc and from October 2015 to February 2018 also as Senior Vice President, Head of Immunology Oncology Franchise. From March 2008 to September 2010, Dr. Yao served as Head of PTL for Immunology, Infectious Diseases, Neuroscience, and Metabolic Disease at Genentech, Inc., a biopharmaceutical company. From October 2000 to September 2007, Dr. Yao held various leadership roles at Tanox Inc., a biopharmaceutical company, and was Vice President and Head of Research before it was acquired by Genentech, Inc. in 2007. Dr. Yao currently serves on the board of directors of NexImmune, Inc., a biopharmaceutical company. Dr. Yao received his Ph.D. in Microbiology and Immunology from the University of Iowa and M.S. in Immunology from Anhui Medical University in Anhui, China. We believe Dr. Yao's significant experience in the biopharmaceutical

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industry, particularly in autoimmune disease, and his experience serving as a chief executive officer of a publicly traded biotechnology company make him well qualified to serve as a member of our board of directors.

### **Composition of Our Board of Directors**

Our business and affairs are organized under the direction of our board of directors, which currently consists of nine members, including one vacancy. The primary responsibilities of our board of directors are to provide oversight, strategic guidance, counseling and direction to our management. Our board of directors meets on a regular basis and additionally as required.

Certain members of our board of directors were elected under the provisions of our Amended and Restated Voting Agreement entered into in March 2024 (the Voting Agreement), which will terminate upon the closing of this offering. Under the terms of our Voting Agreement, the stockholders who are party to the Voting Agreement have agreed to vote their respective shares to elect: (i) one director designated by Matrix Capital Management Master Fund, LP and its affiliates, currently Alan Colowick, M.D., M.P.H.; (ii) one director designated by BBA and its affiliates, currently Julian C. Baker; (iii) one director designated by Foresite Capital Fund V, L.P. and its affiliates (collectively Foresite Capital Management), currently James B. Tananbaum, M.D.; (iv) one director designated by venBio Global Strategic Fund Four, L.P. and its affiliates, currently Richard Gaster, M.D., Ph.D.; (v) one director designated by Samsara BioCapital, LP, currently Srinivas Akkaraju M.D., Ph.D.; (vi) one director who shall be our then-current Chief Executive Officer, currently Martin Babler; and (vii) three directors who are not our employees or affiliates, with such individuals to be designated by mutual agreement of our board of directors, currently persons who are not otherwise our affiliates or of any investor who are mutually acceptable to a majority of the directors then-serving as members of our board of directors; which individuals currently are Zhengbin (Bing) Yao, Ph.D, Sapna Srivasta, Ph.D and one vacancy. The Voting Agreement will terminate upon the closing of this offering, and upon the closing of the offering no stockholder will have any special rights regarding the election or designation of the members of our board of directors. Our current directors elected pursuant to the Voting Agreement will continue to serve as directors until their successors are duly elected and qualified by holders of our common stock. Our board of directors may establish the authorized number of directors from time to time by resolution. In accordance with our amended and restated certificate of incorporation to be filed in connection with this offering, immediately after this offering, our board of directors will be divided into three classes with staggered three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors will be divided among the three classes as follows:

- the Class I directors will be \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_, and their terms will expire at the annual meeting of stockholders to be held in 2024;
- the Class II directors will be \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_, and their terms will expire at the annual meeting of stockholders to be held in 2025; and
- the Class III directors will be \_\_\_\_\_ 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 requirements and rules of The Nasdaq Stock Market LLC (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 none of our directors, other than \_\_\_\_\_, has any

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relationship 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 Martin Babler, by virtue of his position as our Chairman and Chief Executive Officer, is not independent under applicable rules and regulations of the U.S. Securities and Exchange Commission (the SEC) and the Nasdaq Listing Rules. In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our shares by each non-employee director and the transactions described in the section titled “Certain Relationships and Related Person Transactions.”

**Committees of Our Board of Directors**

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

***Audit Committee***

Our audit committee currently consists of \_\_\_\_\_, \_\_\_\_\_, and \_\_\_\_\_, each of whom our board of directors has determined satisfies the independence requirements under the Nasdaq Listing Rules and Rule 10A-3(b)(1) of the Securities Exchange Act of 1934, as amended (Exchange Act). The chair of our audit committee is \_\_\_\_\_, 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, the 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 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;
- 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 currently consists of \_\_\_\_\_ and \_\_\_\_\_. The chair of our compensation committee is \_\_\_\_\_. Our board of directors has determined that each member of our compensation committee is independent under the Nasdaq Listing Rules.

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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 and directors. Specific responsibilities of our compensation committee include:

- reviewing and approving the compensation of our chief executive officer, other executive officers and senior management;
- reviewing and recommending to our board of directors the compensation paid to our directors;
- reviewing and approving the compensation arrangements with our executive officers and other senior management;
- administering our equity incentive plans and other benefit programs;
- reviewing, adopting, amending and terminating, incentive compensation and equity plans, severance agreements, profit sharing plans, bonus plans, change-of-control protections and any other compensatory arrangements for our executive officers and other senior management;
- reviewing, evaluating and recommending to our board of directors succession plans for our executive officers; and
- reviewing and establishing general policies relating to compensation and benefits of our employees, including our overall compensation strategy, including base salary, incentive compensation and equity based grants, to assure that it promotes stockholder interests and supports our strategic and tactical objectives, and that it provides for appropriate rewards and incentives for our management and employees.

***Nominating and Corporate Governance Committee***

Our nominating and corporate governance committee consists of \_\_\_\_\_ and \_\_\_\_\_. The chair of our nominating and corporate governance committee is \_\_\_\_\_. Our board of directors has determined that each member of the nominating and corporate governance committee is independent under the Nasdaq Listing Rules.

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**

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

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**Compensation Committee Interlocks and Insider Participation**

None of the members of the compensation committee is currently, or has been at any time, one of our executive officers or employees. None of our executive officers currently serves, or has served during the last 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 presents the compensation awarded to or earned by or paid to all individuals who served as non-employee directors during the year ended December 31, 2023.

Name	Fees Earned or Paid in Cash (\$)	Option Awards (\$) <sup>(1)</sup>	Total (\$)
Julian C. Baker	—	—	—
Alan Colowick, M.D., M.P.H.	—	—	—
Sapna Srivastava, Ph.D	—	—	—
James B. Tananbaum, M.D.	—	—	—
Zhengbin Yao, Ph.D.	—	—	—

(1) As of December 31, 2023, the aggregate number of shares underlying outstanding options to purchase shares of our Class A common stock held by our non-employee directors were: Dr. Srivastava, 140,000, and Dr. Yao, 20,000. None of our other non-employee directors held options to purchase shares of our Class A common stock as of December 31, 2023. With the exception of Dr. Yao, who held 18,334 shares of our Class A common stock subject to repurchase, none of our other non-employee directors held unvested stock awards as of December 31, 2023.

Mr. Babler also served on our board of directors during the year ended December 31, 2023, but did not receive any additional compensation for his service as a director. See the section titled “Executive Compensation” for more information regarding the compensation earned by Mr. Babler.

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

We intend to adopt a non-employee director compensation policy, pursuant to which our non-employee directors will be eligible to receive compensation for service on our board of directors and committees of our board of directors, to be effective following the completion of this offering.

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**EXECUTIVE COMPENSATION**

Our named executive officers for the year ended December 31, 2023 were:

- Martin Babler, our President, Chief Executive Officer and Chairman of the Board;
- David Goldstein, Ph.D., our Chief Scientific Officer; and
- Roy Hardiman, our Chief Business and Legal Officer.

This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations, and determinations regarding future compensation programs. Actual compensation programs that we adopt following the closing of this offering may differ materially from the currently planned programs summarized in this discussion.

**Emerging Growth Company Status**

We are an “emerging growth company,” as defined in the JOBS Act. As an emerging growth company we will be exempt from certain requirements related to executive compensation, including the requirements to hold a nonbinding advisory vote on executive compensation and to provide information relating to the ratio of total compensation of our chief executive officer to the median of the annual total compensation of all of our employees, each as required by the Investor Protection and Securities Reform Act of 2010, which is part of the Dodd-Frank Wall Street Reform and Consumer Protection Act (the “Dodd-Frank Act”).

**Summary Compensation Table**

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

Name and Principal Position	Year	Salary (\$)	Option Awards (\$) <sup>(1)</sup>	Non-Equity Incentive Plan Compensation (\$) <sup>(2)</sup>	Total (\$)
Martin Babler <i>President, Chief Executive Officer and Director</i>	2023	516,000	4,823,957	185,760	5,525,717
David Goldstein, Ph.D. <i>Chief Scientific Officer</i>	2023	380,000	678,561	119,700	1,178,261
Roy Hardiman <i>Chief Business and Legal Officer</i>	2023	380,000	678,561	119,700	1,178,261

(1) Amounts reflect the aggregate grant-date fair value of option awards granted during 2023 computed in accordance with FASB ASC Topic 718, rather than the actual economic value that may be realized by the named executive officer. See Note 10 to our consolidated financial statements included elsewhere in this prospectus for a discussion of the assumptions used in the calculation. All of the option awards were granted under the 2021 Plan, the terms of which plan are described in the subsection titled “—Equity Benefit Plans—2021 Stock Plan” below.

(2) The amounts disclosed represent performance bonuses earned in 2023 and paid in 2024. For more information, see the description of the annual performance bonuses in the subsection titled “—Narrative to the Summary Compensation Table—Annual Performance Bonus Opportunity” below.

**Narrative to the Summary Compensation Table**

Historically, our board of directors has been responsible for overseeing all aspects of our executive compensation programs. In making compensation determinations, we consider compensation for comparable positions in the market, the historical compensation levels of our executives, individual performance as compared to our expectations and objectives, our desire to motivate our employees to achieve short- and long-term results that are in the best interests of our stockholders and a long-term commitment to our company.

Our board of directors has historically determined our executive officers’ compensation and has typically reviewed and discussed management’s proposed compensation with our chief executive officer for all



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executives other than our chief executive officer. Based on those discussions and its discretion, our board of directors has then approved the compensation of each executive officer.

***Annual Base Salary***

Base salaries for our executive officers are initially established through arm’s-length negotiations at the time of the executive officer’s hiring, taking into account such named 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, and adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance and experience.

The 2023 annual base salaries for our named executive officers are set forth in the table below.

<u>Name</u>	<u>2023 Base Salary (\$)</u>
Martin Babler <sup>(1)</sup>	516,000
David Goldstein, Ph.D. <sup>(2)</sup>	380,000
Roy Hardiman <sup>(3)</sup>	380,000

(1) Mr. Babler’s base salary increased from \$516,000 to \$550,800 effective January 2024.

(2) Dr. Goldstein’s base salary increased from \$380,000 to \$424,400 effective January 2024.

(3) Mr. Hardiman’s base salary increased from \$380,000 to \$423,600 effective January 2024.

***Annual Performance Bonus Opportunity***

Our executive officers are eligible to earn an annual incentive bonus of up to a percentage of such executive officer’s annual base salary, based on the achievement of pre-established performance objectives determined by our board of directors.

For 2023, each of Mr. Babler, Dr. Goldstein and Mr. Hardiman was eligible to receive a target bonus equal to 40%, 35%, and 35% of their base salary, respectively, based on the achievement of certain corporate goals and the respective executive officer’s contributions toward such goals. In February 2024, our board of directors determined that the 2023 corporate goals were achieved at 90%. As a result, our board of directors approved annual performance bonuses for Mr. Babler, Dr. Goldstein and Mr. Hardiman in the amounts of \$185,760, \$119,700 and \$119,700, respectively, as reported in the “Non-Equity Incentive Plan Compensation” column of the Summary Compensation Table above.

***Equity-Based Incentive Awards***

Our equity award program is the primary vehicle for offering long-term incentives to our executive officers. We believe that equity awards provide our executives with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executives and our stockholders. To date, we have used stock option grants and restricted stock awards for this purpose because we believe they are an effective means by which to align the long-term interests of our executive officers with those of our stockholders. We believe that our equity awards are an important retention tool for our executive officers, as well as for our other employees. Grants to our executive officers and other employees are made at the discretion of our board of directors and are not made at any specific time period during a year.

In June 2023, we granted each of Mr. Babler, Dr. Goldstein and Mr. Hardiman an option to purchase 1,230,000 shares, 70,000 shares and 70,000 shares, respectively, of our Class A common stock. Each option has an exercise price of \$2.27 per share and is subject to a four-year vesting schedule, with 25% of the shares vesting in May 2024 on the first anniversary of the vesting commencement date and the balance vesting monthly over 36 months thereafter, subject to the executive officer’s continued service with us. Additionally, in October 2023 we granted each of Mr. Babler, Dr. Goldstein and Mr. Hardiman an option to purchase 500,357 shares, 143,256 shares and 143,256 shares, respectively, of our Class A common stock. Each option has an exercise price of \$3.73 per share and is subject to a four-year vesting schedule, with 25% of the shares vesting

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in October 2024 on the first anniversary of the vesting commencement date and the balance vesting monthly over 36 months thereafter, subject to the executive officer's continued service with us. The options granted to our named executive officers in 2023 are eligible for accelerated vesting under specified circumstances. Please see the subsection titled "—Potential Payments and Benefits upon Termination or Change in Control" below for a description of such potential acceleration.

**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.

Name	Option Awards <sup>(1)</sup>				Stock Awards <sup>(1)</sup>	
	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price Per Share (\$)	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 (\$) <sup>(2)</sup>
Martin Babler	1,780,487 <sup>(3)</sup>	—	0.82	9/14/2031	—	—
	500,000 <sup>(4)</sup>	—	1.98	1/26/2032	—	—
	2,500,000 <sup>(5)</sup>	—	1.98	1/26/2032	—	—
	1,230,000 <sup>(6)</sup>	—	2.27	6/22/2033	—	—
	500,357 <sup>(7)</sup>	—	3.73	10/8/2033	—	—
David Goldstein, Ph.D.	200,000 <sup>(8)</sup>	—	1.98	1/26/2032	—	—
	800,000 <sup>(9)</sup>	—	1.98	1/26/2032	—	—
	56,000 <sup>(10)</sup>	—	2.27	6/22/2033	—	—
	143,256 <sup>(11)</sup>	—	3.73	10/8/2033	—	—
	—	—	—	—	437,500 <sup>(12)</sup>	1,631,875
Roy Hardiman	200,000 <sup>(13)</sup>	—	1.98	1/26/2032	—	—
	710,000 <sup>(14)</sup>	—	1.98	1/26/2032	—	—
	70,000 <sup>(15)</sup>	—	2.27	6/22/2033	—	—
	143,256 <sup>(16)</sup>	—	3.73	10/8/2033	—	—
	—	—	—	—	437,500 <sup>(17)</sup>	1,631,875

- (1) All of the option and stock awards were granted under the 2021 Plan, the terms of which plan are described in the subsection titled "—Equity Benefit Plans—2021 Stock Plan" below. Each award covers shares of our Class A Common Stock. These awards are subject to 50% acceleration upon change in control (as defined below) and 100% acceleration upon a termination within 12 months following a change in control.
- (2) Amounts are calculated by multiplying the number of shares shown in the table by \$3.73, the fair market value of our Class A Common Stock as of December 31, 2023, as determined by our board of directors.
- (3) Stock option award vests over a period of four years with 25% of the shares underlying the option vesting on the one year anniversary of the September 15, 2021 vesting commencement date and 1/48th of the shares underlying the option vesting on a monthly basis thereafter, subject to continued service through each vesting date. The option award includes an early exercise feature.
- (4) Stock option award vests over a period of four years with 25% of the shares underlying the option vesting on the one year anniversary of the January 27, 2022 vesting commencement date and 1/48th of the shares underlying the option vesting on a monthly basis thereafter, subject to continued service through each vesting date. The option award includes an early exercise feature.
- (5) Stock option award vests over a period of six years with 1/3rd of the shares underlying the option vesting on the two year anniversary of the January 27, 2022 vesting commencement date and 1/48th of the remaining shares underlying the option vesting on a monthly basis thereafter, subject to continued service through each vesting date. The option award includes an early exercise feature.
- (6) Stock option award vests over a period of four years with 25% of the shares underlying the option vesting on the one year anniversary of the May 22, 2023 vesting commencement date and 1/48th of the shares underlying the option vesting on a monthly basis thereafter, subject to continued service through each vesting date. The option award includes an early exercise feature.

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- (7) Stock option award vests over a period of four years with 25% of the shares underlying the option vesting on the one year anniversary of the October 9, 2023 vesting commencement date and 1/48th of the shares underlying the option vesting on a monthly basis thereafter, subject to continued service through each vesting date. The option award includes an early exercise feature.
- (8) Stock option award vests over a period of four years with 25% of the shares underlying the option vesting on the one year anniversary of the January 27, 2022 vesting commencement date and 1/48th of the shares underlying the option vesting on a monthly basis thereafter, subject to continued service through each vesting date. The option award includes an early exercise feature.
- (9) Stock option award vests over a period of six years with 1/3rd of the shares underlying the option vesting on the two year anniversary of the January 27, 2022 vesting commencement date and 1/48th of the remaining shares underlying the option vesting on a monthly basis thereafter, subject to continued service through each vesting date. The option award includes an early exercise feature.
- (10) Stock option award vests over a period of four years with 25% of the shares underlying the option vesting on the one year anniversary of the May 22, 2023 vesting commencement date and 1/48th of the shares underlying the option vesting on a monthly basis thereafter, subject to continued service through each vesting date. The option award includes an early exercise feature.
- (11) Stock option award vests over a period of four years with 25% of the shares underlying the option vesting on the one year anniversary of the October 9, 2023 vesting commencement date and 1/48th of the shares underlying the option vesting on a monthly basis thereafter, subject to continued service through each vesting date. The option award includes an early exercise feature.
- (12) Represents restricted stock obtained on October 22, 2021 upon exercise of an early exercise option. Twenty-five percent of the shares subject to the option vested on September 15, 2022, and 1/36th of the remaining shares subject to the award shall vest monthly in equal installments on the 15th of each month, through September 15, 2025, subject to continued service through each vesting date.
- (13) Stock option award vests over a period of four years with 25% of the shares underlying the option vesting on the one year anniversary of the January 27, 2022 vesting commencement date and 1/48th of the shares underlying the option vesting on a monthly basis thereafter, subject to continued service through each vesting date. The option award includes an early exercise feature.
- (14) Stock option award vests over a period of six years with 1/3rd of the shares underlying the option vesting on the two year anniversary of the January 27, 2022 vesting commencement date and 1/48th of the remaining shares underlying the option vesting on a monthly basis thereafter, subject to continued service through each vesting date. The option award includes an early exercise feature.
- (15) Stock option award vests over a period of four years with 25% of the shares underlying the option vesting on the one year anniversary of the May 22, 2023 vesting commencement date and 1/48th of the shares underlying the option vesting on a monthly basis thereafter, subject to continued service through each vesting date. The option award includes an early exercise feature.
- (16) Stock option award vests over a period of four years with 25% of the shares underlying the option vesting on the one year anniversary of the October 9, 2023 vesting commencement date and 1/48th of the shares underlying the option vesting on a monthly basis thereafter, subject to continued service through each vesting date. The option award includes an early exercise feature.
- (17) Represents restricted stock obtained on October 20, 2021 upon exercise of an early exercise option. Twenty-five percent of the shares subject to the option vested on September 15, 2022, and 1/36th of the remaining shares subject to the award shall vest monthly in equal installments on the 15th of each month, through September 15, 2025, subject to continued service through each vesting date.

We did not modify any outstanding equity awards held by our named executive officers in 2023.

Awards held by our named executive officers may be eligible for accelerated vesting under specified circumstances, as described in more detail below under the subsection titled “—Potential Payments and Benefits upon Termination or Change in Control.”

We may in the future, on an annual basis or otherwise, grant additional equity awards to our executive officers pursuant to our 2024 Plan, the terms of which are described below under the subsection titled “—Equity Benefit Plans—2024 Equity Incentive Plan.”

#### **Pension Benefits**

Our named executive officers did not participate in, or otherwise receive any benefits under, any pension or retirement plan sponsored by us during the year ended December 31, 2023.

#### **Nonqualified Deferred Compensation**

Our named executive officers did not participate in, or earn any benefits under, a non-qualified deferred compensation plan sponsored by us during the year ended December 31, 2023.

#### **Employment Agreements**

##### ***Offer Letters***

Below are descriptions of our offer letters with our named executive officers. For a discussion of the severance pay and other benefits to be provided in connection with a termination of employment and/or a change in

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control under the arrangements with our named executive officers, please see the subsection titled “—Potential Payments and Benefits upon Termination or Change in Control” below. Each of our named executive officers is employed at-will.

*Mr. Babler.* In September 2021, we and Mr. Babler entered into an offer letter that governs the terms of Mr. Babler’s employment with us. Pursuant to the agreement, Mr. Babler is entitled to an initial annual base salary of \$500,000, is eligible to receive an annual performance bonus with a target achievement of 40% of his base salary, as determined by our board of directors, and was granted an option exercisable for 3,000,000 shares of our Class A common stock in September 2021. Mr. Babler’s employment is at-will. Mr. Babler is also entitled to certain severance benefits, the terms of which are described below under the subsection titled “—Potential Payments and Benefits upon Termination or Change in Control.”

*Dr. Goldstein.* In September 2021, we and Dr. Goldstein entered into an offer letter that governs the terms of Dr. Goldstein’s employment with us. Pursuant to the agreement, Dr. Goldstein is entitled to an initial annual base salary of \$360,000, is eligible to receive an annual performance bonus with a target achievement of 35% of his base salary, as determined by our board of directors, and was granted an option exercisable for 1,000,000 shares of our Class A common stock in September 2021. Dr. Goldstein’s employment is at-will. Dr. Goldstein is also entitled to certain severance benefits, the terms of which are described below under the subsection titled “—Potential Payments and Benefits upon Termination or Change in Control.”

*Mr. Hardiman.* In September 2021, we and Mr. Hardiman entered into an offer letter that governs the terms of Mr. Hardiman’s employment with us. Pursuant to the agreement, Mr. Hardiman is entitled to an initial annual base salary of \$360,000, is eligible to receive an annual performance bonus with a target achievement of 35% of his base salary, as determined by our board of directors, and was granted an option exercisable for 1,000,000 shares of our Class A common stock in September 2021. Mr. Hardiman’s employment is at-will. Mr. Hardiman is also entitled to certain severance benefits, the terms of which are described below under the subsection titled “—Potential Payments and Benefits upon Termination or Change in Control.”

We intend to enter into new executive employment agreements with our named executive officers prior to the completion of this offering, the details of which have not yet been determined.

**Potential Payments and Benefits upon Termination or Change in Control**

Regardless of the manner in which a named executive officer’s service terminates, each named executive officer is entitled to receive unpaid salary earned during his term of service.

*Mr. Babler.* Pursuant to Mr. Babler’s offer letter, if (a) his employment is terminated without cause (as defined below) or (b) in the event of his constructive termination (as defined below), then Mr. Babler will be entitled to receive severance in the form of (i) continued payments of his then base salary for 12 months, subject to applicable taxes and withholding, (ii) reimbursement for expenses in continuing medical insurance benefits (excluding life insurance) for Mr. Babler and his dependents for up to 12 months and (iii) acceleration of his then-unvested equity grants as to the number of shares underlying such grants that would have been vested as of the first anniversary of the date of his termination, with such acceleration to be effective immediately prior to Mr. Babler’s termination. These severance benefits are conditioned upon Mr. Babler’s delivery of a general release of claims in favor of the company. Further, in the event of a change of control (as defined below), other than an excluded change of control (as defined below), 50% of Mr. Babler’s then-unvested option award for 3,000,000 shares of our Class A common stock granted in September 2021 shall accelerate and become vested as of immediately prior to the closing of such change of control, provided he is still providing services to us at such time. In addition, if, following a change of control, including an excluded change of control, Mr. Babler is subject to a termination without cause or a constructive termination within 12 months following such change of control, then 100% of his then-unvested option award for 3,000,000 shares of our Class A common stock granted in September 2021 shall accelerate and become fully vested as of the termination date, conditioned upon Mr. Babler’s delivery of a general release of claims in favor of the company.

*Dr. Goldstein.* Pursuant to Dr. Goldstein’s offer letter, if (a) his employment is terminated involuntarily without cause (as defined below) or (b) in the event of his constructive termination (as defined below), then Dr. Goldstein will be entitled to receive severance in the form of (i) continued payments of his then base salary for 9 months, subject to applicable taxes and withholding, (ii) reimbursement for expenses in continuing

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medical insurance benefits (excluding life insurance) for Dr. Goldstein and his dependents for up to 9 months and (iii) acceleration of his then-unvested equity grants as to the number of shares underlying such grants that would have been vested as of the first anniversary of the date of his termination, with such acceleration to be effective immediately prior to Dr. Goldstein's termination. These severance benefits are conditioned upon Dr. Goldstein's delivery of a general release of claims in favor of the company. Further, in the event of a change of control (as defined below), other than an excluded change of control (as defined below), 50% of Dr. Goldstein's then-unvested option award for 1,000,000 shares of our Class A common stock granted in September 2021 shall accelerate and become vested as of immediately prior to the closing of such change of control, provided he is still providing services to us at such time. In addition, if, following a change of control, including an excluded change of control, Dr. Goldstein is subject to a termination without cause or a constructive termination within 12 months following such change of control, then 100% of his then-unvested option award for 1,000,000 shares of our Class A common stock granted in September 2021 shall accelerate and become fully vested as of the termination date, conditioned upon Dr. Goldstein's delivery of a general release of claims in favor of the company.

*Mr. Hardiman.* Pursuant to Mr. Hardiman's offer letter, if (a) his employment is terminated involuntarily without cause (as defined below) or (b) in the event of his constructive termination (as defined below), then Mr. Hardiman will be entitled to receive severance in the form of (i) continued payments of his then base salary for 9 months, subject to applicable taxes and withholding, (ii) reimbursement for expenses in continuing medical insurance benefits (excluding life insurance) for Mr. Hardiman and his dependents for up to 9 months and (iii) acceleration of his then-unvested equity grants as to the number of shares underlying such grants that would have been vested as of the first anniversary of the date of his termination, with such acceleration to be effective immediately prior to Mr. Hardiman's termination. These severance benefits are conditioned upon Mr. Hardiman's delivery of a general release of claims in favor of the company. Further, in the event of a change of control (as defined below), other than an excluded change of control (as defined below), 50% of Mr. Hardiman's then-unvested option award for 1,000,000 shares of our Class A common stock granted in September 2021 shall accelerate and become vested as of immediately prior to the closing of such change of control, provided he is still providing services to us at such time. In addition, if, following a change of control, including an excluded change of control, Mr. Hardiman is subject to a termination without cause or a constructive termination within 12 months following such change of control, then 100% of his then-unvested option award for 1,000,000 shares of our Class A common stock granted in September 2021 shall accelerate and become fully vested as of the termination date, conditioned upon Mr. Hardiman's delivery of a general release of claims in favor of the company.

