UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2025
or

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to
Commission file number: 001-36866

Summit Therapeutics Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	37-1979717
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
601 Brickell Key Drive, Suite 1000 Miami FL	33131
(Address of Principal Executive Offices)	(Zip Code)

(305) 203-2034
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.01 per share	SMMT	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the voting common stock held by non-affiliates based on the closing stock price on June 30, 2025, was $2,483.8 million. For purposes of this computation only, all executive officers and directors have been deemed affiliates.

The number of outstanding shares of the registrant's common stock, par value $0.01 per share, as of February 17, 2026 was 775,372,700.

Documents Incorporated by Reference

Portions of the registrant's definitive proxy statement relating to the registrant's 2026 annual meeting of stockholders to be filed hereafter are incorporated by reference into Part III of this Annual Report on Form 10-K. The registrant's definitive proxy statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), regarding the future financial performance, business prospects and growth of Summit Therapeutics Inc., that involve substantial risks and uncertainties. All statements contained in this Annual Report on Form 10-K, other than statements of historical fact, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. The forward-looking statements in this Annual Report on Form 10-K include, among other things, statements about:

- the ability to develop a successful product candidate under the License Agreement (as defined in Part I, Item I Business, Company Overview);
- our ability to raise sufficient additional funds to make payments under the License Agreement, and fund ongoing operations and capital needs;
- the timing of and the ability to effectively execute clinical development of ivonescimab;
- the timing, costs, conduct and outcomes of clinical trials for any product candidates, including ivonescimab;
- our plans with respect to possible future collaborations and partnering arrangements;
- the potential benefits of possible future acquisitions or investments in other businesses, products or technologies;
- our plans to pursue research and development of other future product candidates;
- our estimates regarding the potential market opportunity and patient population for commercializing our product candidates, if approved for commercial use;
- our sales, marketing and distribution capabilities and strategy;
- our ability to establish and maintain arrangements with third parties, such as contract research organizations, contract manufacturing organizations, suppliers and distributors;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against any intellectual property-related claims;
- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- the impact of government laws and regulations in the United States and in foreign countries;
- the timing and likelihood of regulatory filings and approvals for our product candidates;
- whether regulatory authorities determine that additional trials or data are necessary in order to accept a new drug application for review and approval;
- our competitive position;
- our planned use of our existing cash, cash equivalents and marketable securities;
- our ability to attract and retain key scientific or management personnel;
- the impact of public health epidemics, such as the coronavirus pandemic ("COVID-19"), natural disasters or geopolitical instability, the response to such events and the potential effects of such events on our business, financial results, supply chain and market; and
- general economic conditions, including economic slowdowns or other adverse economic conditions, such as periods of increased or prolonged inflation.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Annual Report on Form 10-K, particularly in the "Risk Factors" in Part 1, Item 1A of this Annual Report on Form 10-K, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this Annual Report on Form 10-K and the documents that we have filed as exhibits to this Annual Report on Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements.

SUMMARY OF RISK FACTORS

Below is a summary of the principal factors that make an investment in Summit speculative or risky. The following summary does not contain all of the information that may be important to you, and you should read the below summary in conjunction with the more detailed discussion of risks set forth under the heading "Risk Factors" in Part I, Item IA of this Annual Report on Form 10-K.

Risks Related to Our Financial Position and Need for Additional Capital

- We are a development-stage company and have incurred significant losses since our inception. We anticipate that we will continue to incur significant losses for at least the next several years and may never generate profits from operations or maintain profitability.
- We have not yet demonstrated an ability to successfully complete development of any product candidates, and a Biologics License Application ("BLA") that has been accepted for filing, such as the BLA relating to the HARMONi study, may not ultimately lead to regulatory approval and commercialization of ivonescimab.
- We will need substantial additional capital to fund our operations. Raising additional capital may cause dilution to our investors or restrict our operations.
- We depend heavily on the success of ivonescimab. If we are unable to successfully develop and commercialize ivonescimab, or experience significant delays in doing so, we may extend the period in which we will incur significant financial losses as an organization.
- Worldwide economic, social and geopolitical instability could adversely affect our business and ability to raise capital in the future.

Risks Related to the Development and Commercialization of our Product Candidates

- We can provide no assurance that our clinical product candidates, including our lead product candidate, ivonescimab, will obtain regulatory approval or that the results of clinical studies will be favorable.
- Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials conducted by us or Akeso (as defined in Part I, Item I Business, Company Overview), as well as any interim results thereof, may not be predictive of future trial results and may negatively impact the size and scope of our ongoing or future Phase III clinical trials.
- Regulatory requirements and timelines may affect the scope and timeline of our trials and the potential market for our product candidates.
- If we experience unforeseen events, including unfavorable results, in connection with our clinical trials, potential marketing approval or commercialization of our product candidates could be delayed or prevented.
- Serious adverse events may limit our development of a product candidate.
- Even if a product candidate receives marketing approval, it may fail to achieve commercial success.
- We may expend our limited resources to pursue a particular product candidate and fail to capitalize on product candidates that may be more profitable or for which there is a greater likelihood of success.
- Others may discover, develop or commercialize products before us or more successfully than we do.

Risks Related to our Dependencies on Third Parties

- We depend on our relationship with, and the intellectual property licensed from Akeso.
- We may be reliant on Akeso for knowledge transfer relating to any improvements in manufacturing of ivonescimab.
- We depend on collaborations with third parties for the development and commercialization of some of our product candidates.
- We rely on the use of third parties, including Akeso, to manufacture our product candidate.
- We rely on third parties to conduct our clinical trials and those third parties may not perform satisfactorily.

Legal, Tax, Regulatory and Compliance Risks

- Any approved product candidate may become subject to unfavorable pricing regulations, third-party reimbursement practices or other healthcare reform initiatives.
- Our business is subject to the risks associated with doing business in China, including impacts from tariffs, data security laws and regulations, and restrictions on data transfer.
- Product liability lawsuits against us could materially harm our business.
- If we fail to comply with applicable laws and regulations, we could face material adverse consequences.
- Changes to tax laws or the interpretation thereof could increase our future tax liabilities and adversely affect our business.

- Our future tax liabilities may be greater than expected if our net operating loss carryforwards and other tax attributes are limited, we do not generate expected deductions, or tax authorities challenge our tax positions.
- If we are unsuccessful or delayed in obtaining required regulatory approvals, we may not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.
- Our ability to obtain and maintain conditional marketing authorizations in the EU and other countries in our Licensed Territory (as defined in Part I, Item I Business, Akeso Collaboration and License Agreement) may be more limited in number as well as scope of the relevant authorizations and subject to several conditions and obligations that could prevent us from continuing to market our products.
- The terms of any received marketing approvals, including post-marketing requirements, and regulations may limit how we manufacture, market and price our products.

Risks Related to Our Intellectual Property, Cybersecurity and Data Privacy

- Insufficient patent protection could materially negatively impact our competitive position.
- Any litigation relating to our intellectual property may have a material adverse effect on our business.
- We may be subject to claims by third parties asserting misappropriation of their intellectual property.
- If we are unable to protect the confidentiality of our trade secrets, our business could be harmed.
- Any interruption, malfunction, or lapse related to information technology, including any cybersecurity incidents, could harm our business.
- Failure to comply with data privacy and security obligations could harm our business.

Risks Related to Operations

- We depend on our ability to retain our Co-Chief Executive Officers, Chief Operating Officer and other key executives and personnel.
- We or the third parties we rely on may be adversely affected by social unrest, terrorism or natural disasters.
- Widespread health concerns or pandemics or epidemics could harm our business.
- Any non-compliance with regulations or other misconduct by employees could harm our business.

Risks Related to Owning Our Common Stock

- Our principal stockholder and Co-Chief Executive Officer maintains the ability to control or significantly influence all matters submitted to stockholders for approval.
- We are a "controlled company" under the listing requirements of the Nasdaq Stock Market, which could adversely affect our stockholders.
- The price of our shares of common stock have been, and may continue to be, volatile.
- Substantial future sales of our shares of common stock in the public market, or the perception that these sales could occur, could cause the price of the shares to decline significantly, even if our business is doing well.
- Any failure to maintain an effective system of internal control over financial reporting could decrease confidence in our financial and other public reporting, which would harm our business.
- Our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers and employees is limited by our Certificate of Incorporation.
- Because we do not anticipate paying any cash dividends on our shares of common stock in the foreseeable future, capital appreciation, if any, will be the sole source of gain for our stockholders.
- We are exposed to risks related to currency exchange rates.

PART I

Item 1. Business

Company Overview

Summit Therapeutics Inc. ("we", "Summit" or the "Company") is a biopharmaceutical company focused on the discovery, development, and commercialization of patient-, physician-, caregiver- and societal-friendly medicinal therapies intended to improve quality of life, increase potential duration of life, and resolve serious unmet medical needs. The Company's pipeline of product candidates is designed with the goal to become the patient-friendly, new-era standard-of-care medicines, in the therapeutic area of oncology.

The Company's current lead development candidate is ivonescimab, a novel, potential first-in-class bispecific antibody intending to combine the effects of immunotherapy via a blockade of PD-1 with the anti-angiogenesis effects of an anti-VEGF (as defined in Part I, Item I Business, Company Overview, Ivonescimab) compound into a single molecule. On December 5, 2022, the Company entered into the License Agreement with Akeso, Inc. and its affiliates (collectively, "Akeso") pursuant to which the Company has in-licensed intellectual property rights related to ivonescimab (as amended, the "License Agreement"). Through the License Agreement, the Company obtained the rights to develop and commercialize ivonescimab in the United States, Canada, Europe, and Japan. The License Agreement and transaction closed in January 2023 following customary waiting periods. On June 3, 2024, the Company entered into the Second Amendment with Akeso to expand its territories covered under the License Agreement to also include Latin America, including Mexico and all countries in Central America and South America, the Middle East and Africa. The Company's operations are focused on the development of ivonescimab and other future activities, as the Company determines.

The Company is developing ivonescimab in non-small cell lung cancer ("NSCLC") and colorectal cancer ("CRC"), specifically conducting Phase III clinical trials in the following proposed indications:

(a) ivonescimab combined with chemotherapy in patients with epidermal growth factor receptor ("EGFR")-mutated, locally advanced or metastatic non-squamous NSCLC who were previously treated with a third-generation EGFR tyrosine kinase inhibitor ("TKI") ("HARMONi");

(b) ivonescimab combined with chemotherapy in patients with first-line metastatic NSCLC (including separate statistical analyses planned for patients with squamous NSCLC and non-squamous NSCLC) ("HARMONi-3");

(c) ivonescimab monotherapy in patients with first-line metastatic NSCLC whose tumors have high PD-L1 expression ("HARMONi-7"); and

(d) ivonescimab combined with chemotherapy in patients with first-line unresectable metastatic CRC ("HARMONi-GI3").

In October 2024, the Company completed enrollment in its HARMONi clinical trial. In May 2025, we announced topline results from our multiregional, double-blinded, placebo-controlled, Phase III study HARMONi. At the prespecified primary data analysis, ivonescimab in combination with chemotherapy demonstrated a statistically significant improvement in progression free survival ("PFS"), the magnitude of which we believe to be clinically meaningful, with a hazard ratio of 0.52 (95% CI: 0.41 – 0.66; $p<0.00001$) compared to placebo in combination with chemotherapy; median PFS was 6.8 months for those patients receiving ivonescimab plus chemotherapy compared to 4.4 months for those receiving chemotherapy. PFS was assessed by blinded independent central radiology committee ("BICR").

We believe the PFS hazard ratio that was observed in both Asian and Western sub-populations to be clinically meaningful. The primary analysis demonstrated the consistency of the magnitude of the PFS benefit between patients randomized in Asian and Western territories, as well as the consistency in a single-region study (HARMONi-A) with this multiregional study.

In a longer-term follow-up of PFS, which included all Western patients and at least six months of follow-up time for all patients, ivonescimab plus chemotherapy demonstrated a consistent improvement in PFS with an observed HR of 0.57 (95% CI: 0.46 – 0.71). With the longer-term follow-up analysis, consistency of the magnitude of PFS benefit was demonstrated between patients randomized in Asia and Western patients when measured by hazard ratio. This longer-term follow-up analysis of PFS was performed at the time of the primary overall survival ("OS") analysis.

Ivonescimab in combination with chemotherapy showed a positive trend in OS in the primary analysis without achieving a statistically significant benefit with a hazard ratio of 0.79 (95% CI: 0.62 – 1.01; p=0.057). This trend provides further support for its use in 2L+ EGFRm NSCLC, a setting where high unmet need continues to exist with limited approved options in the United States and other western territories. Currently, there are no FDA-approved regimens that have demonstrated a statistically significant OS benefit in this patient setting. Both Asian and North American patients demonstrated a positive trend in OS. The results of the primary analysis in this multiregional study were consistent with that of the single-region randomized Phase III HARMONi-A study, which demonstrated a statistically significant OS benefit with a hazard ratio of 0.74 in the primary OS analysis in a similar patient population.

In September 2025, an additional ad hoc OS analysis was performed for the HARMONi study whereby the Western patients were followed for a longer period of time (Asian patients were locked at the time of the primary analysis). In this analysis that included longer-term follow-up of Western patients (median follow-up time of Western patients of 13.7 months), a hazard ratio consistent with the primary analysis was observed with an improved nominal p-value (HR=0.78; 95% CI: 0.62 – 0.98; nominal p=0.0332). Median OS for this analysis remained the same in both arms as was observed in the primary analysis. Median OS in Western patients receiving ivonescimab was 17.0 months compared to 14.0 months for those receiving placebo (HR=0.84); median OS in North American patients, specifically, had not yet been reached in the ivonescimab arm compared to 14.0 months in the placebo arm (HR=0.70). The hazard ratios for Western patients in totality, as well as patients from the North American and European regions individually, improved from the primary OS analysis to the analysis with longer-term follow-up of Western patients. Consistent benefit was observed across pre-defined subgroups.

The dual primary endpoints were allocated separate alpha levels and tested individually. The alpha was recycled from the PFS to the OS analysis upon the successful achievement of the PFS endpoint.

Based on the results of the HARMONi clinical trial, we submitted a BLA in the fourth quarter of 2025 to seek approval for ivonescimab plus chemotherapy for this proposed indication. The positive results of the multiregional Phase III study are detailed further under “Product Pipeline” below. As previously disclosed, the FDA noted that a statistically significant overall survival benefit is necessary to support marketing authorization in this setting. After careful consideration of the safety and efficacy profile of the current FDA-approved options for patients in this setting, the positive results of the Phase III multiregional study, including regional consistency, as well as discussions with key opinion leaders and those physicians who have administered ivonescimab to patients in a clinical study setting, we believe that the safety and efficacy data generated in the HARMONi study demonstrates that the ivonescimab regimen offers a potential treatment option for patients impacted by EGFR-mutant NSCLC in this setting with a favorable benefit-risk profile despite the lack of a statistically significant overall survival benefit. Summit announced in January 2026 that the FDA accepted for filing the BLA, seeking approval for ivonescimab in combination with chemotherapy for this proposed indication. The FDA noted it intends to perform a complete review of the accepted and filed BLA, including planned mid-cycle and wrap-up meetings, and, subject to major deficiencies not being identified during the FDA’s review, proposed labeling, prior to the Prescription Drug User Fee Act goal action date of November 14, 2026.

Akeso Collaboration and License Agreement

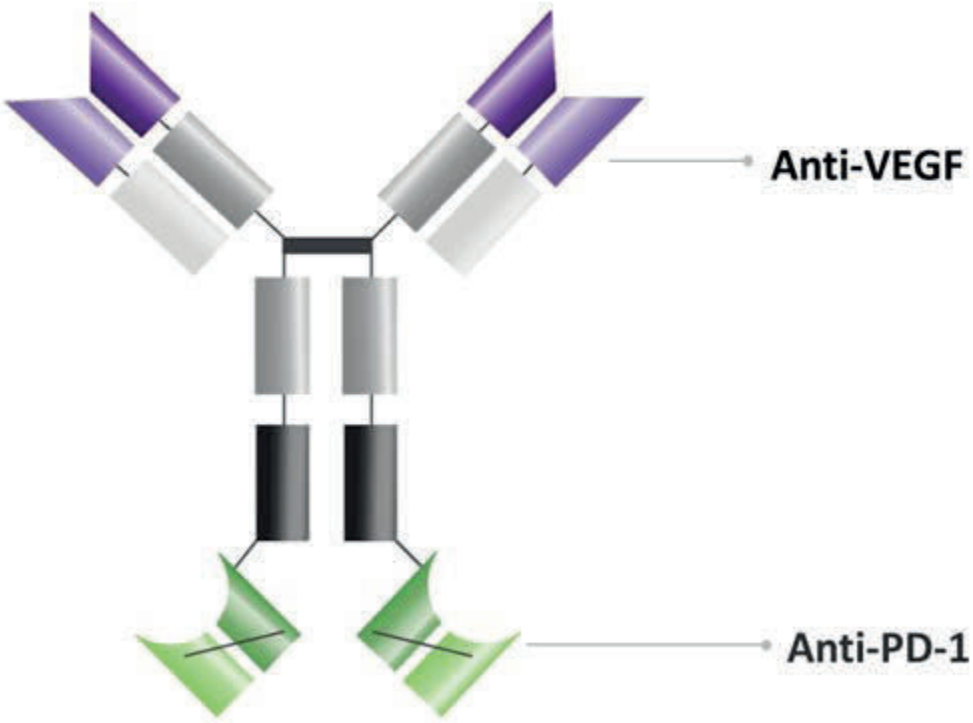
Pursuant to the License Agreement with Akeso, the Company received the rights to develop and commercialize ivonescimab in the United States, Canada, Europe, Japan, Latin America, Middle East and Africa regions (collectively, the “Licensed Territory”). Akeso retained development and commercialization rights for the rest of the world excluding the Licensed Territory. In exchange for these rights, Summit made an upfront payment during the first quarter of 2023 comprised of $474.9 million cash and the issuance of 10 million shares of Company common stock in lieu of $25.1 million cash pursuant to a share transfer agreement. Furthermore, on June 3, 2024, the Company entered into an amendment to the License Agreement with Akeso to expand its territories covered under the License Agreement to also include the Latin America, Middle East and Africa regions for which Summit paid an upfront payment of $15.0 million cash in the third quarter of 2024. In addition, the Company may also pay Akeso (a) milestone payments tied to achievement of regulatory approval of ivonescimab with various regulatory authorities in the Licensed Territory, (b) milestone payments tied to achievement of annual revenue from ivonescimab in the Licensed Territory and (c) royalty payments equal to low-double-digit percentage of annual revenues from ivonescimab in the Licensed Territory. In connection with the License Agreement, the Company agreed to purchase a certain portion of drug substance and/or drug product for clinical and commercial supply and to enter into a supply agreement with Akeso.