In addition to the above, upon a change in control (as defined below) 50% of the then-unvested options held by each of Mr. Babler, Dr. Goldstein, and Mr. Hardiman will accelerate, and 100% of the then-unvested and outstanding options will accelerate upon a termination within 12 months following a change in control (see "—Outstanding Equity Awards as of December 31, 2023").

For the purposes of Mr. Babler's, Dr. Goldstein's and Mr. Hardiman's severance benefits, the following definitions apply:

- "cause" means the officer's separation by us for any of the following reasons: (i) the officer's willful or gross neglect and material failure to perform his or her duties and responsibilities to us, including but not limited to a failure to cooperate with us in any investigation or formal proceeding; (ii) the officer's commission of any act of fraud, embezzlement, dishonesty or any other intentional misconduct in connection with the officer's responsibilities as an employee that is materially injurious to us; (iii) the unauthorized use or disclosure by the officer of any of our proprietary information or trade secrets or any other party to whom the officer owes an obligation of nondisclosure as a result of the officer's relationship with us; (iv) the officer is convicted of, or enters a no contest plea to, a felony; or (v) the officer's breach of any of the officer's material obligations under any policy, written agreement or covenant with us (including the officer's offer letter). A termination of employment under subparts (i), (iii) and (v) shall not be deemed cause unless the officer has first been given specific written notice of subpart and facts relied upon and thirty days to cure. The determination as to whether the officer is being terminated for cause, and whether the officer has cured any such actions or inactions during any thirty day cure period with respect to subparts (i), (iii) and (v) and with respect to subpart (v) whether such breach is capable of being cured, shall be made in good faith by our board of directors.

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- “change of control” means (i) the date any non-affiliated “person” (as such term is used in Sections 13(d) and 14(d) of the Exchange Act) becomes the “beneficial owner” (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of our securities representing 50% or more of the total voting power represented by our then outstanding voting securities, other than pursuant to a sale by us of our securities in a transaction or series of related transactions the primary purpose of which is to raise capital for us; (ii) the date of the consummation of our merger or consolidation with any other corporation that has been approved by our stockholders, other than a merger or consolidation which would result in our voting securities outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) more than fifty percent (50%) of the total voting power represented by our voting securities or such surviving entity outstanding immediately after such merger or consolidation; or (iii) the date of the consummation of our sale or disposition of all or substantially all of our assets.
- “constructive termination” means the officer’s separation as the result of resignation for any of the following, except as otherwise agreed in writing by the officer: (i) a material reduction in the officer’s job duties, position and responsibilities, taken as a whole, other than in connection with an excluded change of control; (ii) we require the officer to relocate to a facility or location more than 35 miles from the primary location at which the officer was working for us immediately before the required change of location; (iii) any reduction of the officer’s base salary in effect immediately prior to such reduction (other than as part of an across-the-board, proportional reduction), or (iv) we materially breach the terms of the officer’s offer letter. In the event of the occurrence of a condition listed above, the officer must provide notice to us within 60 days of the occurrence of a condition listed above and allow us 30 days after the officer’s delivery of notice to cure such condition. Additionally, in the event we fail to cure the condition within the cure period provided, the officer must terminate employment with us within 10 days of the end of the cure period.
- “excluded change of control” means (i) a change of control involving any transaction with Aclaris Therapeutics Inc. or (ii) a change of control with a special purpose acquisition company formed by, or affiliated with, Foresite Capital Management or its affiliated funds within 12 months of the officer’s start date.

Our named executive officers’ option awards granted prior to the execution of the underwriting agreement for this offering are subject to the terms of the 2021 Plan; a description of the 2021 Plan and options granted thereunder is provided in the subsection titled “—Equity Benefit Plans—2021 Stock Plan” below.

We intend to adopt a severance program covering our named executive officers in connection with this offering and will provide a description of such program once it is finalized.

#### **Other Compensation and Benefits**

All of our current named executive officers are eligible to participate in our employee benefit plans, in each case on the same basis as all of our other employees. These employee benefit plans include medical, dental, vision, disability, employee assistance, life, accidental death and dismemberment insurance plans. We pay the premiums for the medical, dental, vision, life, 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. In addition, we provide the opportunity to participate in a 401(k) plan to our employees, including each of our named executive officers, as discussed in the subsection titled “—401(k) Plan” below.

#### **401(k) Plan**

Our named executive officers are eligible to participate in our defined contribution retirement plan that provides eligible employees with an opportunity to save for retirement on a tax advantaged basis. Eligible employees may elect to defer up to 15% of their eligible compensation into the plan on a pretax or after tax basis, up to annual limits prescribed by the Internal Revenue Code of 1986, as amended (the Code).

#### **Equity Benefit Plans**

We believe that our ability to grant equity-based awards is a valuable and necessary compensation tool that aligns the long-term financial interests of our employees, consultants and directors with the financial interests

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of our stockholders. In addition, we believe that our ability to grant options and other equity-based awards helps us to attract, retain and motivate employees, consultants and directors, and encourages them to devote their best efforts to our business and financial success. The principal features of our equity incentive plans are summarized below. These summaries are qualified in their entirety by reference to the actual text of the plans, which are filed as exhibits to the registration statement of which this prospectus forms a part.

***2024 Equity Incentive Plan***

In \_\_\_\_\_, 2024, our board of directors adopted, and our stockholders approved, our 2024 Plan. We expect our 2024 Plan will become effective upon the execution of the underwriting agreement for this offering. Our 2024 Plan came into existence upon its adoption by our board of directors, but no grants will be made under our 2024 Plan prior to its effectiveness. Our 2024 Plan is a successor to and continuation of our 2021 Plan (referred to in the 2024 Plan as our Prior Plan). Once our 2024 Plan becomes effective, no further grants will be made under our 2021 Plan.

*Types of Awards.* Our 2024 Plan provides for the grant of incentive stock options (ISOs) to employees, including employees of any parent or subsidiary, and for the grant of nonstatutory stock options (NSOs), stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of stock awards to employees, directors, and consultants, including employees and consultants of our affiliates.

*Authorized Shares.* Initially, the maximum number of shares of our common stock that may be issued under our 2024 Plan after it becomes effective will not exceed \_\_\_\_\_ shares, which is the sum of (i) \_\_\_\_\_ new shares, plus (ii) an additional number of shares not to exceed \_\_\_\_\_, consisting of (a) \_\_\_\_\_ shares that remain available for the issuance of awards under our 2021 Plan as of immediately prior to the effectiveness of our 2024 Plan and (b) \_\_\_\_\_ shares of our common stock that are subject to outstanding stock options or other stock awards granted under our 2021 Plan that, on or after the 2024 Plan becomes effective, terminate or expire prior to exercise or settlement; are not issued because the award is settled in cash; are forfeited because of the failure to vest; or are reacquired or withheld (or not issued) to satisfy a tax withholding obligation or the purchase or exercise price, if any, as such shares become available from time to time. In addition, the number of shares of our common stock reserved for issuance under our 2024 Plan will automatically increase on January 1 of each calendar year, starting on January 1, 2025 (assuming the 2024 Plan becomes effective in 2024) through January 1, 2034, in an amount equal to \_\_\_\_\_ % of the total number of shares of our capital stock outstanding on the last day of the calendar month before the date of each automatic increase, or a lesser number of shares determined by our board of directors. The maximum number of shares of our common stock that may be issued on the exercise of ISOs under our 2024 Plan is \_\_\_\_\_.

Shares subject to stock awards granted under our 2024 Plan that expire or terminate without being exercised in full, or that are paid out in cash rather than in shares, do not reduce the number of shares available for issuance under our 2024 Plan. Additionally, shares become available for future grant under our 2024 Plan if they were issued stock awards under our 2024 Plan and we repurchase them or they are forfeited. This includes shares used to pay the exercise price of a stock award or to satisfy the tax withholding obligations related to a stock award.

*Plan Administration.* Our board of directors, or a duly authorized committee of our board of directors, will administer our 2024 Plan. Our board of directors may delegate concurrent authority to administer our 2024 Plan to our compensation committee under the terms of our compensation committee's charter. We sometimes refer to our board of directors, or the applicable committee with the power to administer our equity incentive plans, as the administrator. The administrator may also delegate to one or more persons or bodies the authority to (i) designate employees (other than officers) to receive specified awards, and (ii) determine the number of shares subject to such awards. Such persons or bodies may not grant a stock award to themselves and neither our board nor any committee may delegate authority to any person or body (who is not a member of our board or such body that is not comprised solely of members of our board) the authority to determine the fair market value of our common stock for purposes of the 2024 Plan.

The administrator has the authority to determine the terms of awards, including recipients, the exercise, purchase or strike price of awards, if any, the number of shares subject to each award, the fair market value of a share of common stock, the vesting schedule applicable to the awards, together with any vesting acceleration,

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and the form of consideration, if any, payable upon exercise or settlement of the award and the terms of the award agreements for use under our 2024 Plan.

In addition, subject to the terms of the 2024 Plan, the administrator also has the power to modify outstanding awards under our 2024 Plan, including the authority to reprice any outstanding option or stock appreciation right, cancel and re-grant any outstanding option or stock appreciation right in exchange for new stock awards, cash or other consideration, or take any other action that is treated as a repricing under generally accepted accounting principles, with the consent of any materially adversely affected participant.

*Stock Options.* ISOs and NSOs are granted under stock option agreements adopted by the administrator. The administrator determines the exercise price for stock options, within the terms and conditions of the 2024 Plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2024 Plan vest at the rate specified in the stock option agreement as determined by the administrator.

*Tax Limitations on ISOs.* The aggregate fair market value, determined at the time of grant, of our common stock with respect to ISOs that are exercisable for the first time by an optionholder during any calendar year under all of our stock plans may not exceed \$100,000. Options or portions thereof that exceed such limit will generally be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our affiliates unless (i) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant; and (ii) the option is not exercisable after the expiration of five years from the date of grant.

*Restricted Stock Unit Awards.* Restricted stock units are granted under restricted stock unit award agreements adopted by the administrator. Restricted stock units may be granted in consideration for any form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. A restricted stock unit may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the administrator, or in any other form of consideration set forth in the restricted stock unit agreement. Additionally, dividend equivalents may be credited in respect of shares covered by a restricted stock unit. Except as otherwise provided in the applicable award agreement, restricted stock units that have not vested will be forfeited once the participant's continuous service ends for any reason.

*Restricted Stock Awards.* Restricted stock awards are granted under restricted stock award agreements adopted by the administrator. A restricted stock award may be awarded in consideration for cash, check, bank draft or money order, past services to us, or any other form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. The administrator determines the terms and conditions of restricted stock awards, including vesting and forfeiture terms. If a participant's service relationship with us ends for any reason, we may receive any or all of the shares of our common stock held by the participant that have not vested as of the date the participant terminates service with us through a forfeiture condition or a repurchase right.

*Stock Appreciation Rights.* Stock appreciation rights are granted under stock appreciation grant agreements adopted by the administrator. The administrator determines the purchase price or strike price for a stock appreciation right, which generally cannot be less than 100% of the fair market value of our common stock on the date of grant. A stock appreciation right granted under the 2024 Plan vests at the rate specified in the stock appreciation right agreement as determined by the administrator.

*Performance Awards.* The 2024 Plan permits the grant of performance-based stock and cash awards. The administrator may structure awards so that the shares of our stock, cash, or other property will be issued or paid only following the achievement of certain pre-established performance goals during a designated performance period. The performance criteria that will be used to establish such performance goals may be based on any one of, or combination of, the following as determined by the administrator: earnings (including earnings per share and net earnings); earnings before interest, taxes and depreciation; earnings before interest, taxes, depreciation and amortization; total stockholder return; return on equity or average stockholder's equity; return on assets, investment, or capital employed; share price; margin (including gross margin); income (before or after taxes); operating income; operating income after taxes; pre-tax profit; operating cash flow; sales or revenue targets; increases in revenue or product revenue; expenses and cost reduction goals;



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improvement in or attainment of working capital levels; economic value added (or an equivalent metric); market share; cash flow; cash flow per share; share price performance; debt reduction; customer satisfaction; stockholder's equity; capital expenditures; debt levels; operating profit or net operating profit; workforce diversity; growth of net income or operating income; billings; financing; regulatory milestones; stockholder liquidity; corporate governance and compliance; intellectual property; personnel matters; progress of internal research; progress of partnered programs; partner satisfaction; budget management; partner or collaborator achievements; internal controls, including those related to the Sarbanes-Oxley Act of 2002; investor relations, analysts and communication; implementation or completion of projects or processes; employee retention; number of users, including unique users; strategic partnerships or transactions (including in-licensing and out-licensing of intellectual property); establishing relationships with respect to the marketing, distribution and sale of the Company's products; supply chain achievements; co-development, co-marketing, profit sharing, joint venture or other similar arrangements; individual performance goals; corporate development and planning goals; and other measures of performance selected by the administrator.

The performance goals may be based on a company-wide basis, with respect to one or more business units, divisions, affiliates, or business segments, and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise (i) in the award agreement at the time the award is granted or (ii) in such other document setting forth the performance goals at the time the goals are established, we will appropriately make adjustments in the method of calculating the attainment of performance goals as follows: (1) to exclude restructuring and/or other nonrecurring charges; (2) to exclude exchange rate effects; (3) to exclude the effects of changes to generally accepted accounting principles; (4) to exclude the effects of any statutory adjustments to corporate tax rates; (5) to exclude the effects of items that are "unusual" in nature or occur "infrequently" as determined under generally accepted accounting principles; (6) to exclude the dilutive effects of acquisitions or joint ventures; (7) to assume that any business divested by us achieved performance objectives at targeted levels during the balance of a performance period following such divestiture; (8) to exclude the effect of any change in the outstanding shares of our common stock by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change, or any distributions to common stockholders other than regular cash dividends; (9) to exclude the effects of stock based compensation and the award of bonuses under our bonus plans; (10) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to be expensed under generally accepted accounting principles; and (11) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles. In addition, we retain the discretion to reduce or eliminate the compensation or economic benefit due upon attainment of the goals. The performance goals may differ from participant to participant and from award to award.

*Other Stock Awards.* The administrator may grant other awards based in whole or in part by reference to our common stock. The administrator will set the number of shares under the stock award and all other terms and conditions of such awards.

*Non-Employee Director Compensation Limit.* The aggregate value of all compensation granted or paid to any non-employee director with respect to any calendar year beginning in \_\_\_\_\_, including stock awards granted and cash fees paid by us to such non-employee director, will not exceed \$ \_\_\_\_\_ in total value, or in the event such non-employee director is first appointed or elected to the board during such calendar year, \$ \_\_\_\_\_ in total value (in each case, calculating the value of any such stock awards based on the grant date fair value of such stock awards for financial reporting purposes).

*Changes to Capital Structure.* In the event there is a specified type of change in our capital structure, such as a stock split, reverse stock split, or recapitalization, appropriate adjustments will be made to (i) the class and maximum number of shares reserved for issuance under the 2024 Plan, (ii) the class and maximum number of shares by which the share reserve may increase automatically each year, (iii) the class and maximum number of shares that may be issued on the exercise of ISOs, and (iv) the class and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding stock awards.

*Corporate Transactions.* The following applies to stock awards under the 2024 Plan in the event of a corporate transaction, unless otherwise provided in a participant's stock award agreement or other written agreement with us or one of our affiliates or unless otherwise expressly provided by the administrator at the time of grant.

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In the event of a corporate transaction, any stock awards outstanding under the 2024 Plan may be assumed, continued or substituted for by any surviving or acquiring corporation (or its parent company), and any reacquisition or repurchase rights held by us with respect to the stock award may be assigned to the successor (or its parent company). If the surviving or acquiring corporation (or its parent company) does not assume, continue or substitute for such stock awards, then with respect to any such stock awards that are held by participants whose continuous service has not terminated prior to the effective time of the transaction, or current participants, the vesting (and exercisability, if applicable) of such stock awards will be accelerated in full to a date prior to the effective time of the transaction (contingent upon the effectiveness of the transaction), and such stock awards will terminate if not exercised (if applicable) at or prior to the effective time of the transaction, and any reacquisition or repurchase rights held by us with respect to such stock awards will lapse (contingent upon the effectiveness of the transaction). With respect to performance awards with multiple vesting levels depending on performance level, unless otherwise provided by an award agreement or by the administrator, the award will accelerate at 100% of target. If the surviving or acquiring corporation (or its parent company) does not assume, continue or substitute for such stock awards, then with respect to any such stock awards that are held by persons other than current participants, such awards will terminate if not exercised (if applicable) prior to the effective time of the transaction, except that any reacquisition or repurchase rights held by us with respect to such stock awards will not terminate and may continue to be exercised notwithstanding the transaction. The administrator is not obligated to treat all stock awards or portions of stock awards in the same manner and is not obligated to take the same actions with respect to all participants.

In the event a stock award will terminate if not exercised prior to the effective time of a transaction, the administrator may provide, in its sole discretion, that the holder of such stock award may not exercise such stock award but instead will receive a payment equal in value to the excess (if any) of (i) the value of the property the participant would have received upon the exercise of the stock award over (ii) any exercise price payable by such holder in connection with such exercise.

Under our 2024 Plan, a corporate transaction is defined to include the consummation, in a single transaction or in a series of related transactions, of any one or more of the following events: (i) a sale or disposition of all or substantially all of our assets; (ii) a sale or disposition of more than 50% of our outstanding securities; (iii) a merger, consolidation or similar transaction where we do not survive the transaction; and (iv) a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding before such transaction are converted or exchanged into other property by virtue of the transaction, unless otherwise provided in an award agreement or other written agreement between us and the award holder.

*Change in Control.* In the event of a change in control, as defined under our 2024 Plan, awards granted under our 2024 Plan will not receive automatic acceleration of vesting and exercisability, although this treatment may be provided for in an award agreement.

Under the 2024 Plan, a change in control is defined to include: (i) the acquisition by any person or company of more than 50% of the combined voting power of our then outstanding stock; (ii) a consummated merger, consolidation or similar transaction in which our stockholders immediately before the transaction do not own, directly or indirectly, more than 50% of the combined voting power of the surviving entity (or the parent of the surviving entity); (iii) a consummated sale, lease, exclusive license or other disposition of all or substantially all of our assets other than to an entity more than 50% of the combined voting power of which is owned by our stockholders; and (iv) an unapproved change in the majority of the board of directors.

*Transferability.* A participant may not transfer stock awards under our 2024 Plan other than by will, the laws of descent and distribution, or as otherwise provided under our 2024 Plan.

*Plan Amendment or Termination.* Our board of directors has the authority to amend, suspend, or terminate our 2024 Plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. Certain material amendments also require the approval of our stockholders. No ISOs may be granted after the tenth anniversary of the date our board of directors adopted our 2024 Plan. No stock awards may be granted under our 2024 Plan while it is suspended or after it is terminated.

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**2021 Stock Plan**

Our board of directors adopted, and our stockholders approved, our 2021 Plan on February 2, 2021. Our 2021 Plan was most recently amended by our board of directors and our stockholders on March 1, 2024. No further awards will be granted under our 2021 Plan on or after the effectiveness of our 2024 Plan; however, awards outstanding under our 2021 Plan will continue to be governed by their existing terms.

*Awards.* Our 2021 Plan provides for the direct award or sale of shares and for the grant of ISOs within the meaning of Section 422 of the Code, NSOs, and RSU awards. ISOs may only be granted to our employees. All other awards may be granted to our employees, non-employee members of our board of directors and consultants and any of our subsidiary corporations' employees and consultants.

*Authorized Shares.* As of March 31, 2024, we had reserved 34,229,147 shares of our Class A common stock for issuance under our 2021 Plan, all of which could be issued on the exercise of ISOs. As of March 31, 2024, options to purchase 23,587,922 shares of our common stock were outstanding under our 2021 Plan, and 5,385,992 shares of our common stock remained available for issuance under our 2021 Plan. Unissued shares of our common stock underlying awards that expire or are canceled, or shares otherwise issuable under our 2021 Plan that are withheld by us for payment of the purchase price, exercise price or withholding taxes in respect of an award will remain available for issuance under our 2021 Plan. Shares issued under our 2021 Plan that are forfeited to or repurchased by us due to failure to vest are currently added back to the shares of common stock available for issuance under our 2021 Plan. Shares issued under our 2021 Plan that are settled in cash rather than in shares will not reduce the number of shares remaining available for issuance under our 2021 Plan. Upon the effectiveness of our 2024 Plan, shares available for issuance under our 2021 Plan will be added to the shares available for issuance under our 2024 Plan and no additional awards will be granted under the 2021 Plan. In addition, upon the effectiveness of our 2024 Plan, shares subject to awards granted under the 2021 Plan that expire, lapse or are terminated, exchanged for cash, surrendered, repurchased, or forfeited following the effective date of the 2024 Plan will be available for issuance under the 2024 Plan in accordance with its terms.

*Plan Administration.* Our board of directors or one or more committees appointed by our board of directors may administer our 2021 Plan. We sometimes refer to our board of directors, or the applicable committee appointed by our board of directors, as the administrator. Subject to the terms of our 2021 Plan, the administrator has full authority and discretion to take any actions it deems necessary or advisable for the plan administration of our 2021 Plan. With respect to the terms and conditions of awards granted to participants outside the United States, our board of directors may vary from the provisions of our 2021 Plan that do not require stockholder approval to the extent it determines it necessary and appropriate to do so.

Within the limitations of our 2021 Plan, the administrator also has the authority to modify, reprice, extend or assume outstanding options and to accept the cancellation of outstanding options (whether granted by us or another issuer) in return for the grant of new options or a different type of award for the same or a different number of shares of our common stock and at the same or a different exercise price. However, no modification of an option may impair the participant's rights or increase the participant's obligations under the option without the consent of the participant (except as otherwise provided in the 2021 Plan).

*Stock Options.* Stock options have been granted under our 2021 Plan. Subject to the terms and conditions of our 2021 Plan, the administrator determines the terms and conditions of stock options, including, but not limited to, the number of shares subject to the stock option, the exercise price of the stock option, the term of the stock option and the time(s) at which the stock option may become exercisable. The exercise price of stock options granted under our 2021 Plan generally cannot be less than 100% of the fair market value of a share of our common stock on the grant date. The term of a stock option may not exceed ten years from the grant date. With respect to any participant who owns more than 10% of the voting power of all classes of our (or any of our parent's or subsidiary's) outstanding stock, the term of an ISO granted to such participant must not exceed five years from the grant date and the per share exercise price cannot be less than 110% of the fair market value of a share of our common stock on the grant date. The exercise price of a stock option may be paid by cash or cash equivalents, or by one or any combination of other payment methods permitted by the administrator, which may include (without limitation): (i) in consideration of services rendered, (ii) the delivery of a promissory note by the participant, (iii) the tender of shares of our common stock previously owned by the participant, (iv) "same day sale" or "cashless exercise" procedure, (v) "net exercise" or (vi) other legal

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consideration permitted by applicable law. Unless otherwise provided in a participant's option agreement, if a participant's service terminates, the participant's then-vested stock options granted under our 2021 Plan will remain exercisable following termination for a period of three months if the termination is for any reason other than death or disability (as defined in our 2021 Plan), for a period of six months if termination is due to disability, for a period of 12 months if the termination is due to death, or such longer or shorter period as the administrator may determine. In no event may a stock option be exercised later than the expiration of its term.

*Transferability of Awards.* Our 2021 Plan generally does not allow for the transfer of awards except by a beneficiary designation, a will or the laws of descent and distribution, and an ISO may be exercised during the lifetime of the participant only by the participant or the participant's guardian or legal representative.

*Changes in Capitalization.* In the event of a subdivision of our outstanding common stock, a stock dividend, a combination or consolidation of our outstanding common stock into a lesser number of shares, a reclassification or any other increase or decrease in the number of issued shares of our common stock effected without receipt of consideration by us, proportionate adjustments will automatically be made in each of (i) the number and kind of shares available for issuance under our 2021 Plan, (ii) the number and kind of shares covered by each outstanding award and any outstanding and unexercised right to purchase shares that has not yet expired, (iii) the exercise price or purchase price, if any, applicable to each outstanding award, and (iv) any repurchase price applicable to shares granted under our 2021 Plan. In the event of an extraordinary dividend payable in a form other than shares of our common stock in an amount that has a material effect on the fair market value of our common stock, a recapitalization, spin-off, or other similar occurrence, the administrator at its sole discretion may make appropriate adjustments to one or more of the items described above.

*Corporate Transactions.* If we are a party to a merger or consolidation, or in the event of a sale of all or substantially all of our stock or assets, outstanding awards under our 2021 Plan will be treated in the manner set forth in the definitive transaction agreement (or, if the transaction does not involve such an agreement, in the manner determined by our board of directors), which agreement or determination need not treat all outstanding awards in an identical manner, and may include one or more of the following treatments with respect to each outstanding award: (i) continuation, assumption or substitution of the award by the surviving corporation (or its parent); (ii) cancellation of the award in exchange for a payment with respect to each share subject to the portion of the award that is vested as of the transaction date equal to the excess of (a) the value of the property (including cash) received by the holder of a share of our common stock as a result of the transaction over (b) the per share exercise price (if any) of the award; (iii) cancellation of the stock option for no consideration; however, the participant will be notified of such treatment and given an opportunity to exercise the option (to the extent it is vested or it becomes vested as of the effective date of the transaction) during a period that will generally be not less than five business days preceding the effective date of the transaction; (iv) suspension of the right to exercise the stock option for a limited period preceding the closing of the transaction if administratively necessary to permit the closing of the transaction; or (v) termination of any right to exercise shares subject to the stock option prior to vesting so that the stock option may only be exercised for vested shares after the closing of the transaction. Our board of directors has discretion to accelerate, in whole or part, the vesting and exercisability of an award in connection with a corporate transaction described above.

*Amendment and Termination.* Our board of directors may amend, suspend or terminate our 2021 Plan at any time and for any reason, subject to stockholder approval where such approval is required by applicable law. No termination or amendment of our 2021 Plan may adversely affect any then-outstanding award without the consent of the affected participant. As noted above, no further awards will be granted under our 2021 Plan on or after the effectiveness of our 2024 Plan; however, awards outstanding under our 2021 Plan will continue to be governed by their existing terms.

#### ***2024 Employee Stock Purchase Plan***

Our board of directors adopted, and our stockholders approved, our 2024 Employee Stock Purchase Plan, (ESPP) in 2024. The ESPP will become effective immediately prior to the execution of the underwriting agreement for this offering. The purpose of the ESPP is to secure and retain the services of new employees, to retain the services of existing employees, and to provide incentives for such individuals to exert maximum efforts toward our success and that of our affiliates. Our ESPP will include two components. One component will be designed to allow eligible U.S. employees to purchase our ordinary shares in a manner that may qualify

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for favorable tax treatment under Section 423 of the Code. The other component will permit the grant of purchase rights that do not qualify for such favorable tax treatment in order to allow deviations necessary to permit participation by eligible employees who are foreign nationals or employed outside of the U.S. while complying with applicable foreign laws.

*Share Reserve.* Following this offering, the ESPP authorizes the issuance of shares of our common stock under purchase rights granted to our employees or to employees of any of our designated affiliates. The number of shares of our common stock reserved for issuance will automatically increase on January 1 of each calendar year, beginning on January 1, 2025 (assuming the ESPP becomes effective in 2024) through January 1, 2034, by the lesser of (i) % of the total number of shares of our capital stock outstanding on the last day of the calendar month before the date of the automatic increase, and (ii) shares; provided that before the date of any such increase, our board of directors may determine that such increase will be less than the amount set forth in clauses (i) and (ii). As of the date hereof, no shares of our common stock have been purchased under the ESPP.

*Administration.* Our board of directors, or a duly authorized committee thereof, will administer our ESPP. Our board may delegate concurrent authority to administer the ESPP to our compensation committee under the terms of the compensation committee's charter. The ESPP is implemented through a series of offerings under which eligible employees are granted purchase rights to purchase shares of our common stock on specified dates during such offerings. Under the ESPP, we may specify offerings with durations of not more than 27 months and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of our common stock will be purchased for employees participating in the offering. An offering under the ESPP may be terminated under certain circumstances.

*Payroll Deductions.* Generally, all regular employees, including executive officers, employed by us or by any of our designated affiliates, may participate in the ESPP and may contribute, normally through payroll deductions, up to % of their earnings (as defined in the ESPP) for the purchase of our common stock under the ESPP. Unless otherwise determined by our board of directors, common stock will be purchased for the accounts of employees participating in the ESPP at a price per share that is at least the lesser of (i) 85% of the fair market value of a share of our common stock on the first date of an offering; or (ii) 85% of the fair market value of a share of our common stock on the date of purchase.

*Limitations.* Employees may have to satisfy one or more of the following service requirements before participating in the ESPP, as determined by our board of directors, including: (i) customary employment with us or one of our affiliates for more than 20 hours per week and more than five months per calendar year; or (ii) continuous employment with us or one of our affiliates for a minimum period of time (not to exceed two years). No employee may purchase shares under the ESPP at a rate in excess of \$25,000 worth of our common stock based on the fair market value per share of our common stock at the beginning of an offering for each year such a purchase right is outstanding. Finally, no employee will be eligible for the grant of any purchase rights under the ESPP if immediately after such rights are granted, such employee has voting power over 5% or more of our outstanding capital stock measured by vote or value under Section 424(d) of the Code.

*Changes to Capital Structure.* In the event that there occurs a change in our capital structure through such actions as a stock split, merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, liquidating dividend, combination of shares, exchange of shares, change in corporate structure, or similar transaction, the board of directors will make appropriate adjustments to: (i) the number of shares reserved under the ESPP; (ii) the maximum number of shares by which the share reserve may increase automatically each year; (iii) the number of shares and purchase price of all outstanding purchase rights; and (iv) the number of shares that are subject to purchase limits under ongoing offerings.

*Corporate Transactions.* In the event of certain significant corporate transactions, including the consummation, in a single transaction or in a series of related transactions, of any one or more of the following events: (i) a sale of all or substantially all of our assets; (ii) a sale or disposition of more than 50% of our outstanding securities; (iii) a merger or consolidation where we do not survive the transaction; and (iv) a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding immediately before such transaction are converted or exchanged into other property by virtue of the transaction, any then-outstanding rights to purchase our stock under the ESPP may be assumed, continued or

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substituted for by any surviving or acquiring entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue, or substitute for such purchase rights, then the participants' accumulated payroll contributions will be used to purchase shares of our common stock within ten business days before such corporate transaction, and such purchase rights will terminate immediately after such purchase.

*ESPP Amendment or Termination.* Our board of directors has the authority to amend or terminate our ESPP, provided that except in certain circumstances such amendment or termination may not materially impair any outstanding purchase rights without the holder's consent. We will obtain stockholder approval of any amendment to our ESPP as required by applicable law or listing requirements.

**Limitations on Liability and Indemnification**

Our amended and restated certificate of incorporation, which will become effective immediately prior to the closing of this offering, will contain provisions that limit the liability of our current and former directors and officers for monetary damages to the fullest extent permitted by Delaware law. Delaware law provides that directors and officers of a corporation will not be personally liable for monetary damages for any breach of fiduciary duties as directors or officers, except liability for:

- any breach of the director's or officer'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;
- as a director, unlawful payments of dividends or unlawful stock repurchases or redemptions;
- as an officer, derivative claims brought on behalf of the corporation by a stockholder; or
- any transaction from which the director or officer derived an improper personal benefit.

Such limitation of liability does not apply to liabilities arising under federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our amended and restated certificate of incorporation will authorize us to indemnify our directors, officers, employees and other agents to the fullest extent permitted by Delaware law. Our amended and restated bylaws will provide that we are required to indemnify our directors and officers to the fullest extent permitted by Delaware law and may indemnify our other employees and agents. Our amended and restated bylaws will also provide that, on satisfaction of certain conditions, we will advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee, or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under the provisions of Delaware law. We have entered and expect to continue to enter into agreements to indemnify our directors, executive officers and other employees as determined by the board of directors. With certain exceptions, these agreements provide for indemnification for related expenses including attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding.

We believe that these amended and restated certificate of incorporation and amended and restated bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain customary directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions.

Insofar as indemnification for liabilities arising under the Securities Act 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.

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**Rule 10b5-1 Plans**

Our directors, officers and key 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 common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades under parameters established by the director or officer when entering into the plan, without further direction from them. The director or officer may amend a Rule 10b5-1 plan in some circumstances and may terminate a plan at any time. Our directors and executive officers may also buy or sell additional shares outside of a Rule 10b5-1 plan when they do not possess of material nonpublic information, subject to compliance with the terms of our insider trading policy. During the first 180 days from this offering, the sale of any shares under such plan would be subject to the lock-up agreement that the director or officer has entered into with the underwriters.

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**CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS**

The following includes a summary of transactions since our inception and any currently proposed transactions to which we have been or are to be a party in which the amount involved exceeded or will exceed the lesser of \$120,000 and 1% of our total assets, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under the sections titled “Executive Compensation” and “Management—Non-Employee Director Compensation.” We also describe below certain other transactions with our directors, executive officers and stockholders.

**Foresite Labs Asset Acquisition**

In February 2021, we agreed to assume the simple agreements for future equity (SAFEs) of Foresite Labs, an entity affiliated with Foresite Capital Management, a holder of more than 5% of our outstanding capital stock, in exchange for the intellectual property rights for an analytics platform in development, as well as prepaid assets and cash. The SAFEs immediately converted into 1,880,001 shares of our Series Seed redeemable convertible preferred stock. The transaction was measured based on the \$1.9 million fair value of the Series Seed redeemable convertible preferred stock issued.

**Foresite Labs Services Agreement**

In January 2021, we entered into a services agreement with Foresite Labs, an entity affiliated with Foresite Capital Management, a holder of more than 5% of our outstanding capital stock, which was amended on August 24, 2021 and further amended on December 22, 2023, and expires in December 2026, unless terminated earlier by the parties, pursuant to which Foresite Labs provides us with data and analytics services and other scientific support. Foresite Labs invoices us for the services quarterly in advance based on a mutually-agreed service fee estimate, which is reconciled at the end of each quarter. During the years ended December 31, 2022 and 2023, we recognized \$1.6 million and \$1.5 million as research and development expenses under the service agreement, respectively. General and administrative expenses under the service agreement were immaterial. Accrued expenses under the service agreement were \$0 and less than \$0.1 million as of December 31, 2022 and 2023, respectively.

**Series Seed Redeemable Convertible Preferred Stock Financing**

In February 2021, we issued and sold an aggregate of 10,500,000 shares of our Series Seed Preferred convertible preferred stock, including 1,880,001 shares converted from simple agreements for future equity (SAFEs) of Foresite Labs, an entity affiliated with Foresite Capital Management, a holder of more than 5% of our outstanding capital stock, at a purchase price of \$1.00 per share for aggregate proceeds of \$10.5 million, resulting in gross proceeds of \$8.6 million.

The following table summarizes the Series Seed redeemable convertible preferred stock purchased by holders of more than 5% of our capital stock and entities affiliated with our executive officers and members of our board of directors.

<b>Participants<sup>(1)</sup></b>	<b>Shares of Series Seed Redeemable Convertible Preferred Stock Purchased (#)</b>	<b>Aggregate Proceeds (\$)</b>
Entities affiliated with Foresite Capital Management <sup>(2)</sup>	10,000,000	10,000,000.00

(1) Additional details regarding these stockholders and their equity holdings are included in this prospectus under the section titled “Principal Stockholders.”

(2) Consists of (i) \$7,381,810.80 new cash investment by Foresite Capital Fund V, L.P. and the cancellation of \$1,709,089.20 in SAFEs held by Foresite Capital Fund V, L.P. converted in connection with the financing, and (ii) \$738,189.20 new cash investment by Labs Co-Invest V, LLC and the cancellation of \$170,910.80 in SAFEs held by Labs Co-Invest V, LLC converted in connection with the financing. Entities affiliated with Foresite Capital Management collectively beneficially own more than 5% of our outstanding capital stock. James B. Tananbaum, M.D., a member of our board of directors, is President, Chief Executive Officer and a director of Foresite Capital Management.



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**Series A Redeemable Convertible Preferred Stock Financing**

In March 2021, we issued and sold an aggregate of 7,500,000 shares of our Series A redeemable convertible preferred stock at a purchase price of \$4.00 per share for aggregate proceeds of \$30.0 million.

The following table summarizes the Series A redeemable convertible preferred stock purchased by holders of more than 5% of our capital stock and entities affiliated with our executive officers and members of our board of directors.

<u>Participants<sup>(1)</sup></u>	Shares of Series A Redeemable Convertible Preferred Stock Purchased (#)	Aggregate Proceeds (S)
Entities affiliated with Foresite Capital Management <sup>(2)</sup>	7,500,000	30,000,000.00

(1) Additional details regarding these stockholders and their equity holdings are included in this prospectus under the section titled “Principal Stockholders.”

(2) Consists of (i) 5,250,000 shares of Series A redeemable convertible preferred stock issued to Foresite Capital Fund V, L.P. and (ii) 2,250,000 shares of Series A redeemable convertible preferred stock issued to Foresite Capital Opportunity Fund V, L.P. Entities affiliated with Foresite Capital Management beneficially own more than 5% of our outstanding capital stock. James B. Tananbaum, M.D., a member of our board of directors, is President, Chief Executive Officer and a director of Foresite Capital Management.

**Convertible Promissory Notes**

In March 2021, we issued convertible promissory notes to entities affiliated with Foresight Capital Management, a holder of more than 5% of our outstanding capital stock, with a total principal amount of \$30.0 million in exchange for \$30.0 million in cash. In August 2021, we issued additional convertible promissory notes to entities affiliated with Foresight Capital Management with a total principal amount of \$1.5 million in exchange for \$1.5 million in cash. In September 2021, we amended and restated all outstanding convertible promissory notes and issued an additional convertible promissory note to an entity affiliated with Foresight Capital Management with a total principal amount of \$6.0 million in exchange for \$6.0 million in cash. Pursuant to the terms of such notes, the outstanding indebtedness was cancelled, and the convertible promissory notes converted into 9,760,088 shares of Series B-1 redeemable convertible preferred stock in connection with the Series B and Series B-1 redeemable convertible preferred stock financing, as described below under the subsection titled “—Series B and Series B-1 Redeemable Convertible Preferred Stock Financing.” All of the convertible promissory notes bore interest at a rate of 6% per year, compounded annually and could not be prepaid without written consent from the holders.

**Series B and Series B-1 Redeemable Convertible Preferred Stock Financing**

In multiple closings between December 2021 and January 2022, we issued and sold an aggregate of 40,200,000 shares of our Series B redeemable convertible preferred stock at a purchase price of \$5.00 per share, resulting in aggregate gross proceeds of \$201.0 million. In December 2021, upon the occurrence of a qualified financing, the convertible notes automatically converted into 9,760,088 shares of our Series B-1 redeemable convertible preferred stock at a conversion price of \$4.00 per share, which was equal to 80% of the cash issuance price of our Series B redeemable convertible preferred stock, resulting in the cancellation of indebtedness of \$39.0 million.

The following table summarizes the Series B and Series B-1 redeemable convertible preferred stock purchased by holders of more than 5% of our capital stock and entities affiliated with our executive officers and members of our board of directors.

<u>Participants<sup>(1)</sup></u>	Shares of Series B Redeemable Convertible Preferred Stock (#)	Shares of Series B-1 Redeemable Convertible Preferred Stock (#)	Aggregate Proceeds (S)
AyurMaya Capital Management Fund, LP <sup>(2)</sup>	20,000,000	—	100,000,000.00
Entities affiliated with BBA <sup>(3)</sup>	20,000,000	—	100,000,000.00
Entities affiliated with Foresite Capital Management <sup>(4)</sup>	—	9,760,088	39,040,356.18

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- (1) Additional details regarding these stockholders and their equity holdings are included in this prospectus under the section titled “Principal Stockholders.”
- (2) Alan Colowick, M.D., M.P.H., a member of our board of directors, is Managing Director of Matrix Capital Management Company, an affiliate of AyurMaya Capital Management Fund LP, a holder of greater than 5% of our capital stock.
- (3) Consists of (i) 18,506,264 shares of Series B redeemable convertible preferred stock issued to Baker Brothers Life Sciences, L.P. (BBA) and (ii) 1,493,736 shares of Series B redeemable convertible preferred stock issued to 667, L.P. Julian C. Baker, a member of our board of directors, is a Managing Partner of BBA, the management company and investment adviser to Baker Brothers Life Sciences, L.P. and 667, L.P. (together the BBA Funds). The BBA Funds beneficially own more than 5% of our outstanding capital stock. Immediately prior to the closing of this offering, all shares of our redeemable convertible preferred stock held by entities affiliated with BBA will convert into \_\_\_\_\_ shares of our common stock and \_\_\_\_\_ shares of our non-voting common stock.
- (4) Consists of (i) 2,618,356 shares of Series B-1 redeemable convertible preferred stock issued to Foresite Capital Fund V, L.P., (ii) 2,618,356 shares of Series B-1 redeemable convertible preferred stock issued to Foresite Capital Opportunity Fund V, L.P., and (iii) 4,523,376 shares of Series B-1 redeemable convertible preferred stock issued to Foresite Labs Fund I, L.P. Entities affiliated with Foresite Capital Management beneficially own more than 5% of our outstanding capital stock. James B. Tananbaum, M.D., a member of our board of directors, is President, Chief Executive Officer and a director of Foresite Capital Management.

### Series B-2 and Series B-2A Convertible Preferred Stock Financing

In May 2023 and October 2023, we issued and sold an aggregate of 14,943,510 shares of our Series B-2 redeemable convertible preferred stock at a purchase price of \$5.00 per share. We also sold an aggregate of 3,056,490 shares of our Series B-2A redeemable convertible preferred stock at a price of \$5.00 per share. The aggregate proceeds for the Series B-2 and Series B-2A redeemable convertible preferred shares were \$90,000,000.00.

The following table summarizes the Series B-2 and Series B-2A convertible preferred stock purchased by holders of more than 5% of our capital stock and entities affiliated with our executive officers and members of our board of directors.

Participants <sup>(1)</sup>	Shares of Series B-2 Redeemable Convertible Preferred Stock (#)	Shares of Series B-2A Redeemable Convertible Preferred Stock (#)	Aggregate Proceeds (\$)
AyurMaya Capital Management Fund, LP <sup>(2)</sup>	4,058,829	1,277,660	26,682,445.00
Entities affiliated with BBA <sup>(3)</sup>	3,557,659	1,778,830	26,682,445.00
Entities affiliated with Foresite Capital Management <sup>(4)</sup>	7,273,658	—	36,368,290.00

- (1) Additional details regarding these stockholders and their equity holdings are included in this prospectus under the section titled “Principal Stockholders.”
- (2) Alan Colowick, M.D., M.P.H., a member of our board of directors, is Managing Director of Matrix Capital Management Company, an affiliate of AyurMaya Capital Management Fund LP, a holder of greater than 5% of our capital stock. Note that AyurMaya Capital Management Fund, LP later converted its Series B-2A redeemable convertible preferred stock into Series B-2 redeemable convertible preferred stock in July 2023.
- (3) Consists of (i) 3,263,415 shares of our Series B-2 redeemable convertible preferred stock and 1,631,708 shares of our Series B-2A redeemable convertible preferred stock issued to Baker Brothers Life Sciences, L.P. and (ii) 294,244 shares of our Series B-2 redeemable convertible preferred stock and 147,122 shares of our Series B-2A redeemable convertible preferred stock issued to 667, L.P. Julian C. Baker, a member of our board of directors, is a Managing Partner of BBA, the management company and investment adviser to the BBA Funds, which beneficially own more than 5% of our outstanding capital stock. Immediately prior to the closing of this offering, all shares of our redeemable convertible preferred stock held by entities affiliated with BBA will convert into \_\_\_\_\_ shares of our common stock and \_\_\_\_\_ shares of our non-voting common stock.
- (4) Consists of (i) 2,909,464 shares of our Series B-2 redeemable convertible preferred stock issued to Foresite Capital Fund V, L.P., (ii) 1,454,731 shares of our Series B-2 redeemable convertible preferred stock issued to Foresite Capital Opportunity Fund V, L.P., (iii) 1,454,732 shares of our Series B-2 redeemable convertible preferred stock issued to Foresite Labs Fund I, L.P., and (iv) 1,454,731 shares of our Series B-2 redeemable convertible preferred stock issued to Foresite Capital Fund VI, L.P. Entities affiliated with Foresite Capital Management beneficially own more than 5% of our outstanding capital stock. James B. Tananbaum, M.D., a member of our board of directors, is President, Chief Executive Officer and a director of Foresite Capital Management.

### Series C and Series C-1 Convertible Preferred Stock Financing

In March 2024, we issued and sold an aggregate of 41,264,891 shares of our Series C redeemable convertible preferred stock at a purchase price of \$3.13826 per share. The aggregate proceeds for the Series C redeemable convertible preferred shares were \$129,499,956.96

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The following table summarizes the Series C and Series C-1 convertible preferred stock purchased by holders of more than 5% of our capital stock and entities affiliated with our executive officers and members of our board of directors.

Participants <sup>(1)</sup>	Shares of Series C Redeemable Convertible Preferred Stock (#)	Shares of Series C-1 Redeemable Convertible Preferred Stock (#)	Aggregate Proceeds (\$)
AyurMaya Capital Management Fund, LP <sup>(2)</sup>	6,372,958	—	19,999,999.18
Entities affiliated with BBA <sup>(3)</sup>	4,126,490	—	12,949,998.52
Entities affiliated with Foresite Capital Management <sup>(4)</sup>	9,559,435	—	29,999,992.50
Samsara BioCapital, LP <sup>(5)</sup>	3,983,098	—	12,499,997.13
venBio Global Strategic Fund IV, L.P. <sup>(6)</sup>	4,779,718	—	14,999,997.82

- (1) Additional details regarding these stockholders and their equity holdings are included in this prospectus under the section titled “Principal Stockholders.”
- (2) Alan Colowick, M.D., M.P.H., a member of our board of directors, is Managing Director of Matrix Capital Management Company, an affiliate of AyurMaya Capital Management Fund LP, a holder of greater than 5% of our capital stock.
- (3) Consists of (i) 3,786,664 shares of our Series C redeemable convertible preferred stock issued to Baker Brothers Life Sciences, L.P. and (ii) 339,826 shares of our Series C redeemable convertible preferred stock issued to 667, L.P. Julian C. Baker, a member of our board of directors, is a Managing Partner of BBA, the management company and investment adviser to the BBA Funds, which beneficially own more than 5% of our outstanding capital stock. Immediately prior to the closing of this offering, all shares of our redeemable convertible preferred stock held by entities affiliated with BBA will convert into \_\_\_\_\_ shares of our common stock and \_\_\_\_\_ shares of our non-voting common stock.
- (4) Consists of (i) 2,389,859 shares of our Series C redeemable convertible preferred stock issued to Foresite Capital Fund V, L.P., (ii) 1,593,239 shares of our Series C redeemable convertible preferred stock issued to Foresite Capital Opportunity Fund V, L.P., (iii) 1,593,239 shares of our Series C redeemable convertible preferred stock issued to Foresite Labs Fund I, L.P., and (iv) 3,983,098 shares of our Series C redeemable convertible preferred stock issued to Foresite Capital Fund VI, L.P. Entities affiliated with Foresite Capital Management beneficially own more than 5% of our outstanding capital stock. James B. Tananbaum, M.D., a member of our board of directors, is President, Chief Executive Officer and a director of Foresite Capital Management.
- (5) Srinivas Akkaraju, M.D., Ph.D., one of our directors, is the managing member of Samsara BioCapital, LP.
- (6) Richard Gaster, M.D., Ph.D., a member of our board of directors, is a managing partner of venBio Partners LLC.

#### **Employment Agreements and Stock Option Grants to Directors and Executive Officers**

We have entered into employment agreements with certain of our named executive officers, and granted stock options to our named executive officers and certain of our directors, as more fully described in the sections titled “Executive Compensation” and “Management—Non-Employee Director Compensation.”

#### **Investor Rights, Voting and Right of First Refusal Agreements**

In connection with our redeemable convertible preferred stock financings, we entered into investor rights, voting and right of first refusal agreements containing registration rights, information rights, voting rights, board representation rights, indemnification provisions and rights of first refusal, among other things, with certain holders of our redeemable convertible preferred stock and certain holders of our common stock, including AyurMaya Capital Management Fund LP, which is affiliated with our director Alan Colowick, M.D., M.P.H., entities affiliated with Foresite Capital Management, which are affiliated with our director, James B. Tananbaum, M.D., entities affiliated with BBA, which are affiliated with our director Julian C. Baker, Martin Babler, our Chief Executive Officer, each of which hold greater than 5% of our outstanding capital stock, Samsara BioCapital, LP, which is affiliated with our director Srinivas Akkaraju, M.D., Ph.D., and venBio Partners LLC, which is affiliated with our director Richard Gaster M.D., Ph.D.

The covenants included in these stockholder agreements generally will terminate upon the closing of this offering, except with respect to registration rights, as more fully described in the section titled “Description of Capital Stock—Registration Rights.” See also the section titled “Principal Stockholders” for additional information regarding beneficial ownership of our capital stock.

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**Registration Rights Agreement**

In connection with the sale of our sale of Series B redeemable convertible preferred stock, we agreed to enter into a registration rights agreement with Bakers Brothers Life Sciences, L.P. and 667, L.P. prior to closing of this offering, pursuant to which, among other things, we will provide the BBA Funds certain “resale” registration rights and related “piggyback” rights.

**Limitations on Liability and Indemnification Agreements**

Our amended and restated certificate of incorporation will contain provisions limiting the liability of directors, and our amended and restated bylaws will provide that we will indemnify each of our directors and officers to the fullest extent permitted under Delaware law. Our amended and restated certificate of incorporation and amended and restated bylaws will also provide our board of directors with discretion to indemnify our employees and other agents when determined appropriate by the board. In addition, we have entered into or intend to enter into an indemnification agreement with each of our directors and executive officers, which will require us to indemnify them. For more information regarding these agreements, see the section titled “Executive Compensation—Limitations on Liability and Indemnification.”

**Policies and Procedures for Transactions with Related Persons**

Prior to closing of this offering, we intend to adopt a written policy that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of any class of our common stock and any members of the immediate family of any of the foregoing persons are not permitted to enter into a related person transaction with us without the approval or ratification of our board of directors or our audit committee. Any request for us to enter into a transaction with an executive officer, director, nominee for election as a director, beneficial owner of more than 5% of any class of our common stock, or any member of the immediate family of any of the foregoing persons, in which the amount involved exceeds \$120,000 (or, if less, 1% of the average of our total assets in a fiscal year) and such person would have a direct or indirect interest, must be presented to our board of directors or our audit committee for review, consideration and approval. In approving or rejecting any such proposal, our board of directors or our audit committee is to consider the material facts of the transaction, including whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person’s interest in the transaction.

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**PRINCIPAL STOCKHOLDERS**

The following table sets forth information regarding beneficial ownership of our capital stock as of March 21, 2024 by:

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

We have determined beneficial ownership in accordance with the rules and regulations of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Except as indicated by the footnotes below, we believe, based on information furnished to us, that the persons and entities named in the table below have sole voting and sole investment power with respect to all shares that they beneficially own, subject to applicable community property laws.

Applicable percentage ownership before the offering is based on \_\_\_\_\_ shares of our common stock and nonvoting common stock (including \_\_\_\_\_ shares of unvested restricted common stock subject to repurchase as of such date) outstanding as of March 21, 2024, after giving effect to (i) the Preferred Stock Conversion and (ii) the Common Stock Reclassification (as if each had occurred as of March 31, 2024).

Applicable percentage ownership after the offering is based on \_\_\_\_\_ shares of our common stock and nonvoting common stock (including \_\_\_\_\_ shares of unvested restricted common stock subject to repurchase as of such date) outstanding immediately after the closing of this offering (assuming no exercise of the underwriters' over-allotment option), after giving effect to (i) the Preferred Stock Conversion and (ii) the Common Stock Reclassification (as if each had occurred as of March 31, 2024), and includes \_\_\_\_\_ shares of common stock subject to repurchase. In computing the number of shares beneficially owned by a person and the percentage ownership of such person, we divided the number of shares held by the sum of (1) the number of shares of common stock outstanding as of March 21, 2024 and (2) the number of shares of common stock that a person has the right to acquire within 60 days after the date of this table (which includes the number of shares of non-voting common stock owned by such person to the extent they can be converted to common stock within 60 days after the date of this table).

Unless otherwise indicated, the address for each beneficial owner listed in the table below is c/o Alumis Inc., 280 East Grand Avenue, South San Francisco, CA 94080.