Pursuant to the terms of the License Agreement, Summit has final decision-making authority with respect to all of its commercialization activities including, but not limited to, commercial strategy, pricing and reimbursement in the Licensed Territory.

Summit has not assumed any liabilities (including contingent liabilities), nor acquired any physical assets or trade names, or hired or acquired any employees from Akeso in connection with the License Agreement.

Ivonescimab

Ivonescimab is a novel potential first-in-class PD-1 / VEGF-A bispecific antibody, believed to be the most advanced in clinical development in the Licensed Territory. Engineered with Akeso's unique Tetrabody technology, ivonescimab, as a single molecule, blocks programmed cell death protein 1 ("PD-1") from binding to PD-L1 and PD-L2, and blocks the protein vascular endothelial growth factor-A ("VEGF") from binding to VEGF receptors. Ivonescimab is designed to potentially allow cooperative binding of the intended targets, such that the binding of VEGF increases the binding affinity of PD-1. In view of the co-expression of VEGF and PD-1 in the tumor micro-environment ("TME"), ivonescimab may block these two pathways more effectively and enhance the antitumor activity, as compared to combination therapy through what is believed to be a unique cooperative binding mechanism.



This could differentiate ivonescimab as there is potentially higher expression (presence) of both PD-1 and VEGF in tumor tissue and the TME as compared to normal tissue in the body. As shown in Akeso's *in-vitro* studies, ivonescimab's tetravalent structure (four binding sites) enables higher avidity (accumulated strength of multiple binding interactions) in the TME with over 10-fold increased binding affinity to PD-1 in the presence of VEGF. This tetravalent structure, the intentional novel design of the molecule, and bringing these two targets into a single bispecific antibody with cooperative binding qualities has the potential to direct ivonescimab to the tumor tissue versus healthy tissue. The intent of this design is to improve upon previously established efficacy thresholds, in addition to side effects and safety profiles associated with these targets.

Ivonescimab is currently being developed by both Akeso and the Company in multiple Phase III clinical trials. Over 4,000 patients have been treated with ivonescimab in clinical studies globally, and over 60,000 patients when considering those treated in a commercial setting in China as noted by Akeso.

Product Pipeline

Summit Sponsored Ivonescimab Trials

Ivonescimab is currently being investigated in global Phase III clinical trials. Phase I and II trials were completed by or are ongoing with our partner Akeso. This pipeline reflects Phase III clinical trials that have been or are planned to be initiated by Summit in its Licensed Territory.

TUMOR TYPE	STUDY	LINE & INDICATION	REGIMEN
Lung	HARMONi	2L advanced EGFRm+ NSCLC	ivonescimab + chemo vs. placebo + chemo
	HARMONi-3	1L metastatic NSCLC	ivonescimab + chemo vs. pembrolizumab + chemo
	HARMONi-7	1L metastatic PD-L1 high (≥50%) NSCLC	ivonescimab vs. pembrolizumab
Gastrointestinal	HARMONi-GI3	1L metastatic CRC	ivonescimab + chemo vs. bevacizumab + chemo

HARMONi

HARMONi study (NCT05184712) is a Phase III, multi-regional, potentially registration-enabling clinical trial, which enrolled patients in North America, Europe, and China. Patients enrolled in China were also enrolled as a part of the HARMONi-A study. We completed enrollment of patients in North America and Europe in October 2024. The two primary endpoints for this study are PFS and OS, and the study compares ivonescimab plus platinum-based doublet chemotherapy versus placebo plus platinum-based doublet chemotherapy in patients with advanced or metastatic EGFR-mutated NSCLC whose tumors have progressed following treatment with a third generation EGFR-TKI.

In May 2025, we announced topline results from our multiregional, double-blinded, placebo-controlled, Phase III study HARMONi. At the prespecified primary data analysis, ivonescimab in combination with chemotherapy demonstrated a statistically significant improvement in PFS, the magnitude of which we believe to be clinically meaningful, with a hazard ratio of 0.52 (95% CI: 0.41 – 0.66; p<0.00001) compared to placebo in combination with chemotherapy; median PFS was 6.8 months for those patients receiving ivonescimab plus chemotherapy compared to 4.4 months for those receiving chemotherapy. PFS was assessed by BICR.

We believe the PFS hazard ratio that was observed in both Asian and Western sub-populations to be clinically meaningful. The primary analysis demonstrated the consistency of the magnitude of the PFS benefit between patients randomized in Asia and Western territories, as well as the consistency in a single-region study (HARMONi-A) with this multiregional study.

In a longer-term follow-up of PFS, which included all Western patients and at least six months of follow-up time for all patients, ivonescimab plus chemotherapy demonstrated a consistent improvement in PFS with an observed HR of 0.57 (95% CI: 0.46 – 0.71). With the longer-term follow-up analysis, consistency of the magnitude of PFS benefit was demonstrated between patients randomized in Asia and Western patients when measured by hazard ratio. This longer-term follow-up analysis of PFS was performed at the time of the primary OS analysis.

Ivonescimab in combination with chemotherapy showed a positive trend in OS in the primary analysis without achieving a statistically significant benefit with a hazard ratio of 0.79 (95% CI: 0.62 – 1.01; p=0.057). This trend provides further support for its use in 2L+ EGFRm NSCLC, a setting where high unmet need continues to exist with limited approved options in the United States and other western territories. Currently, there are no FDA-approved regimens that have demonstrated a statistically significant overall survival benefit in this patient setting. Both Asian and North American patients demonstrated a positive trend in overall survival. The results of the primary analysis in this multiregional study were consistent with that of the single-region randomized Phase III HARMONi-A study, which demonstrated a statistically significant OS benefit hazard ratio of 0.74 in the primary OS analysis in a similar patient population.

In September 2025, an additional ad hoc OS analysis was performed for the HARMONi study whereby the Western patients were followed for a longer period of time (Asian patients were locked at the time of the primary analysis). In this analysis that included longer-term follow-up of Western patients (median follow-up time of Western patients of 13.7 months), a hazard ratio consistent with the primary analysis was observed with an improved nominal p-value (HR=0.78; 95% CI: 0.62 – 0.98; nominal p=0.0332). Median OS for this analysis remained the same in both arms as was observed in the primary analysis. Median OS in Western patients receiving ivonescimab was 17.0 months compared to 14.0 months for those receiving placebo (HR=0.84); median OS in North American patients, specifically, had not yet been reached in the ivonescimab arm compared to 14.0 months

in the placebo arm (HR=0.70). The hazard ratios for Western patients in totality, as well as patients from the North American and European regions individually, improved from the primary OS analysis to the analysis with longer-term follow-up of Western patients. Consistent benefit was observed across pre-defined subgroups.

The dual primary endpoints were allocated separate alpha levels and tested individually. The alpha was recycled from the PFS to the OS analysis upon the successful achievement of the PFS endpoint.

The safety profile of ivonescimab in combination with chemotherapy was acceptable and manageable in the context of the observed clinical benefit with comparable rates of discontinuation and death between both arms. There were 16 patients (7.3%) who discontinued ivonescimab due to treatment-related adverse events ("TRAEs") compared to 11 patients (5.0%) who discontinued placebo due to TRAEs. There were four patients (1.8%) in the ivonescimab plus chemotherapy arm and five patients (2.3%) in the chemotherapy alone arm who died as a result of TRAEs. In the ivonescimab plus chemotherapy arm, 50.0% of patients experienced Grade 3 or higher TRAEs compared to 42.2% in the chemotherapy arm. Of note, 0.9% of patients in the ivonescimab plus chemotherapy arm experienced Grade 3 or higher treatment-related hemorrhagic (bleeding) events. Based on the results of the HARMONi clinical trial, Summit submitted a BLA in the fourth quarter of 2025 in order to seek approval for ivonescimab plus chemotherapy in this setting. Summit announced in January 2026 that the FDA accepted for filing the BLA, seeking approval for ivonescimab in combination with chemotherapy for this proposed indication. The FDA noted it intends to perform a complete review of the accepted and filed BLA, including planned mid-cycle and wrap-up meetings, and, subject to major deficiencies not being identified during the FDA's review, proposed labeling, prior to the Prescription Drug User Fee Act goal action date of November 14, 2026.

HARMONi-3

HARMONi-3 study (NCT05899608) is a Phase III, multi-regional, potentially registration-enabling clinical trial for which we initiated sites in North America, China and Europe. The two primary endpoints for this study are PFS and OS, and the study compares ivonescimab plus platinum-based doublet chemotherapy versus pembrolizumab plus platinum-based doublet chemotherapy in first-line patients with metastatic squamous NSCLC and non-squamous NSCLC. Enrollment is ongoing in all regions for patients with squamous and non-squamous tumors.

In October 2025, the Company announced a protocol amendment to separate the statistical analysis of the primary endpoints by histology. Therefore, there will be separate analyses conducted to evaluate ivonescimab plus chemotherapy compared to pembrolizumab plus chemotherapy in patients with squamous NSCLC and in patients with non-squamous NSCLC.

In order to sufficiently power for both primary endpoints (PFS and OS) in both cohorts of this study, Summit plans to enroll approximately 600 patients with squamous NSCLC and 1,000 patients with non-squamous NSCLC.

As a result of having two separate intention-to-treat analyses within the HARMONi-3 study, the analyses for squamous tumors and non-squamous tumors may be conducted at separate times, as each analysis will be conducted upon the prespecified numbers of events being reached in the separate cohorts.

Screening for patient enrollment has been completed for the planned patient count for the squamous cohort of HARMONi-3 in the first quarter of 2026. For the squamous cohort, we amended the study's statistical analysis plan and expect to conduct an interim analysis for PFS in the second quarter of 2026. We anticipate that OS will be immature at the time of the interim PFS analysis. The Company expects to reach the prespecified number of events for the final PFS analysis for this cohort, if required, in the second half of 2026. An interim analysis for OS may be conducted at a similar time.

Enrollment in the non-squamous cohort of HARMONi-3 is expected to complete in the second half of 2026. The Company expects to perform the final PFS analysis for this cohort in the first half of 2027. The Company will determine if an interim PFS analysis will be conducted for the study in the second half of 2026. Interim analyses for OS are planned to be conducted, based upon reaching prespecified numbers of events.

HARMONi-7

Based on the results of HARMONi-2, the Company is enrolling in the HARMONi-7 study (NCT06767514). HARMONi-7 is a multi-regional, potentially registration-enabling Phase III clinical trial that will compare ivonescimab monotherapy to pembrolizumab monotherapy in patients with metastatic squamous and non-squamous NSCLC whose tumors have high PD-L1 expression. The sample size for this study is currently planned to have an estimated 780 patients with two primary endpoints, PFS and OS.

HARMONi-GI3

In the fourth quarter of 2025, the Company activated trial sites and began enrolling patients in HARMONi-GI3, a Phase III, multi-regional, clinical trial evaluating ivonescimab plus chemotherapy compared to bevacizumab plus chemotherapy as first line therapy in patients with unresectable metastatic CRC. The primary endpoint for this study is PFS and Summit plans to enroll approximately 600 patients.

Non-Sponsored Phase III Clinical Studies (Summit's License Territories)

In the first quarter of 2026, the Company announced that GORTEC, a cooperative group dedicated to Head and Neck Oncology, will begin to activate clinical trial sites in the Phase III clinical study, ILLUMINE (NCT07264075), which will evaluate ivonescimab monotherapy and ivonescimab in combination with ligufalimab, Akeso's proprietary anti-CD47 monoclonal antibody, against monotherapy pembrolizumab in a three-arm study. The study is intended to be conducted in multiple countries in Europe and in China; Summit will consider the expansion of this study into the United States. The primary endpoint for the study is OS. The study, currently planned to enroll 780 patients with recurrent or metastatic PD-L1 positive head and neck squamous cell carcinoma (HNSCC), is expected to begin enrollment in the second quarter of 2026.
Data supporting this study was previously presented at ESMO 2024, whereby ivonescimab in combination with ligufalimab demonstrated an objective response rate of 60% in 20 patients with a median PFS of 7.1 months after a median follow-up time of 4.1 months; OS was not mature at the time of this analysis. At the time of data cut-off for this presentation, no patients receiving ivonescimab plus ligufalimab permanently discontinued drug treatment due to treatment-related adverse events.

Potential Future Clinical Development and Additional Current Activities

Summit is conducting its current clinical trials and plans to design and conduct additional clinical trial activities for ivonescimab within its Licensed Territory to support and submit relevant regulatory filings. We intend to explore further clinical development of ivonescimab in solid tumor settings outside of metastatic NSCLC and metastatic CRC, our current areas of focus in our Phase III clinical trials.

In the fourth quarter of 2023, we began collaborating with multiple institutions globally and opened our investigator- sponsored trials program across several disease areas. We continued to expand this program in 2024 and 2025 in order to discover additional opportunities for ivonescimab, including in several tumors outside of our current development plan.

We plan to review the data generated from these clinical trials as well as Akeso-sponsored clinical trials as a part of our consideration for advancing our clinical development pipeline for ivonescimab in the Licensed Territory.

Additional Ivonescimab Development: Akeso-Sponsored Trials

Akeso is currently developing ivonescimab in NSCLC and other solid tumor settings. Ivonescimab was approved by the National Medical Products Administration ("NMPA") in May 2024 in China in combination with chemotherapy for patients with EGFR-mutated NSCLC whose tumors have progressed following an EGFR-TKI based on the results of the HARMONi-A clinical trial. Subsequently, ivonescimab was approved by the NMPA in April 2025 as monotherapy based on the results of the HARMONi-2 study in first-line, PD-L1 positive NSCLC. Also in October 2025, Akeso announced the positive data for the HARMONi-6 study in first-line squamous NSCLC for ivonescimab in combination with chemotherapy. Further details related to these three trials, in addition to other Phase II clinical data, are described further below. Akeso is currently conducting Phase III clinical trials in combination with chemotherapy in first-line biliary tract cancer ("HARMONi-GI1"), in first-line advanced PD-L1 low or negative triple-negative breast cancer ("TNBC") ("HARMONi-BC1"), in first-line advanced microsatellite stable CRC ("HARMONi-GI6") and in NSCLC for patients whose tumors have progressed following PD-(L)1 inhibitor based therapy ("HARMONi-8A"), as well as in combination with ligufalimab, a proprietary Akeso-owned investigational CD-47 monoclonal antibody, in first-line recurrent / metastatic PD-L1 positive head-and-neck cancer ("HARMONi-HN1") and in combination with ligufalimab plus chemotherapy in first-line advanced pancreatic cancer ("HARMONi-GI2"). In addition, Akeso is conducting a Phase 3 study with ivonescimab after consolidation chemotherapy and radiotherapy in the limited stage small cell lung cancer ("SCLC") setting (HARMONi-9).

HARMONi-A

Based on data published by Akeso at the American Society of Clinical Oncology ("ASCO 2024") and in a publication in the *Journal of the American Medical Association (JAMA)* in the HARMONi-A study, in a single-region (China), randomized, double-blinded Phase III study in patients with NSCLC who have progressed following an EGFR-TKI, ivonescimab achieved its primary endpoint of PFS when combined with doublet chemotherapy (pemetrexed and carboplatin). Patients experienced a 54% reduction in disease progression or death as compared to placebo plus doublet-chemotherapy (HR: 0.46, 95% CI: 0.34 - 0.62; $p<0.001$). In a pre-specified subgroup analysis of patients who received a previous third-generation TKI, a hazard ratio of 0.48 was observed. At the primary OS analysis of HARMONi-A, ivonescimab achieved a hazard ratio of 0.74 (95% CI: 0.58,

0.95, p=0.019), demonstrating a statistically significant and clinically meaningful OS benefit, which was presented in November 2025 at the 2025 Annual Meeting for the Society for Immunotherapy for Cancer (SITC 2025). Ivonescimab demonstrated an acceptable and manageable safety profile, which was consistent with previous studies. There were nine patients (5.6%) who discontinued ivonescimab plus chemotherapy due to TRAEs compared to four patients (2.5%) who discontinued chemotherapy plus placebo due to TRAEs. No TRAEs resulted in the death of a patient in either arm in this Phase III study. Full results were published in JAMA (Fang et al. 2024).

HARMONi-2

After announcing positive qualitative results on May 30, 2024 for the HARMONi-2 trial, also referred to as AK112-303, a randomized, single-region (China) Phase III study sponsored by Akeso, quantitative data was presented on September 8, 2024 from the primary analysis as part of the Presidential Symposium at the International Association for the Study of Lung Cancer's ("IASLC") 2024 World Conference on Lung Cancer ("WCLC 2024"). The HARMONi-2 presentation evaluated monotherapy ivonescimab compared to monotherapy pembrolizumab in patients with locally advanced or metastatic NSCLC whose tumors have positive PD-L1 expression. HARMONi-2 is a single region, multi-center, double-blinded Phase III study conducted in China sponsored by Akeso, with all relevant data exclusively generated, managed, and analyzed by Akeso.

In the HARMONi-2 primary analysis, ivonescimab monotherapy demonstrated a statistically significant improvement in the trial's primary endpoint, PFS by Independent Radiologic Review Committee ("IRRC"), when compared to monotherapy pembrolizumab, achieving a hazard ratio of 0.51 (95% CI: 0.38, 0.69; p<0.0001). A clinically meaningful benefit was demonstrated across clinical subgroups, including patients with tumors with high PD-L1 expression. OS data was not yet mature at the time of the data cutoff of the primary PFS analysis.

Ivonescimab demonstrated an acceptable and manageable safety profile, which was consistent with previous studies. There were three patients (1.5%) who discontinued ivonescimab due to TRAEs compared to six patients (3.0%) who discontinued pembrolizumab due to TRAEs. There was one patient in the ivonescimab arm and two patients in the pembrolizumab arm who died as a result of TRAEs in this Phase III study. Full results were published in Lancet (Xiong et al. 2025).