<u>Name of Beneficial Owner</u>	<u>Beneficial Ownership Before the Offering</u>		<u>Beneficial Ownership After the Offering</u>		<u>% of Total Voting Power After the Offering</u>
	<u>Shares</u>	<u>%</u>	<u>Shares</u>	<u>%</u>	
<b>Greater than 5% Holders:</b>					
AyurMaya Capital Management Fund, LP <sup>(1)</sup>					
Entities affiliated with Baker Brothers Life Sciences, L.P. <sup>(2)</sup>					
Entities affiliated with Foresite Capital Management <sup>(3)</sup>					
<b>Directors and Named Executive Officers:</b>					
Martin Babler <sup>(4)</sup>					
David Goldstein, Ph.D. <sup>(5)</sup>					
Roy Hardiman <sup>(6)</sup>					
Julian C. Baker <sup>(2)</sup>					
Alan Colowick, M.D., M.P.H.					
Sapna Srivastava <sup>(7)</sup>					
James B. Tananbaum, M.D. <sup>(3)</sup>					

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<u>Name of Beneficial Owner</u>	<u>Beneficial Ownership Before the Offering</u>		<u>Beneficial Ownership After the Offering</u>		<u>% of Total Voting Power After the Offering</u>
	<u>Shares</u>	<u>%</u>	<u>Shares</u>	<u>%</u>	
Zhengbin Yao, Ph.D. <sup>(8)</sup>					
Srinivas Akkaraju, M.D., Ph.D. <sup>(9)</sup>					
Richard Gaster, M.D., Ph.D.					
All directors and executive officers as a group (15 persons) <sup>(10)</sup>					

\* Represents beneficial ownership of less than 1%.

- (1) Consists of (i) \_\_\_\_\_ shares of common stock issuable upon conversion of Series B Preferred Stock, (ii) \_\_\_\_\_ shares of common stock issuable upon conversion of Series B-2 Preferred Stock and (iii) \_\_\_\_\_ shares of common stock issuable upon conversion of Series C Preferred Stock, in each case directly held by AyurMaya Capital Management Fund, LP (the AyurMaya Fund). AyurMaya Capital Management Company, LP (the Investment Manager), a Delaware limited partnership, serves as the investment advisor to the AyurMaya Fund with respect to the securities directly held by the AyurMaya Fund. David E. Goel (Mr. Goel) serves as the Managing Member of AyurMaya Capital Management Company GP, LLC, the general partner of the Investment Manager, and may be deemed to hold voting and dispositive power with respect to the securities directly held by the AyurMaya Fund. The business address for each of the AyurMaya Fund, the Investment Manager and Mr. Goel is c/o AyurMaya Capital Management LP, Bay Colony Corporate Center, 1000 Winter St., Suite 4500, Waltham, MA 02451.
- (2) Immediately prior to the closing of this offering, all shares of our redeemable convertible preferred stock held of record by entities affiliated with Baker Bros. Advisors LP (BBA) will convert into \_\_\_\_\_ shares of our common stock and \_\_\_\_\_ shares of our non-voting common stock. Consists of (i) \_\_\_\_\_ shares of non-voting common stock issuable upon conversion of our Series B Preferred Stock, \_\_\_\_\_ shares of non-voting common stock issuable upon conversion of our Series B-2 Preferred Stock, \_\_\_\_\_ shares of non-voting common stock issuable upon conversion of our Series B-2A Preferred Stock and \_\_\_\_\_ shares of non-voting common stock issuable upon conversion of our Series C Preferred Stock held by Baker Brothers Life Sciences, L.P.; and (ii) \_\_\_\_\_ shares of non-voting common stock issuable upon conversion of our Series B Preferred Stock, \_\_\_\_\_ shares of non-voting common stock issuable upon conversion of our Series B-2 Preferred Stock, \_\_\_\_\_ shares of non-voting common stock issuable upon conversion of our Series B-2A Preferred Stock and \_\_\_\_\_ shares of non-voting common stock issuable upon conversion of our Series C Preferred Stock held by 667, L.P. (together with Baker Brothers Life Sciences, L.P., the BBA Funds). BBA is the management company and investment adviser to the BBA Funds and has the sole voting and investment power with respect to the shares held by the BBA Funds. Baker Bros. Advisors (GP) LLC (BBA-GP) is the sole general partner of BBA. The managing members of BBA-GP are Julian C. Baker and Felix J. Baker. Each of BBA-GP, Felix J. Baker and Julian C. Baker, as a managing member of BBA-GP and BBA, may be deemed to be beneficial owners of the shares directly held by the BBA Funds. Each of Julian C. Baker, Felix J. Baker, BBA-GP and BBA disclaim beneficial ownership of these securities, except to the extent of his or its pecuniary interest therein. The business address for the BBA Funds is 860 Washington St. 3rd Fl., New York, NY 10014.
- (3) Consists of (i) \_\_\_\_\_ shares of common stock issuable upon conversion of our Series Seed Preferred Stock, \_\_\_\_\_ shares of common stock issuable upon conversion of our Series A Preferred Stock, \_\_\_\_\_ shares of common stock issuable upon conversion of our Series B-1 Preferred Stock, \_\_\_\_\_ shares of common stock issuable upon conversion of our Series B-2 Preferred Stock, and \_\_\_\_\_ shares of common stock issuable upon conversion of our Series C Preferred Stock held by Foresite Capital Fund V, L.P. (Fund V); (ii) shares of common stock issuable upon conversion of our Series B-2 Preferred Stock and \_\_\_\_\_ shares of common stock issuable upon conversion of our Series C Preferred Stock held by Foresite Capital Fund VI, L.P. (Fund VI); (iii) shares of common stock issuable upon conversion of our Series A Preferred Stock, \_\_\_\_\_ shares of common stock issuable upon conversion of our Series B-1 Preferred Stock, \_\_\_\_\_ shares of common stock issuable upon conversion of our Series B-2 Preferred Stock and \_\_\_\_\_ shares of common stock issuable upon conversion of our Series C Preferred Stock held by Foresite Capital Opportunity Fund V, L.P. (Opportunity Fund V); (iv) shares of common stock issuable upon conversion of our Series Seed Preferred Stock held by Labs Co-Invest V, LLC (Labs Co-Invest); (v) \_\_\_\_\_ shares of common stock held by Foresite Labs Affiliates 2021, LLC (Labs Affiliates); and (vi) \_\_\_\_\_ shares of common stock issuable upon conversion of our Series B-1 Preferred Stock, \_\_\_\_\_ shares of common stock issuable upon conversion of our Series B-2 Preferred Stock and \_\_\_\_\_ shares of common stock issuable upon conversion of our Series C Preferred Stock held by Foresite Labs Fund I, L.P. (Labs Fund). Foresite Capital Management V, LLC (FCM V) is the general partner of Fund V and may be deemed to have sole voting and dispositive power over the shares held by Fund V; Foresite Capital Management VI, LLC (FCM VI) is the general partner of Fund VI and may be deemed to have sole voting and dispositive power over the shares held by Fund VI; Foresite Capital Opportunity Management V, LLC (FCOM V) is the general partner of Opportunity Fund V and may be deemed to have sole voting and dispositive power over the shares held by Opportunity Fund V; Labs Co-Invest may be deemed to have sole and dispositive power over the shares held by Labs Co-Invest; Labs Affiliates may be deemed to have sole and dispositive power over the shares held by Labs Affiliates; and Labs Fund may be deemed to have sole and dispositive power over the shares held by Labs Fund. James B. Tananbaum, M.D. is the sole managing member of FCM V, FCM VI, FCOM V, Labs Co-Invest, Lab Affiliates and Labs Fund and may be deemed to have sole voting and dispositive power over these shares. Each entity and Dr. Tananbaum disclaims beneficial ownership of these shares except to the extent of their respective pecuniary interests therein. The business address of Dr. Tananbaum and each of the entities listed above is 900 Larkspur Landing Circle, Suite 150, Larkspur, CA 94939.
- (4) Consists of (i) \_\_\_\_\_ shares of common stock held of record by the Martin Babler revocable trust UAD October 25, 2006, for which Martin Babler serves as a trustee, (ii) \_\_\_\_\_ shares of common stock held of record by the Justin A. Babler-Kuebler Irrevocable Trust UAD 11/30/20, for which Tim Bücher serves as a trustee, (iii) \_\_\_\_\_ shares of common stock held of record by the Natalie F. Babler-Kuebler Irrevocable Trust UAD 11/30/20, for which Tim Bücher serves as a trustee, (iv) \_\_\_\_\_ shares of common stock held of record by the Angelina V. Babler-Kuebler Irrevocable Trust UAD 11/30/20, for which Tim Bücher serves as a trustee and (v) \_\_\_\_\_ shares of common stock subject to options that are exercisable with 60 days of March 21, 2024.
- (5) Consists of (i) \_\_\_\_\_ shares of common stock held of record by the Baily Goldstein Living Trust dated March 4, 2014, for which

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- Dr. Goldstein serves as a trustee, (ii) shares of common stock held of record by family members of Dr. Goldstein residing in his primary residence and (iii) shares of common stock subject to options that are exercisable with 60 days of March 21, 2024.
- (6) Consists of (i) shares of common stock held of record by Mr. Hardiman, (ii) shares of common stock held of record by family members of Mr. Hardiman residing in his primary residence, and (iii) shares of common stock subject to options that are exercisable within 60 days of March 21, 2024.
- (7) Consists of subject to options that are exercisable within 60 days of March 21, 2024.
- (8) Consists of (i) shares of common stock held of record by Dr. Yao and (ii) shares of common stock subject to options that are exercisable within 60 days of March 21, 2024.
- (9) Consists of shares of common stock issuable upon conversion of our Series C Preferred Stock held of record by Samsara BioCapital, L.P. (Samsara LP). Samsara BioCapital GP, LLC (Samsara GP) is the general partner of Samsara LP. Dr. Srinivas Akkaraju (Akkaraju) as the managing member of Samsara GP, shares voting and investment authority over the shares held by Samsara LP. The business address of Akkaraju and each of the entities listed above is 628 Middlefield Road, Palo Alto, CA 94301. Samsara GP disclaims beneficial ownership in these shares except to the extent of its respective pecuniary interest therein.
- (10) Consists of (i) shares of common stock beneficially owned by our current executive officers and directors and (ii) shares of common stock subject to options that are exercisable within 60 days of March 21, 2024.

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**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, which will each become effective upon the completion of this offering, our registration rights agreement and relevant provisions of Delaware General Corporation Law (DGCL). The descriptions herein are summaries qualified in their entirety by our amended and restated certificate of incorporation and amended and restated bylaws, copies of which have been filed as exhibits to the registration statement of which this prospectus is a part, as well as the relevant provisions of DGCL. The descriptions of our common stock, non-voting common stock and preferred stock reflect changes to our capital structure that will be in effect on the closing of this offering.

Upon the filing of our amended and restated certificate of incorporation and the closing of this offering, our authorized capital stock will consist of \_\_\_\_\_ shares of common stock, \$0.0001 par value per share, \_\_\_\_\_ shares of non-voting common stock, \$0.00001 par value per share, and \_\_\_\_\_ shares of preferred stock, \$0.0001 par value per share.

As of March 31, 2024, after giving effect to the Preferred Stock Conversion and the Common Stock Reclassification, we had \_\_\_\_\_ shares of common stock and \_\_\_\_\_ shares of non-voting common stock outstanding.

**Common Stock and Non-Voting Common Stock**

Our amended and restated certificate of incorporation will authorize the issuance of up to \_\_\_\_\_ shares of our common stock and \_\_\_\_\_ shares of our non-voting common stock. All outstanding shares of our common stock and non-voting common stock are validly issued, fully paid and nonassessable, and the shares of our common stock to be issued in connection with this offering will be validly issued, fully paid and nonassessable.

The holders of our common stock and our non-voting 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 common stock are entitled to one vote per share of common stock, and holders of our non-voting common stock are not entitled to any votes per share of non-voting common stock, including for the election of directors, and (ii) holders of our common stock have no conversion rights, while holders of our non-voting common stock shall have the right to convert each share of our non-voting common stock into one share of common stock at such holder's election, provided that as a result of such conversion, such holder, together with its affiliates and any members of a Schedule 13(d) group with such holder, would not beneficially own in excess of \_\_\_\_\_ % of our common stock immediately prior to and following such conversion, unless otherwise as expressly provided for in our amended and restated certificate of incorporation. However, the beneficial ownership limitation may be increased or decreased to any other percentage (not to exceed \_\_\_\_\_ %) designated by such holder of non-voting common stock upon 61 days' notice to us.

***Voting Rights***

Our common stock is entitled to one vote per share on any matter that is submitted to a vote of our stockholders, except on matters relating solely to terms of preferred stock, and our non-voting common stock is not entitled to any votes per share, except as may be required by law. However, as long as any shares of non-voting common stock are outstanding, we will not, without the affirmative vote of the holders of a majority of the then outstanding shares of non-voting common stock, (i) alter or change adversely the powers, preferences or rights given to the non-voting common stock, alter, amend or repeal any provision of, or add any provision to, our amended and restated certificate of incorporation or bylaws, or file any articles of amendment, certificate of designations, preferences, limitations and relative rights of any series of preferred stock, if such action would adversely alter or change the preferences, rights, privileges or powers of, or restrictions provided for the benefit of the non-voting common stock, regardless of whether any of the foregoing actions shall be by means of amendment to our amended and restated certificate of incorporation or by merger, consolidation or otherwise, (ii) issue further shares of non-voting common stock or increase or



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decrease the number of authorized shares of non-voting common stock, (iii) prior to the requisite stockholder approval or at any time while at least % of the originally issued non-voting common stock remains issued and outstanding, consummate either: (A) any Fundamental Transaction (as defined in our amended and restated certificate of incorporation) or (B) any merger or consolidation of us with or into another entity or any stock sale to, or other business combination in which our stockholders immediately before such transaction do not hold at least a majority of our capital stock immediately after such transaction or (iv) enter into any agreement with respect to any of the foregoing.

***Economic Rights***

Except as otherwise expressly provided in our amended and restated certificate of incorporation or required by applicable law, all shares of common stock and non-voting common stock will have the same rights and privileges and rank equally, share ratably, and be identical in all respects for all matters, including those described below.

*Dividends.* Subject to preferences that may apply to any shares of preferred stock outstanding at the time, the holders of our common stock and non-voting common stock are entitled to receive dividends out of funds legally available if our board of directors, in its discretion, determines to issue dividends and then only at the times and in the amounts that our board of directors may determine. See the section titled “Dividend Policy” for further information.

*Liquidation Rights.* On our liquidation, dissolution, or winding-up, the holders of common stock and non-voting common stock will be entitled to share equally, identically, and ratably in all assets remaining after the payment of any liabilities, liquidation preferences and accrued or declared but unpaid dividends, if any, with respect to any outstanding preferred stock, unless a different treatment is approved by the affirmative vote of the holders of a majority of the outstanding shares of such affected class, voting separately as a class.

***No Preemptive or Similar Rights***

The holders of our shares of common stock and non-voting common stock are not entitled to preemptive rights, and are not subject to conversion, redemption or sinking fund provisions. The rights, preferences and privileges of the holders of our common stock or non-voting common stock are subject to, and may be adversely affected by, the right of the holders of shares of any series of preferred stock that we may designate in the future.

***Fully Paid and Non-Assessable***

In connection with this offering, our legal counsel will opine that the shares of our common stock and non-voting common stock to be issued under this offering will be fully paid and non-assessable.

**Preferred Stock**

As of March 31, 2024, there were shares of redeemable convertible preferred stock outstanding, consisting of shares of Series Seed redeemable convertible preferred stock, shares of Series A redeemable convertible preferred stock, shares of Series B redeemable convertible preferred stock, shares of Series B-1 redeemable convertible preferred stock, shares of Series B-2 redeemable convertible preferred stock, shares of Series B-2A redeemable convertible preferred stock, shares of Series C redeemable convertible preferred stock and shares of Series C-1 redeemable convertible preferred stock. All outstanding shares of redeemable convertible preferred stock will be converted into an aggregate of shares of common stock and shares of non-voting common stock immediately prior to the closing of this offering.

Following the closing of this offering, under the terms of our amended and restated certificate of incorporation, our board of directors will have the authority, without further action by our stockholders, to issue up to 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 dividend, voting and other 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.

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Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock and non-voting 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 and may adversely affect the market price of our common stock and non-voting common stock and the voting and other rights of the holders of our common stock and non-voting common stock. We have no current plans to issue any shares of preferred stock.

**Stock Options; Shares Reserved for Future Issuance under the 2023 Plan**

As of March 31, 2024, after giving effect to the Common Stock Reclassification, there were options to purchase \_\_\_\_\_ shares of common stock outstanding under our 2021 Plan. For additional information regarding the terms of our 2021 Plan, see the section titled “Executive Compensation—Equity Benefit Plans.” Following completion of this offering, \_\_\_\_\_ shares of our common stock will be reserved for future issuance under the 2024 Plan, which will become effective immediately prior to the execution of the underwriting agreement for this offering, as well as any future automatic annual increases in the number of shares of common stock reserved for issuance under the 2024 Plan and any shares underlying outstanding stock awards granted under the 2021 Plan, that expire or are repurchased, forfeited, cancelled, or withheld. For additional information regarding terms of our equity incentive plans, see the section titled “Executive Compensation—Equity Benefit Plans.”

**Registration Rights**

Upon the closing of this offering and subject to the lock-up agreements entered into in connection with this offering and federal securities laws, certain holders of shares of our common stock, including those shares of common stock and non-voting stock that will be issued upon the conversion of our convertible preferred stock in connection with this offering, will initially be entitled to certain rights with respect to registration of such shares under the Securities Act. These shares are referred to as registrable securities. The holders of these registrable securities possess registration rights pursuant to the terms of a registration rights agreement and are described in additional detail below. The registration of shares of our common stock and non-voting common stock pursuant to the exercise of the registration rights described below would enable the holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective. We will pay the registration expenses, other than underwriting discounts, selling commissions and stock transfer taxes, of the shares registered pursuant to the demand, piggyback and Form S-3 registrations described below.

Generally, in an underwritten offering, the managing underwriter, if any, has the right, subject to specified conditions and limitations, to limit the number of shares the holders may include. The demand, piggyback and Form S-3 registration rights described below will expire no later than three years after the closing of this offering.

***Demand Registration Rights***

Upon the closing of this offering, holders of an aggregate of \_\_\_\_\_ shares of our common stock will be entitled to certain demand registration rights. At any time beginning 180 days after the closing of this offering, the holders of \_\_\_\_\_ % of these shares may request that we register all or a portion of their shares. We are not required to effect more than \_\_\_\_\_ registration statements which are declared or ordered effective. Such request for registration must cover shares with an anticipated aggregate offering price, net of selling expenses, of at least \$ \_\_\_\_\_ million. With certain exceptions, we are not required to effect the filing of a registration statement during the period starting with the date of the filing of, and ending on a date 180 days following the effective date of the registration statement for this offering.

***Piggyback Registration Rights***

In connection with this offering, the holders of an aggregate of \_\_\_\_\_ shares of our 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

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security holders, the holders of these shares will be entitled to certain piggyback registration rights allowing the holder to include their shares in such registration, subject to certain marketing and other limitations.

***Form S-3 Registration Rights***

Upon the closing of this offering, holders of an aggregate of \_\_\_\_\_ shares of our common stock will be entitled to certain Form S-3 registration rights. Holders of \_\_\_\_\_ % of these shares can make a request that we register their shares on Form S-3 if we are qualified to file a registration statement on Form S-3 and if the reasonably anticipated aggregate net proceeds of the shares offered would equal or exceed \$ \_\_\_\_\_ million. We will not be required to effect more than \_\_\_\_\_ registrations on Form S-3 within any 12-month period.

***Anti-Takeover Provisions***

The provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws, which are summarized below, may have the effect of delaying, deferring or discouraging another person from acquiring control of our company. They are also designed, in part, to encourage persons seeking to acquire control of us to negotiate first with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us because negotiation of these proposals could result in an improvement of their terms.

***Certificate of Incorporation and Bylaws to be in Effect in connection with this Offering***

Because our stockholders do not have cumulative voting rights, stockholders holding a majority of the voting power of our shares of common stock will be able to elect all of our directors. Our amended and restated certificate of incorporation, to be effective immediately after the closing of this offering, and our amended and restated bylaws, to be effective on the closing of this offering, will provide for stockholder actions at a duly called meeting of stockholders or, before the date on which all shares of common stock convert into a single class, by written consent. A special meeting of stockholders may be called by a majority of our board of directors, the chair of our board of directors, or our chief executive officer or president. Our amended and restated bylaws will establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors.

As described above in “Management—Composition of Our Board of Directors,” in accordance with our amended and restated certificate of incorporation to be filed in connection with this offering, immediately prior to the completion of this offering, our board of directors will be divided into three classes with staggered three-year terms.

The foregoing provisions will make it more difficult for another party to obtain control of us by replacing our board of directors. Since 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 preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of deterring hostile takeovers or delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts.

***Section 203 of the Delaware General Corporation Law***

When we have a class of voting stock that is either listed on a national securities exchange or held of record by more than 2,000 stockholders, we will be subject to Section 203 of the 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.

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***Choice of Forum***

Our amended and restated certificate of incorporation to be effective immediately prior to the closing of this offering will provide that the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) and any appellate court therefrom is the sole and exclusive forum for the following claims or causes of action under the Delaware statutory or common law: (i) any derivative claim or cause of action brought on our behalf; (ii) any claim or cause of action for a breach of fiduciary duty owed by any of our current or former directors, officers, or other employees to us or our stockholders; (iii) any claim or cause of action against us or any of our current or former directors, officers or other employees arising out of or pursuant to any provision of the DGCL, our amended and restated certificate of incorporation, or our bylaws (as each may be amended from time to time); (iv) any claim or cause of action seeking to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws (as each may be amended from time to time, including any right, obligation, or remedy thereunder); (v) any claim or cause of action as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; and (vi) any claim or cause of action against us or any of our current or former directors, officers, or other employees governed by the internal-affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants. Our amended and restated certificate of incorporation to be effective on the closing of this offering will further provide that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause or causes of action arising under the Securities Act, including all causes of action asserted against an defendant to such complaint. The choice of forum provision would not apply to claims or causes of action brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction.

For the avoidance of doubt, these provisions are intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. We note that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

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

**Limitations on Liability and Indemnification**

See the section titled "Executive Compensation—Limitations on Liability and Indemnification."

**Exchange Listing**

Our common stock is currently not listed on any securities exchange. We intend to apply to have common stock approved for listing on The Nasdaq Global Market under the symbol "ALMS." Our non-voting common stock will not be listed on any securities exchange.

**Transfer Agent and Registrar**

On the closing of this offering, the transfer agent and registrar for our common stock will be . The transfer agent's address is .

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**SHARES ELIGIBLE FOR FUTURE SALE**

Before the closing of this offering, there has been no public market for our common stock. Future sales of substantial amounts of our common stock, including shares issued on the exercise of outstanding options or upon conversion of our non-voting common stock, in the public market after this offering, or the possibility of these sales or issuances occurring, could adversely affect the prevailing market price for our common stock or impair our ability to raise equity capital.

Based on our shares of common stock outstanding as of March 31, 2024, upon the completion of this offering, a total of \_\_\_\_\_ shares of common stock will be outstanding, assuming (i) the Preferred Stock Conversion and (ii) the Common Stock Reclassification (as if each had occurred as of March 31, 2024). Of these shares, all of the common stock sold in this offering by us, plus any shares sold by us on exercise of the underwriters' over-allotment option, will be freely tradable in the public market without restriction or further registration under the Securities Act, unless these shares are held by "affiliates," as that term is defined in Rule 144 under the Securities Act (Rule 144).

The remaining shares of common stock and non-voting common stock will be, and shares of common stock subject to stock options will be on issuance, "restricted securities," as that term is defined in Rule 144. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rules 144 or 701 under the Securities Act, which are summarized below. Restricted securities may also be sold outside of the United States to non-U.S. persons in accordance with Rule 904 of Regulation S.

Subject to the lock-up agreements described below and the provisions of Rule 144 or Regulation S under the Securities Act, as well as our insider trading policy, these restricted securities will be available for sale in the public market after the date of this prospectus.

**Rule 144**

In general, under Rule 144 as currently in effect, once we have been subject to public company reporting requirements of Section 13 or Section 15(d) of the Exchange Act for at least 90 days, an eligible stockholder is entitled to sell such shares without complying with the manner of sale, volume limitation, or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. To be an eligible stockholder under Rule 144, such stockholder must not be deemed to have been one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and must have beneficially owned the shares proposed to be sold for at least six months, including the holding period of any prior owner other than our affiliates. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then such person is entitled to sell such shares without complying with any of the requirements of Rule 144, subject to the expiration of the lock-up agreements described below.

In general, under Rule 144, as currently in effect, our affiliates or persons selling shares on behalf of our affiliates are entitled to sell shares on expiration of the lock-up agreements described below. Beginning 90 days after the date of this prospectus, within any three-month period, such stockholders may sell a number of shares that does not exceed the greater of:

- 1% of the number of shares of common stock and non-voting common stock then outstanding, which will equal approximately shares immediately after this offering, assuming no exercise of the underwriters' over-allotment option; or
- the average weekly trading volume of our common stock on The Nasdaq Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us.

**Rule 701**

Rule 701 of the Securities Act (Rule 701) generally allows a stockholder who was issued shares under a written compensatory plan or contract and who is not deemed to have been an affiliate of our company during the

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immediately preceding 90 days, to sell these shares in reliance on Rule 144, but without being required to comply with the public information, holding period, volume limitation, or notice provisions of Rule 144. Rule 701 also permits affiliates of our company to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required by that rule to wait until 90 days after the date of this prospectus before selling those shares under Rule 701, subject to the expiration of the lock-up agreements described below.

#### **Form S-8 Registration Statements**

We intend to file one or more registration statements on Form S-8 under the Securities Act with the SEC to register the offer and sale of shares of our common stock that are issuable upon exercise of outstanding stock options and shares of our common stock reserved for future issuance under the 2023 Plan and ESPP. These registration statements will become effective immediately on filing. Shares covered by these registration statements will then be eligible for sale in the public markets, subject to vesting restrictions, any agreements described below, and Rule 144 limitations applicable to affiliates.

#### **Lock-Up Arrangements**

We, and all of our directors, executive officers and the holders of substantially all of our common stock and securities exercisable for or convertible into our common stock outstanding, have agreed with the underwriters that, until 180 days after the date of the underwriting agreement related to this offering, we and they will not, without the prior written consent of the representatives of the underwriters, subject to certain exceptions, directly or indirectly, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of any of our shares of common stock, or any securities convertible into or exercisable or exchangeable for shares of our common stock (including shares of our non-voting common stock), or enter into any hedging, swap or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of the securities, whether any such swap or transaction is to be settled by delivery of our common stock or other securities, in cash or otherwise. These agreements are described in the section titled “Underwriting.” The representatives of the underwriters may, in their sole discretion, release any of the securities subject to these lock-up agreements at any time.

In addition to the restrictions contained in the lock-up agreements described above, we have entered into agreements with certain of our security holders, including the amended and restated investors’ rights agreement and our standard forms of option agreement, that contain market stand-off provisions or incorporate market stand-off provisions from our equity incentive plan imposing restrictions on the ability of such security holders to offer, sell or transfer our equity securities for a period of 180 days following the date of this prospectus.

#### **Registration Rights**

Upon the closing of this offering, pursuant to our amended and restated investors’ rights agreement, the holders of \_\_\_\_\_ shares of our common stock, or their transferees, will be entitled to certain rights with respect to the registration of the offer and sale of their shares (including shares of common stock issuable upon conversion of our non-voting common stock) under the Securities Act, subject to the terms of the lock-up agreements described under the subsection titled “—Lock-Up Arrangements” above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act immediately on the effectiveness of the registration. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock. See the section titled “Description of Capital Stock—Registration Rights” for additional information.

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**CERTAIN MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO 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 common stock offered pursuant to this prospectus. 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 Internal Revenue Code of 1986, as amended (the Code), and 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 non-U.S. tax laws. This discussion is based on the Code and applicable Treasury Regulations promulgated thereunder, judicial decisions and published rulings, and administrative pronouncements of the Internal Revenue Service, or the IRS, all as in effect as of 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, and do not intend to request, a ruling from the IRS with respect to the U.S. federal income tax consequences discussed below, and there can be no assurance that the IRS or a court will agree with such tax consequences.

This discussion is limited to non-U.S. holders who purchase our common stock pursuant to this offering and who hold our 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 U.S. federal income tax consequences that may be relevant to a particular non-U.S. holder in light of such non-U.S. holder’s particular circumstances. Finally, this discussion does not address any specific facts or circumstances that may be relevant to non-U.S. holders subject to special rules under U.S. federal income tax laws, including:

- certain former citizens or long-term residents of the United States;
- partnerships, S corporations, or other entities or arrangements treated as partnerships, pass-through entities, or disregarded entities (including hybrid entities) for U.S. federal income tax purposes (and investors therein);
- “controlled foreign corporations” within the meaning of Section 957(a) of the Code;
- “passive foreign investment companies” within the meaning of Section 1297(a) of the Code;
- corporations that accumulate earnings to avoid U.S. federal income tax;
- banks, financial institutions, investment companies, insurance companies, brokers, dealers or traders in securities;
- real estate investment trusts or regulated investment companies;
- persons that have elected to mark securities to market;
- tax-exempt organizations (including private foundations), governmental organizations, or international organizations;
- tax-qualified retirement plans;
- persons that acquired our common stock through the exercise of employee stock options or otherwise as compensation;
- persons that acquired our common stock through the exercise of warrants or conversion rights under convertible instruments;
- persons that hold our common stock as “qualified small business stock” under Section 1202 of the Code or “Section 1244 stock” under Section 1244 of the Code;
- persons that acquired our common stock in a transaction subject to the gain rollover provisions of the Code (including Section 1045 of the Code);
- persons that own, or have owned, actually or constructively, more than 5% of our common stock;
- “qualified foreign pension funds” within the meaning of Section 897(1)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds; and

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- persons that hold our common stock as part of a hedging or conversion transaction, straddle, a constructive sale, or any other risk reduction strategy or integrated investment.

If a partnership (or an entity or arrangement that is treated as a partnership for U.S. federal income tax purposes) holds our common stock, the U.S. federal income tax treatment of a partner in such partnership will generally depend on the status of the partner and the activities of the partnership. Partnerships that hold our 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 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 COMMON STOCK, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL, OR NON-U.S. TAX LAWS AND ANY U.S. FEDERAL NON-INCOME 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 common stock that is not a “United States person” or a partnership (including any entity or arrangement treated as a partnership) for U.S. federal income tax purposes. A U.S. person 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 (or any entity treated as a corporation for U.S. federal income tax purposes) 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 “United States persons” within the meaning of Section 7701(a)(30) of the Code 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 United States person.

**Distributions on Our Common Stock**

As described in the section titled “Dividend Policy” above, we have not paid and do not anticipate declaring or paying dividends in the foreseeable future. However, if we make cash or other property distributions on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid out of our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Any portion of a distribution that exceeds our current and accumulated earnings and profits will constitute a return of capital and first will be applied against and reduce the non-U.S. holder’s tax basis in our common stock, but not below zero. Any amount distributed in excess of tax basis will be treated as gain realized on the sale or other disposition of our common stock and, therefore, will be treated as described in the subsection titled “—Gain on Sale or Other Disposition of Our Common Stock” below.

Subject to the discussions below regarding effectively connected income, backup withholding, and FATCA (as defined below), dividends paid to a non-U.S. holder generally will be subject to U.S. federal withholding tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) of the gross amount of the dividends. To receive the benefit of a lower treaty rate, a non-U.S. holder must furnish the applicable withholding agent with a valid IRS Form W-8BEN or IRS Form W-8BEN-E (or applicable successor form) certifying such non-U.S. holder’s qualification for such rate. This certification must be provided to the applicable withholding agent before the payment of dividends and updated periodically. If the non-U.S. holder holds our 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 financial institution or agent, which then will be required to provide certification to the applicable withholding agent, either directly or through other intermediaries.



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If a non-U.S. holder holds our common stock in connection with the conduct of a trade or business in the United States, and dividends paid on our common stock are effectively connected with such non-U.S. holder's U.S. trade or business (and are attributable to such non-U.S. holder's permanent establishment in the United States, if required by an applicable tax treaty), the non-U.S. holder generally 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 common stock generally will be subject to U.S. federal income tax on a net income basis at regular U.S. federal income tax rates in the same manner as if the non-U.S. 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.

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 are urged to consult their tax advisors about any applicable income tax treaties that may provide for different rules.

**Gain on Sale or Other Disposition of Our Common Stock**

Subject to the discussions below regarding backup withholding and FATCA, 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 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 the non-U.S. holder's 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 sale or other disposition, and certain other requirements are met; or
- our common stock constitutes a "United States real property interest" by reason of our status as a United States real property holding corporation, or USRPHC, for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding the sale or other disposition or the non-U.S. holder's holding period for our common stock, and our common stock is not regularly traded on an established securities market as defined by applicable Treasury Regulations.

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 do not believe that we are, or have been, and do not anticipate becoming, a USRPHC for U.S. federal income tax purposes, although there can be no assurance that we will not in the future become a USRPHC. Even if we are or were to become a USRPHC, gain arising from the sale or other disposition by a non-U.S. holder of our common stock may not be subject to U.S. federal income tax if our common stock is "regularly traded," as defined by applicable Treasury Regulations, on an established securities market.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at regular U.S. federal income tax rates in the same manner as if the non-U.S. 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. A non-U.S. holder 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) on gain realized upon the sale or other taxable disposition of our common stock which 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. If we are or become a USRPHC during the period described in the third bullet point above and our common stock is not regularly traded for purposes of the relevant rules, gain arising from the sale or other taxable disposition of our common stock by a non-U.S. holder will generally be subject to U.S. federal income tax in the same manner as gain that is effectively

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connected with the conduct of a U.S. trade or business, except that the branch profits tax generally will not apply to a corporate non-U.S. holder. Non-U.S. holders are urged to consult their tax advisors about 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 common stock paid to such non-U.S. 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 non-U.S. holder's conduct of a U.S. trade or business, or withholding was reduced or eliminated by an applicable income tax treaty) and regardless of whether such distributions constitute dividends. 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 sale or other disposition of our common stock provided that 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 certain other requirements are met. Backup withholding may apply if the payor has actual knowledge, or reason to know, that the non-U.S. holder is a United States person who is not an exempt recipient.

Backup withholding is not an additional tax. If any amount is withheld under the backup withholding rules, non-U.S. holders are urged to consult their tax advisors about 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.

**Foreign Account Tax Compliance Act**

Sections 1471 through 1474 of the Code (commonly referred to as FATCA), imposes a U.S. federal withholding tax of 30% on certain payments made to a "foreign financial institution" (as specially defined under the FATCA 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 will impose a U.S. federal withholding tax of 30% on certain payments made to a non-financial foreign entity unless such entity provides the withholding agent a certification identifying certain direct and indirect U.S. owners of the entity or an exemption applies. An intergovernmental agreement between the United States and an applicable non-U.S. 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 common stock and, subject to the proposed Treasury Regulations described below, also applies to payments of gross proceeds from sales or other dispositions of our common stock. The U.S. Treasury Department released proposed Treasury Regulations which, if finalized in their present form, would eliminate the U.S. federal withholding tax of 30% applicable to the gross proceeds of a sale or other disposition of our common stock. In its preamble to such proposed Treasury Regulations, the U.S. Treasury Department stated that taxpayers may generally rely on the proposed Treasury Regulations until final regulations are issued.

Prospective investors are urged to consult with their tax advisors about the possible implications of FATCA on their investment in our common stock.

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**UNDERWRITING**

Under the terms and subject to the conditions in an underwriting agreement dated the date of this prospectus, the underwriters named below, for whom Morgan Stanley & Co. LLC is acting as representative, have severally agreed to purchase, and we have agreed to sell to them, severally, the number of shares indicated below:

<u>Name</u>	<u>Number of Shares</u>
Morgan Stanley & Co. LLC	
<b>Total:</b>	

The underwriters and the representative are collectively referred to as the “underwriters” and the “representative,” respectively. The underwriters are offering the shares of common stock subject to their acceptance of the shares from us and subject to prior sale. The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the shares of common stock offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters are obligated to take and pay for all of the shares of common stock offered by this prospectus if any such shares are taken. However, the underwriters are not required to take or pay for the shares covered by the underwriters’ over-allotment option described below.

The underwriters initially propose to offer part of the shares of common stock directly to the public at the offering price listed on the cover page of this prospectus and part to certain dealers at a price that represents a concession not in excess of \$ \_\_\_\_\_ per share under the public offering price. After the initial offering of the shares of common stock, the offering price and other selling terms may from time to time be varied by the representative.

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to \_\_\_\_\_ additional shares of common stock at the public offering price listed on the cover page of this prospectus, less underwriting discounts and commissions. The underwriters may exercise this option solely for the purpose of covering over-allotments, if any, made in connection with the offering of the shares of common stock offered by this prospectus. To the extent the option is exercised, each underwriter will become obligated, subject to certain conditions, to purchase about the same percentage of the additional shares of common stock as the number listed next to the underwriter’s name in the preceding table bears to the total number of shares of common stock listed next to the names of all underwriters in the preceding table.

The following table shows the per share and total public offering price, underwriting discounts and commissions, and proceeds before expenses to us. These amounts are shown assuming both no exercise and full exercise of the underwriters’ option to purchase up to an additional \_\_\_\_\_ shares \_\_\_\_\_ of common stock.

	<u>Per Share</u>	<u>Total</u>	
		<u>No Exercise</u>	<u>Full Exercise</u>
Public offering price	\$	\$	\$
Underwriting discounts and commissions to be paid by us	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$

The estimated offering expenses payable by us, exclusive of the underwriting discounts and commissions, are approximately \$ \_\_\_\_\_. We have agreed to reimburse the underwriters for expense relating to clearance of this offering with the Financial Industry Regulatory Authority up to \$ \_\_\_\_\_.

The underwriters have informed us that they do not intend sales to discretionary accounts to exceed 5% of the total number of shares of common stock offered by them.

We intend to apply to list our shares of common stock on \_\_\_\_\_ under the trading symbol “ALMS”.

We and all directors and officers and the holders of all of our outstanding stock and stock options have agreed that, without the prior written consent of Morgan Stanley & Co. LLC on behalf of the underwriters, we and

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they will not, and will not publicly disclose an intention to, during the period ending 180 days after the date of this prospectus (the “restricted period”):

- offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock;
- file any registration statement with the Securities and Exchange Commission relating to the offering of any shares of common stock or any securities convertible into or exercisable or exchangeable for common stock; or
- enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock.

whether any such transaction described above is to be settled by delivery of common stock or such other securities, in cash or otherwise. In addition, we and each such person agrees that, without the prior written consent of Morgan Stanley & Co. LLC on behalf of the underwriters, we or such other person will not, during the restricted period, make any demand for, or exercise any right with respect to, the registration of any shares of common stock or any security convertible into or exercisable or exchangeable for common stock.

The restrictions described in the immediately preceding paragraph to do not apply to:

- the sale of shares to the underwriters; or
- the issuance by the Company of shares of common stock upon the exercise of an option or a warrant or the conversion of a security outstanding on the date of this prospectus of which the underwriters have been advised in writing;
- transactions by any person other than us relating to shares of common stock or other securities acquired in open market transactions after the completion of the offering of the shares; provided that no filing under Section 16(a) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), is required or voluntarily made in connection with subsequent sales of the common stock or other securities acquired in such open market transactions; or
- facilitating the establishment of a trading plan on behalf of a shareholder, officer or director of the Company pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of common stock, provided that (i) such plan does not provide for the transfer of common stock during the restricted period and (ii) to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made by the Company regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of common stock may be made under such plan during the restricted period.

Morgan Stanley & Co. LLC, in its sole discretion, may release the common stock and other securities subject to the lock-up agreements described above in whole or in part at any time.

In order to facilitate the offering of the common stock, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the common stock. Specifically, the underwriters may sell more shares than they are obligated to purchase under the underwriting agreement, creating a short position. A short sale is covered if the short position is no greater than the number of shares available for purchase by the underwriters under the over-allotment option. The underwriters can close out a covered short sale by exercising the over-allotment option or purchasing shares in the open market. In determining the source of shares to close out a covered short sale, the underwriters will consider, among other things, the open market price of shares compared to the price available under the over-allotment option. The underwriters may also sell shares in excess of the over-allotment option, creating a naked short position. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in this offering. As an additional means of facilitating this offering, the underwriters may bid for, and purchase, shares of common stock in the open market to stabilize the price of the common stock. These activities may raise or maintain the market price of the common stock above independent market levels or prevent or retard a decline in the

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market price of the common stock. The underwriters are not required to engage in these activities and may end any of these activities at any time.

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

A prospectus in electronic format may be made available on websites maintained by one or more underwriters, or selling group members, if any, participating in this offering. The representative may agree to allocate a number of shares of common stock to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the representative to underwriters that may make Internet distributions on the same basis as other allocations.

#### **Other Relationships**

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. Certain of the underwriters and their respective affiliates have, from time to time, performed, and may in the future perform, various financial advisory and investment banking services for us, for which they received or will receive customary fees and expenses.

In addition, in the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers and may at any time hold long and short positions in such securities and instruments. Such investment and securities activities may involve our securities and instruments. The underwriters and their respective affiliates may also make investment recommendations or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long or short positions in such securities and instruments.

#### **Pricing of the Offering**

Prior to this offering, there has been no public market for our common stock. The initial public offering price was determined by negotiations between us and the representative. Among the factors considered in determining the initial public offering price were our future prospects and those of our industry in general, our sales, earnings and certain other financial and operating information in recent periods, and the price-earnings ratios, price-sales ratios, market prices of securities, and certain financial and operating information of companies engaged in activities similar to ours.

#### **Directed Share Program**

At our request, the underwriters have reserved \_\_\_\_\_ percent of the shares of common stock to be issued by the Company and offered by this prospectus for sale, at the initial public offering price, to directors, officers, employees, business associates and related persons of the Company. If purchased by these persons, these shares will be subject to a 180-day lock-up restriction. The number of shares of common stock available for sale to the general public will be reduced to the extent these individuals purchase such reserved shares. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same basis as the other shares offered by this prospectus. The underwriters will receive the same discount from such reserved shares as they will from other shares of our shares of common stock sold to the public in this offering. We have agreed to indemnify the underwriters against certain liabilities and expenses, including liabilities under the Securities Act, in connection with sales of the reserved shares.

#### **Selling Restrictions**

##### ***Australia***

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission, in relation to the offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the

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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 (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 the shares must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

***Canada***

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser’s province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser’s province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 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.

***Dubai International Financial Centre***

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority (the DFSA). This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

***European Economic Area***

In relation to each Member State of the European Economic Area and the United Kingdom (each, a “Relevant State”), no securities have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the securities which has been approved by the

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competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that offers of securities may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

- (a) to any legal entity which is a qualified investor as defined under the Prospectus Regulation;
- (b) to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the representative; or
- (c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares shall require us or any of our representative to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression an “offer to the public” in relation to any shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase any shares, and the expression “Prospectus Regulation” means Regulation (EU) 2017/1129 (as amended).

***United Kingdom***

Each underwriter has represented and agreed that:

- (a) it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000 (“FSMA”) received by it in connection with the issue or sale of our shares of common stock in circumstances in which Section 21(1) of the FSMA does not apply to us; and
- (b) it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares of common stock in, from or otherwise involving the 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 (as defined below);
- (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 representative 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 us or any of the representative 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.

This prospectus is only for distribution to and directed at: (i) in the United Kingdom, persons having professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the Order), and high net worth entities falling within Article 49(2)(a) to (d) of the Order; (ii) persons who are outside the United Kingdom; and

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(iii) any other person to whom it can otherwise be lawfully distributed (all such persons together, Relevant Persons). Any investment or investment activity to which this prospectus relates is available only to and will be engaged in only with Relevant Persons, and any person who is not a Relevant Person should not rely on it.

***Hong Kong***

The shares of common stock have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to “professional investors” as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance or (b) in other circumstances which do not result in the document being a “prospectus” as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the shares of common stock has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares of common stock which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” as defined in the Securities and Futures Ordinance and any rules made under that Ordinance.

***Israel***

In the State of Israel this prospectus shall not be regarded as an offer to the public to purchase shares of common stock under the Israeli Securities Law, 5728 - 1968, which requires a prospectus to be published and authorized by the Israel Securities Authority, if it complies with certain provisions of Section 15 of the Israeli Securities Law, 5728 - 1968, including if: (i) the offer is made, distributed or directed to not more than 35 investors, subject to certain conditions (the Addressed Investors); or (ii) the offer is made, distributed or directed to certain qualified investors defined in the First Addendum of the Israeli Securities Law, 5728 - 1968, subject to certain conditions (the Qualified Investors). The Qualified Investors shall not be taken into account in the count of the Addressed Investors and may be offered to purchase shares of common stock in addition to the 35 Addressed Investors. The company has not and will not take any action that would require it to publish a prospectus in accordance with and subject to the Israeli Securities Law, 5728 - 1968. We have not and will not distribute this prospectus or make, distribute or direct an offer to subscribe for our shares of common stock to any person within the State of Israel, other than to Qualified Investors and up to 35 Addressed Investors.

Qualified Investors may have to submit written evidence that they meet the definitions set out in of the First Addendum to the Israeli Securities Law, 5728 - 1968. In particular, we may request, as a condition to be offered shares of common stock, that Qualified Investors will each represent, warrant and certify to us and/or to anyone acting on our behalf: (i) that it is an investor falling within one of the categories listed in the First Addendum to the Israeli Securities Law, 5728 - 1968; (ii) which of the categories listed in the First Addendum to the Israeli Securities Law, 5728 - 1968 regarding Qualified Investors is applicable to it; (iii) that it will abide by all provisions set forth in the Israeli Securities Law, 5728 - 1968 and the regulations promulgated thereunder in connection with the offer to be issued shares of common stock; (iv) that the shares of common stock that it will be issued are, subject to exemptions available under the Israeli Securities Law, 5728 - 1968: (a) for its own account; (b) for investment purposes only; and (c) not issued with a view to resale within the State of Israel, other than in accordance with the provisions of the Israeli Securities Law, 5728 - 1968; and (v) that it is willing to provide further evidence of its Qualified Investor status. Addressed Investors may have to submit written evidence in respect of their identity and may have to sign and submit a declaration containing, inter alia, the Addressed Investor’s name, address and passport number or Israeli identification number.

***Japan***

The shares of common stock have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold, directly or indirectly, in Japan, or for the benefit of any Japanese Person (as defined below) or to others for re-offering or resale, directly or indirectly, in Japan or to any Japanese Person, except in compliance with all applicable laws, regulations and ministerial guidelines promulgated by relevant Japanese governmental or



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regulatory authorities in effect at the relevant time. For the purposes of this paragraph, “Japanese Person” means any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

***Singapore***

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, the shares of common stock were not offered or sold or caused to be made the subject of an invitation for subscription or purchase and will not be offered or sold or caused to be made the subject of an invitation for subscription or purchase, and this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares of common stock, has not been circulated or distributed, nor will it be circulated or distributed, whether directly or indirectly, to any person in Singapore other than (i) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore (as modified or amended from time to time, the SFA)) pursuant to Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares of common stock are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- (a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- (b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor;

securities or securities-based derivatives contracts (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiaries’ rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the securities pursuant to an offer made under Section 275 of the SFA except:

- (a) to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- (b) where no consideration is or will be given for the transfer;
- (c) where the transfer is by operation of law; or
- (d) as specified in Section 276(7) of the SFA.

***Switzerland***

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (the SIX) or on any other stock exchange or regulated trading facility in Switzerland. This prospectus has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this prospectus nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this prospectus nor any other offering or marketing material relating to us, the offering, or the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this prospectus will not be filed with, and the offering of shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, and the offering of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes (the CISA). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of the shares.

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**LEGAL MATTERS**

The validity of the shares of our common stock being offered in this prospectus will be passed upon for us by Cooley LLP. Certain legal matters in connection with this offering will be passed upon for the underwriters by Latham & Watkins LLP. As of the date of this prospectus, GC&H Investments, LLC, an entity comprised of partners and associates of Cooley LLP, beneficially owns \_\_\_\_\_ shares of common stock issuable upon the conversion of our redeemable convertible preferred stock.

**EXPERTS**

The financial statements as of December 31, 2022 and December 31, 2023 and for each of the two years in the period ended December 31, 2023 included in this Prospectus have been so included in reliance on the report (which contains an explanatory paragraph relating to the Company's ability to continue as a going concern as described in Note 1 to the financial statements) of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

**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 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 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](http://www.sec.gov).

On the closing of this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for inspection and copying at the public reference room and website of the SEC referred to above. We also maintain a website at [www.alumis.com](http://www.alumis.com). Upon the completion of this offering, you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained in or accessible through our website is not part of this prospectus or the registration statement of which this prospectus forms a part, and investors should not rely on such information in making a decision to purchase our common stock in this offering.

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ALUMIS INC.

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***Report of Independent Registered Public Accounting Firm***

To the Board of Directors and Stockholders of Alumis Inc.

***Opinion on the Financial Statements***

We have audited the accompanying consolidated balance sheets of Alumis Inc. and its subsidiaries (the “Company”) as of December 31, 2023 and 2022, and the related consolidated statements of operations and comprehensive loss, of redeemable convertible preferred stock and stockholders’ deficit and of cash flows for the years then ended, including the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

***Substantial Doubt about the Company’s Ability to Continue as a Going Concern***

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

***Basis for Opinion***

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated 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 of these consolidated financial statements in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/PricewaterhouseCoopers LLP

San Jose, California  
April 10, 2024

We have served as the Company’s auditor since 2022.

**CONFIDENTIAL TREATMENT REQUESTED BY ALUMIS INC.  
PURSUANT TO 17 C.F.R. SECTION 200.83**

**ALUMIS INC.  
CONSOLIDATED BALANCE SHEETS**

(in thousands, except share and per share amounts)	December 31, 2022	December 31, 2023
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 25,610	\$ 45,996
Marketable securities	67,255	2,956
Restricted cash	206	113
Research and development prepaid expenses	8,186	2,661
Other prepaid expenses and current assets	1,298	1,631
Total current assets	102,555	53,357
Restricted cash, non-current	1,138	1,024
Property and equipment, net	2,780	22,441
Operating lease right-of-use assets, net	1,695	12,783
Other long-term assets	—	7
Total assets	<u>\$ 108,168</u>	<u>\$ 89,612</u>
<b>Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Deficit</b>		
Current liabilities		
Accounts payable	\$ 1,720	\$ 1,118
Research and development accrued expenses	5,779	10,946
Other accrued expenses and current liabilities	4,543	7,087
Operating lease liabilities, current	1,310	1,720
Total current liabilities	13,352	20,871
Operating lease liabilities, non-current	469	30,860
Share repurchase liability	3,605	1,771
Other liabilities, non-current	511	—
Total liabilities	17,937	53,502
Commitments and contingencies (Note 7)		
Redeemable convertible preferred stock, \$0.0001 par value; 67,960,088 and 89,016,578 shares authorized as of December 31, 2022 and 2023, respectively; 67,960,088 and 85,960,088 shares issued and outstanding as of December 31, 2022 and 2023, respectively; aggregate liquidation preference of \$280,540 and \$370,540 as of December 31, 2022 and 2023, respectively	285,473	375,370
Stockholders' deficit:		
Common stock, \$0.0001 par value; 100,000,000 and 125,000,000 Class A shares authorized as of December 31, 2022 and 2023, respectively; 12,353,021 and 12,510,338 Class A shares issued and outstanding as of December 31, 2022 and 2023, respectively; 67,960,088 and 85,960,088 Class B shares authorized as of December 31, 2022 and 2023, respectively; no Class B shares issued and outstanding as of December 31, 2022 and 2023	1	1
Additional paid-in capital	14,209	25,055
Accumulated other comprehensive (loss) income	(127)	2
Accumulated deficit	(209,325)	(364,318)
Total stockholders' deficit	(195,242)	(339,260)
<b>Total liabilities, redeemable convertible preferred stock and stockholders' deficit</b>	<u><b>\$ 108,168</b></u>	<u><b>\$ 89,612</b></u>

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

**CONFIDENTIAL TREATMENT REQUESTED BY ALUMIS INC.  
PURSUANT TO 17 C.F.R. SECTION 200.83**

**ALUMIS INC.  
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**

<u>(in thousands, except share and per share amounts)</u>	<u>Year ended December 31, 2022</u>	<u>Year ended December 31, 2023</u>
Operating expenses:		
Research and development expenses, including related party expenses of \$1,570 and \$1,519 for the years ended December 31, 2022 and 2023, respectively	\$ 101,304	\$ 137,676
General and administrative expenses	12,546	20,498
Total operating expenses	<u>113,850</u>	<u>158,174</u>
Loss from operations	(113,850)	(158,174)
Other income (expense):		
Interest income	1,992	3,368
Change in fair value of derivative liability	—	(119)
Other income (expenses), net	(72)	(68)
Total other income (expense), net	<u>1,920</u>	<u>3,181</u>
Net loss	<u>\$ (111,930)</u>	<u>\$ (154,993)</u>
Other comprehensive (loss) income:		
Unrealized (loss) gain on marketable securities, net	(127)	129
Net loss and other comprehensive loss	<u>\$ (112,057)</u>	<u>\$ (154,864)</u>
Net loss per share attributable to Class A common stockholders, basic and diluted	<u>\$ (14.93)</u>	<u>\$ (15.42)</u>
Weighted-average Class A common shares outstanding, basic and diluted	<u>7,497,622</u>	<u>10,052,198</u>