On April 25, 2025, Akeso announced that ivonescimab was approved in China by the NMPA for a second indication based on the results of the HARMONi-2 trial. As a part of the review of the supplemental marketing application submitted by Akeso seeking a label expansion of ivonescimab in China, the NMPA requested that Akeso perform an interim analysis of OS. Akeso announced that the results of this interim OS analysis included a clinically meaningful hazard ratio of 0.777. The analysis was conducted at 39% data maturity, with a nominal alpha level of 0.0001 that had not reached statistical significance.

HARMONi-6

After announcing positive qualitative results for the HARMONi-6 trial, on April 23, 2025, detailed clinical trial results of the study were presented as part of the Presidential Symposium at the European Society for Medical Oncology's 2025 Congress ("ESMO 2025"). The HARMONi-6 study evaluated ivonescimab in combination with platinum-based chemotherapy compared to tislelizumab (a PD-1 inhibitor) in combination with platinum-based chemotherapy in patients with previously untreated advanced NSCLC irrespective of PD-L1 expression. HARMONi-6, also referred to as AK112-306, is a single region, multi-center, double-blinded Phase III study conducted in China sponsored by Akeso, with all relevant data exclusively generated, managed, and analyzed by Akeso.

In the HARMONi-6 planned PFS interim analysis, ivonescimab in combination with chemotherapy demonstrated a statistically significant improvement in the primary endpoint, PFS, by IRRC, when compared to tislelizumab in combination with chemotherapy, achieving a hazard ratio of 0.60 (95% CI: 0.46, 0.78; p<0.0001). A clinically meaningful benefit was demonstrated across clinical subgroups, including those with either PD-L1 negative or positive expression, as well as high-risk patients. OS data was not yet mature at the time of the data cutoff and is planned to be evaluated in the future.

Ivonescimab demonstrated an acceptable and manageable safety profile in the HARMONi-6 study, which was consistent with previous Phase III studies conducted studying ivonescimab. Nine patients (3.4%) discontinued ivonescimab plus chemotherapy due to TRAEs compared to 11 patients (4.2%) receiving tislelizumab plus chemotherapy due to TRAEs. There were eight patients in the ivonescimab plus chemotherapy arm and 10 patients in the tislelizumab plus chemotherapy arm who died as a result of TRAEs in this Phase III study. Results were published in Lancet (Chen et al. 2025)

Additional Phase II Data Sets

In addition to the HARMONi-2 data announced at WCLC 2024, Akeso also announced Phase II trial results from AK112-205, for patients with Stage II or III resectable NSCLC. Further, the Company announced data for ivonescimab was presented as a part of the 2024 European Society for Medical Oncology Annual Congress ("ESMO 2024") featuring updated Phase II ivonescimab data in advanced TNBC, for which subsequent updates to the data have been presented thereafter, recurrent /

metastatic head and neck squamous cell carcinoma, and metastatic microsatellite-stable CRC. At ASCO 2024, Akeso presented ivonescimab Phase II data in biliary-tract cancer. Earlier, at the 2024 European Lung Cancer Conference, Akeso announced updated data from AK112-201 (Cohort 1), a Phase II study for patients with first-line advanced NSCLC. Each trial from which the data was generated was a multi-center Phase II study conducted in China sponsored by Akeso, with data generated and analyzed by Akeso.

Competition

The markets for oncology pharmaceuticals, in which we compete, are characterized by significant scientific innovation, regulatory oversight and intense competition. The key competitive factors affecting the success of our product candidates are likely to be their efficacy, safety, convenience, price and availability of coverage and reimbursement from government and other third-party payors.

Many of our competitors may have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop. Our competitors also may obtain marketing approvals for their products more rapidly than we obtain approval for ours giving them significant first movers advantage. Our commercial opportunity could also be reduced or eliminated if the results of our clinical trials, both safety and efficacy, combined with other factors, do not lead to significant adoption of our product.

Competition for ivonescimab

The Company is developing ivonescimab in NSCLC and CRC, specifically conducting Phase III clinical trials in the following proposed indications:

(a) ivonescimab combined with chemotherapy in patients with EGFR-mutated, locally advanced or metastatic non-squamous NSCLC who were previously treated with a third-generation EGFR-TKI ("HARMONi");

(b) ivonescimab combined with chemotherapy in patients with first-line metastatic NSCLC (including separate statistical analyses planned for patients with squamous NSCLC and non-squamous NSCLC) ("HARMONi-3");

(c) ivonescimab monotherapy in patients with first-line metastatic NSCLC whose tumors have high PD-L1 expression ("HARMONi-7"); and

(d) ivonescimab combined with chemotherapy in patients with first-line unresectable metastatic CRC ("HARMONi-GI3").

Ivonescimab is also being investigated in multiple Phase II and Phase III clinical trials in China. We plan to review the data generated from these clinical trials as well as other data generated in studies with ivonescimab as a part of our consideration for advancing our clinical development pipeline for ivonescimab in the Licensed Territory.

There are no known PD-1-based bispecific antibodies currently approved by the FDA, the European Medicines Agency ("EMA"), or Japan's Pharmaceuticals and Medical Devices Agency ("PMDA"). There are currently no known approved PD-1 / VEGF bispecific antibodies that are further advanced in clinical trial development or approved in the territories in which we have licensed ivonescimab. However, there are several PD-(L)1/VEGF(R2) bispecific antibodies in development around the world, including multiple that are currently in development or with planned development globally. These include, but are not limited to pumitamig (BNT327), which is owned by BioNTech SE and being developed in a collaboration with Bristol Myers Squibb Co. since June 2025, which has begun conducting Phase III clinical studies globally, PF'4404 (SSGJ-707 / PF-08634404), which was licensed globally, ex-China by Pfizer Inc. in July 2025, LM-299, which was licensed globally by Merck & Co., Inc. in November 2024, and RC148, which was licensed outside of Greater China by AbbVie Inc. in January 2026.

Our current clinical development plan in the Licensed Territory has focused primarily on NSCLC. Several pharmaceutical and biotechnology companies have established themselves in the market for the treatment of NSCLC, and several additional companies are developing products for the treatment of NSCLC. Currently, the most commonly used treatments for first-line NSCLC without genomic alterations are several immuno-oncology drugs and chemotherapies, administered either individually as monotherapy, in combination with each other, or in combination with other approved therapeutics. In addition to various chemotherapies, several immunotherapies have been approved by the FDA for these treatments, including, but not limited to pembrolizumab, atezolizumab, nivolumab, durvalumab, cemiplimab and ipilimumab. There are anti-angiogenic therapies which are approved for the treatment of certain lung cancers, including bevacizumab in front-line non-squamous NSCLC, as well as ramucirumab for patients who have progressed after platinum-based chemotherapy. The proposed indications for ivonescimab in the HARMONi-3 and HARMONi-7 clinical trial settings in first-line NSCLC may face competition from clinical candidates such as novel immunotherapy targets including various clinical candidates targeting T-cell immunoreceptors with Ig and ITIM domains (TIGIT) and lymphocyte activation gene 3 (LAG-3) each of which have various developers for different candidates as either monoclonal antibodies or multispecific antibodies, a bispecific antibody, volrustomig (AstraZeneca), rilvegostomig (AstraZeneca) and antibody drug conjugates (ADCs) with novel targets such as datopotamab deruxetecan (AstraZeneca and Daiichi Sankyo), sacituzumab tirumotecan (Merck), and sigvotatug vedotin (Pfizer), each having announced, are currently enrolling in, or having completed enrollment in Phase III clinical trials. Phase III clinical trials with pumitamig and PF'4404 are being conducted or intentions to conduct have been announced by their respective sponsors in first-line NSCLC in combination with chemotherapy, similar to the setting in which HARMONi-3 is currently being conducted.

For those patients with advanced NSCLC with EGFR mutations, there are several targeted therapies that have also been approved in the front-line setting, including, but not limited to, osimertinib (AstraZeneca) with or without chemotherapy and amivantamab and lazertinib (both from Johnson & Johnson). The proposed indication for ivonescimab in the HARMONi clinical trial setting, post third-generation EGFR-TKIs such as osimertinib or lazertinib, may face competition from amivantamab plus chemotherapy and datopotamab deruxetecan (AstraZeneca and Daiichi Sankyo), which are fully approved post TKI and have an accelerated approval post TKI and post chemotherapy, respectively. In addition, investigational agents such as sacituzumab tirumotecan (Merck), izalontamab brengitecan (BMS), telisotuzumab adizutecan (AbbVie) and savolitinib (AstraZeneca) are currently being investigated in the post-TKI setting in those patients with advanced EGFR mutation positive NSCLC.

Beyond NSCLC, we are currently conducting the Phase III study for patients with first line metastatic unresectable CRC, HARMONi-GI3. For those patients with metastatic unresectable CRC whose tumors are not designated as mismatch repair deficient or have a specific treatable driver mutation (e.g., BRAF) in the first-line setting, there are limited treatment options beyond the currently approved regimens of bevacizumab plus chemotherapy, as well as cetuximab plus chemotherapy for a subset of these patients. Intentions to conduct Phase III clinical trials with pumitamig and PF'4404 have been announced by their respective sponsors in first-line metastatic unresectable CRC, similar to the setting in which HARMONi-GI3 is currently being conducted. In addition, novel agents such as amivantamab plus chemotherapy are currently being investigated in a subset of this setting.

Should ivonescimab ultimately receive marketing authorization in certain jurisdictions within the Licensed Territory, the marketing authorization holder for some of the approved agents may lose exclusive rights to these agents, increasing competition from biosimilar agents or generic compounds.

As we intend to explore further clinical development of ivonescimab in solid tumor settings outside of metastatic NSCLC and metastatic CRC, our current area of focus in our Phase III clinical trials, we will encounter significant competition in the development of ivonescimab in each of these potential settings.

Manufacturing

We do not own or operate, and currently have no plans to own manufacturing facilities for the production of clinical or commercial quantities of ivonescimab. We currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates and any products that we may develop.

Ivonescimab

In connection with the License Agreement, we agreed to purchase a certain portion of drug substance and/or drug product for clinical and commercial use and to enter into a supply agreement with Akeso. Until such time that we are able to establish second source suppliers or are able to manufacture the drug substance independently, Akeso shall be solely responsible for the manufacture of the drug substance for use in the Licensed Territory. We continue to make progress in transferring relevant

know-how to third parties to establish additional supply sources. We are using a different third-party supplier for clinical packaging, labeling and distribution of the clinical drug product.

Intellectual Property

We have obtained and maintain proprietary protection for our product candidates, technology and know-how. We strive to protect the proprietary technology by, among other methods, seeking and maintaining patents, where available, that are intended to cover our product candidates, compositions and formulations, their methods of use and processes for their manufacture and any other inventions that are commercially important to the development of our business. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary and competitive position.

Ivonescimab Program. Following the completion of the License Agreement with Akeso, we have in-licensed the rights to various Akeso patents and patent applications covering ivonescimab and related compositions of matter and methods of manufacture/use in the Licensed Territory and have rights to control prosecution of such in-licensed intellectual property in the Licensed Territory in collaboration with Akeso. We continue to develop, identify, and strive to protect other technologies that are commercially relevant to our ivonescimab position. Our current ivonescimab patents cover regions including the United States, Europe and Japan and include compositions of matter and methods of preparation / use. Our current ivonescimab patents expire from 2039 – 2040. The protection afforded by any particular patent depends upon many factors, including the type of patent, scope of coverage encompassed by the granted claims, availability of extensions of patent term, availability of legal remedies in the particular territory in which the patent is granted, and success of any challenges to the patent, if asserted. Changes in either patent laws or in the interpretation of patent laws in the United States and other countries could diminish our ability to protect our inventions and to enforce our intellectual property rights. Accordingly, we cannot predict with certainty the enforceability of any granted patent claims or of any claims that may be granted from our patent applications.

Trade Secrets. In addition to patents, we rely on trade secrets and know-how to develop and maintain our competitive position. Trade secrets and know-how can be difficult to protect; however, we take reasonable steps to protect our proprietary technology and processes, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors, manufacturers, and commercial partners. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. We also seek to preserve the integrity and confidentiality of our data, trade secrets and know-how by maintaining physical security of our premises and physical and electronic security of our information technology systems.

Trademarks. We are in the process of selecting a name for ivonescimab, which we will pursue protection for as a trademark in the Licensed Territory. In connection with the development of our product pipeline, we will seek protection for marks we currently use and future marks when appropriate.

We may not be able to obtain, maintain or protect the intellectual property rights necessary to conduct our business, and we may be subject to claims, whether or not meritorious, that we infringe or otherwise violate the intellectual property rights of third parties or that our patent claims are not valid. For more information, please see the section on “Risk Factors – Risks Related to Intellectual Property”.

Government Regulation

As a biopharmaceutical company focused on the discovery, development, and commercialization of novel therapeutics for serious diseases, we are subject to extensive and ongoing regulation by government authorities, including regulation by the FDA under the Federal Food, Drug, and Cosmetic Act (“FDCA”) and its implementing regulations, as well as by other regulatory bodies in the United States, Europe and other countries in which we operate. Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, record keeping, labeling, pricing, reimbursement, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, import and export and patenting of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

Review and Approval of Drugs and Biological Products in the United States

In the United States, the FDA regulates drugs under the FDCA and implementing regulations. An entity that takes responsibility for the initiation and management of a clinical development program for such products, and for their regulatory approval, is

typically referred to as a "sponsor" or "applicant." Biological products used for the prevention, treatment or cure of a disease or condition of a human being are subject to regulation under the FDCA, except that the section of the FDCA that governs the approval of new drug applications ("NDAs") does not apply to the approval of biological products. Biological products are approved for marketing under provisions of the Public Health Service Act (the "PHSA"), via a BLA. However, the application process and requirements for approval of BLAs are very similar to those for NDAs, and biologics are associated with similar approval risks and costs as drugs. The failure of a sponsor to comply with the FDCA and applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant or sponsor to a variety of administrative or judicial sanctions, including imposition of a clinical hold or other delays in the conduct of a study, refusal by the FDA to approve pending applications, withdrawal of an approval, issuance of warning letters and other types of letters, product recalls, product seizures, total or partial suspension of production, importation or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the FDA and the Department of Justice ("DOJ"), or other federal and state governmental entities.

An applicant seeking approval to market and distribute a new drug or biological product in the United States must typically undertake the following:

- completion of nonclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice ("GLP") regulations;
- submission to the FDA of an Investigational New Drug ("IND") Application, which must take effect before human clinical trials may begin;
- approval by an independent institutional review board ("IRB") of each clinical study at each research site before a clinical trial may be initiated at the site;
- performance of adequate and well-controlled human clinical trials in accordance with current good clinical practice ("GCP") standards, to establish the safety and efficacy of the proposed drug product for each indication;
- preparation and submission to the FDA of an NDA or BLA;
- a determination by the FDA within 60 days of its receipt of an NDA or BLA to file the submission for review;
- review of the product candidate by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with current Good Manufacturing Practices ("cGMP"), requirements and to ensure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of FDA audits of clinical trial sites to ensure compliance with GCPs and the integrity of the clinical data submitted in support of the NDA/BLA;
- payment of user fees and securing FDA approval of the NDA/BLA for the marketing of the drug product; and
- compliance with any post-approval requirements, including Risk Evaluation and Mitigation Strategies ("REMS"), where applicable, and any post-approval studies required by the FDA.

Nonclinical Studies

Before an applicant begins testing a compound with potential therapeutic value in humans, the product candidate must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluation of the purity and stability of the API and the formulated drug product, as well as *in vitro* and animal studies to assess the safety and activity of the drug for initial testing in humans and to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations and the United States Department of Agriculture's Animal Welfare Act, if applicable. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted.

Companies usually must complete some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, and must also develop additional information about the synthesis and physical characteristics of the investigational product. Prior to submission of an NDA or BLA, a manufacturer must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the candidate product and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested. Stability studies must be conducted to demonstrate that the candidate product does not undergo unacceptable deterioration over its shelf-life.

The IND and IRB Processes

An IND is an exemption from the FDCA that allows an unapproved drug to be shipped in interstate commerce for use in a clinical investigation and serves as a request for FDA authorization to administer an investigational drug to humans. Such authorization must be secured prior to interstate shipment and administration of any new drug that is not the subject of an approved NDA/BLA. In support of a request for an IND, a sponsor must submit a protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, are submitted to the FDA as part of an IND. The FDA requires a 30-day waiting period after the submission of each new IND before clinical trials may begin. This waiting period is designed to allow the FDA to review the IND to determine whether human research subjects will be exposed to unreasonable health risks. At any time during this 30-day period, the FDA may raise concerns or questions about the conduct of the trials as outlined in the IND and impose a clinical hold. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin.

Following commencement of a clinical trial under an IND, the FDA may also place a clinical hold or partial clinical hold on that trial. Clinical holds are imposed by the FDA when there is concern for patient safety and may be a result of new data, findings, or developments in clinical, nonclinical, and/or chemistry, manufacturing, and controls ("CMC"). A clinical hold is an order issued by the FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation, and FDA must provide a basis for its imposition within 30 days after imposition of a clinical hold. A partial clinical hold is a delay or suspension of fewer than all of the clinical investigations, or certain parts of a clinical investigation, subject to the IND.

Following issuance of a clinical hold or partial clinical hold, an investigation, or the parts of the investigation subject to the partial clinical hold, may only resume after the FDA has notified the sponsor that the investigation may proceed. The FDA will base that determination on information provided by the sponsor correcting the deficiencies previously cited or otherwise satisfying the FDA that the investigation can proceed.

A sponsor may choose, but is not required, to conduct a foreign clinical study under an IND. When a foreign clinical study is conducted under an IND, all FDA IND requirements must be met unless waived. When the foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with certain regulatory requirements of the FDA in order to use the study as support for an IND or application for marketing approval. Specifically, such studies must be conducted in accordance with GCP, including review, approval, and continuing review by an independent ethics committee, or IEC, and freely given informed consent from subjects. The GCP requirements encompass both ethical and data integrity standards for clinical studies. The FDA's requirements are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical studies, as well as the quality and integrity of the resulting data. They further help ensure that non-IND foreign studies are conducted in a manner comparable to that required for IND studies.