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

CONFIDENTIAL TREATMENT REQUESTED BY ALUMIS INC.  
PURSUANT TO 17 C.F.R. SECTION 200.83

**ALUMIS INC.**  
**CONSOLIDATED 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 Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
<b>Balance at December 31, 2021</b>	<b>47,960,088</b>	<b>\$185,580</b>	<b>11,468,295</b>	<b>\$ 1</b>	<b>\$ 6,598</b>	<b>\$ —</b>	<b>\$ (97,395)</b>	<b>\$ (90,796)</b>
Issuance of B redeemable convertible preferred stock for cash, net of issuance costs of \$107	20,000,000	99,893	—	—	—	—	—	—
Issuance of common stock upon exercise of stock options and early exercise of stock options	—	—	884,726	—	12	—	—	12
Vesting of early exercised stock options	—	—	—	—	1,596	—	—	1,596
Vesting of restricted shares of common stock	—	—	—	—	43	—	—	43
Stock-based compensation expense	—	—	—	—	5,960	—	—	5,960
Other comprehensive loss, net	—	—	—	—	—	(127)	—	(127)
Net loss	—	—	—	—	—	—	(111,930)	(111,930)
<b>Balance at December 31, 2022</b>	<b>67,960,088</b>	<b>285,473</b>	<b>12,353,021</b>	<b>1</b>	<b>14,209</b>	<b>(127)</b>	<b>(209,325)</b>	<b>(195,242)</b>
Issuance of B-2 and B-2A redeemable convertible preferred stock in May 2023 for cash, net of derivative liability of \$2,112 and issuance costs of \$208	12,000,000	57,679	—	—	—	—	—	—
Issuance of B-2 and B-2A redeemable convertible preferred stock in October 2023 for cash, net of issuance costs of \$13, and settlement of derivative liability of \$2,231	6,000,000	32,218	—	—	—	—	—	—
Issuance of common stock upon exercise of stock options and early exercise of stock options	—	—	226,484	—	277	—	—	277
Vesting of early exercised stock options	—	—	—	—	1,921	—	—	1,921
Vesting of restricted shares of common stock	—	—	—	—	23	—	—	23
Repurchase of unvested early exercised stock options	—	—	(69,167)	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	8,625	—	—	8,625
Other comprehensive income, net	—	—	—	—	—	129	—	129
Net loss	—	—	—	—	—	—	(154,993)	(154,993)
<b>Balance at December 31, 2023</b>	<b>85,960,088</b>	<b>\$375,370</b>	<b>12,510,338</b>	<b>\$ 1</b>	<b>\$25,055</b>	<b>\$ 2</b>	<b>\$(364,318)</b>	<b>\$(339,260)</b>

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

**CONFIDENTIAL TREATMENT REQUESTED BY ALUMIS INC.  
PURSUANT TO 17 C.F.R. SECTION 200.83**

**ALUMIS INC.  
CONSOLIDATED STATEMENTS OF CASH FLOWS**

<u>(in thousands)</u>	<u>Year ended December 31, 2022</u>	<u>Year ended December 31, 2023</u>
<b>Cash flows from operating activities</b>		
Net loss	\$(111,930)	\$(154,993)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	5,960	8,625
Non-cash lease expense	950	2,010
Depreciation and amortization	250	1,284
Net accretion of discounts on marketable securities	(1,036)	(544)
Loss on abandonment of right-of-use assets	—	645
Loss on disposal of fixed assets	—	266
Change in fair value of derivative liability	—	119
Write-off of deferred offering costs	—	555
Changes in operating assets and liabilities:		
Research and development prepaid expenses	(7,334)	5,526
Other prepaid expenses and current assets	(1,019)	(340)
Accounts payable	1,294	(642)
Research and development accrued expenses, including changes in related party balances of (\$614) and \$2 for the years ended December 31, 2022 and 2023, respectively	2,383	5,168
Other accrued expenses and current liabilities	3,580	2,490
Operating lease liabilities	(820)	(144)
Net cash used in operating activities	<u>(107,722)</u>	<u>(129,975)</u>
<b>Cash flows from investing activities</b>		
Maturities of marketable securities	142,730	76,250
Purchases of marketable securities	(209,075)	(11,279)
Purchases of property and equipment	(2,406)	(4,499)
Net cash (used in) provided by investing activities	<u>(68,751)</u>	<u>60,472</u>
<b>Cash flows from financing activities</b>		
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	99,893	89,778
Proceeds from issuance of common stock upon exercise of stock options	1,734	453
Payments of deferred offering costs	—	(485)
Repurchase of unvested stock options	—	(64)
Net cash provided by financing activities	<u>101,627</u>	<u>89,682</u>
Net increase (decrease) in cash, cash equivalents and restricted cash	(74,846)	20,179
Cash, cash equivalents and restricted cash at beginning of period	101,800	26,954
Cash, cash equivalents and restricted cash at end of period	<u>\$ 26,954</u>	<u>\$ 47,133</u>
<b>Supplemental disclosures:</b>		
Right-of-use assets obtained in exchange for operating lease liabilities	\$ 896	\$ 14,255
Vesting of early exercised stock options and unvested restricted shares of common stock	\$ 1,639	\$ 1,944
Purchases of property and equipment in other accrued expenses and current liabilities	\$ 27	\$ 49
Property and equipment acquired through tenant improvement allowance	\$ 511	\$ 16,691
Recognition of derivative liability upon issuance of redeemable convertible preferred stock	\$ —	\$ 2,112
Settlement of derivative liability upon issuance of redeemable convertible preferred stock	\$ —	\$ (2,231)
<b>Reconciliation of cash, cash equivalents and restricted cash:</b>		
Cash and cash equivalents	\$ 25,610	\$ 45,996
Restricted cash	206	113
Restricted cash, non-current	1,138	1,024
Total cash, cash equivalents and restricted cash	<u>\$ 26,954</u>	<u>\$ 47,133</u>

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



**CONFIDENTIAL TREATMENT REQUESTED BY ALUMIS INC.  
PURSUANT TO 17 C.F.R. SECTION 200.83**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Organization and Nature of the Business**

***Organization and Business***

Alumis Inc. (the “Company”) is a clinical stage biopharmaceutical company focused on identifying, acquiring, and accelerating the development and commercialization of transformative medicines for autoimmune disorders. The Company leverages its precision data analytics platform, biological insights, and a team of experts with deep experience in precision medicine drug discovery, development, and immunology, to create medicines that significantly improve the lives of patients by replacing broad immunosuppression with targeted therapies.

The Company was founded on January 29, 2021 as a Delaware corporation under the name FL2021-001, Inc. FL2021-001, Inc.’s name was changed to Esker Therapeutics, Inc. on March 8, 2021 and to Alumis Inc. on January 6, 2022. The Company is headquartered in South San Francisco, California.

As of December 31, 2022 and 2023, the Company had two wholly owned subsidiaries, FronThera U.S. Holdings, Inc. and FronThera U.S. Pharmaceuticals LLC. These subsidiaries have no operations during 2022 and 2023 years.

***Liquidity and Going Concern***

The Company has incurred negative operating cash flows and significant losses from operations since its inception. For the years ended December 31, 2022 and 2023, the Company incurred net losses of \$111.9 million and \$155.0 million, respectively. Cash used in operating activities was \$107.7 million and \$130.0 million for the years ended December 31, 2022 and 2023, respectively. As of December 31, 2023, the Company had an accumulated deficit of \$364.3 million.

The Company has historically financed its operations primarily through issuance of redeemable convertible preferred stock and convertible promissory notes in private placements. The Company expects to continue to incur substantial losses for the foreseeable future, and its ability to achieve and sustain profitability will depend on the successful development, approval, and commercialization of any product candidates it may develop, and on the achievement of sufficient revenue to support its cost structure. The Company may never achieve profitability and, unless and until it does, it will need to continue to raise additional capital. As of December 31, 2023, the Company had cash, cash equivalents and marketable securities of \$49.0 million. In March 2024, the Company received aggregate gross proceeds of \$129.5 million from the issuance and sale of 41,264,891 shares of its Series C redeemable convertible preferred stock at a purchase price of \$3.13826 per share (the “First Tranche Series C Closing”) and, at the discretion of the Company’s board of directors, the Company is obligated to sell and Series C investors are obligated to purchase up to \$129.5 million worth of additional shares of Series C redeemable convertible preferred stock on the same terms and at the same purchase price per share as in the First Tranche Series C Closing of on or before December 31, 2024 (the “Second Tranche Series C Closing”). The Second Tranche Series C Closing is subject to certain conditions and events as described in Note 14, Subsequent Events.

Management expects that existing cash, cash equivalents and marketable securities together with the Series C financing aggregate gross proceeds of \$129.5 million received in March 2024 are not sufficient to fund its current operating plan for at least the next 12 months from the date of issuance of these consolidated financial statements. Additional funds are necessary to maintain current operations and to continue research and development activities. The Company’s management plans to monitor expenses and may raise additional capital through a combination of public and private equity, debt financings, strategic alliances, and licensing arrangements. The Company’s ability to access capital when needed is not assured and, if capital is not available to the Company when, and in the amounts, needed, on the terms which are favorable, the Company could be required to delay, scale back, or abandon some or all of its development programs and other operations, which could materially harm the Company’s business, financial condition and results of operations. These factors raise substantial doubt about the Company’s ability to continue as a going concern.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the

**CONFIDENTIAL TREATMENT REQUESTED BY ALUMIS INC.  
PURSUANT TO 17 C.F.R. SECTION 200.83**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**1. Organization and Nature of the Business (Continued)**

*Liquidity and Going Concern (Continued)*

normal course of business. The accompanying consolidated financial statements do not reflect any adjustments relating to the recoverability and reclassifications of assets and liabilities that might be necessary if the Company is unable to continue as a going concern.

**2. Summary of Significant Accounting Policies and Basis of Presentation**

*Basis of Presentation*

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The Company's consolidated financial statements include the accounts of FronThera U.S. Holdings, Inc. and FronThera U.S. Pharmaceuticals LLC, two wholly owned subsidiaries, and all intercompany transactions are eliminated.

Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

*Use of Estimates*

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. On an ongoing basis, the Company evaluates estimates and assumptions, including but not limited to those related to the fair value of its common and redeemable convertible preferred stock, the fair value of derivative liability, stock-based compensation expense, accruals for research and development expenses and the valuation of deferred tax assets. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from those estimates.

*Segment and Geographical Information*

The Company operates and manages its business as one reportable and operating segment, which is the business of developing medicines for autoimmune disorders. The chief executive officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance. All of the Company's long-lived assets are located in the United States.

*Concentration of Credit Risk*

Financial instruments which potentially subject the Company to concentration of credit risk consist primarily of cash, investments in marketable securities and restricted cash. The Company maintains bank deposits in federally insured financial institutions and these deposits exceed federally insured limits. To date, the Company has not experienced any losses on its deposits of cash and periodically evaluates the creditworthiness of its financial institutions.

The Company may also invest in money market funds, commercial paper, U.S. treasuries, corporate bonds, supranational debt securities and agency bonds, which can be subject to certain credit risks. The Company mitigates the risks by investing in high-grade instruments, limiting its exposure to any one issuer and monitoring the ongoing creditworthiness of the financial institutions and issuers. The Company has not experienced any loss of principal on its financial instruments.

**CONFIDENTIAL TREATMENT REQUESTED BY ALUMIS INC.  
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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. Summary of Significant Accounting Policies and Basis of Presentation (Continued)**

***Risks and Uncertainties***

The Company is subject to certain risks and uncertainties, including, but not limited to, changes in any of the following areas that the Company believes could have a material adverse effect on the future financial position or results of operations: the Company's ability to advance the development of its analytics platform, timing and ability to advance its product candidates through preclinical and clinical development; costs and timelines associated with the manufacturing of clinical supplies; regulatory approval, market acceptance of, and reimbursement for, any product candidates the Company may develop; performance of third-party vendors; competition from pharmaceutical or other biotechnology companies with greater financial resources or expertise; protection of intellectual property; litigation or claims against the Company based on intellectual property or other factors; and its ability to attract and retain employees necessary to support its growth.

The Company's business and operations may be affected by worldwide economic conditions, which may continue to be impacted by global macroeconomic challenges, such as the effects of the ongoing military conflicts in Ukraine, Israel, and the Middle East, tensions in U.S.-China relations, uncertainty in the markets, including disruptions in the banking industry, the COVID-19 pandemic and inflationary trends. Fiscal years 2022 and 2023 were marked by significant market uncertainty and increasing inflationary pressures. These market dynamics continue into 2024, and these and similar adverse market conditions may negatively impact the Company's business, financial position and results of operations.

***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 2023, cash and cash equivalents consisted of bank deposits and investments in money market funds and U.S. treasuries.

***Restricted Cash***

Restricted cash of \$1.3 million and \$1.1 million as of December 31, 2022 and 2023, respectively, represents security deposits in the form of letters of credit issued in connection with the Company's leases (see Note 7).

***Marketable Securities***

Marketable securities may consist of commercial paper, U.S. treasuries, corporate bonds, supranational debt securities and agency bonds with original maturities of three months or more at the time of purchase and are included in current assets. As the Company's entire investment portfolio is considered available for use in current operations, the Company classifies all investments as available-for-sale and as current assets, even though the stated maturity may be more than one year from the current balance sheet date. Marketable securities are carried at fair value, with change in fair value reported as unrealized gains or losses in accumulated other comprehensive (loss) income, which is a separate component of stockholders' deficit in the consolidated balance sheets.

The amortized cost of marketable securities is adjusted for amortization of premiums and accretion of discounts to maturity, which is included in interest income in the consolidated statements of operations and comprehensive loss.

Realized gains and losses on the sale of securities are determined by specific identification of each security's cost basis. The Company regularly reviews its investment portfolio to determine if any security is impaired, which would require it to record an allowance for credit losses or an impairment charge in the period any such determination is made. In making this judgment, the Company evaluates, among other things, the extent to which the fair value of a security is less than its amortized cost, its intent to sell or whether it is more likely than not that the Company will be required to sell the security before recovery of its amortized cost basis, the financial condition of the issuer and any changes thereto, and, as necessary, the portion of a decline in fair value that is credit-related. This assessment could change in the future due to new developments or changes in

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PURSUANT TO 17 C.F.R. SECTION 200.83**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. Summary of Significant Accounting Policies and Basis of Presentation (Continued)**

***Marketable Securities (Continued)***

assumptions related to any particular security. Realized gains and losses, allowances for credit losses and impairments on available-for-sale securities, if any, are recorded in the consolidated statements of operations and comprehensive loss.

***Fair Value Measurement***

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The carrying amounts of cash equivalents, prepaid expenses and other current assets, accounts payable, accrued expenses and other liabilities, approximate fair value due to their short-term maturities. Financial instruments, such as money market funds, marketable securities and derivative liability are measured at fair value at each reporting date (see Note 3).

***Deferred Finance Issuance Costs***

Deferred finance issuance costs, consisting of legal, accounting and other third-party fees directly relating to in-process equity financings or offerings are capitalized. The deferred finance issuance costs will be offset against offering proceeds upon the completion of the financing or the offering. In the event the financing or the offering is terminated or delayed, deferred finance issuance costs will be expensed immediately as a charge to general and administrative expenses in the consolidated statements of operations and comprehensive loss. As of December 31, 2022 and 2023, the Company did not have any capitalized deferred finance issuance costs.

***Property and Equipment, net***

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation is calculated using the straight-line method over the estimated useful lives of assets. Costs for capital assets not yet placed into service are capitalized as construction-in-progress and depreciated once placed into service. Repair and maintenance costs, which are not considered improvements and do not extend the useful life of property and equipment, are expensed as incurred. Improvements are capitalized as additions to property and equipment. Upon sale or retirement of assets, the costs and related accumulated depreciation are removed from the consolidated balance sheets and the resulting gain or loss is reflected within operating expenses in the consolidated statements of operations and comprehensive loss.

***Asset Acquisitions and Acquired In-Process Research and Development Expenses***

The Company measures and recognizes asset acquisitions that are not deemed to be business combinations based on the cost to acquire the asset or group of assets, which includes transaction costs. The Company determines if the acquisition should be accounted for as an asset acquisition after considering whether substantially all of the fair value of the gross assets acquired is concentrated in a single asset or group of assets and whether the Company acquired a substantive process capable of significantly contributing to the Company's ability to create outputs. Goodwill is not recognized in asset acquisitions. If acquired in-process technology assets, including licenses, know-how and patents are determined to not have an alternative future use, the cost is charged to research and development expenses at the acquisition date.

The Company accounts for contingent consideration identified in an asset acquisition that does not meet the definition of a derivative under ASC 815, *Derivatives and Hedging*, when the payment becomes probable and reasonably estimable. Such amounts are expensed or capitalized based on the nature of the associated asset at the date the related contingency is recognized.

***Leases***

The Company determines whether an arrangement is or contains a lease at the inception of the arrangement and whether such a lease should be classified as a financing lease or operating lease at the commencement date

**CONFIDENTIAL TREATMENT REQUESTED BY ALUMIS INC.  
PURSUANT TO 17 C.F.R. SECTION 200.83**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. Summary of Significant Accounting Policies and Basis of Presentation (Continued)**

***Leases (Continued)***

of the lease. Leases with a term greater than one year are recognized on the consolidated balance sheets as operating right-of-use assets ("ROU assets") and operating lease liabilities. The Company elected not to recognize the right-of-use assets and lease liabilities for leases with lease terms of one year or less (short-term leases). Lease liabilities and their corresponding ROU assets are recorded based on the present value of lease payments over the lease term. The Company considers the lease term to be the noncancelable period that it has the right to use the underlying asset, together with any periods where it is reasonably certain it will exercise an option to extend (or not terminate) the lease. As the interest rate implicit in the Company's lease contracts is not readily determinable, the Company utilizes its incremental borrowing rate ("IBR") to determine the present value of lease payments. The IBR is derived from information available at the lease commencement date and represents the rate of interest that a lessee would have to pay to borrow an amount equal to the lease payments on a collateralized basis over a similar term in a similar economic environment.

Rent expense for operating leases is recognized on a straight-line basis over the lease term. The Company has elected to not separate lease and non-lease components for its real estate leases and instead accounts for each separate lease component and the non-lease components associated with that lease component as a single lease component. Variable lease payments are recognized as incurred.

As of December 31, 2022 and 2023, the Company had no finance leases.

***Impairment of Long-Lived Assets***

The Company regularly reviews the carrying value and estimated lives of all of its long-lived assets, including property and equipment, and ROU assets to determine whether indicators of impairment may exist which warrant adjustments to carrying values or estimated useful lives. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset group to future undiscounted net cash flows expected to be generated by the asset or asset group. Should impairment exist, the impairment loss to be recognized is measured by the amount by which the carrying amount of the asset exceeds the projected discounted future net cash flows arising from the asset.

***Derivative Liability***

The Company may issue financial instruments, such as promissory notes or redeemable convertible preferred stock to its investors, which include embedded derivatives, such as call options. Derivatives are accounted for under ASC 815, *Derivatives and Hedging*. The Company performs analysis of derivatives embedded in the financial instruments, and if any requires bifurcation, accounts for these at fair value at the issuance date. In May 2023, the Company issued Series B-2/B-2A redeemable convertible preferred stock shares, which included embedded derivatives that required bifurcation.

A derivative liability is accounted for separately from the financial instrument at fair value on the issuance date and is remeasured each reporting period. The changes in the fair value of the derivative liability are included in change in fair value of derivative liability within the consolidated statements of operations and comprehensive loss.

***Redeemable Convertible Preferred Stock***

The Company records redeemable convertible preferred stock at their respective fair values on the dates of issuance, net of issuance costs. The redeemable convertible preferred stock is recorded outside of permanent equity because while it is not mandatory, redemption is contingent upon the occurrence of certain events considered 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 stock, because it is uncertain whether or when a deemed liquidation event would occur that would obligate the Company to pay the liquidation preferences to holders 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 deemed liquidation event will occur.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. Summary of Significant Accounting Policies and Basis of Presentation (Continued)**

***Research and Development Costs and Accruals***

Research and development costs are expensed as incurred. Research and development costs consist primarily of costs associated with acquiring technology and intellectual property licenses that have no alternative future uses, costs incurred under in-license or assignment agreements, salaries and benefits of research and development personnel, costs related to research activities, preclinical studies, clinical trials, drug manufacturing, third-party professional research and development consulting services, and allocated overhead and facility-related expenses. Payments associated with licensing agreements to acquire exclusive licenses to develop, use, manufacture and commercialize products that have not reached technological feasibility and do not have alternate future use will also be expensed as incurred.

The Company records accrued liabilities for estimated costs of its research and development activities conducted by third-party service providers. The Company accrues these costs based on factors such as estimates of the work completed and in accordance with the third-party service agreements. If the Company does not identify costs that have begun to be incurred or if the Company underestimates or overestimates the level of services performed or the costs of these services, actual expenses could differ from the estimates. To date, the Company has not experienced any material differences between accrued costs and actual costs incurred.

Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed and classified as current or non-current prepaid expenses and other assets.

The Company makes payments in connection with clinical trials to contract manufacturing organizations (“CMOs”) that manufacture the materials for its product candidates and to clinical research organizations (“CROs”) and clinical trial sites that conduct and manage the Company’s clinical trials. The financial terms of these contracts are subject to negotiation, which vary by contract and may result in payments that do not match the periods over which materials or services are provided. Generally, these agreements set forth the scope of work to be performed at a fixed fee, unit price or on a time and materials basis. The Company makes estimates of accrued research and development expenses as of each balance sheet date based on facts and circumstances known at that time. The Company periodically confirms the accuracy of its estimates with the service providers and makes adjustments, if necessary. Research and development accruals are estimated based on the level of services performed, progress of the studies, including the phase or completion of events, and contracted costs. The estimated costs of research and development services provided, but not yet invoiced, are included in accrued expenses on the consolidated balance sheets. If the actual timing of the performance of services or the level of effort varies from the original estimates, the Company will adjust the accrual accordingly.

***Patent Costs***

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

***Stock-Based Compensation***

The Company grants stock-based awards to employees, directors and non-employee consultants in the form of stock options to purchase shares of its common stock. The Company measures stock options with service-based vesting granted based on the fair value of the award on the grant date using the Black-Scholes option-pricing model. The model requires management to make a number of assumptions, including common stock fair value, expected volatility, expected term, risk-free interest rate and expected dividend yield. The Company estimates common stock fair value using methodologies, approaches and assumptions consistent with the

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. Summary of Significant Accounting Policies and Basis of Presentation (Continued)**

***Stock-Based Compensation (Continued)***

American Institute of Certified Public Accountants Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation* (the “Practice Aid”). The Company expenses the fair value of its equity-based compensation awards on a straight-line basis over the requisite service period, which is the period in which the related services are received. The Company accounts for award forfeitures as they occur.

The Company classifies stock-based compensation expense in its consolidated statements of operations and comprehensive loss in the same manner in which the award recipient’s salary or services costs are classified.

***Income Taxes***

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company’s tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes.

The Company assesses the likelihood of deferred tax assets being realized. It provides a valuation allowance when it is more likely than not that some portion or all of a deferred tax asset will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which the temporary differences representing net future deductible amounts become deductible.

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. Tax positions that meet the more-likely-than-not threshold are measured at the largest amount of tax benefit that is greater than 50% likely of being realized upon settlement with the taxing authority. Interest and penalties related to unrecognized tax benefits are included within the provision for income tax.

***Comprehensive Loss***

Comprehensive loss represents all changes in stockholders’ deficit except those resulting from distributions to stockholders. The Company’s other comprehensive (loss) income for the years ended December 31, 2022 and 2023 consisted of unrealized gains or losses on investments in marketable securities, net of taxes.

***Net Loss Per Share Attributable to Common Stockholders***

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, the redeemable convertible preferred stock, unvested common stock shares subject to repurchase and stock options are considered to be potentially dilutive securities.

Basic and diluted net loss attributable to common stockholders per share is presented in conformity with the two-class method required for participating securities as the redeemable convertible preferred stock are considered participating securities. The Company’s participating securities do not have a contractual obligation to share in the Company’s losses. As such, the net loss is attributed entirely to common stockholders. Because the Company has reported a net loss for the reporting periods presented, the diluted net loss per common share is the same as basic net loss per common share for those periods.

***Recent Accounting Pronouncements***

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. The Company qualifies as an “emerging

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. Summary of Significant Accounting Policies and Basis of Presentation (Continued)**

*Recent Accounting Pronouncements (Continued)*

growth company” as defined in the Jumpstart Our Business Startups Act of 2012, as amended (the “JOBS Act”), and has elected not to “opt out” of the extended transition related to complying with new or revised accounting standards, which means that when a standard is issued or revised and it has different application dates for public and nonpublic companies, the Company will adopt the new or revised standard at the time nonpublic companies adopt the new or revised standard and will do so until such time that the Company either (i) irrevocably elects to “opt out” of such extended transition period or (ii) no longer qualifies as an emerging growth company. The Company may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for nonpublic companies.

*Recently Adopted Accounting Pronouncements*

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, which is intended to simplify the accounting for income taxes. This standard removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing standards to improve consistent application. The Company adopted this standard on January 1, 2022. The adoption of this standard did not have a material impact on its consolidated financial statements at the adoption date.

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*. The amendments in the ASU simplifies the accounting for convertible debt instruments and convertible preferred stock by removing the existing guidance that requires entities to account for beneficial conversion features and cash conversion features in equity, separately from the host convertible debt or preferred stock. In addition, the amendments revise the scope exception from derivative accounting in ASC 815-40 for freestanding financial instruments and embedded features that are both indexed to the issuer’s own stock and classified in stockholders’ equity, by removing certain criteria required for equity classification. The amendments further revise the guidance in ASC 260, *Earnings Per Share*, to require entities to calculate diluted earnings per share for convertible instruments by using the if-converted method. In addition, entities must presume share settlement for purposes of calculating diluted earnings per share when an instrument may be settled in cash or shares. The Company adopted this standard on January 1, 2022. The adoption of this standard did not have a material impact on its consolidated financial statements.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326), Measurement of Credit Losses on Financial Instruments*, as clarified in subsequent amendments. ASU 2016-13 changes the impairment model for certain financial instruments. The new model is a forward-looking expected loss model and will apply to financial assets subject to credit losses and measured at amortized cost and certain off-balance sheet credit exposures. This includes loans, held-to-maturity debt securities, loan commitments, financial guarantees and net investments in leases, as well as trade receivables. For available-for-sale debt securities with unrealized losses, credit losses will be measured in a manner similar to today, except that the losses will be recognized as allowances rather than reductions in the amortized cost of the securities. Topic 326 is effective for the Company for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. Early adoption is permitted. The Company adopted this standard on January 1, 2022. The adoption of this standard did not have a material impact on its consolidated financial statements at the adoption date.

*Recently Issued and not Yet Adopted Accounting Pronouncements*

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*. This ASU requires public entities to disclose information about their



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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. Summary of Significant Accounting Policies and Basis of Presentation (Continued)**

***Recent Accounting Pronouncements (Continued)***

reportable segments' significant expenses and other segment items on an interim and annual basis. Public entities with a single reportable segment are required to apply the disclosure requirements in ASU 2023-07, as well as all existing segment disclosures and reconciliation requirements in ASC 280 on an interim and annual basis. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and for interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact of adopting ASU 2023-07 on its consolidated financial statements.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which requires the disclosure of specific categories in the rate reconciliation and greater disaggregation for income taxes paid. This standard is effective for annual periods beginning after December 15, 2024 and should be adopted prospectively with the option to be adopted retrospectively. The Company is currently evaluating the impact of this standard on its disclosure on its consolidated financial statements.

**3. Fair Value Measurements**

The Company discloses and recognizes the fair value of its assets and liabilities using a hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The guidance establishes three levels of the fair value hierarchy as follows:

Level 1—Quoted prices in active markets for identical assets or liabilities.

Level 2—Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

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 recognizes transfers into and out of levels within the fair value hierarchy in the period in which the actual event or change in circumstances that caused the transfer occurs.

The Company's financial instruments consist of Level 1, Level 2 and Level 3 financial instruments. Changes in the ability to observe valuation inputs may result in a reclassification of levels of certain securities within the fair value hierarchy.

Level 1 financial instruments are comprised of money market funds and U.S. treasuries. Level 2 financial instruments are comprised of commercial paper, U.S. treasuries, corporate bonds, supranational debt securities and agency bonds. Level 3 financial instruments include a derivative liability issued in May 2023 and settled in October 2023 in connection with the closing of the second tranche of the Series B-2 and B-2A redeemable convertible preferred stock financing.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**3. Fair Value Measurements (Continued)**

The following tables represent the Company's fair value hierarchy for financial assets measured at fair value on a recurring basis as of December 31, 2022 and 2023 (in thousands):

<u>(in thousands)</u>	<u>Fair Value Measurements as of December 31, 2022</u>			
	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
<b>Assets:</b>				
<b>Cash equivalents</b>				
Money market funds	\$19,546	\$ —	\$ —	\$19,546
<b>Marketable securities</b>				
Commercial paper	—	31,271	—	31,271
U.S. treasuries	19,255	—	—	19,255
Corporate bonds	—	10,795	—	10,795
Supranational debt securities	—	3,976	—	3,976
Agency bonds	—	1,958	—	1,958
Total	<u>\$38,801</u>	<u>\$48,000</u>	<u>\$ —</u>	<u>\$86,801</u>

<u>(in thousands)</u>	<u>Fair Value Measurements as of December 31, 2023</u>			
	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
<b>Assets:</b>				
<b>Cash equivalents</b>				
Money market funds	\$21,310	\$ —	\$ —	\$21,310
U.S. treasuries	2,000	—	—	2,000
<b>Marketable securities</b>				
U.S. treasuries	1,958	998	—	2,956
Total	<u>\$25,268</u>	<u>\$998</u>	<u>\$ —</u>	<u>\$26,266</u>

The derivative liability is a freestanding financial instrument and represents the Company's obligation to issue additional shares of Series B-2 and B-2A redeemable convertible preferred stock at a fixed price upon the approval by the board of directors. The derivative liability's fair value was estimated using a Black-Scholes option pricing model adjusted for the probability of occurring. Significant estimates and assumptions impacting fair value include the estimated time and probability of closing of the second tranche financing, preferred stock fair value and estimated stock volatility.

The following table provides roll-forward of the fair value of the Company's Level 3 financial instruments, the derivative liability, for the year ended December 31, 2023 (in thousands):

Balance as of January 1, 2023	\$ —
Fair value upon issuance	2,112
Changes in fair value	119
Fair value upon settlement (see Note 8)	(2,231)
Balance as of December 31, 2023	<u>\$ —</u>

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**3. Fair Value Measurements (Continued)**

The following table provides a range of assumptions used in the valuation of the derivative liability for the year ended December 31, 2023:

Expected term (in years)	0.01 – 0.41
Volatility	43.19% – 83.25%
Risk-free interest rate	5.23% – 5.55%
Dividend yield	0%
Probability of event occurring	30% – 100%

There were no transfers between Level 1, Level 2 or Level 3 categories for the years ended December 31, 2022 and 2023.

**4. Marketable Securities**

Marketable securities, which are classified as available-for-sale, consisted of the following as of December 31, 2022 and 2023 (in thousands):

	Amortized Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value as of December 31, 2022
Short-term marketable securities:				
Commercial paper	\$31,271	\$—	\$ —	\$31,271
U.S. treasuries	19,309	—	(54)	19,255
Corporate bonds	10,841	—	(46)	10,795
Supranational debt securities	4,005	—	(29)	3,976
Agency bonds	1,956	2	—	1,958
Total short-term marketable securities	<u>\$67,382</u>	<u>\$ 2</u>	<u>\$(129)</u>	<u>\$67,255</u>

	Amortized Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value as of December 31, 2023
Short-term marketable securities:				
U.S. treasuries	\$2,954	\$2	\$ —	\$2,956
Total short-term marketable securities	<u>\$2,954</u>	<u>\$2</u>	<u>\$ —</u>	<u>\$2,956</u>

All marketable securities held as of December 31, 2022 and 2023 had contractual maturities of less than one year.

As of December 31, 2022 and 2023, no significant facts or circumstances were present to indicate a deterioration in the creditworthiness of the issuers of the marketable securities, and the Company has no requirement or intention to sell these securities before maturity or recovery of their amortized cost basis. The Company considered the current and expected future economic and market conditions and determined that its investments were not significantly impacted. For all securities with a fair value less than its amortized cost basis, the Company determined the decline in fair value below amortized cost basis to be immaterial and non-credit related, and therefore no allowance for losses has been recorded. For the years ended December 31, 2022 and 2023, the Company did not recognize any impairment losses on its investments.

As of December 31, 2022 and 2023, accrued interest receivable was \$0.1 million and \$0, which is recorded in the marketable securities in the consolidated balance sheets.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**5. Balance Sheet Components**

***Property and Equipment, net***

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

	Estimated Useful Life (in years)	December 31, 2022	December 31, 2023
Laboratory equipment	5	\$ 1,899	\$ 3,577
Computer equipment	5	371	896
Furniture and fixtures	5	143	1,709
Leasehold improvements	Shorter of useful life or lease term	31	17,592
Capitalized software	3	15	75
Construction in progress		578	—
Total property and equipment, gross		3,037	23,849
Less: Accumulated depreciation and amortization		(257)	(1,408)
Total property and equipment, net		<u>\$2,780</u>	<u>\$22,441</u>

Depreciation and amortization expense was \$0.3 million and \$1.3 million for the years ended December 31, 2022 and 2023, respectively.

***Other Prepaid Expenses and Current Assets***

Other prepaid expenses and current assets consist of the following (in thousands):

	December 31, 2022	December 31, 2023
Tax receivable	\$ 500	\$ 614
Prepaid subscriptions	296	703
Other prepaid expenses	502	314
Total other prepaid expenses and current assets	<u>\$1,298</u>	<u>\$1,631</u>

***Other Accrued Expenses and Current Liabilities***

Other accrued expenses and current liabilities consist of the following (in thousands):

	December 31, 2022	December 31, 2023
Accrued personnel and related expenses	\$3,576	\$5,585
Accrued professional services	455	1,093
Accrued other expenses	512	409
Total other accrued expenses and current liabilities	<u>\$4,543</u>	<u>\$7,087</u>

**6. Related Party Transactions**

***Foresite Labs Services Agreement***

In January 2021, the Company entered into a services agreement with Foresite Labs, LLC (“Foresite Labs”), which was amended and restated in August 2021 and in December 2023, and expires in December 2026, unless terminated earlier by the parties. Thereafter, on each anniversary of the effective date, the agreement will automatically renew for an additional one year term, unless terminated earlier by the parties. Foresite Labs

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**6. Related Party Transactions (Continued)**

***Foresite Labs Services Agreement (Continued)***

assists the Company in exploring specified immunology genetic targets and general and administrative services. Unless there is a specific statement of work signed, Foresite Labs invoices the Company for the services quarterly in advance. For the years ended December 31, 2022 and 2023, the Company recognized \$1.6 million and \$1.5 million as research and development expenses under the service agreement, respectively. General and administrative expenses under the service agreement were immaterial. Accrued expenses under the service agreement were \$0 and less than \$0.1 million as of December 31, 2022 and 2023, respectively.

**7. Commitments and Contingent Liabilities**

***Operating Leases***

In 2021, the Company entered into a lease agreement for 14,000 square feet of office space in South San Francisco, California, which commenced in August 2021 and had a contractual termination date of September 2024. In September 2023, the Company abandoned this right-of-use asset as it had moved to its new office space described below; the Company recognized a loss on this abandonment in the amount of \$0.6 million.

In January 2022, the Company entered into a lease agreement for 12,000 square feet of office and laboratory space in South San Francisco, California, that commenced in July 2022 and had a contractual termination date of July 2029. This lease contained an early termination option, allowing the Company to terminate this lease before the expiry of the lease term. The Company concluded the lease term for accounting purposes ended in August 2023. In April 2023, this lease was modified to reduce the contractual lease term to terminate in October 2023. The accounting impact of the modification was not material.

In August 2022, the Company entered into a lease agreement for 55,000 square feet of additional office and laboratory space in South San Francisco, California, which commenced in January 2023 and has a contractual termination date in August 2033. The Company constructed leasehold improvements in the space and the lessor agreed to provide the Company a tenant improvement allowance of up to \$18.1 million, of which \$0.5 million and \$16.7 million was used and was accounted for as a reduction to lease payments for the years ended December 31, 2022 and 2023, respectively. The Company recorded the leasehold improvements in property and equipment, net in the consolidated balance sheet as of December 31, 2022 and 2023. The lease agreement also includes a renewal option allowing the Company to extend this lease for an additional three years at the prevailing rental rate, which the Company was not reasonably certain to exercise.

The Company maintains letters of credit on these leases in the amount of \$1.3 million and \$1.1 million at December 31, 2022 and 2023, respectively. The lease letters of credit are reflected on the Company's consolidated balance sheets in restricted cash, current and restricted cash, noncurrent as of December 31, 2022 and 2023.

The components of lease costs were as follows (in thousands):

	<b>Year Ended December 31, 2022</b>	<b>Year Ended December 31, 2023</b>
Operating lease costs	\$1,074	\$4,747
Variable lease costs	121	545
Total lease costs	<u>\$1,195</u>	<u>\$5,292</u>

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**7. Commitments and Contingent Liabilities (Continued)**

***Operating Leases (Continued)***

Supplemental cash flow information related to the operating leases were as follows (in thousands):

	<b>Year Ended December 31, 2022</b>	<b>Year Ended December 31, 2023</b>
Cash payments included in the measurement of operating lease liabilities	\$1,111	\$2,903

Weighted-average remaining lease term and incremental borrowing rate for the operating leases were as follows:

	<b>December 31, 2022</b>	<b>December 31, 2023</b>
Weighted-average remaining lease term (years)	1.4	9.5
Weighted-average incremental borrowing rate	6.7%	11.4%

Future minimum lease payments under non-cancelable leases as of December 31, 2023 were as detailed below (in thousands):

2024	\$ 5,269
2025	4,962
2026	5,128
2027	5,299
2028	5,477
2029 and thereafter	27,526
<b>Total undiscounted lease payments</b>	<b>53,661</b>
Less: Imputed interest	(21,081)
<b>Total operating lease liabilities</b>	<b>\$ 32,580</b>

***FronThera Contingent Consideration***

In March, 2021, the Company entered into a stock purchase agreement to acquire FronThera U.S. Holdings, Inc. and its wholly owned subsidiary, FronThera U.S. Pharmaceuticals LLC., and the transaction was accounted for as an asset acquisition. Under the stock purchase agreement, the Company is obligated to pay contingent consideration of up to \$120.0 million based on the achievement of specified milestones related to patient enrollments in clinical trials of up to \$70.0 million and commercialization approvals of up to \$50.0 million. In 2022, the Company achieved the first clinical milestone and paid \$37.0 million, which was recorded as research and development expenses in the consolidated statement of operations and comprehensive loss for the year ended December 31, 2022. No clinical milestone was achieved or probable during the year ended December 31, 2023.

***Research and Development Agreements***

The Company enters into various agreements in the ordinary course of business, such as those with suppliers, CROs, CMOs and clinical trial sites. These agreements provide for termination at the request of either party, generally with less than one-year notice and are, therefore, cancellable contracts and, if cancelled, are not anticipated to have a material effect on the Company's financial condition, results of operations, or cash flows.

***Legal Contingencies***

From time to time, the Company may become involved in legal proceedings arising from the ordinary course of business. The Company records a liability for such matters when it is probable that future losses will be

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**7. Commitments and Contingent Liabilities (Continued)**

*Legal Contingencies (Continued)*

incurred and that such losses can be reasonably estimated. Significant judgment by the Company is required to determine both probability and the estimated amount. Management is currently not aware of any legal matters that could have a material adverse effect on the Company's financial position, results of operations or cash flows.

*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. Its exposure under these agreements is unknown because it involves claims that may be made against the Company in the future. To the extent permitted under Delaware law, the Company has agreed to indemnify its directors and officers for certain events or occurrences while the director or officer is, or was serving, at a request in such capacity. 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 2023, the Company did not have any material indemnification claims that were probable or reasonably possible and consequently has not recorded related liabilities.

**8. Redeemable Convertible Preferred Stock**

In January 2022, the Company issued and sold an aggregate of 20,000,000 shares of Series B redeemable convertible preferred stock at a price of \$5.00 per share for gross cash proceeds of \$100.0 million and incurred \$0.1 million of issuance costs.

In May 2023, the Company issued and sold an aggregate of 10,722,340 shares of Series B-2 redeemable convertible preferred stock for gross cash proceeds of \$53.6 million and 1,277,660 shares of Series B-2A redeemable convertible preferred stock for gross proceeds of \$6.4 million and incurred \$0.2 million of issuance costs. The purchase price for Series B-2 and B-2A redeemable convertible preferred stock was \$5.00 per share. The Series B-2 and Series B-2A stock purchase agreement contains an obligation to issue additional shares of Series B-2 or Series B-2A redeemable convertible preferred stock in a second tranche closing by October 2023 (Second Tranche Closing) upon the occurrence of certain events, including the board of directors' consent. The Company recognized this call option as a derivative liability and estimated its fair value of \$2.1 million.

In July 2023, the holders of the shares of Series B-2A redeemable convertible preferred stock elected to convert its 1,277,660 shares into the same number of Series B-2 redeemable convertible preferred stock.

In October 2023, the Company closed the Second Tranche Closing and issued an additional 4,221,170 shares of Series B-2 redeemable convertible preferred stock and 1,778,830 shares of Series B-2A redeemable convertible preferred stock at a price of \$5.00 per share and received gross proceeds of \$21.1 million and \$8.9 million, respectively. Accordingly, the derivative liability was settled, and the Company reclassified the derivative liability, remeasured at fair value of \$2.2 million, into redeemable convertible preferred stock. The Company incurred less than \$0.1 million of issuance costs in connection with the Second Tranche Closing.

The Series Seed and Series A redeemable convertible preferred stock are collectively referred to as the "Junior Redeemable Convertible Preferred Stock". The Series B, Series B-1, Series B-2 and Series B-2A redeemable convertible preferred stock are collectively referred to as the "Senior Redeemable Convertible Preferred Stock".

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**8. Redeemable Convertible Preferred Stock (Continued)**

The Company's redeemable convertible preferred stock as of each period, consisted of the following:

	December 31, 2022			
	Shares Authorized	Shares Issued and Outstanding	Aggregate Liquidation Preference	Net Carrying Value
	(in thousands, except share amounts)			
Seed redeemable convertible preferred stock	10,500,000	10,500,000	\$ 10,500	\$ 10,480
A redeemable convertible preferred stock	7,500,000	7,500,000	30,000	29,972
B redeemable convertible preferred stock	40,200,000	40,200,000	201,000	200,711
B-1 redeemable convertible preferred stock	9,760,088	9,760,088	39,040	44,310
<b>Total redeemable convertible preferred stock</b>	<b>67,960,088</b>	<b>67,960,088</b>	<b>\$ 280,540</b>	<b>\$ 285,473</b>

	December 31, 2023			
	Shares Authorized	Shares Issued and Outstanding	Aggregate Liquidation Preference	Net Carrying Value
	(in thousands, except share amounts)			
Seed redeemable convertible preferred stock	10,500,000	10,500,000	\$ 10,500	\$ 10,480
A redeemable convertible preferred stock	7,500,000	7,500,000	30,000	29,972
B redeemable convertible preferred stock	40,200,000	40,200,000	201,000	200,711
B-1 redeemable convertible preferred stock	9,760,088	9,760,088	39,040	44,310
B-2 redeemable convertible preferred stock	18,000,000	16,221,170	81,106	80,969
B-2A redeemable convertible preferred stock	3,056,490	1,778,830	8,894	8,928
<b>Total redeemable convertible preferred stock</b>	<b>89,016,578</b>	<b>85,960,088</b>	<b>\$ 370,540</b>	<b>\$ 375,370</b>

The significant rights and obligations of the Company's redeemable convertible preferred stock are as follows:

***Liquidation Preference***

In the event of the liquidation, dissolution or winding up of the Company, or a deemed liquidation event, including a merger or consolidation, or a sale or other disposition of all or substantially all of the Company's assets, the holders of shares of the Senior Redeemable Convertible Preferred Stock are entitled to receive, before any payments are made to the holders of the Junior Redeemable Convertible Preferred Stock and holders of common stock, an amount per share equal to the greater of (i) the Series B, Series B-1, Series B-2 and Series B-2A original issuance price of \$5.00, \$4.00, \$5.00, and \$5.00 respectively, plus any dividends declared but unpaid, or (ii) such amount per share as would have been payable had all shares of the applicable series of Senior Redeemable Convertible Preferred Stock been converted into common stock immediately prior to such liquidation, dissolution, winding up or deemed liquidation. If the proceeds are insufficient to pay the holders of shares of Senior Redeemable Convertible Preferred Stock their full liquidation preference, then the proceeds available for distribution are payable ratably among the holders of the Senior Redeemable Convertible Preferred Stock in proportion to the full preferential amount that each such holder is entitled to receive.

After the distributions to the holders of the Senior Redeemable Convertible Preferred Stock have been paid in full, the holder of shares of Junior Redeemable Convertible Preferred Stock shall be entitled to receive, prior to and in preference to any distributions of the assets of the Company to the holders of common stock, an amount equal to the greater of (i) the Series Seed and Series A original issuance price of \$1.00 and \$4.00, respectively, plus any dividends declared but unpaid, or (ii) such amount per share as would have been payable had all shares of such series of Junior Redeemable Convertible Preferred Stock been converted into common



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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**8. Redeemable Convertible Preferred Stock (Continued)**

***Liquidation Preference (Continued)***

stock immediately prior to such liquidation, dissolution, winding up or deemed liquidation. If the proceeds are insufficient to pay the holder of share of Junior Redeemable Convertible Preferred Stock their full liquidation preference, then the proceeds available for distribution are payable ratably among the holders of the Junior Redeemable Convertible Preferred Stock in proportion to the full preferential amount that each such holder is entitled to receive.

After the distributions described above have been paid in full, the remaining assets of the Company available for distribution to its stockholders will be distributed among the holders of shares of common stock, pro rata based on the number of shares held by each such holder.

***Conversion***

Each share of Series B-2 redeemable convertible preferred stock is convertible at the option of a holder into one share of Series B-2A redeemable convertible preferred stock.

Each share of Series B-2A redeemable convertible preferred stock is convertible at the option of a holder into one share of Series B-2 redeemable convertible preferred stock.

Each share of redeemable convertible preferred stock is convertible at the option of a holder into shares of Class A common stock or Class B common stock at a conversion rate, which is the redeemable convertible preferred stock original issuance price per share divided by the conversion price in effect at the time of conversion. The conversion price is initially equal to the redeemable convertible preferred stock original issuance price, and is subject to adjustments for recapitalization, dilutive issuances, stock dividends, stock splits, and other distributions. As of December 31, 2022 and 2023, the conversion rate was one-for-one.

All outstanding shares of redeemable convertible preferred stock are automatically converted into shares of Class A common stock, provided that, a holder of shares of redeemable convertible preferred stock may elect, upon written notice to the Company at least seven days prior to a qualified public offering, to have all or a portion of its shares of redeemable convertible preferred stock automatically convert into shares of Class B common stock at the then effective conversion rate, upon the earlier of: (i) the closing of the sale of shares of common stock to the public, in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in at least \$75.0 million of proceeds to the Company, net of underwriting discounts and commissions, or (ii) upon a vote or a written consent of the holders of a majority of outstanding shares of redeemable convertible preferred stock, voting together as a single class and on an as-converted basis.

***Dividend Rights***

The Company cannot declare, pay or set aside any dividends on shares of any other class or series of capital stock of the Company (other than dividends on shares of common stock payable in shares of common stock), unless the holders of the redeemable convertible preferred stock then outstanding will first receive, or simultaneously receive, a dividend on each outstanding share of redeemable convertible preferred stock in an amount at least equal to (i) in the case of a dividend on common stock or any class or series that is convertible into common stock, the product of (a) the dividend payable on each share of such series determined as if all shares of such series had been converted into common stock and (b) the number of shares of common stock issuable upon conversion of a share of redeemable convertible preferred stock, calculated on the record date for determination of holders entitled to receive such dividend or (ii) in the case of a dividend on any class or series that is not convertible into common stock, at a rate per share of redeemable convertible preferred stock determined by (a) dividing the amount of the dividend payable on each share of such class or series of capital stock by the original issuance price of such class or series of capital stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to such class or series) and (b) multiplying such fraction by an amount equal to the applicable original issue price.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**8. Redeemable Convertible Preferred Stock (Continued)**

*Dividend Rights (Continued)*

No dividends were declared and paid or payable for the years ended December 31, 2022 and 2023.

*Voting Rights*

Each holder of outstanding shares of redeemable convertible preferred stock is entitled to cast the number of votes equal to the number of whole shares of common stock into which the shares of redeemable convertible preferred stock held by such holder are convertible. Holders of redeemable convertible preferred stock vote together with the holders of common stock as a single class and on an as-converted to common stock basis. Holders of Series B-2A redeemable convertible preferred stock have no voting rights for election of directors or for the size of the board.

*Election of Directors*

At any time when at least 1,875,000 shares of Series A redeemable convertible preferred stock are outstanding, the holders of the shares of Series A redeemable convertible preferred stock, voting as a separate class on an as-converted to common stock basis, are entitled to elect one director of the Company.

At any time when at least 10,050,000 shares of the voting Senior Redeemable Convertible Preferred Stock are outstanding, the holders of the shares of the voting Senior Redeemable Convertible Preferred Stock, voting as a separate class on an as-converted to common stock basis, are entitled to elect two directors of the Company.

The holders of the shares of common stock, voting as a separate class, are entitled to elect one director of the Company.

The holders of common stock and redeemable convertible preferred stock, voting together as a single class on an as-converted basis, are entitled to elect all remaining members of the board of directors, if any.

*Redemption*

The redeemable convertible preferred stock is recorded in mezzanine equity because while it is not mandatorily redeemable, it will become redeemable at the option of the preferred stockholders upon the occurrence of certain deemed liquidation events that are considered not solely within the Company's control.

**9. Common Stock**

As of December 31, 2023, the Company was authorized to issue 125,000,000 shares of Class A common stock and 85,960,088 shares of Class B common stock, both with par values of \$0.0001 per share (Class A common stock and Class B common stock, collectively referred to as "common stock"). As of December 31, 2022 and 2023, there were no shares of Class B common stock outstanding.

The rights, powers and preferences of the holders of the Class A common stock and Class B common stock are subject to and qualified by the rights, powers and preferences of the holders of the redeemable convertible preferred stock. The holders of Class A and Class B common stock have the same rights except that Class B common stock do not have voting rights, except as may be required by law. Each holder of Class B common stock has a right to convert each share of Class B common stock to one share of Class A common stock. The Company cannot issue shares of Class B common stock other than upon conversion of redeemable convertible preferred stock. At any time following the Company's registration of any class of equity securities under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), the holders of shares of Class B common stock may not convert a number of shares of Class B common stock into shares of Class A common stock in excess of that number of shares of Class B common stock which would cause the holder thereof to beneficially own (for purposes of Section 13(d) of the Exchange Act), in excess of 4.99% of the total number of issued and outstanding shares of Class A common stock (including shares of Class A common stock issuable upon conversion of the redeemable convertible preferred stock). Such maximum percentage may be increased or

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**9. Common Stock (Continued)**

decreased to such other percentage as any holder of outstanding shares of Class B common stock may designate in writing upon 61 days' prior written notice.

Common stock reserved for issuance, on an as-converted basis, consisted of the following as of December 31, 2022 and 2023:

	<u>December 31, 2022</u>	<u>December 31, 2023</u>
Redeemable convertible preferred stock issued and outstanding	67,960,088	85,960,088
Outstanding and issued common stock options	19,179,979	23,825,003
Shares available for grant under 2021 Stock Plan	<u>187,029</u>	<u>1,384,688</u>
Total	<u>87,327,096</u>	<u>111,169,779</u>

***Common Stock Issued to Executives***

In February 2021, the Company issued 470,000 shares of common stock to two executives at a purchase price of \$0.20 per share. The shares vest over a four-year period with a one-year cliff. The holders have voting and dividends rights. The Company has a right to repurchase unvested shares at the price paid by the holder in the event of termination of the holder's continuous status as a service provider. The Company estimated the fair value of the restricted stock awards based on the fair value of common stock at the grant dates. The expense is recognized ratably over the vesting terms. The Company recognized \$0.1 million for each of the years ended December 31, 2022 and 2023.

The following table summarizes the activity for the Company's restricted common stock for the years ended December 31, 2022 and 2023:

	<u>Number of Shares</u>	<u>Weighted-Average Grant Date Fair Value</u>
Unvested as of December 31, 2022	254,584	\$0.62
Vested	<u>(117,500)</u>	\$0.62
Unvested as of December 31, 2023	<u>137,084</u>	<u>\$0.62</u>

As of December 31, 2023, the remaining unamortized stock-based compensation expense of \$0.1 million will be recognized over the remaining vesting period 1.1 years.

**10. Stock-Based Compensation**

***2021 Stock Plan***

In February 2021, the Company adopted the 2021 Stock Plan (the "2021 Plan"), which provides for stock awards to eligible employees, directors and consultants of the Company. Awards issuable under the 2021 Plan include incentive stock options ("ISO"), non-statutory stock options ("NSO"), restricted stock units ("RSU") and stock grants.