In addition to the foregoing IND requirements, an IRB/Ethics Committee ("EC") representing each institution participating in any clinical trial for which data is intended to be submitted to FDA must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the study at least annually. The IRB/EC must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB/EC must operate in compliance with FDA/HA ("Health Authority") regulations. An IRB/EC can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's/EC's requirements or if the product candidate has been associated with unexpected serious harm to patients.

Additionally, some trials are overseen by an independent group of qualified experts with relevant expertise known as a data safety monitoring board or data safety monitoring committee ("DSMB"). A DSMB is organized by the trial sponsor but should be independent of the sponsor. The DSMB recommends to the sponsor whether to continue, modify, or stop a trial or trials based on its periodic review of accumulating data from one or more clinical trials. Suspension or termination of a clinical trial or a clinical development program during any phase of clinical trials can occur if it is determined by the FDA, an IRB/EC, the sponsor, or the clinical investigator that the participants or patients are being exposed to an unacceptable health risk. Other reasons for suspension or termination may be made by us based on evolving business objectives and/or competitive climate.

Information about certain clinical trials must be submitted within specific timeframes for public dissemination on its ClinicalTrials.gov website. The failure to submit such clinical trial information to clinicaltrials.gov, as required, is a prohibited act under the FDCA with violations subject to potential civil monetary penalties.

Expanded Access to an Investigational Drug for Treatment Use

Expanded access, sometimes called "compassionate use," is the use of investigational new drug products outside of clinical trials to treat patients with serious or immediately life-threatening diseases or conditions when there are no comparable or satisfactory alternative treatment options. The rules and regulations related to expanded access are intended to improve access to investigational drugs for patients who may benefit from investigational therapies. FDA regulations allow access to investigational drugs under a protocol submitted to an IND for: individual patients (single-patient IND applications for treatment in emergency settings and non-emergency settings); intermediate-size patient populations; and larger populations for use of the drug.

When considering an IND application for expanded access to an investigational product with the purpose of treating a patient or a group of patients, the sponsor and treating physicians or investigators will determine suitability when all of the following criteria apply: patient(s) have a serious or immediately life-threatening disease or condition, and there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition; the potential patient benefit justifies the potential risks of the treatment and the potential risks are not unreasonable in the context or condition to be treated; and the expanded use of the investigational drug for the requested treatment will not interfere with initiation, conduct, or completion of clinical investigations that could support marketing approval of the product or otherwise compromise the potential development of the product.

Sponsors of one or more investigational drugs for the treatment of a serious disease(s) or condition(s) must make publicly available their policy for evaluating and responding to requests for expanded access for individual patients. Sponsors are required to make expanded access policy publicly available upon the earlier of the first initiation of a Phase II or Phase III study with respect to such investigational drug; or 15 days after the drug or biologic receives designation as a breakthrough therapy, fast track product, or regenerative medicine advanced therapy. Sponsors are not required to provide access to investigational products via expanded access, but the manufacturer must develop an internal policy and respond to patient requests according to that policy.

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

Human Clinical Trials in Support of an NDA/BLA

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their freely given informed consent in accordance with FDA regulations and applicable local laws before their participation in any clinical trial. Clinical trials are conducted under written study protocols detailing, among other things, the inclusion and exclusion criteria, the objectives of the study, the parameters to be used in monitoring the study and the safety and effectiveness criteria to be evaluated.

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

Phase 1. The investigational drug is initially introduced into healthy human subjects or, in certain indications such as cancer, patients with the target disease or condition, and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness and to determine optimal dosage.

Phase 2. The investigational drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

Phase 3. The investigational drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate sufficient data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product. These clinical trials are commonly referred to as "pivotal" studies, which denotes a study that is intended to generate data that will be relied upon by the FDA or another relevant regulatory agency as the primary basis for approval of a product candidate.

Progress reports of the clinical trials must be submitted at least annually to the FDA, and more frequently in some circumstances, such as if serious adverse events occur. In addition, IND safety reports must be submitted to the FDA for any of the following: serious and unexpected suspected adverse reactions; findings from other studies or animal or *in vitro* testing that suggest a significant risk in humans exposed to the drug; and any clinically important increase in the case of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all.

Under the Pediatric Research Equity Act ("PREA") of 2003, an application or supplement to an NDA or BLA for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration must contain a pediatric assessment unless the applicant has obtained a waiver or deferral. The pediatric assessment includes data to assess the safety and effectiveness of the drug product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective or reasons why dosing in pediatric patients is not recommended. Sponsors of drug product applications subject to PREA must also submit pediatric study plans during the development program. Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, any deferral or waiver requests and other information required or applicable by regulation. The applicant, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other, and agree upon a final plan. The FDA or the applicant may request an amendment to the pediatric plan at any time.

A sponsor must submit an initial pediatric study plan, if required under PREA, no later than either 60 calendar days after the date of the end-of-phase II meeting or such other time as agreed upon between FDA and the sponsor. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements.

Any company that submits an NDA/BLA for certain cancer indications must submit pediatric assessments with the NDA/BLA if the drug is intended for the treatment of an adult cancer and is directed at a molecular target that the FDA determines to be substantially relevant to the growth or progression of a pediatric cancer. The investigation must be designed to yield clinically meaningful pediatric study data regarding the dosing, safety and preliminary efficacy to inform pediatric labeling for the product.

Submission of an NDA/BLA to the FDA

Assuming successful completion of required clinical investigations and other requirements, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA or BLA requesting approval to market the drug product for one or more indications. Under federal law, the submission of most NDAs and BLAs is subject, under the Prescription Drug User Fee Reauthorization Act of 2022 ("PDUFA VII"), to an application user fee, which for federal fiscal year 2026 is $4,682,000 for an application requiring clinical data. The applicant for an approved NDA/BLA is also subject to an annual program fee, which for the fiscal year 2026 is $442,213. Certain exceptions and waivers are available for some of these fees, such as an exception from the application fee for products with orphan designation and a waiver for the first application for certain small businesses.

Following submission of an application, the FDA conducts a filing review of an NDA or BLA within 60 calendar days of its receipt and strives to inform the sponsor by the 74th day after the FDA's receipt of the submission whether the application is sufficiently complete to permit substantive review. The FDA may refuse to file any NDA or BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information rather than file an NDA or BLA. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA files it. Once the submission is filed, the FDA begins an in-depth substantive review.

The FDA has agreed to certain performance goals in the review process of NDAs and BLAs. Under the agency's PDUFA VII commitments, 90% of applications seeking approval of new molecular entities ("NMEs") are meant to be reviewed within ten months from the date on which FDA files the NDA or BLA, and 90% of applications for NMEs that have been designated for "priority review" are meant to be reviewed within six months of the filing date. The review process may be extended by the FDA for three additional months to consider new information or clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission. The FDA does not always meet its PDUFA goal dates for standard and priority applications.

Before approving an NDA or BLA, the FDA typically will inspect the facility or facilities where the product is or will be manufactured. These pre-approval inspections cover all or selected facilities associated with an NDA/BLA submission,

including drug component manufacturing (such as API), finished drug product manufacturing, and control testing laboratories. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to ensure consistent production of the product within required specifications. Additionally, before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to ensure compliance with GCP.

In addition, as a condition of approval, the FDA may require an applicant to develop a REMS. REMS use risk minimization strategies beyond the professional labeling to ensure that the benefits of the product outweigh the potential risks. To determine whether a REMS is needed, the FDA will consider the size of the population likely to use the product, seriousness of the disease, expected benefit of the product, expected duration of treatment, seriousness of known or potential adverse events, and whether the product is a new molecular entity. REMS can include medication guides, physician communication plans for healthcare professionals, and elements to ensure safe use ("ETASU"). ETASU may 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 FDA may require a REMS before approval or post-approval if it becomes aware of a serious risk associated with use of the product. The requirement for a REMS can materially affect the potential market and profitability of a product.

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

Fast Track, Breakthrough Therapy and Priority Review

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs are referred to as fast-track designation, breakthrough therapy designation and priority review designation.

Specifically, the FDA may grant fast track designation to a product if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For fast track products, sponsors may have greater interactions with the FDA, and the FDA may initiate review of sections of a fast track product's application before the NDA or BLA is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast-track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's goal for reviewing a fast track application does not begin until the last section of the NDA or BLA is submitted. In addition, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging from the clinical development program.

Second, a product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner.

Third, the FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case-by-case basis, whether the proposed product represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months following the FDA's filing of the application.

Accelerated Approval Pathway

The FDA may grant accelerated approval to a drug for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a drug when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality ("IMM"), and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a drug.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a drug, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. For example, accelerated approval has been used extensively in the development and approval of drugs for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large clinical trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase IV or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

The Food and Drug Omnibus Reform Act of 2022 modified certain statutory provisions governing accelerated approval of drug and biologic products. Specifically, the new legislation authorized the FDA to: require a sponsor to have its confirmatory clinical trial well underway before accelerated approval is awarded, require a sponsor of a product granted accelerated approval to submit progress reports on its post-approval studies to FDA every six months; and use expedited procedures to withdraw accelerated approval of an NDA or BLA if a confirmatory trial fails to verify the product's clinical benefit or the sponsor fails to conduct the required confirmatory trial with due diligence. In March 2023, the FDA issued draft guidance outlining its current thinking and approach to accelerated approval for oncology therapeutics. Noting that the accelerated approval pathway is commonly used for approval of oncology drugs due to the serious and life-threatening nature of cancer, FDA's guidance outlined considerations for designing, conducting, and analyzing data for trials intended to support accelerated approvals of oncology products. FDA recommended a randomized controlled trial as the preferred approach to assessing the safety and efficacy as it provides a more robust efficacy and safety assessment and allows for direct comparisons to a concurrent control. This is a departure from the previously common use of single-arm trials to support accelerated approval of oncology products. While this draft guidance is not legally binding, sponsors seeking consideration of a product for accelerated approval typically adhere to the FDA's guidance to enhance the likelihood of their products qualifying for accelerated approval.

The FDA's Decision on an NDA or BLA

On the basis of the FDA's evaluation of the NDA or BLA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA will issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA or BLA, 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. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase IV clinical trials, be conducted to further assess the drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record keeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences related to the use of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual program fee requirements for any marketed product.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-marketing testing, including post-marketing clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and some state agencies and submit to FDA an annual listing of products manufactured for commercial distribution at each facility. Drug manufacturers are subject to periodic announced or unannounced inspections by the FDA and these state agencies for compliance with cGMP and other regulatory requirements. Changes to the manufacturing process for a drug product are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production, quality control and pharmacovigilance to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw marketing approval for a drug product if compliance with regulatory requirements and standards is not maintained or if unanticipated adverse events or other safety concerns occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, suspension of the approval, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or imposition of clinical holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates the marketing, labeling, advertising and promotion of prescription drug products placed on the market. Regulation includes, among other things, standards and regulations for direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities, and promotional activities involving the Internet and social media. Promotional claims about a drug's safety or effectiveness are prohibited before the drug is approved. After approval, a drug product may not be promoted for uses that are not approved by the FDA, as reflected in the product's approved prescribing information. In the United States, health care professionals are generally permitted to prescribe drugs for such uses not described in the drug's labeling, known as off-label uses, because the FDA does not regulate the practice of medicine. However, FDA regulations impose rigorous restrictions on manufacturers' communications, prohibiting manufacturers and their representatives from promoting a drug product for off-label uses or uses that are otherwise inconsistent with the product's labeling. It may be permissible, under very specific, narrow conditions, for a manufacturer to engage in non-

promotional, non-misleading communication regarding uses of a product that are inconsistent with a product's labeling, such as distributing certain scientific information or publications such as medical journal articles.

If a company is alleged to have promoted a product for off-label uses, it may become subject to investigations, adverse public relations and administrative and judicial enforcement by the FDA, the DOJ, or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. In addition, an action may be brought on behalf of the government by a *qui tam* relator under the Federal False Claims Act asserting that a manufacturer's communications regarding an off-label use of its product caused submission of false claims for payment by a government health care program. These actions could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products. These actions have resulted in the imposition of large civil and criminal fines and penalties against, and substantial settlements by, companies for alleged improper promotion. As a result of these actions, companies have entered into consent decrees, non-prosecution agreements, deferred prosecution agreements or corporate integrity agreements under which specified promotional conduct is changed or curtailed, and substantial compliance obligations are imposed on manufacturers.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act ("PDMA"), and its implementing regulations, as well as the Drug Supply Chain Security Act ("DSCSA"), which regulate the distribution and tracing of prescription drug samples at the federal level, and set minimum standards for the regulation of distributors by the states. The PDMA, its implementing regulations and state laws limit the distribution of prescription pharmaceutical product samples, and the DSCSA imposes requirements to ensure accountability in distribution and to identify and remove counterfeit and other illegitimate products from the market.

Marketing Exclusivity and Biosimilars

The Biologics Price Competition and Innovation Act of 2009 created an abbreviated approval pathway for biological products shown to be biosimilar to an FDA-licensed reference biological product. Biosimilarity, which requires that the biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, toxicity studies, and a clinical trial or trials. A biosimilar may be approved as interchangeable with its reference biological product. Interchangeability requires that a biological product both be biosimilar to the reference product and that the product can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times to an individual, that the product and the reference product may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product without such alternation or switch. Under most state laws, interchangeable products may be used in place of the reference biological product.

A reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product during which the FDA will not approve a biosimilar referencing the reference biological product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. "First licensure" typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity or potency.

Pediatric Exclusivity

Pediatric exclusivity is an extension of existing non-patent marketing exclusivity available to biological product manufacturers in the United States who have met criteria qualifying their products for pediatric exclusivity and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity for each of the manufacturers products with the same active moiety, including the non-patent and orphan exclusivity. This six-month exclusivity may be granted if an NDA/BLA sponsor submits pediatric data or fairly responds to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the studies were completed using appropriate formulations and within the requested time frame, and the studies were conducted in accordance with commonly accepted scientific principles, the additional protection may be granted. Upon any exclusivity determination by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity cover the product are extended by six months.

Patent Term Restoration and Extension

The term of a U.S. patent that covers a drug, biological product or medical device approved pursuant to a premarket approval may also be eligible for patent term extension when FDA approval is granted, provided that certain statutory and regulatory requirements are met. The length of the patent term extension is related to the length of time the drug is under development and regulatory review while the patent is in force, reduced by any time during which the applicant failed to exercise due diligence. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration date set for the patent. Patent extension 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 each regulatory review period may be granted an extension, and only those claims reading on the approved drug may be extended. Similar provisions are available in Europe and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug, provided that statutory and regulatory requirements are met. The U.S. Patent and Trademark Office ("USPTO") reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

Orphan-Drug Designation and Exclusivity

Under the Orphan Drug Act, FDA may grant orphan drug designation to a drug or biologic product intended to treat a rare disease or condition. A rare disease or condition is defined as one that either affects fewer than 200,000 individuals in the United States or for which a manufacturer has no reasonable expectation that the cost of developing and making the product available in the United States for the disease or condition will be recovered from sales of the product. A manufacturer may request an orphan drug designation for either a previously unapproved product or a new use of an FDA-approved product. Orphan drug designation must be requested before submission of an NDA or BLA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process, though companies developing orphan products may be eligible for certain financial incentives such as tax credits for qualified clinical testing or waiver of certain application fees.

If a product that has orphan drug designation subsequently receives the first FDA approval for the rare disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity. This is a seven-year period of marketing exclusivity during which FDA may not approve any other applications to market the same active ingredient or active moiety for the same indication, except in limited circumstances. Such limited circumstances may include a subsequent product's showing of clinical superiority over the product with orphan drug exclusivity or drug shortage. Competitors, however, may receive approval of different active ingredients or active moieties for the same indication or obtain approval for the same therapeutic agent or active moiety for a different indication.

Regulation Outside the United States

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, promotion, commercial sales and distribution of drug products. Whether or not it obtains FDA approval for a product, the company would need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. The approval process ultimately varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Regulation and Marketing Authorization in the European Union ("E.U.")

Clinical Trial Approval

The Clinical Trials (EU) No Regulation 536/2014 ("CTR"), Commission Implementing Regulation (EU) 2017/556 on the detailed arrangements for the GCP, Commission Delegated Regulation (EU) 2017/1569 and Commission Directive (EU) 2017/1572 on Good Manufacturing Practice ("GMP") and Commission Guidelines such as Volume 10 of "The rules governing medicinal products in the European Union" govern the system for the approval of clinical trials in the E.U. Under this system, an applicant planning to conduct a clinical trial on an investigational medicinal product in the EU or European Economic Area (EEA") must apply for authorization of this trial through the EU central single entry point: the Clinical Trials Information

System ("CTIS"). The applicant submits its application dossier via CTIS, consisting of (among other documents) the cover letter, the EU application form, the study protocol and the Investigational Medicinal Product Dossier. The applicant shall submit this dossier to the intended Member States concerned through CTIS and shall propose one of the Member States concerned as the Reporting Member State ("RMS"). The RMS validates the application and reviews whether the application dossier is complete. After this, the RMS will draw up an assessment report (Part I of the approval process). For Part II of the approval process, all Concerned Member States shall assess, for their own territory, the application dossier of the applicant. Each Concerned Member State shall notify the applicant through the EU CTIS portal as to whether the clinical trial is authorized, whether it is authorized subject to conditions, or whether authorization is refused.

On January 31, 2022, the CTR became applicable. From this date, a three-year transition period started, to ensure that ongoing clinical trials could align with the rules as laid down in the CTR. From 31 January 2025 onwards, all clinical trials in the EU/EEA must be conducted in accordance with the CTR. This means that the Clinical Trials Directive 2001/20/EC (and any national legislation implementing the Directive) is now fully replaced by the CTR. The CTR is directly applicable in all the E.U. Member States.

The CTR simplifies and streamlines the approval of clinical trials in the E.U. The main characteristics of the Regulation include: a streamlined application procedure via a single entry point, the CTIS; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts as described above. Part I is assessed by the appointed RMS, whose assessment report is submitted for review by the sponsor and all other competent authorities of all E.U. Member States in which an application for authorization of a clinical trial has been submitted. Part II is assessed separately by each Concerned Member State. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the Concerned Member State. However, overall related timelines will be defined by the Clinical Trials Regulation.

As in the United States, similar requirements for posting clinical trial information are present in the E.U. and in other countries.

Marketing Authorization

To obtain a marketing authorization for a product under E.U. regulatory systems, an applicant must submit a marketing authorization application ("MAA") either under a centralized procedure administered by the EMA, or one of the procedures administered by competent authorities in the E.U. Member States (decentralized procedure, national procedure or mutual recognition procedure). A marketing authorization may be granted only to an applicant established in the E.U. Prior to obtaining a marketing authorization in the E.U., applicants have to demonstrate compliance with all measures included in an EMA-approved Paediatric Investigation Plan ("PIP"), covering all subsets of the pediatric population, unless the EMA has granted (1) a product-specific waiver, (2) a class waiver or (3) a deferral for one or more of the measures included in the PIP. These requirements are discussed in more detail below.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid across the European Economic Area (i.e., the E.U. as well as Iceland, Liechtenstein and Norway). Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products and products with a new active substance indicated for the treatment of certain diseases, including products for the treatment of cancer. For products with a "new active substance" indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional. The centralized procedure may at the request of the applicant also be used in certain other cases. We anticipate that the centralized procedure will be mandatory for the product candidates we are developing.

Under the centralized procedure, the Committee for Medicinal Products for Human Use ("CHMP") – EMA's committee responsible for human medicines – is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing marketing authorization. Under the centralized procedure in the E.U., the maximum timeframe for the evaluation of an MAA is 210 days after submission of a valid application, excluding clock stops, when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Overall, the assessment of a new medicine usually lasts around a year. Accelerated evaluation might be granted by the CHMP in exceptional cases when a medicinal product is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. If the CHMP accepts such request, the time limit of 210 days will be reduced to 150 days, but the CHMP can revert to the standard time limit for the centralized procedure if it determines that it is no longer appropriate to conduct an accelerated assessment. At the end of this period, the CHMP provides a scientific opinion

on whether or not a marketing authorization should be granted in relation to a medicinal product. Within 15 calendar days of receipt of a final opinion from the CHMP, the European Commission must prepare a draft decision concerning an application for marketing authorization. This draft decision must take the opinion and any relevant provisions of E.U. law into account. Before arriving at a final decision on an application for centralized authorization of a medicinal product, the European Commission must consult the Standing Committee on Medicinal Products for Human Use. The Standing Committee is composed of representatives of the E.U. Member States and chaired by a non- voting European Commission representative. The European Parliament also has a related "droit de regard." The European Parliament's role is to ensure that the European Commission has not exceeded its powers in deciding to grant or refuse to grant a marketing authorization.

The European Commission may grant a so-called "marketing authorization under exceptional circumstances" on the basis of article 14(8) of Regulation (EC) No 726/2004. Such authorization is intended for products for which the applicant can demonstrate that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use, for objective, verifiable reasons, for instance because the indications for which the product in question is intended are encountered so rarely that the applicant cannot reasonably be expected to provide comprehensive evidence, or in the present state of scientific knowledge, comprehensive information cannot be provided, or it would be contrary to generally accepted principles of medical ethics to collect such information. The Rapporteur, Co-Rapporteur and the other CHMP members will assess the justification/data submitted for exceptional circumstances as part of the overall assessment of the benefit/risk of the application. Consequently, marketing authorization under exceptional circumstances may be granted subject to certain specific obligations, which may include the following:

- the applicant must complete an identified program of studies within a time period specified by the competent authority, the results of which form the basis of a reassessment of the benefit/risk profile;
- the medicinal product in question may be supplied on medical prescription only and may in certain cases be administered only under strict medical supervision, possibly in a hospital and in the case of a radiopharmaceutical, by an authorized person; and
- the package leaflet and any medical information must draw the attention of the medical practitioner to the fact that the particulars available concerning the medicinal product in question are as yet inadequate in certain specified respects.

A marketing authorization under exceptional circumstances is subject to annual review to reassess the risk-benefit balance in an annual reassessment procedure. Continuation of the authorization is linked to the annual reassessment and a negative assessment could potentially result in the marketing authorization being suspended or revoked. The renewal of a marketing authorization of a medicinal product under exceptional circumstances, however, follows the same rules as a "normal" marketing authorization. Thus, a marketing authorization under exceptional circumstances is granted for an initial five years, after which the authorization will become valid indefinitely, unless the EMA decides that safety grounds merit one additional five-year renewal.

The European Commission may also grant a so-called "conditional marketing authorization" on the basis of article 14a of Regulation (EC) No 726/2004, prior to the applicant obtaining the comprehensive clinical data required for an application for a full marketing authorization, in order to meet unmet medical needs of patients and in the interest of public health. Such conditional marketing authorizations may be granted for product candidates (including medicines designated as orphan medicinal products) if: (i) the risk-benefit balance of the product candidate is positive, (ii) it is likely that the applicant will be in a position to provide the required comprehensive clinical trial data, (iii) the product fulfills an unmet medical need and (iv) the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required. A conditional marketing authorization may contain specific obligations to be fulfilled by the marketing authorization holder, including obligations with respect to the completion of ongoing or new studies, and with respect to the collection of pharmacovigilance data. Conditional marketing authorizations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions and/or specific obligations. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a conditional marketing authorization. Applicants for a potential conditional marketing authorization are strongly encouraged to engage in early dialogue with EMA and other stakeholders (e.g. health technology assessment bodies) and discuss their development plan. EMA also encourages applicants to request accelerated assessment for products deemed suitable for a conditional marketing authorization.

The E.U. medicines framework preserves the competence of the E.U. Member States to adopt national legislation prohibiting or restricting the sale, supply or use of any medicinal product containing, consisting of or derived from a specific type of human or animal cell, such as embryonic stem cells. While the products we have in development do not make use of embryonic stem

cells, it is possible that the national laws in certain E.U. Member States may prohibit or restrict us from commercializing our products, even if they have been granted an E.U. marketing authorization.

Unlike the centralized authorization procedure, the decentralized marketing authorization procedure requires a separate application to, and leads to separate approval by, the competent authorities of each E.U. Member State in which the product is to be marketed (these are known as the "Concerned" Member States). This application is identical to the application that would be submitted to the EMA for authorization through the centralized procedure. The referenced E.U. Member State prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned E.U. Member States who, within 90 days of receipt, must decide whether to approve the assessment report and related materials. If a concerned E.U. Member State cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the European Commission, whose decision is binding on all E.U. Member States.

The mutual recognition procedure similarly is based on the acceptance by the competent authorities of the E.U. Member States of the marketing authorization of a medicinal product by the competent authorities of other E.U. Member States. The holder of a national marketing authorization may submit an application to the competent authority of an E.U. Member State requesting that this authority recognize the marketing authorization delivered by the competent authority of another E.U. Member State.

For certain applications, such as applications for products designated as orphan medicinal products or products falling under the compulsory scope of the centralized procedure, the mutual recognition procedure and the decentralized procedure cannot be used.

Regulatory Data Protection in the E.U.

In the E.U., innovative medicinal products approved on the basis of a complete independent data package qualify for eight years of data exclusivity after grant of the marketing authorization and an additional two years of market exclusivity pursuant to Directive 2001/83/EC. Regulation (EC) No 726/2004 repeats this entitlement for medicinal products authorized in accordance to the centralized authorization procedure. Data exclusivity prevents applicants for authorization of generics of these innovative products, from referencing the innovator's data to assess a generic (or abridged) application for a period of eight years. During an additional two-year period of market exclusivity, a generic MAA can be submitted and authorized, and the innovator's data may be referenced, but no generic medicinal product can be placed on the E.U. market until the expiration of the market exclusivity. The overall ten-year period will be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be a new chemical entity so that the innovator gains the prescribed period of data exclusivity, another company nevertheless could also market another version of the product if such company obtained marketing authorization based on an MAA with a complete independent data package of pharmaceutical tests, preclinical tests and clinical trials.

In April 2023, the European Commission published a proposal to reform the current pharmaceutical framework, including revision of the regulatory data protection system. In the latest version of the proposal, published on 11 December 2025, the regulatory data protection will consist of 8 years of data exclusivity, same as under the current legal framework, and one additional year of market exclusivity. This means a total of 8+1 years of protection, instead of the current 8+2 years. Under the reformed legislation, there will be a possibility to obtain one additional year of exclusivity (8+1+1) under certain circumstances and another year (8+1+1 or 8+1+1+1) for a new indication of significant clinical benefit, with a capped overall regulatory protection of 11 years.

The final text of the reform proposal is expected to be endorsed and published in the first half of 2026 and, after a transition period, the new legislation is expected to start to apply from mid-2028.

Orphan Drug Designation and Exclusivity

Regulation (EC) No. 141/2000, as implemented by Regulation (EC) No. 847/2000 provides that a medicine can be designated as an orphan medicinal product by the European Commission if its sponsor can establish: that the product is intended for the diagnosis, prevention or treatment of (1) a life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the E.U. when the application is made, or (2) a life-threatening, seriously debilitating or serious and chronic condition in the E.U. and that without incentives it is unlikely that the marketing of the drug in the EU would generate sufficient return to justify the necessary investment. For either of these conditions, the sponsor must demonstrate that there

exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the E.U. or, if such method exists, the medicinal product will be of significant benefit to those affected by that condition.

Once authorized, orphan medicinal products are entitled to 10 years of market exclusivity in all E.U. Member States and in addition a range of other benefits during the development and regulatory review process including scientific assistance for study protocols, authorization through the centralized marketing authorization procedure covering all Member States and a reduction or elimination of registration and marketing authorization fees. However, marketing authorization may be granted to a similar medicinal product with the same orphan indication during the 10-year period with the consent of the marketing authorization holder for the original orphan medicinal product, or if the manufacturer of the original orphan medicinal product is unable to supply the medicine in sufficient quantities. Marketing authorization may also be granted to a similar medicinal product with the same orphan indication if this product is shown to be safer, more effective or otherwise clinically superior to the original orphan medicinal product. The period of market exclusivity may, in addition, be reduced to six years if it can be demonstrated on the basis of available evidence that the original orphan medicinal product (a) no longer satisfies the original designation criteria; or (b) is sufficiently profitable not to justify maintenance of market exclusivity.

The proposal to reform the current pharmaceutical framework as mentioned above also intends to revise the orphan drug designation and exclusivity regime. In the latest version of the proposal, orphan market exclusivity will be reduced from the current 10 years to 9 years. Extension by another 2 years will be possible for so-called "breakthrough orphan medicinal products". Although the final text has not yet been published, previous drafts also included the concept of "global orphan marketing authorization", which would no longer grant additional separate orphan market exclusivity for second or further orphan therapeutic indications. Also, previous drafts allowed generics, biosimilars or other second applicants to apply for marketing authorization two years before expiry of orphan market exclusivity thus effectively reducing the innovator's market exclusivity compared to the current legal framework. Again, final text of the reform proposal is expected to be endorsed and published in Q1 or Q2 of 2026 and, after a transition period, the new legislation is expected to start to apply from mid-2028.

Periods of Authorization and Renewals

A marketing authorization has an initial validity for five years in principle. The marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the E.U. Member State. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. The European Commission or the competent authorities of the E.U. Member States decide on justified grounds relating to pharmacovigilance, whether to proceed with one further five-year period of marketing authorization. Once subsequently definitively renewed, the marketing authorization shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the E.U. market (in the case of the centralized procedure) or on the market of the authorizing E.U. Member State within three years after authorization ceases to be valid (the so-called sunset clause).

Pediatric Studies

Prior to obtaining a marketing authorization in the E.U., applicants have to demonstrate compliance with all measures included in an EMA-approved Paediatric Investigation Plan, covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, a class waiver, or a deferral for one or more of the measures included in the PIP. The respective requirements for all marketing authorization procedures are set forth in Regulation (EC) No 1901/2006, which is referred to as the Paediatric Regulation. This requirement also applies when a company wants to add a new indication, pharmaceutical form or route of administration for a medicine that is already authorized. The Paediatric Committee of the EMA ("PDCO") may grant deferrals for some medicines, allowing a company to delay development of the medicine in children until there is enough information to demonstrate its effectiveness and safety in adults. The PDCO may also grant waivers when development of a medicine in children is not needed or is not appropriate, such as for diseases that only affect the elderly population.

Before an MAA can be filed, or an existing marketing authorization can be amended, the EMA determines that companies actually comply with the agreed studies and measures listed in each relevant PIP.

Regulatory Requirements after a Marketing Authorization has been Obtained

In case an authorization for a medicinal product in the E.U. is obtained, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. These include:

- Compliance with the E.U.'s stringent pharmacovigilance or safety reporting rules. These rules can impose post-authorization studies and additional monitoring obligations;
- The manufacturing of authorized medicinal products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the applicable E.U. laws, regulations and guidance, including Directive 2001/83/EC, Directive 2017/1572/EC, Regulation (EC) No 726/2004 and the European Commission Guidelines for GMP. These requirements include compliance with E.U. cGMP standards when manufacturing medicinal products and active pharmaceutical ingredients, including the manufacture of active pharmaceutical ingredients outside of the E.U. with the intention to import the active pharmaceutical ingredients into the E.U.;
- The marketing and promotion of authorized medicines, including industry-sponsored continuing medical education and advertising directed toward the prescribers of medicines and/or the general public, are strictly regulated in the E.U. notably under Directive 2001/83EC, Regulation (EC) 726/2004 and E.U. Member State laws. Direct-to- consumer advertising of prescription medicines is prohibited across the E.U.

Patent Term Extension

In order to compensate the patentee for delays in obtaining a marketing authorization for a patented product, a supplementary protection certificate ("SPC") in E.U. Member State or Patent Term Extension ("PTE") in U.S. may be granted extending the exclusivity period for that specific product by up to five years. PTE applications must be filed with the USPTO within 60 days of regulatory approval. Applications for SPCs must be made to the relevant patent office in each E.U. Member State and the granted certificates are valid only in the Member State of grant. An application has to be made by the patent owner within six months of the first marketing authorization being granted in the E.U. (assuming the patent in question has not expired, lapsed or been revoked) or within six months of the grant of the patent (if the marketing authorization is granted first). In the context of SPCs, the term "product" means the active ingredient or combination of active ingredients for a medicinal product and the term "patent" means a patent protecting such a product or a new manufacturing process or application for it. The duration of an SPC is calculated as the difference between the patent's filing date and the date of the first marketing authorization, minus five years, subject to a maximum term of five years.

A six month pediatric extension of an SPC may be obtained where the patentee has carried out an agreed Pediatric Investigation Plan, the authorized product information includes information on the results of the studies and the product is authorized in all E.U. Member States.

Regulatory Framework in the United Kingdom ("UK")

The United Kingdom's withdrawal from the E.U. took place on January 31, 2020 ("Brexit"). The EU and the UK have two separate markets governed by two distinct regulatory and legal regimes, although the UK's GMP and GCP frameworks remain largely based on the EU frameworks.

On February 27, 2023, the UK government and the European Commission announced a political agreement in principle to replace the "Northern Ireland Protocol" which was put in place shortly after Brexit with a new set of arrangements, known as the "Windsor Framework". The Windsor Framework was approved by the EU-UK Joint Committee on March 24, 2023, and each of the UK government and the E.U. have enacted legislative measures to bring it into law. The Windsor Framework fundamentally changed the post-Brexit system under the Northern Ireland Protocol, including with respect to the regulation of medicinal products in the UK. From January 1, 2025, the UK's Medicines and Healthcare products Regulatory Agency (the "MHRA") became responsible for approving all medicinal products destined for the UK market (i.e., Great Britian and Northern Ireland) via a single UK-wide marketing authorization, enabling products to be sold in a single pack and under a single authorization throughout the UK. New medicinal products assessed by the MHRA are designated as one of two categories. "Category 1" medicinal products are those which fall within the mandatory or optional scope of the EU's centralized procedure and are assessed on the basis of UK legislation. "Category 2" medicinal products are those which do not fall within Category 1 and are authorized in accordance with UK and EU law. Under the MHRA's international recognition framework (in place since January 1, 2024), the MHRA will have regard to decisions on the approval of MAs made by the EMA and certain other regulators when determining an application for a new UK MA.

The Human Medicines Regulations 2012 (SI 2012/1916) (as amended) ("HMR") is the primary legal instrument for the regulation of medicines in the UK. The HMR has incorporated into the domestic law the body of EU law instruments governing medicinal products that pre-existed prior to the UK's withdrawal from the EU.

EU laws which have been transposed into UK law through secondary legislation continue to be applicable as "retained EU law." New EU legislation, such as the (EU) Clinical Trials Regulation, is not applicable in Great Britain but does apply in Northern Ireland as a result of the Windsor Framework. The UK's Medicines for Human Use (Clinical Trials) Regulations 2004 implement the requirements of the previous EU clinical trials regime under Directive 2001/20/EC, but will be modernized by the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2024, which were passed into law on April 10, 2025 and come into effect of April 28, 2026.

Healthcare Law and Regulation

Health Care Providers and third-party payors play a primary role in the recommendation and prescription of drug products that are granted marketing approval. Arrangements between drug product manufacturers and providers, consultants, third-party payors and customers are subject to broadly applicable fraud and abuse, anti-kickback, false claims laws, patient privacy laws and regulations, and other healthcare laws and regulations that may constrain business and/or financial arrangements. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward 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 healthcare program such as Medicare and Medicaid;
- the federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false, fictitious or fraudulent or knowingly making, using or causing to be made or used a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created additional federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false statements relating to health care matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, impose obligations on covered entities and their business associates, as defined by HIPAA, including mandatory contractual terms, and requirements for safeguarding the privacy, security and transmission of individually identifiable protected health information;
- Foreign Corrupt Practices Act ("FCPA"), which prohibits companies and their intermediaries from making, or offering or promising to make improper payments to non-U.S. officials for the purpose of obtaining or retaining business or otherwise seeking favorable treatment;
- the federal false statements statute, which prohibits 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;
- the federal transparency requirements known as the federal Physician Payments Sunshine Act, under the Patient Protection and Affordable Care Act, as amended by the Health Care Education Reconciliation Act, or the Affordable Care Act ("ACA"), which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services ("CMS"), within the United States Department of Health and Human Services, information related to payments and other transfers of value made by that entity to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by non-government third-party payors, including private insurers.