The exercise price of ISOs shall not be less than the estimated fair value of the underlying common stock on the date of grant. The exercise price of ISOs granted to an employee who owns more than 10% of the voting power of all classes of stock of the Company shall be no less than 110% of the estimated fair market value of the underlying common stock on the grant date. Stock option grants under the 2021 Plan generally vest over four years. The contractual term of an option is no longer than five years for ISOs for which an employee owns greater than 10% of the voting power of all classes of stock and no longer than ten years for all other options. As of December 31, 2023, the Company was authorized to grant 30,450,029 shares, and 1,384,688 shares were available for issuance under the 2021 Plan.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**10. Stock-Based Compensation (Continued)**

***2021 Stock Plan (Continued)***

The terms of the 2021 Plan permit option holders to exercise options before their options are vested. The shares of common stock granted upon early exercise that have not yet vested are subject to repurchase by the Company in the event of termination of the holder's continuous status as a service provider, at the price paid by the holder.

***Stock Option Activity***

The following table summarizes the Company's option activity for the years ended December 31, 2022 and 2023. The table includes early exercised shares as part of options exercised.

	Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2022	19,179,979	\$1.85	9.20	\$ 4,933
Options granted	5,313,134	\$2.85		
Options exercised	(226,484)	\$2.00		\$ 224
Options forfeited or expired	(441,626)	\$2.03		
Outstanding and expected to vest as of December 31, 2023	<u>23,825,003</u>	\$2.07	8.50	\$15,033
Exercisable as of December 31, 2023	<u>23,825,003</u>	\$2.07	8.50	\$15,033

The intrinsic value of options exercised during the year ended December 31, 2022 was \$0.1 million. The weighted-average grant date fair value was \$1.47 and \$2.34 per option for the years ended December 2022 and 2023, respectively. The total fair value of shares vested for the years ended December 31, 2022 and 2023 was \$2.3 million and \$8.1 million, respectively.

***Stock Option Valuation***

The fair value of stock options granted for the years ended December 31, 2022 and 2023 was estimated using the Black-Scholes option pricing model with the following assumptions:

	Year Ended December 31, 2022	Year Ended December 31, 2023
Expected term (in years)	5.57 – 6.68	5.77 – 6.63
Volatility	82.45% – 86.66%	97.65% – 102.54%
Risk-free interest rate	1.71% – 4.10%	3.66% – 4.77%
Dividend yield	0%	0%

***Expected Term***

The expected term represents the weighted-average period the stock options are expected to remain outstanding and is based on the options' vesting terms and contractual terms, as the Company did not have sufficient historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**10. Stock-Based Compensation (Continued)**

*Stock Option Valuation (Continued)*

*Expected Volatility*

The expected stock price volatility assumption was determined by examining the historical volatilities for industry peers, as the Company did not have any trading history for the Company's common stock. The Company will continue to analyze the historical stock price volatility and expected term assumption as more historical data for the Company's common stock becomes available.

*Risk-Free Interest Rate*

The risk-free interest rate assumption is based on the U.S. Treasury instruments whose term was consistent with the expected term of the Company's stock options.

*Dividends*

The Company has not paid any cash dividends on common stock and does not anticipate paying any dividends in the foreseeable future. Consequently, an expected dividend yield of zero was used.

*Common Stock Fair Value*

The fair market value of the Company's common stock is determined by the board of directors with assistance from management and external valuation experts. The approach to estimating the fair market value of common stock is consistent with the methods outlined in the Practice Aid.

Prior to May 2023, the Company utilized an Option Pricing Method ("OPM") based analysis, primarily the OPM backsolve methodology, to determine the estimated fair value of the common stock. Within the OPM framework, the backsolve method, for inferring the total equity value implied by a recent financing transaction or by an estimated equity value of the Company's pipeline product candidates, involves the construction of an allocation model that takes into account the Company's capital structure and the rights, preferences and privileges of each class of stock, then assumes reasonable inputs for the other OPM variables (expected time to liquidity, volatility, and risk-free rate). The total equity value is then iterated in the model until the model output value for the equity class sold in a recent financing round equals the price paid in that round. The OPM is generally utilized when specific future liquidity events are difficult to forecast (i.e., the enterprise has many choices and options available), and the enterprise's value depends on how well it follows an uncharted path through the various possible opportunities and challenges. In determining the estimated fair value of the common stock, the board of directors also considered the fact that the stockholders could not freely trade the common stock in the public markets. Accordingly, the Company applied discounts to reflect the lack of marketability of its common stock based on the weighted-average expected time to liquidity. The estimated fair value of the common stock at each grant date reflected a non-marketability discount partially based on the anticipated likelihood and timing of a future liquidity event.

For valuations performed on and after May 2023, the Company utilized a hybrid method that combines the Probability-Weighted Expected Return Method ("PWERM"), an accepted valuation method described in the Practice Aid, and the OPM. The Company determined this was the most appropriate method for determining the fair value of its common stock based on the stage of development and other relevant factors. The PWERM is a scenario-based analysis that estimates the value per share of common stock based on the probability-weighted present value of expected future equity values for the common stock, under various possible future liquidity event scenarios, considering the rights and preferences of each class of shares, discounted for a lack of marketability. Under the hybrid method, an option pricing model was utilized to determine the fair value of

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**10. Stock-Based Compensation (Continued)**

*Stock Option Valuation (Continued)*

the Company's common stock in certain of the PWERM scenarios (capturing situations where its development path and future liquidity events were difficult to forecast), potential exit events were explicitly modeled in the other PWERM scenarios. A discount for lack of marketability was applied to the value derived under each scenario to account for a lack of access to an active public market to estimate the common stock fair value. The assumptions underlying these valuations represented management's best estimates, which involved inherent uncertainties and the application of management's judgment. As a result, if the Company had used significantly different assumptions or estimates, the fair value of the common stock and the stock-based compensation expense could have been materially different.

The Company also considers the amount of time between the independent third-party valuation dates and the grant dates and performs an interpolation of the fair value between the two valuation dates to estimate common stock fair value at each grant date. This determination includes an evaluation of whether the subsequent valuation indicated that any significant change in valuation had occurred between the previous valuation and the grant date.

*Early Exercise of Employee Options*

Proceeds from the early exercise of stock options are recorded as share repurchase liability, and as shares vest are recognized to additional paid-in capital in the consolidated balance sheets. As of December 31, 2022 and 2023, there was \$3.5 million and \$1.8 million share repurchase liability related to the unvested shares, respectively. The following table summarizes the activity for the Company's early exercisable shares for the years ended December 31, 2022 and 2023:

	Number of Shares	Weighted- Average Exercise Price Per Share
Unvested as of December 31, 2022	3,103,939	\$1.15
Early exercised	86,370	\$2.03
Vested	(1,591,923)	\$1.21
Repurchased	(69,167)	\$0.93
Unvested as of December 31, 2023	<u>1,529,219</u>	\$1.14

*Stock-Based Compensation Expense*

The following table summarizes the stock-based compensation expense granted to employees and non-employees for the years ended December 31, 2022 and 2023 (in thousands):

	Year Ended December 31, 2022	Year Ended December 31, 2023
Research and development	\$3,119	\$4,745
General and administrative	2,841	3,880
Total stock-based compensation expense	<u>\$5,960</u>	<u>\$8,625</u>

The following table summarizes the stock-based compensation expense related to the following equity-based awards (in thousands):

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**10. Stock-Based Compensation (Continued)**

*Stock-Based Compensation Expense (Continued)*

	Year Ended December 31, 2022	Year Ended December 31, 2023
Stock options	\$5,888	\$8,553
Restricted stock awards	72	72
Total stock-based compensation expense	<u>\$5,960</u>	<u>\$8,625</u>

Stock-based compensation expense related to non-employee awards was immaterial for all periods presented. As of December 31, 2023, there was unrecognized stock-based compensation expense of \$29.6 million related to unvested stock options which the Company expects to recognize over a weighted-average period of 3.14 years.

**11. Net Loss Per Share Attributable to Class A Common Stockholders**

The following table sets forth the computation of the basic and diluted net loss per share attributable to Class A common stockholders for the years ended December 31, 2022 and 2023 (in thousands, except share and per share amounts):

	Year Ended December 31, 2022	Year Ended December 31, 2023
<b>Numerator:</b>		
Net loss	\$ (111,930)	\$ (154,993)
<b>Denominator:</b>		
Weighted average Class A common shares outstanding	11,537,145	12,384,372
Less: Weighted-average Class A common shares subject to repurchase	<u>(4,039,523)</u>	<u>(2,332,174)</u>
Weighted-average Class A common shares outstanding, basic and diluted	7,497,622	10,052,198
Net loss per share attributable to Class A common stockholders, basic and diluted	<u>\$ (14.93)</u>	<u>\$ (15.42)</u>

The following outstanding potentially dilutive securities were excluded from the computation of diluted net loss per share attributable to Class A common stockholders for the periods presented, because including them would have been anti-dilutive (on an as-converted basis):

	December 31, 2022	December 31, 2023
Redeemable convertible preferred stock issued and outstanding	67,960,088	85,960,088
Common stock options issued and outstanding	19,179,979	23,825,003
Unvested restricted common stock and early exercised stock options	<u>3,358,523</u>	<u>1,666,303</u>
Total	<u>90,498,590</u>	<u>111,451,394</u>

**12. Income Taxes**

No provision for income taxes was recorded for the years ended December 31, 2022 and 2023, as the Company operated with taxable losses. The Company has incurred net operating losses only in the United States since inception.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**12. Income Taxes (Continued)**

The differences between the effective income tax rate and the U.S. federal statutory income tax rate for the years ended December 31, 2022 and 2023 were as follows (in thousands):

	Year Ended December 31, 2022	Year Ended December 31, 2023
Amount at statutory tax rates	\$(23,505)	\$(32,548)
Permanent differences	7,770	7
Valuation allowance	16,113	34,961
Stock-based compensation	829	892
Federal research and development credit	(1,207)	(3,322)
Other	—	10
<b>Total</b>	<b>\$ —</b>	<b>\$ —</b>

Significant components of the deferred tax asset balances as of December 31, 2022 and 2023 were as follows (in thousands):

	December 31, 2022	December 31, 2023
<b>Deferred tax assets:</b>		
Net operating losses	\$ 6,404	\$ 10,519
Tax credits	2,509	6,243
Research and development capitalization	16,617	39,059
Accruals and reserves	331	15
Stock-based compensation	423	1,361
Operating lease liabilities	373	6,842
Other capitalized expenses	303	4,567
Gross deferred tax assets	26,960	68,606
Valuation allowance	(26,023)	(61,404)
Deferred tax assets, net of valuation allowance	\$ 937	\$ 7,202
<b>Deferred tax liabilities:</b>		
Fixed assets	(581)	(1,025)
Operating lease right-of-use assets	(356)	(6,177)
Deferred tax liabilities	(937)	(7,202)
<b>Total net deferred tax assets</b>	<b>\$ —</b>	<b>\$ —</b>

A valuation allowance is required to be established when it is more likely than not that all or a portion of a deferred tax asset will not be realized. Realization of deferred tax assets is dependent upon future earnings, the timing and amount of which are uncertain. The Company believes that, based on a number of factors such as the history of operating losses, it is more likely than not that the deferred tax assets will not be fully realized, such that a full valuation allowance has been recorded. The valuation allowance increased by \$15.7 million and by \$35.4 million for the years ended December 31, 2022 and 2023, respectively, primarily due to the net operating losses carryforwards and research and development credits.



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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**12. Income Taxes (Continued)**

The following table sets forth the Company's federal and state net operating loss carryforwards and tax credits as of December 31, 2023 (dollars in thousands):

	Amount	Begin to Expire
Net operating losses, Federal	\$32,120	Do not expire
Net operating losses, Federal	\$16,520	2037
Net operating losses, States	\$ 4,378	2041
Tax credits, Federal	\$ 7,902	2039
Tax credits, States	\$ 3,110	2037

Utilization of some of the federal and state net operating loss and credit carryforwards may be subject to annual limitations due to the change in ownership provisions of the Internal Revenue Code of 1986, as amended ("Internal Revenue Code"), and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization. As of December 31, 2023, the Company has not completed an I.R.C. section 382 study to determine if a limitation exists. As the Company has recorded a full valuation allowance, any potential limitation is not expected to have a material impact to the consolidated financial statements.

***Uncertain Tax Positions***

A reconciliation of the beginning and ending balances of the unrecognized tax benefits for the years ended December 31, 2022 and 2023, is as follows (in thousands):

	Year Ended December 31, 2022	Year Ended December 31, 2023
Beginning balance	\$ 104	\$ 2,451
Increases in tax positions in the current period	2,347	3,572
Decreases related to prior year's tax position	—	(1,907)
Ending balance	<u>\$2,451</u>	<u>\$ 4,116</u>

The entire amount of the unrecognized tax benefits would not impact the Company's effective tax rate if recognized. The Company has elected to include interest and penalties as a component of other income (expense), net. For the years ended December 31, 2022 and 2023, the Company did not recognize accrued interest and penalties related to unrecognized tax benefits. The Company does not anticipate that the amount of existing unrecognized tax benefits will significantly increase or decrease during the next 12 months.

As of December 31, 2023, the Company is not under audit by the Internal Revenue Service or any state authority for income taxes for any open years. Due to the Company's net operating loss carryforwards, the Company's domestic income tax returns are open to examination by the Internal Revenue Service beginning with tax year 2017 and by state taxing authorities beginning with tax year 2021.

**13. Employee Benefit Plans**

The Company sponsors a qualified 401(k) defined contribution plan covering eligible employees. Participants may contribute a portion of their annual compensation limited to a maximum annual amount set by the Internal Revenue Service. There were no employer contributions under this plan for the years ended December 31, 2022 and 2023.

**CONFIDENTIAL TREATMENT REQUESTED BY ALUMIS INC.  
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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**14. Subsequent Events**

The Company has evaluated subsequent events for financial statement purposes occurring through April 10, 2024, the date when these consolidated financial statements are issued. No subsequent events have been identified for disclosure to or adjustment in the consolidated financial statements, other than the matters noted below.

From January 2024 through March 2024, the Company granted stock options for the purchase of an aggregate of 2,431,929 shares of common stock, with an exercise price of \$1.89 per share to employees under the 2021 Plan. These options have vesting terms of four years with one-year cliff vesting.

In March 2024, the Company's board of directors approved the repricing of all outstanding options as of March 29, 2024, which have an exercise price exceeding \$1.89 per share. The exercise price of outstanding options with a weighted average exercise price of \$2.19 for 21,521,882 common stock shares was reduced to the estimated common stock fair value of \$1.89 per share at the date of the repricing.

In March 2024, the Company amended its certification of incorporation to increase the authorized number of shares of the Company. Under the new amended and restated certificate of incorporation, the Company is authorized to issue 225,000,000 shares of Class A common stock, 168,489,897 shares of Class B common stock and 202,643,727 shares of redeemable convertible preferred stock consisting of 10,500,000 shares of Series Seed redeemable convertible preferred stock, 7,500,000 shares of Series A redeemable convertible preferred stock, 40,200,000 shares of Series B redeemable convertible preferred stock, 9,760,088 shares of Series B-1 redeemable convertible preferred stock, 18,000,000 shares of Series B-2 redeemable convertible preferred stock, 1,778,830 shares of Series B-2A redeemable convertible preferred stock, 82,529,809 shares of Series C redeemable convertible preferred stock and 32,375,000 shares of Series C-1 redeemable convertible preferred stock.

In March 2024, the Company entered into a Series C preferred stock purchase agreement and received \$129.5 million gross cash proceeds from the issuance of 41,264,891 shares at a purchase price of \$3.13826 per share in the First Tranche Series C Closing. Any time prior to December 31, 2024, at the discretion of the Company's board of directors, the Company is obligated to sell and each Series C purchaser is obligated to purchase additional shares of Series C redeemable convertible preferred stock with the amount equal to the purchaser's aggregate purchase price in the First Tranche Series C Closing less any previous payments by the purchaser as part of the Put Right (as defined below) exercise. If the purchaser does not purchase its full share in the Second Tranche Series C Closing, all of its existing shares of Series C redeemable convertible stock and Series C-1 redeemable convertible preferred stock convert into common stock at a 10-to-1 basis. Additionally, a purchaser has a right to purchase shares of Series C-1 redeemable convertible preferred stock at a purchase price of \$4.00 per share beginning from the earlier of (a) September 4, 2024 or (b) the date of a significant partnering or collaboration agreement and expiring upon the earlier of (a) December 31, 2024, (b) the public filing of a registration statement on Form S-1 for the initial public offering, (c) the Second Tranche Series C Closing and (d) the execution of a letter of intent for the sale of the Company (the "Put Right"). The Put Right can only be exercised once.

CONFIDENTIAL TREATMENT REQUESTED BY ALUMIS INC.  
PURSUANT TO 17 C.F.R. SECTION 200.83

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***Shares***



***Common Stock***

***PROSPECTUS***

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***Morgan Stanley***

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*Through and including \_\_\_\_\_, 2024 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.*

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**CONFIDENTIAL TREATMENT REQUESTED BY ALUMIS INC.  
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**PART II**

**INFORMATION NOT REQUIRED IN PROSPECTUS**

Unless otherwise indicated, all references to “Alumis,” the “company,” “we,” “our,” “us” or similar terms refer to Alumis Inc.

**Item 13. Other Expenses of Issuance and Distribution.**

The following table sets forth all expenses to be paid by us, other than underwriting discounts and commissions, in connection with this offering. All amounts shown are estimates except for the Securities and Exchange Commission (SEC) registration fee, the Financial Industry Regulatory Authority, Inc. (FINRA) filing fee and Nasdaq Global Market (Nasdaq) listing fee.

	<b>Amount</b>
SEC registration fee	\$ *
FINRA filing fee	*
Nasdaq listing fee	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Transfer agent and registrar fees and expenses	*
Miscellaneous expenses	*
<b>Total</b>	<b>\$ *</b>

\* To be provided by amendment.

**Item 14. Indemnification of Directors and Officers.**

Section 145 of the Delaware General Corporation Law (DGCL) authorizes a court to award, or a corporation’s board of directors to grant, indemnity to directors and executive officers in terms sufficiently broad to permit such indemnification under certain circumstances for liabilities, including reimbursement for expenses incurred, arising under the Securities Act of 1933, as amended (the Securities Act). Our amended and restated certificate of incorporation that will be in effect immediately prior to the closing of this offering permits indemnification of our directors, officers, employees and other agents to the maximum extent permitted by the DGCL, and our amended and restated bylaws that will be in effect on the closing of this offering provide that we will indemnify our directors and executive 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 executive officers, whereby we have agreed to indemnify our directors and executive officers to the fullest extent permitted by law, including indemnification against expenses and liabilities incurred in legal proceedings to which the director or executive officer was, or is threatened to be made, a party by reason of the fact that such director or executive officer is or was a director, executive officer, employee, or agent of Alumis, provided that such director or executive officer acted in good faith and in a manner that the director or executive officer reasonably believed to be in, or not opposed to, the best interest of Alumis.

At present, there is no pending litigation or proceeding involving a director or executive officer of Alumis 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 underwriter is obligated, under certain circumstances, under the underwriting agreement to be filed as Exhibit 1.1 to this Registration Statement, to indemnify us and our officers and directors against liabilities under the Securities Act.

**CONFIDENTIAL TREATMENT REQUESTED BY ALUMIS INC.  
PURSUANT TO 17 C.F.R. SECTION 200.83**

**Item 15. Recent Sales of Unregistered Securities.**

Set forth below is information regarding unregistered securities issued by us since our inception in April 4, 2021.

***Equity Plan-Related Issuances***

From September 1, 2021 through the filing date of this registration statement, we granted to certain directors, officers, employees, consultants and other service providers options to purchase an aggregate of 34,229,147 shares of our Class A common stock under the 2021 Plan at exercise prices ranging from \$0.82 to \$3.73 per share.

***Preferred Stock Issuances***

In February 2021, we issued and sold an aggregate of 10,500,000 shares of our Series Seed redeemable convertible preferred stock at a purchase price of \$1.00 per share for an aggregate purchase price of \$10,500,000.00.

In March 2021, we issued and sold an aggregate of 7,500,000 shares of our Series A redeemable convertible preferred stock at a purchase price of \$4.00 per share for an aggregate purchase price of \$30,000,00.00.

From December 2021 through January 2022, we sold an aggregate of 40,200,000 shares of our Series B redeemable convertible preferred stock at a purchase price of \$5.00 per share. We also sold an aggregate of 9,760,088 shares of our Series B-1 redeemable convertible preferred stock upon the conversion of certain convertible promissory notes at a price of \$4.00 per share. The aggregate purchase price for the Series B and Series B-1 redeemable convertible preferred shares was \$240,040,356.18, \$39,040,356.18 of which consisted of the conversion of outstanding convertible promissory notes.

In May 2023 and October 2023, we sold an aggregate of 14,943,510 shares of our Series B-2 redeemable convertible preferred stock at a purchase price of \$5.00 per share. We also sold an aggregate of 3,056,490 shares of our Series B-2A redeemable convertible preferred stock at a price of \$5.00 per share. The aggregate purchase price for the Series B-2 and Series B-2A redeemable convertible preferred shares was \$90,000,000.00.

In March 2024, we sold an aggregate of 41,264,891 shares of our Series C redeemable convertible preferred stock at a purchase price of \$3.13826 per share. The aggregate purchase price for the Series C redeemable convertible preferred shares was \$129,499,956.96.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. Unless otherwise stated, the sales of the above securities were deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act (and Regulation D or Regulation S promulgated thereunder) or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving any public offering or pursuant to benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed on the share certificates issued in these transactions. All recipients had adequate access, through their relationships with us, to information about us. The sales of these securities were made without any general solicitation or advertising.

**CONFIDENTIAL TREATMENT REQUESTED BY ALUMIS INC.  
PURSUANT TO 17 C.F.R. SECTION 200.83**

**Item 16. Exhibits and Financial Statement Schedules.**

(a) Exhibits.

Exhibit Number	Description
1.1+	Form of Underwriting Agreement.
3.1+	Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect.
3.2+	Form of Amended and Restated Certificate of Incorporation of the Registrant, to be in effect immediately after the closing of the offering.
3.3+	Bylaws of the Registrant, as currently in effect.
3.4+	Form of Amended and Restated Bylaws of the Registrant, to be in effect on the closing of the offering.
4.1+	Form of Common Stock Certificate.
4.2+	Amended and Restated Investors' Rights Agreement, by and among the Registrant and certain of its stockholders, dated March 4, 2024.
4.3+	Registration Rights Agreement dated as of _____, 2024 by and between the Registrant and certain of its stockholders.
5.1+	Opinion of Cooley LLP.
10.1+#	Alumis Inc. 2021 Stock Plan, as amended.
10.2+#	Forms of Stock Option Grant Notice under Alumis Inc. 2021 Stock Plan, as amended.
10.3+#	Alumis Inc. 2024 Equity Incentive Plan.
10.4+#	Forms of Stock Option Grant Notice, Stock Option Agreement and Notice of Exercise under the Alumis Inc. 2024 Equity Incentive Plan.
10.5+#	Forms of Restricted Stock Unit Grant Notice and Award Agreement under the Alumis Inc. 2024 Equity Incentive Plan.
10.6+#	Alumis Inc. 2024 Employee Stock Purchase Plan.
10.7+#	Alumis Inc. 2024 Non-Employee Director Compensation Policy.
10.8+#	Alumis Inc. Severance Plan.
10.9+#	Form of Indemnification Agreement by and between the Registrant and its directors and executive officers.
10.10+	Lease Agreement dated as of July 29, 2021 by and between the Registrant and 611 Gateway Center LP.
10.11+	Lease Agreement dated January 18, 2022 by and between the Registrant and Bayside Acquisition, LLC.
10.12+	Lease Agreement dated as of August 11, 2022 by and between the Registrant and PG VII 280 East Grand, LLC.
10.13+#	Offer Letter, dated as of September 15, 2021, by and between the Registrant and Martin Babler.
10.14+#	Offer Letter, dated as of September 15, 2021, by and between the Registrant and David Goldstein.
10.15+#	Offer Letter, dated as of September 15, 2021, by and between the Registrant and Roy Hardiman.
10.16+#	Offer Letter, dated as of March 1, 2021, by and between the Registrant and Mark Bradley.
10.17+#	Amendment to Offer Letter, dated as of July 18, 2023, by and between the Registrant and Mark Bradley.
10.18+#	Offer Letter, dated as of November 12, 2021, by and between the Registrant and Derrick Richardson.
10.19+#	Offer Letter, dated as of January 12, 2022, by and between the Registrant and Sara Klein.
10.20+#	Offer Letter, dated as of March 22, 2022, by and between the Registrant and John Schroer.
10.21+#	Offer Letter, dated as of June 24, 2022, by and between the Registrant and Jörn Drappa.

**CONFIDENTIAL TREATMENT REQUESTED BY ALUMIS INC.  
PURSUANT TO 17 C.F.R. SECTION 200.83**

<b>Exhibit Number</b>	<b>Description</b>
21.1+	List of Subsidiaries of the Registrant.
23.1+	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.
23.2+	Consent of Cooley LLP (included in Exhibit 5.1).
24.1+	Power of Attorney (included on signature page).
107+	Filing Fee Table.

+ To be filed by amendment.

# Indicates management contract or compensatory plan.

(b) Financial Statement Schedules.

All financial statement schedules are omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or the notes thereto.

**Item 17. Undertakings.**

(a) The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

(b) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant under the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the U.S. Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer, or controlling person of the registrant in the successful defense of any action, suit, or proceeding) is asserted by such director, officer, or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

(c) The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance on Rule 430A and contained in a form of prospectus filed by the registrant under Rule 424(b)(1) or (4) or 497(h) under the Securities Act will be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus will be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time will be deemed to be the initial bona fide offering thereof.

**CONFIDENTIAL TREATMENT REQUESTED BY ALUMIS INC.  
PURSUANT TO 17 C.F.R. SECTION 200.83**

**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 the City of South San Francisco, State of California, on \_\_\_\_\_, 2024.

**ALUMIS INC.**

By: \_\_\_\_\_

Name: Martin Babler

Title: Chief Executive Officer

**POWER OF ATTORNEY**

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Martin Babler and John Schroer and each one of them, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in their name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement, and to sign any registration statement for the same offering covered by this registration statement that is to be effective on filing pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and all post-effective amendments thereto, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
_____ Martin Babler	President and Chief Executive Officer and Director ( <i>Principal Executive Officer</i> )	, 2024
_____ John Schroer	Chief Financial Officer ( <i>Principal Financial and Accounting Officer</i> )	, 2024
_____ Julian C. Baker	Director	, 2024
_____ Alan B. Colowick, M.D., M.P.H.	Director	, 2024
_____ Sapna Srivastava	Director	, 2024
_____ James B. Tananbaum, M.D.	Director	, 2024
_____ Zhengbin Yao, Ph.D.	Director	, 2024



CONFIDENTIAL TREATMENT REQUESTED BY ALUMIS INC.  
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<u>Signature</u>	<u>Title</u>	<u>Date</u>
_____ Srinivas Akkaraju, M.D., Ph.D.	Director	, 2024
_____ Richard Gaster, M.D., Ph.D.	Director	, 2024