Some state and local laws impose regulations restricting the activities of pharmaceutical manufacturers that sell products in the state. Some of these laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and/or the relevant compliance guidance promulgated by the local, state or federal government. Manufacturers are required by the laws of some states to make certain disclosures or certifications related to their compliance activities to state agencies or on the manufacturer's website. Others may impose restrictions on, or registration requirements for, a manufacturer's sales representatives. Some state laws require manufacturers to report information related to payments to physicians and other healthcare providers, marketing expenditures, or price information for certain drug products. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each

other in significant ways and often are broader than and/or not preempted by HIPAA, thus complicating compliance efforts. Manufacturers are expected to expend substantial resources to implement compliance controls to prevent and detect noncompliance with these requirements.

Pharmaceutical Coverage and Reimbursement

In the United States and markets in many other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Thus, even if a product candidate is approved, sales of the product will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage and establish adequate reimbursement levels for, the product. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication. Other times, they will attempt to dictate the utilization of products to treat a disease via clinical guidelines or pathways.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable marketing approvals. Nonetheless, product candidates may not be considered medically necessary or cost effective resulting in payers deciding to limit reimbursement of a product. A decision by a third-party payor not to cover a product could reduce physician utilization once the product is approved and have a material adverse effect on sales, results of operations and financial condition. Additionally, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not ensure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor.

Pricing Decisions for Approved Products

In the E.U., pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies or so- called health technology assessments in order to obtain reimbursement or pricing approval. For example, the E.U. provides options for its Member States to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Member States may approve a specific price for a product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other Member States allow companies to fix their own prices for products, but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the E.U. have increased the amount of discounts (or rebates) required on pharmaceuticals and these efforts could continue as countries attempt to manage health care expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the E.U. The downward pressure on health care costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various Member States, and parallel trade, i.e., arbitrage between low-priced and high-priced Member States, can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any products, if approved in those countries.

Pharmaceutical Price Reforms

The prices of pharmaceutical and biopharmaceutical products have been a focal point of federal, state, and foreign governments' efforts to contain health care costs. Most significantly, interest in the adoption and implementation of cost-containment programs, including price controls, mandated price negotiations, tenders based on perceived therapeutic equivalence, restrictions on reimbursement, and requirements for substitution of generic products, have increased. Adoption of such price controls and cost-containment measures—including adoption of more restrictive policies in jurisdictions with existing controls and measures—could further limit the revenue a company might generate from the sale of an approved product, particularly if such measures result in more restrictive coverage or lower reimbursement from third party payors.

Prescription pharmaceutical pricing has been the subject of considerable discussion and activity in the United States on both the federal and state levels and from both political parties. A number of foreign, federal, and state laws impose limitations on the pricing of pharmaceutical and biopharmaceutical products. These laws may also impose controls that limit coverage and reimbursement for drugs and other medical products. Recent approaches to contain pharmaceutical costs have varied and include—among other strategies—increasing transparency in pharmaceutical pricing, reviewing the relationship between pricing and manufacturer patient programs, and directly addressing the costs of pharmaceuticals in the Medicare and Medicaid programs.

Most significantly, on the federal level, the Inflation Reduction Act (the "IRA") was signed into law on August 16, 2022. The IRA contained substantial pharmaceutical pricing updates to the Medicare programs. The extent and scope of impacts the IRA may have will continue to evolve as the current administration advances implementation of the IRA's pharmaceutical pricing provisions. Several changes included in the IRA may impact pricing, disrupt current pharmaceutical supply chain operations, and alter stakeholder behavior in a manner that ultimately reshapes the industry and impacts areas beyond the Medicare program. For example, each year, CMS will engage with selected high-spend Medicare Part D and Part B single-source drug and biologic products as part of the "Medicare Drug Price Negotiations Program." These negotiations compel manufacturers of these products to negotiate substantial discounts to the Medicare program or face substantial penalties. The pricing reached during these negotiations will likely have significant impacts on selected and related products, such as on pricing, prescribing, and formulary management, within Medicare and secondarily in other coverage markets. The "Medicare Drug Inflation Rebate Program," which penalizes manufacturers for increasing prices of Medicare Part B and Medicare Part D drugs faster than the rate of inflation may also further impact industry pricing considerations for future products. Changes stemming from the Part D benefit redesign may similarly impact downstream stakeholder behavior and formulary management practices that may influence pricing and the demand for certain drugs.

Additionally, on October 20, 2020, HHS and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program to import certain prescription drugs from Canada into the U.S. That regulation was challenged in a lawsuit by the Pharmaceutical Research and Manufacturers of America ("PhRMA"), but the case was dismissed by a federal district court in February 2023 after the court found that PhRMA did not have standing to sue HHS. Nine states (Colorado, Florida, Maine, New Hampshire, New Mexico, North Dakota, Texas, Vermont and Wisconsin) have passed laws allowing for the importation of drugs from Canada. Certain of these states have submitted Section 804 Importation Program proposals and are awaiting FDA approval. On January 5, 2024, the FDA approved Florida's plan for Canadian drug importation. This plan was granted extensions until May 6, 2026. It is unclear how this program will be implemented, if at all, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada.

Recent litigation, enforcement activity, and state and federal legislative interest and efforts have resulted in changes within the landscape of the 340B Drug Pricing Program (the "340B Program"). Established by Section 340B of the PHSA and overseen by the Health Resources and Services Administration ("HRSA"), the 340B Program requires manufacturers to sell outpatient prescription drugs to certain statutorily-defined safety net "covered entities" at significantly discounted prices. In recent years, there has been increased third-party utilization of the 340B Program as a result of expanded interpretations of the statute by covered entities, which has had implications for manufacturers of covered outpatient drugs.

Potential statutory or regulatory updates at the federal level, in addition to 340B-related litigation, could significantly reshape the 340B Program and its resulting impact on future sales, as approved. Notably, the landscape of contract pharmacy involvement in the dispensing of 340B drugs sold to covered entities particularly on the state-level—has continued to evolve through enforcement activity, litigation, and state-level legislation. The changes stemming from continued litigation and state activity, as well as the growing number of contract pharmacies, or any related federal legislative activity may continue to impact the volume of drugs purchased at 340B prices and the 340B Program's impact on our product candidates, if approved.

In May 2025, the current administration published an executive order regarding most favored nation ("MFN") drug pricing, which is sometimes referred to as international reference pricing. This executive order directs the Secretary of Health and Human Services to communicate MFN price targets to pharmaceutical manufacturers, and if significant progress towards MFN pricing is not delivered, to propose a rule making plan to impose MFN pricing. HHS is currently developing a proposed rule to establish a demonstration model under the auspices of CMS's Center for Medicare and Medicaid Innovation that will require MFN pricing, but the proposed rule has not yet been published, so it is not yet known which drugs will be covered, how long the model will be in effect, or how pricing will be determined. If that rule or other MFN pricing rules are finalized, they are likely to establish reference price controls on U.S. drug prices, using prices in comparator countries as the benchmark for allowable U.S. reimbursement.

More broadly, individual states are increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, provisions designed to encourage importation from other countries and bulk purchasing of drug products by state agencies. A number of states, for example, require drug manufacturers and other entities in the drug supply chain, including health carriers, pharmacy benefit managers, wholesale distributors, to disclose information about pricing of pharmaceuticals. Several states have also authorized the use of prescription drug affordability boards to impose price constraints on certain high-cost prescription drugs. In addition, regional healthcare organizations and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription pharmaceutical and other healthcare programs.

The evolving nature of these federal and state measures could reduce ultimate demand for products, once approved, or put pressure on our product pricing. Additional state and federal healthcare reform measures may be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could also impact third party payor behavior and result in reduced demand or additional pricing pressures.

General Data Protection Regulation and other Privacy Laws

We are subject to or affected by numerous data privacy and security obligations, that apply in Europe and other countries, including the European Economic Area's (EEA's) General Data Protection Regulation ("GDPR"). Following the withdrawal of the United Kingdom from the EU, the U.K. Data Protection Act 2018 was enacted and includes parallel obligations to those set forth by GDPR.

The GDPR is wide-ranging in scope and imposes numerous strict requirements on companies that process personal data, including heightened requirements on companies that process health and other sensitive data, such as requiring in many situations that a company obtain consent of individuals before processing their personal data. Other examples of obligations imposed by the GDPR include providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, appointing a data protection officer, taking certain measures when engaging third-party processors, and providing notification of data breaches. The GDPR also permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. In addition, the GDPR confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR.

The GDPR also imposes strict rules on the transfer of personal data to countries outside the EEA, including the U.S. The transfer of personal data from the EEA to the U.S. is generally restricted unless a company participates in the EU-U.S. Data Privacy Framework or have otherwise implemented specific safeguards to protect the data. Some privacy advocacy groups are interested in challenging these mechanisms, so the uncertainty surrounding what will constitute a legal cross-border transfer of data in the future may impact our business.

Compliance with the GDPR is a rigorous and time-intensive process that may increase the cost of doing business. Moreover, failure to comply may lead to significant penalties or reputational harm. Beyond the GDPR, there are privacy and data security laws in a growing number of countries around the world. While many loosely follow the GDPR as a model, other laws contain different or conflicting provisions.

Human Capital

Summit employees are the cornerstone of our strategy. We believe our ability to hire, retain and develop top talent is key in achieving our long-term strategic goals. We are committed to fostering an inclusive work environment where employees are empowered to contribute to Summit's mission while simultaneously enhancing their professional development.

Our workforce consists of world-class leaders and experienced professionals to include, scientists, researchers, regulatory experts, clinical development specialists and business administrators working together to resolve serious, unmet medical needs for the betterment of overall human health and making a significant difference in the quality and potential duration of life for oncology patients. We are committed to employing the best talent regardless of the employee's gender, age, ethnicity, sexual orientation, or any other characteristic protected by applicable law.

As of December 31, 2025, we had 265 total employees. Of our total workforce, approximately 71% work in research and development, and 29% work in finance, legal, information technology, general management and other administrative functions. Approximately 91% of our workforce is in the United States and approximately 9% is outside of the United States.

Compensation and Benefits

To address a competitive and dynamic labor market and attract and retain talent, Summit provides a comprehensive total rewards package which includes market competitive salaries, stock options, an annual performance discretionary bonus, employer contributions to pension/401(k) plans, an employee stock purchase plan, paid vacations, holidays and a hybrid work schedule.

Summit visits its compensation practices and reviews its benefit programs annually, adjusting as needed to ensure that its total reward offerings continue to address the needs of its employees and compensation packages assist Summit in hiring and retaining top-talent to meet business goals and objectives.

Culture and Engagement

Summit's culture continues to be at the center of its success. Summit's core values are a huge part of Summit's culture, and include: Integrity – to uphold the highest standards; Passion for Excellence – a learning mindset embracing change to drive success; Purposeful Urgency – unwavering commitment to fulfill our mission to patients pursuing audacious goals; Accountability – assuming responsibility for our actions and outcomes; Collaboration – the power of teamwork; and Our Commitment to People – prioritizing patients and the health and safety of every Summit colleague actively providing impactful growth opportunities.

As Summit continues to grow, maintaining and emphasizing Summit's core values will be essential in maintaining its culture.

Belief in Summit's mission and commitment to help patients is not only a core value but continues to be at the forefront of employee engagement.

In November 2025, Summit employees participated in the Great Place to Work Survey and has been able to maintain its Great Place To Work® certification for a second year in a row, with 81% of employees believing in the statement that Summit is a great place to work. We believe these results continue to show employees to be engaged, enthusiastic and strongly aligned with the Company's mission.

Learning and Development

We are committed to investing in learning and development for our employees and provide ongoing education through the employee's life-cycle led by "Summit University". The employee education process begins during orientation where all new employees receive a comprehensive overview of the Company, partnership, and the molecule's mechanism of action. This educational program also includes oncology training, anatomy, physiology, disease state awareness, testing, and symptoms along with the patient journey as it pertains to the Summit clinical trials. This strategy helps to ensure scientists as well as administrators start their employment with a strong foundation of shared knowledge to power the Company and its culture.

Workplace Health and Safety

We are committed to the health and safety of all of our employees. We accomplish this through goals of compliance with applicable workplace safety laws and regulations, continuous risk assessment and expeditious action. We had no reportable health and safety issues in 2025.

Our Corporate Information

Summit Therapeutics Inc. was incorporated in Delaware on July 17, 2020. Our principal executive office is located at 601 Brickell Key Drive, Suite 1000, Miami, Florida 33131 and our phone number is (305) 203-2034. Our website is https://www.smmttx.com. The information contained on, or that can be accessed through, our website is not incorporated by reference into this Annual Report on Form 10-K or in any other report or document we file with the SEC, and any reference to our website address is intended to be an inactive textual reference only.

We own or have rights to trademarks, service marks, and trade names that we use in connection with the operation of our business, including our corporate name, logos and website names. Other trademarks, service marks, and trade names appearing in this Annual Report on Form 10-K are the property of their respective owners. Solely for convenience, some of the trademarks, service marks, and trade names referred to in this Annual Report on Form 10-K are listed without the ® and ™ symbols.

Available Information

We maintain a website with the address https://www.smmttx.com/. We are not including the information contained on our website as part of, or incorporating it by reference into, this Annual Report on Form 10-K. Through our website, we make available free of charge our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, amendments to these reports in a timely manner after we provide them to the SEC, and other material information from time to time in our press releases, annual meetings of stockholders, publicly accessible conferences and investor presentations.

Item 1A. Risk Factors

This section describes certain risks we face in our business. Additional risks we do not yet know of or that we currently believe are immaterial may also impair our business. If any of the events or circumstances described in this section actually occurs, our business, financial condition or operating results could suffer, and the market price of our common stock could decline. In assessing these risks, investors should also refer to the other information contained or incorporated by reference in this Annual Report on Form 10-K and our other filings with the SEC.

Risks Related to our Financial Position and Need for Additional Capital

We are a development-stage company and have incurred significant losses since our inception. We expect to incur losses for at least the next several years and may never generate or maintain profits.

We are a development-stage company and we cannot ensure profitability. Since inception, we have incurred significant operating losses. During the year ended December 31, 2025, we incurred a net loss of $1,079.6 million, and cash flows used in operating activities was $322.9 million. As of December 31, 2025 we had an accumulated deficit of $2,294.2 million, cash and cash equivalents of $225.3 million, short-term investments in U.S. treasury securities of $488.2 million, and current and long-term research and development tax credits receivable of $0.9 million. These losses could continue for the next several years as we invest in clinical development of ivonescimab. We expect to continue to generate operating losses for the foreseeable future. Until we can generate substantial revenue and achieve profitability, we will need to raise additional capital to fund ongoing operations and capital needs.

To become and remain profitable, we must succeed in developing and eventually either commercializing or partnering with other organizations to commercialize products that generate significant revenue. This will require us to be successful in a range of challenging activities, including but not limited to completing preclinical testing and clinical trials of our product candidates, discovering additional product candidates, obtaining regulatory approval for these product candidates, and manufacturing, marketing, and selling any products for which we may obtain regulatory approval. We are in the preliminary stages of many of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with pharmaceutical products and biological development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress our value and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations.

We have not yet demonstrated an ability to successfully complete development of any product candidates, which may make it difficult for you to evaluate our success and future viability.

We have not yet demonstrated an ability to successfully complete development of any product candidates, obtain marketing approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities or otherwise obtain a partner to do so, as is necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In January 2026, the FDA accepted for filing our BLA seeking approval of ivonescimab in combination with chemotherapy in patients with EGFR-mutated locally advanced or metastatic non-squamous NSCLC post-TKI therapy and provided a PDUFA target action date of November 14, 2026. The delay or denial of regulatory approval, inability to maintain regulatory approval, inability to complete post-marketing requirements, or the requirement to resubmit any marketing application with additional data or information could mean that we otherwise negatively would delay commercialization of ivonescimab and adversely impact our ability to generate revenue, our business and our operations.

Assuming we obtain marketing approval for any of our product candidates, we will need to transition from a company with a research and development focus to a company capable of supporting commercial activities or seek an appropriate partner or partners to maximize the commercial opportunity of our products with a deal structure that maximizes our opportunities for profitability. We may encounter unforeseen expenses, difficulties, complications, and delays, and may not be successful in such a transition.

We will need substantial additional capital to fund our operations and to make payments under the License Agreement, and if we fail to obtain necessary financing, we could be forced to delay, reduce or eliminate the development and commercialization of our product candidates.

Conducting preclinical testing and clinical trials is a time-consuming, expensive, and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval or achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that may not be commercially available for several years, if at all.

We expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly in connection with the License Agreement. In addition, if we obtain marketing approval for our potential future product candidates where we retain commercial rights or any other product candidates we develop, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing.

Accordingly, we will need to continue to rely on additional financing in connection with our continuing operations. Additional financing may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we may 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.

We expect to continue to generate operating losses for the foreseeable future. Our primary future capital requirements will be related to our obligations under the License Agreement and funding research and development efforts.

The License Agreement, as amended, calls for initial consideration payments of $515 million (of which $500 million was paid in 2023 and $15 million was paid in 2024), as well as total contingent payments by the Company of up to $4.56 billion, as Akeso will be eligible to receive regulatory milestones of up to $1.05 billion, some of which will be due before the Company anticipates generating revenue and commercial milestones of up to $3.51 billion. We will need additional capital to fund our operations and payments under the License Agreement, which we may do via issuances of equity or debt or through global or regional partnerships in the Licensed Territory.

Raising additional capital may cause dilution to our investors, restrict our operations or require us to relinquish rights to our product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, collaborations, strategic alliances, grants and clinical trial support from government entities, philanthropic, non-government and not-for-profit organizations and patient advocacy groups, debt financings, and marketing, distribution or licensing arrangements. We do not have any committed external source of funds. We will need to seek additional funding in the future to fund operations. Additional capital, when needed, may not be available to us 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 existing stockholders may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders. Additional debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends or other distributions. If we raise additional funds through collaborations, strategic alliances or marketing, distribution, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us.

If we are unable to raise additional funds through equity or debt financings, or other arrangements when needed based on our liquidity needs, we may 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.

Worldwide economic, social and geopolitical instability could adversely affect our operations, revenue, financial condition, results of operations or ability to raise capital.

Generally, worldwide economic conditions remain uncertain, particularly due to the effects of the conflict between Russia and Ukraine, the conflicts in the Middle East, including those in Gaza, Lebanon and Yemen, the escalating tensions in Venezuela and Greenland, and disruptions in the banking system and financial markets, including those in Japan, increased inflation and rising interest rates. The general economic and capital market conditions, both in the U.S. and worldwide, have been volatile in the past and at times have adversely affected the Company's access to capital and increased the cost of capital. The ongoing

geopolitical conflicts in various parts of the world, including but not limited to Russia, Ukraine, the Middle East, Venezuela and Greenland, are difficult to predict and could adversely affect our business in the Licensed Territory as well as our ability to enroll patients and supply ivonescimab to various clinical sites in the world, resulting in adverse effects on our business and financial condition.

The capital and credit markets may not be available to support future capital raising activity on favorable terms. If economic conditions decline, the Company's future cost of equity or debt capital and access to the capital markets could be adversely affected. In addition, adverse economic conditions, such as recent supply chain disruptions and labor shortages and persistent inflation, may negatively impact our business. These economic conditions make it more difficult for us to accurately forecast and plan our future business activities.

We depend heavily on the success of ivonescimab. If we are unable to successfully develop or commercialize ivonescimab, or experience significant delays in doing so, we may continue to incur significant financial losses.

We have and plan to continue investing a significant portion of our efforts and financial resources in the development of ivonescimab, which is still in clinical development. Our ability to generate product revenues, which may not occur for several years, if ever, will depend heavily on the successful development and commercialization of ivonescimab. The success of this product candidate depends on a number of factors, including, but not limited to, the following:

- our ability to use preclinical data and data of patients from Akeso's clinical trials in China supporting registration studies and regulatory approval;
- successful completion of global clinical development;
- receipt of clinical trial approvals and future marketing approvals from applicable regulatory authorities in all the countries where we intend to conduct clinical trials or seek marketing approval; the costs of post-marketing studies, if any, that could be required by regulatory authorities in jurisdictions where approval is obtained;
- establishing supply chain and commercial manufacturing arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity;
- enforcing our rights in our intellectual property portfolio;
- establishing sales, marketing and distribution capabilities;
- launching commercial sales of ivonescimab if and when approved, whether alone or in collaboration with others;
- acceptance of ivonescimab, if and when approved, by patients, the medical community and third-party payors;
- obtaining timely and adequate pricing and reimbursement from payors;
- ensuring no disruption in supply or lack of sufficient quantities of ivonescimab;
- effectively competing with other therapies; and
- maintaining an acceptable safety profile of ivonescimab during development and following approval.

Risks and uncertainties related to these factors could cause us to experience significant delays or an inability to successfully commercialize ivonescimab, which would materially harm our business.

Risks Related to the Development and Commercialization of our Product Candidates

Clinical development is a lengthy process with an uncertain outcome, and results of earlier studies and trials, conducted by us or Akeso, as well any interim results thereof, may not be predictive of future trial results and may negatively impact the size and scope of our ongoing or future Phase III clinical trials.

Clinical development can take several years to complete and is an expensive process with inherent uncertainty in outcomes. Failure can occur at any time during the clinical development process. The results of preclinical studies and early clinical trials of ivonescimab, conducted by us or Akeso, may not be predictive of the results of our later-stage clinical trials. Similarly, initial or interim results of a clinical trial may not be predictive of the final results and results for one indication, in one cohort, or in one of the primary endpoints or secondary endpoints, may not be predictive of the success in additional indications, with different cohorts or in additional primary or secondary endpoints. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Several factors can lead to significant variability in safety and/or efficacy results between different trials of the same drug candidate, including changes in trial procedures set forth in protocols, differences in the size, type and geographic location of the patient populations, including genetic differences, patient adherence to the dosing regimen, and other trial protocol elements and the rate of dropout among clinical trial participants. In the case of any trials we conduct, results may differ from earlier trials due to the larger number of clinical trial sites and additional countries involved in such later trials. Results may differ materially in clinical trials held across multiple cohorts or subgroups, which could lead to unfavorable regulatory or health authority decisions.

If ongoing Phase II or Phase III clinical trials conducted by Summit or Akeso involving ivonescimab, or future clinical trial results, are unfavorable, the size and scope, including the number of patients, primary and secondary endpoints, and population of patients, of ongoing and future clinical trials could be impacted. Further, we may incur additional product development costs, experience delays or become unable to obtain regulatory approval of ivonescimab for the whole clinical trial or the approved label may be restricted to one cohort or subgroup, thereby adversely affecting our business.

If we experience delays or difficulties in the enrollment of patients in our clinical trials, our receipt of necessary marketing approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our product candidates for several factors including inability to get required regulatory approvals to initiate clinical trials in all the planned countries, as well as inability to locate and enroll a sufficient number of eligible patients to participate in these clinical trials. For our clinical trials of ivonescimab, we need to identify potential patients, potentially test them for specific diagnoses and enroll them. In addition, our competitors in NSCLC have ongoing clinical trials for product candidates that could be competitive with our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates or choose not to enroll in any clinical trials for various reasons, including due to fears of contagious diseases, illnesses or side effects.

Patient enrollment is affected by several factors, including, but not limited to:

- severity of the disease under investigation;
- eligibility criteria for the clinical trial in question;
- perceived risks and benefits of the product candidate under study;
- competition for patients, time and resources at clinical trials sites from other investigational therapies in clinical trials that target the same patient population;
- changes in the standard of care, including new clinical trial data;
- approval of other therapies to treat the indication that is being investigated in the clinical trial;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- proximity and availability of clinical trial sites for prospective patients.

Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. Our inability to enroll a sufficient number of patients in our planned clinical trials of ivonescimab or any other planned clinical trials would result in significant delays, may generate a limited data set from which no meaningful conclusions could be made, or may require us to abandon one or more clinical trials altogether.

If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities, or do not otherwise produce favorable results, we may incur additional costs or experience delays, or ultimately be unable to, develop and commercialize any product candidate.

Prior to obtaining marketing approval from regulatory authorities (including the FDA, EMA, PMDA or any other regulatory authority in the Licensed Territory) for the sale of ivonescimab, or any other product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. In particular, due to the small number of patients in our early clinical trials, results from such trials may not be predictive of the outcome of later clinical trials. The design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced or completed. We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. For instance, although we believe that the safety and efficacy data generated in the HARMONi study demonstrates that the ivonescimab regimen offers a potential treatment option for patients impacted by EGFR-mutant NSCLC in this setting with a favorable benefit-risk profile, FDA has noted that a statistically significant OS benefit is necessary to support marketing authorization in this setting. If the FDA does not agree with our analysis of the HARMONi data, they may delay or deny regulatory approval in

this proposed indication, require us to resubmit the marketing application with additional data or information, or take other actions that could delay commercialization of ivonescimab and adversely impact our ability to generate revenue, our business and our operations. We cannot predict the results of our ongoing or future clinical trials.

Regulatory authorities have substantial discretion in the approval process. They may refuse to accept any application or may decide that our data are insufficient for approval and require additional clinical trials or other studies. In our public communications, we may designate certain of our clinical trials as "pivotal" if we believe that these clinical trials, if successful, will support BLA submissions; however, there can be no assurance that any clinical trial that we designate as "pivotal" will be viewed as sufficient by the FDA, the EMA and other comparable regulatory authorities in other jurisdictions to support regulatory approval. If we are required to conduct additional clinical trials or other testing of any of our product candidates beyond those that are contemplated, we may incur significant additional costs and regulatory approval may be delayed or prevented.

There can be no guarantee that the FDA or other regulatory authorities will interpret the results or reach the same conclusions from the data as we do, or fully agree that our development plans are sufficient for submission or approval of a BLA. In the event that the FDA requires us to conduct clinical trials with more patients than planned, to conduct clinical trials with designs or endpoints other than we currently anticipate, we may not have the funding to enlarge or conduct such trials and we may not be able to raise sufficient funding to do so, which could delay or prevent commercialization of our product candidates. In addition, the FDA or other regulatory authorities may change their views on aspects of the clinical programs, including clinical trial designs, or the ability of the trials as designed to support approval of a product. If we are unable to effectively and efficiently resolve and comply with the inquiries and requests of the FDA and other comparable international regulatory authorities, the approval of our product candidates may be delayed, which could delay or prevent commercialization of our product candidates.

Regulatory requirements and timelines may affect the scope and timeline of our trials and the potential market for our product candidates.

As we expand into additional countries and sites for our current and additional clinical trials, we are required to obtain the regulatory approval of the applicable clinical trial applications with the respective regulatory authorities and approvals from central or local institutional review boards. We may decide to modify our plans to enter certain regions or countries based on the timelines and requirements for the respective regulatory regions. If the process to obtain regulatory approvals in a given region or country places onerous requirements on the Company or if the Company cannot reasonably obtain such approvals without material delays to its plans, we may choose not to enter certain regions or countries for our clinical trials, which may delay the development of our product in those countries and impact the scope of our dataset and market for our products.

If we experience any number of possible unforeseen events in connection with our clinical trials, potential marketing approval or commercialization of our product candidates could be delayed or prevented.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to complete the clinical trials and receive marketing approval for or commercialize our product candidates, including:

- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- in clinical trials that include multiple endpoints, unfavorable results in any individual endpoint may limit any regulatory approval or commercialization of the applicable product candidate;
- the number of patients required for clinical trials of our product candidates may be larger, and the diversity of the patient population required for our clinical trials may be higher, than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate for various reasons, including due to contagious diseases or illnesses;
- our ability to combine data from different regions and countries may be limited due to lack of consistency in data in these regions and countries, potentially delaying or preventing marketing approval for our product in some or all of the Licensed Territory;
- in our multi-regional trials, we may experience delays in enrollment across one or more countries and/or regions that could lead to variability in data or the trial missing the required endpoints resulting in lack of approval from regulatory authorities in some or all of the Licensed Territory;
- we may be unable to enroll a sufficient number of patients in our clinical trials to ensure adequate statistical power to detect any statistically significant treatment effects;
- we or our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

- regulators, institutional review boards or independent ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with multiple prospective trial sites;
- we may have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;
- regulators, institutional review boards or independent ethics committees may require that we or our investigators materially modify the terms of our clinical research in order to meet additional requirements for receiving marketing approval, including by requiring that we enlarge our trials, broaden the scope of our research, or perform studies in addition to those we currently anticipate, which may delay our ability to obtain marketing approval or impose additional costs;
- regulators, institutional review boards or independent ethics committees may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the supply or quality of our product candidates, comparator drugs or other materials necessary to conduct clinical trials of our product candidates in adolescent patients may be insufficient or inadequate, which may occur if, for example, enrollment for our clinical trial programs are delayed and the clinical supply of ivonescimab or related comparator drug manufactured for such trials was not utilized prior to its expiration and needed to be replaced, or if there were disruptions in our supply chain due to weather conditions, natural disasters or contagious diseases or illnesses, or pandemics or epidemics;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators, institutional review boards or independent ethics committees to suspend or terminate the clinical trials;
- preclinical tests or clinical trials not beginning as planned, needing to be restructured or not being completed on schedule, or at all; and
- data privacy or other laws being implemented that restrict transfer of patient data from one country to another.

If serious adverse or inappropriate side effects are identified during the development of any product candidate, we may need to abandon or limit our development of that product candidate.

All of our product candidates are in clinical or early-stage development and their risk of failure is high. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive marketing approval. If our product candidates are associated with undesirable side effects or have characteristics that are unexpected, we may need to abandon their development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective.

Many compounds that initially showed promise in clinical or earlier stage testing have later been found to cause side effects or other safety issues that prevented further development of the compound. If we elect or are forced to suspend or terminate any clinical trial of our product candidates, the commercial prospects of such product candidate will be harmed and our ability to generate product revenues from such product candidate will be delayed or eliminated. Any of these occurrences could materially harm our business.

We have conducted, 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, 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 are currently conducting clinical trials in China, and we expect to continue to conduct trials internationally in the future. The acceptance of data from clinical trials conducted outside the United States by the FDA or other regulatory authorities 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 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 the data may be considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-conducted in accordance with GCPs and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements. In

addition, such foreign trials are subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. Conducting clinical trials outside the United States also exposes us to additional risks, including risks associated with foreign exchange fluctuations, compliance with foreign manufacturing, customs, shipment and storage requirements, and cultural differences in medical practice and clinical research, and diminished protection of intellectual property in some countries.

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. For example, for FDA acceptance, we will have to demonstrate that the foreign data are applicable to the U.S. population and U.S. medical practice. If the FDA or other regulatory authorities do 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 a product candidate receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If ivonescimab or any of our other product candidates receive marketing approval, such products may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If these products do not achieve an adequate level of acceptance, it could make it more difficult to enter into third-party partnership arrangements, and we may not generate significant product revenues or revenue from collaboration agreements or any income from operations. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages compared to alternative treatments or competitive products;
- the prevalence and severity of any side effects;
- the ability to offer our product candidates for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement;
- the timing of any such marketing approval in relation to other product approvals;
- support from patient advocacy groups; and
- any restrictions on concomitant use of other medications.

The ability to negotiate, secure and maintain third-party coverage and reimbursement may be affected by political, economic and regulatory developments in the United States, the E.U., Japan and other jurisdictions in the Licensed Territory.

Governments continue to impose cost containment measures, and third-party payors are increasingly challenging prices charged for medicines and examining their cost effectiveness, in addition to their safety and efficacy. These and other similar developments could significantly limit the degree of payor acceptance of ivonescimab or any of our other product candidates that receive marketing approval.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be successful in commercializing a product candidate if and when such product candidates are approved.

With our BLA submission in Q4, 2025 and the FDA's acceptance for filing the BLA in January 2026, we are in the process of building our Sales, Marketing and Market Access organization. We have already hired our senior commercial leadership team with extensive experience in the sale and marketing of pharmaceutical products. In addition, we are in the process to build infrastructure of supporting operations to ensure a successful commercial launch. To achieve commercial success for any approved product, we must either develop a sales and marketing organization and/or outsource these functions to third parties . If ivonescimab receives marketing approval, we may seek commercialization partners in some parts of the Licensed Territory. There are risks involved with establishing our own sales and marketing capabilities as well as entering into arrangements with third parties to perform these services. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel in a timely fashion;
- Inability to build a marketing operations infrastructure with the development of advance analytics allowing for different channels to be utilized for promotions beyond the sales organization
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe any future products;
- Lack of appropriate guidelines, pathways, and formulary placement for reimbursement;
- Lack of key opinion development for the support of the product data;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

Evolving competition with new products or existing products with new data or combinations which may confer efficacy or safety advantages.

If we enter into arrangements with third parties to perform sales and marketing services, our product revenues or the profitability of these product revenues to us are likely to be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are acceptable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

Biologics, such as ivonescimab, carry unique risks and uncertainties that could negatively impact our business.

The successful development, manufacturing and sale of biologics is a long, expensive and uncertain process. There are unique risks and uncertainties with biologics. For example, access to and supply of necessary biological materials, such as cell lines, may be limited and governmental regulations restrict access to and regulate the transport and use of such materials. In addition, the development, manufacturing and sale of biologics is subject to regulations that are often more complex and extensive than the regulations applicable to other pharmaceutical products. Manufacturing biologics, especially in large quantities, is often complex and may require the use of innovative technologies. Such manufacturing also requires facilities specifically designed and validated for this purpose and sophisticated quality assurance and quality control procedures. Biologics are also frequently costly to manufacture. Failure to successfully develop, manufacture and sell ivonescimab could adversely affect our business.

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

Notwithstanding our large investment to date and anticipated future expenditures in proprietary technologies, we have not yet developed, and may never successfully develop, any marketed drugs. As a result of pursuing the development of product candidates using our proprietary technologies, we may fail to develop product candidates or address indications based on other scientific approaches that may offer greater commercial potential or for which there is a greater likelihood of success. Research programs to identify new product candidates require substantial technical, financial and human resources. These research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development.

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 face substantial competition, which may result in others discovering, developing or commercializing products before us or more successfully than we do.

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidate and any products we may seek to develop or commercialize whether ourselves or through third-party partners, in the future from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide.

Several pharmaceutical and biotechnology companies have established themselves in the market for the treatment of NSCLC, and several additional companies are developing products for the treatment of NSCLC. Currently, the most commonly used treatments for first-line NSCLC without genomic alterations are several immuno-oncology drugs and chemotherapies, administered either individually as monotherapy, in combination with each other, or in combination with other approved therapeutics. In addition to various chemotherapies, several immunotherapies have been approved by the FDA for these treatments, including, but not limited to pembrolizumab, atezolizumab, nivolumab, durvalumab, cemiplimab and ipilimumab. There are anti-angiogenic therapies which are approved for the treatment of certain lung cancers, including bevacizumab in front-line non-squamous NSCLC as well as ramucirumab for patients who have progressed after platinum-based chemotherapy. The proposed indications for ivonescimab in the HARMONi-3 and HARMONi-7 clinical trial settings in first-line NSCLC may face competition from clinical candidates such as novel immunotherapy targets including various clinical candidates targeting T-cell immunoreceptors with Ig and ITIM domains (TIGIT) and lymphocyte activation gene 3 (LAG-3) each of which have various developers for different candidates as either monoclonal antibodies or multispecific antibodies, a bispecific antibody, volrustomig (AstraZeneca), and antibody drug conjugates (ADCs) with novel targets such as datopotamab deruxetecan (AstraZeneca and Daiichi Sankyo), sacituzumab tirumotecan (Merck), and sigvotatug vedotin (Pfizer), each having announced, are currently enrolling in, or having completed enrollment in Phase III clinical trials.

For those patients having EGFR mutations, there are several targeted therapies that have also been approved in the front-line setting, including, but not limited to, osimertinib (AstraZeneca) with or without chemotherapy and amivantamab and lazertinib (both from Johnson & Johnson). The proposed indication for ivonescimab in the HARMONi clinical trial setting, post third-generation EGFR-TKIs such as osimertinib or lazertinib, may face competition from amivantamab plus chemotherapy, as well as clinical candidates such as datopotamab deruxetecan (AstraZeneca and Daiichi Sankyo) and patritumab deruxtecan (Merck and Daiichi Sankyo).

There are several PD-(L)1/VEGF(R2) bispecific antibodies in development or with planned development globally. These include, but are not limited to pumitamig (BNT327), which is owned by BioNTech SE and being developed in a collaboration with Bristol Myers Squibb Co. since June 2025, which has begun conducting Phase III clinical studies globally, PF-08634404 (PF'4404 / SSGJ-707), which was licensed globally, ex-China by Pfizer Inc. in July 2025, LM-299, which was licensed globally by Merck & Co., Inc. in November 2024, and RC148, which was licensed outside of Greater China by AbbVie Inc. in January 2026.

Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are more effective, safer, have fewer or less severe side effects, are approved for broader indications or patient populations, or are more convenient or less expensive than any products that we develop and commercialize. Our competitors may also obtain marketing approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

We believe that many competitors are attempting to develop therapeutics for the target indications of our product candidates, including academic institutions, government agencies, public and private research organizations, large pharmaceutical companies and smaller more focused companies.

Multiple in-class and related competitors for our product candidate are and can be developed, our competitive position could be compromised because it may be more difficult for us to obtain marketing approval for that product candidate and market acceptance of that product candidate due to a similar competitor. In addition, any product that competes with another approved product typically must demonstrate compelling advantages in efficacy, convenience, tolerability or safety, or some combination of these factors, to gain regulatory approvals, overcome price competition and be commercially successful.

Many of our competitors may have significantly greater financial and operational resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining approvals from regulatory authorities and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other 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 scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to or necessary for our programs.

If we fail to plan, execute and manage our growth effectively, our ability to develop and commercialize products could suffer.

We expect that if our clinical product candidates continue to progress in development, and we continue to build our clinical operations and invest in our commercial operations, we will require significant additional investment in personnel, infrastructure and resources. Our ability to achieve our research, development and commercialization objectives depends on our ability to respond timely and effectively to these demands and expand our internal organization, systems and controls to accommodate additional anticipated growth. The expansion of our operations may lead to significant costs and may divert our management and business resources. Failure to effectively manage our growth may impact our ability to successfully develop and commercialize our product candidates.

Risks Related to our Dependencies on Third Parties

We depend on our relationship with, and the comprehensiveness of the intellectual property licensed from, Akeso, and termination of the License Agreement, or issues related to intellectual property could have a material adverse effect on our business.

We depend on the know-how and other intellectual property licensed from Akeso through the License Agreement for the development and, if approved, commercialization of the bispecific antibody, ivonescimab. If the License Agreement is terminated, or found to be unenforceable, it could result in the loss of significant rights and could harm our ability to commercialize ivonescimab.

The License Agreement imposes certain obligations on us, including obligations to use diligent efforts to meet development thresholds, funding requirements, payment obligations, and commercialization. If we are unable to meet our obligations, some or all of our rights under the License Agreement may be restricted or terminated.

Our primary product candidate, ivonescimab, is subject to the License Agreement from Akeso, which is revocable in certain circumstances, including in the event we do not achieve certain payment deadlines. Without the rights to the patents under the License Agreement, we will not be able to continue to develop ivonescimab.

The License Agreement may be terminated by Akeso in the event of a material breach by Summit or if we default in the performance of any of our material obligations under the License Agreement, and such default continues for 90 days, or with respect to any breach of any undisputed payment obligations, for 60 days, or with respect to any breach of a supply requirement, for 30 days after written notice thereof.

Additionally, the ability of Summit to realize the full potential of the License Agreement may be severely limited by factors involving intellectual property rights, including:

- whether and to what extent our technology and processes infringe on intellectual property rights of other third parties that are not subject to the License Agreement;
- whether third parties are entitled to compensation or equitable relief, such as an injunction, for our use of intellectual property without their authorization;
- our right to sublicense patent and other intellectual property rights to third parties under collaborative development relationships;
- our compliance with our obligations with respect to the use of the licensed technology in relation to our development and commercialization of product candidates;
- ownership of specific intellectual property; and
- the impact on payments and costs associated with commercialization if there is blocking intellectual property or the costs associated with prosecution, maintenance and enforcement of intellectual property under the License Agreement.

These issues, if they arise, could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, increase what we believe to be our financial or other obligations under the relevant agreement, or increase our costs to develop, manufacture and commercialize products under the License Agreement.

We may be reliant on Akeso for knowledge transfer relating to any improvements in manufacturing of ivonescimab. The loss of any of the knowledge transferred relating to ivonescimab from Akeso may cause us to incur additional transition costs or result in delays in the manufacturing and delivery of ivonescimab.

We have entered into the License Agreement pursuant to which we agreed to purchase a certain portion of drug substance and/or drug product for clinical and commercial supply, and the termination or Akeso's breach of these agreements could have a material adverse effect on our business. Akeso's drug substance and drug product may not comply with regulatory authority quality requirements or have sufficient stability for commercialization which may require additional investment and delay our development, approval and commercialization plans. Further, failure of Akeso to adequately transfer knowledge to Summit relating to any improvements in producing ivonescimab could have a material adverse effect on our business.

Manufacturing of biological compounds is inherently complex and establishing new manufacturing relationships with a third-party manufacturer may take longer, resulting in higher costs and potential inventory issues. Manufacturing processes may use materials which Summit may not be able to secure, requiring Summit to develop alternative processes and delay manufacturing. The product may not comply with regulatory authority quality requirements or have sufficient stability for commercialization, which may require additional manufacturing development and delays. As Summit is relying initially on supply from Akeso, any delays in obtaining import or export licenses may delay development.

We depend on collaborations with third parties for the development and commercialization of some of our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

We may enter into third-party collaborations for the development and commercialization of ivonescimab. Additionally, we may seek third-party collaborators for development and commercialization of any other product candidates.

Our likely future collaborators for any marketing, distribution, development, licensing or broader collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. Under our license and commercialization agreements we have, and under any such arrangements we enter into with any third parties in the future, we will likely have, limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements.

Our current collaborations pose, and any future collaborations likely will pose, numerous risks to us, including without limitation the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and may not perform their obligations as expected;
- collaborators may de-emphasize or not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus, including as a result of a sale or disposition of a business unit or development function, or available funding, or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new or unsuccessful clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of our product relative to other products;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- disputes may arise between the collaborator and Summit as to the ownership of intellectual property arising during the collaboration;
- we may grant exclusive rights to our collaborators, which would prevent us from collaborating with others;

- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our products or product candidates or that result in costly litigation or arbitration that diverts management attention and resources; and
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated.

We rely on the use of third parties, including Akeso, to manufacture our product candidate, which may increase the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable time and cost, which could delay, prevent or impair our development or commercialization efforts.

We do not own or operate manufacturing facilities for the production of clinical or commercial supplies of our product candidates. We have limited personnel with experience in drug manufacturing and lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. We currently rely on third parties for supply of the active pharmaceutical ingredients ("API"), drug substance and drug product in our product candidates. Our strategy is to outsource all manufacturing of our product candidates and products to third parties.

We have supply agreements with Akeso for supply of ivonescimab for use in clinical trials as well as for commercial supply. We have agreements with third-party manufacturers for development, validation and manufacturing of ivonescimab to secure the long-term clinical or commercial supply of our product candidates. We are in the process of setting up agreements with third party manufacturers for the long-term clinical and commercial supply of ivonescimab. We may be unable to conclude agreements for commercial supply with third-party manufacturers, or may be unable to do so on acceptable terms. The third-party manufacturers may not successfully carry out their contractual duties or obligations, the occurrence of which could substantially increase our costs and limit our supply of such product candidates. The demand for third-party manufacturers' services is very high, and such manufacturers could be subject to market transactions including mergers, acquisitions and other market consolidation transactions that limit their ability to provide products and services to us thereby increasing the time and cost it could take us to manufacture our product.

Even if we are able to establish and maintain arrangements with third-party manufacturers, reliance on third-party manufacturers, including Akeso, entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible diversion of manufacturing capacity to other customers by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or non-renewal of the agreement by the third party at a time that is costly or inconvenient for us.

The manufacturing process for a product candidate is subject to FDA and other 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 requirements, such as cGMP. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the FDA and other foreign regulatory authorities. If our contract manufacturers are unable to maintain a compliance status acceptable to the FDA and other foreign regulatory authorities, our product candidates may not be approved. If our contract manufacturers 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 manufacturing facilities for the manufacture of components of any product candidates. Moreover, although we do not control the manufacturing process at our contract manufacturers and are completely dependent on them for compliance with current regulatory requirements, we are nonetheless responsible for ensuring that any product candidates are manufactured in accordance with applicable laws and 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 supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to enter into an agreement with another third party, which we may not be able to do on reasonable terms, if at all.

Third-party manufacturers, including Akeso, may not be able to comply with cGMP, regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, including Akeso, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays,

suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates.

Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

In addition, in order to conduct late-stage clinical trials of our product candidates, we will need to have them manufactured in large quantities. Our third-party manufacturers, including Akeso, may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all.

Moreover, if our third-party manufacturers, including Akeso, are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or infeasible, and regulatory approval or commercial launch of that product candidate may be delayed or not obtained, which could significantly harm our business.

If the third parties, including Akeso, that we engage to manufacture product for our preclinical tests and clinical trials should cease to continue to do so for any reason, including due to the coronavirus or another outbreak, we likely would experience delays in advancing these clinical trials while we identify and qualify replacement suppliers, and we may be unable to obtain replacement supplies on terms that are favorable to us. In addition, if we are not able to obtain adequate supplies of our product candidates or the drug substances used to manufacture them, it will be more difficult for us to develop our product candidates and compete effectively.

Large pharmaceutical companies with greater resources, either through acquisitions, market consolidation or otherwise, may be able to obtain privileged access to manufacturing capacity and supply of material needed for the manufacture of ivonescimab or other similar competing drugs. If our competitors are able to use their resources to secure preferential access to the supply capacity of third party manufacturers, or if third party manufacturers elect to terminate their contracts with us in favor of exclusive contracts with other larger pharmaceutical companies, our ability to obtain a supply of ivonescimab or any other future product candidates may be impacted resulting in significant delays and higher costs for development and commercialization of our products. We may not be able to complete our clinical trials or market our products at scale without stable partnerships with third party manufacturers who produce ivonescimab or other drug compounds necessary for our product candidates. Shifting manufacturing relationship to another third-party manufacturer takes significant time and resources, and could delay development and commercialization of our product.

We rely on third parties to conduct our clinical trials and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such clinical trials.

We do not independently conduct clinical trials for our product candidates. We rely on third parties, such as contract research organizations, clinical data management organizations, medical institutions and clinical investigators, to perform this function. Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it would delay our product development activities.

Our reliance on these third parties for clinical development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the clinical trial. Moreover, the FDA requires us to comply with standards, commonly referred to as GCP, for conducting, recording and reporting the results of clinical trials to ensure that data and reported results are credible and accurate and that the rights, integrity of data and confidentiality of clinical trial participants are protected. The EMA and PDMA impose similar requirements on us for products that are the subject of clinical trials in the E.U., including the U.K., and Japan.

Furthermore, third parties that we rely on for our clinical development activities may also have relationships with other entities, some of which may be our competitors. If 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, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. Our product development costs will increase if we experience delays in testing or obtaining marketing approvals.

We also rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

If we are not able to establish additional collaborations, we may have to alter our development and commercialization plans.

Our product development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. For some of our product candidates, we may decide to collaborate further with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge; and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under future license agreements from entering into agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators and changes to the strategies of the combined company.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Legal, Tax, Regulatory, and Compliance Risks

Even if we are able to commercialize a product candidate, it may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which could harm our business.

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

Our ability to commercialize ivonescimab or any other product candidate successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Significant uncertainty exists as to the coverage and reimbursement status of any of our products for which we obtain regulatory approval. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. In the United States, although private third-party payors tend to follow Medicare practices, no uniform or consistent policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor as well as from state to state. Consequently, the coverage determination process is often a time-consuming and costly process that must be played out across many jurisdictions and different entities and that will require us to provide scientific, clinical and health

economics support for the use of our products compared to current alternatives and do so to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained and in what time frame.

We cannot be sure that coverage and reimbursement will be available for ivonescimab or any other product that we commercialize and, if coverage and reimbursement are available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. In addition, third-party payors are likely to impose strict requirements for reimbursement of a higher priced drug. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the applicable regulatory authority. Moreover, eligibility for coverage and reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including, but not limited to, research, development, intellectual property, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs, and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain and maintain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

In addition, third-party payors, whether domestic or foreign, governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to healthcare systems that could impact our ability to sell our product candidates, if approved, profitably. There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of, and containing or lowering the cost of, healthcare. The implementation of cost containment measures that third-party payors and healthcare providers are instituting and any other healthcare reforms may prevent us from being able to generate, or may reduce, our revenues from the sale of our product candidates, if approved, and our product candidates may not be profitable. Such reforms could have an adverse effect on anticipated revenue from product candidates for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

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

In some countries, particularly the E.U. Member States, 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 marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various E.U. Member States and parallel distribution, or arbitrage between low-priced and high-priced E.U. Member States, can further reduce prices. In some countries, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidate to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

Our business is subject to the risks associated with doing business in China.

As a result of our reliance on Akeso, located in China, our results of operations, financial condition, and prospects are subject to a significant degree to economic, political, and legal developments in China including government control over capital investments or changes in tax regulations that are applicable to us. China's economy differs from the economies of most developed countries in many respects, including with respect to the amount of government involvement, level of development, growth rate and control of foreign exchange, and allocation of resources. Since we rely on an entity located in China, our business is subject to the risks associated with doing business in China, including:

- adverse political and economic conditions, particularly those potentially negatively affecting the trade relationship between the United States and China;
- trade protection measures, such as tariff increases, and import and export licensing and control requirements;
- potentially negative consequences from changes in tax laws;
- difficulties associated with the Chinese legal system, including increased costs and uncertainties associated with enforcing contractual obligations in China;
- historically lower protection of intellectual property rights;
- requirements relating to China's data security rules and regulations;
- requirements relating to China personal information protection laws;
- changes and volatility in currency exchange rates;
- unexpected or unfavorable changes in regulatory requirements;
- changes in U.S. law regarding data security and providing sensitive personal data to China; and
- difficulties in managing foreign relationships and operations generally.

We are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the U.S. or Chinese governments, political unrest or unstable economic conditions in China. New legislation, regulations or court decisions may impede, delay, limit, or increase the cost of manufacturing our therapeutic candidates. Such events could result in our clinical or commercial supply of drug being interrupted or limited, which could harm our business.

U.S.-China trade relations may adversely impact our supply chain operations and business.

The U.S. and Chinese governments have taken certain actions that change trade policies, including tariffs and threats of additional tariffs that affect certain products which are manufactured in China and mutual exchange of certain types of data. Due to our collaboration with Akeso, we are reliant on collaborating with a company with significant operations in China. We do not know whether and to what extent the Trump administration will in the future implement or alter any tariffs, laws or regulations that may increase the cost or feasibility of importing and exporting products, components and information from China to the United States and vice versa. Further, the effect of any such new tariffs or actions on our industry or customers, and whether they may be subject to any exceptions, is unknown and difficult to predict. As additional tariffs, legislation or regulations are implemented, or if existing trade agreements are renegotiated, or if China or other affected countries take retaliatory trade actions, such changes could have a material adverse effect on our clinical development plans, business, financial condition, results of operations or cash flows.

In addition, certain Chinese biotechnology companies may become subject to trade restrictions, sanctions, other regulatory requirements, or proposed legislation by the U.S. government, which could restrict or even prohibit our ability to work with such entities, thereby potentially disrupting the supply of material to us. For example, the BIOSECURE Act, which was recently signed into law in December 2025, prohibits U.S. federal agencies from entering into or renewing any contract with any entity that uses biotechnology equipment or services produced or provided by a "biotechnology company of concern" to perform that contract as well as authorizes the U.S. government to name additional Chinese "biotechnology companies of concern." While prior versions of the BIOSECURE Act explicitly named "biotechnology companies of concern," the revised version defines a "biotechnology company of concern" as an entity that is identified on the annual 1260H List of Chinese military companies (the "1260H List") issued by the U.S. Department of Defense, any entity designated by the U.S. Government as such, and certain affiliates of the foregoing. If this law, or similar laws that may be enacted, impact Chinese biotechnology manufacturing companies that are or may become contractors or subcontractors of ours or provide biotechnology equipment or services in the manufacture of our products or products candidates, we may be restricted in our ability to work with such Chinese biotechnology manufacturing companies to the extent we would contract with, or otherwise receive funding from, the U.S. government, or work with sites or institutions that may receive funding from the U.S. government. As a result, we may need to seek alternative contract manufacturer relationships. While we believe we will be able to identify and contract with such alternative contract manufacturers, we cannot predict the terms of any such alternative arrangement nor what actions may ultimately be taken with respect to trade relations between the United States and China or other countries, what products and services may be subject to such actions or what actions may be taken by China or the other countries in retaliation.

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

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- reduced resources of our management to pursue our business strategy;
- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to clinical trial participants or patients;
- loss of revenue;
- increased insurance costs; and
- the inability to commercialize any products that we may develop.

The insurance policies covering our clinical trials are subject to a per claim deductible. The amount of insurance that we currently hold may not be adequate to cover all liabilities that we may incur. We will need to increase our insurance coverage when and if we begin commercializing ivonescimab or any other product candidate that receives marketing approval. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes.

Our operations currently, and may in the future, involve the use of hazardous and flammable materials, including chemicals and medical and biological materials, and produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and wastes, we cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials or disposal of hazardous wastes, we could be held liable for any resulting damages, and any liability could exceed our resources.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Recent and potential future changes to U.S. and non-U.S. tax laws or the interpretation thereof or the imposition of new or increased taxes or fees could increase our future tax liabilities and adversely affect our operating results and cash flows.

Changes to tax laws in the US, UK, and other countries, as well as new or increased taxes or fees, could raise our future tax liabilities and negatively impact our operating results and cash flows. Recent US tax reforms, such as the IRA and the One Big Beautiful Bill Act ("OBBBA"), have introduced significant changes to corporate taxation, including new rules for interest deductions, research and development expenses, and stock repurchases. The OBBBA, signed into law on July 4, 2025, has multiple effective dates, with certain provisions effective in 2025 and others implemented through 2027. In the UK, updates to the research and development tax regime may reduce the cash benefits we receive, especially for spending outside the UK, and further changes are expected as the government considers merging existing research and development schemes. The interpretation and implementation of these laws may change, and any new legislation or guidance could affect our tax rates, increase compliance costs, and have an adverse effect on our financial position.

Our future tax liabilities may be greater than expected if our net operating loss carryforwards and other tax attributes are limited or tax authorities challenge our tax positions.

Our ability to utilize net operating loss (NOL) carryovers and other tax attributes to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income, which cannot be ensured. In addition, our ability to use NOL carryforwards and other tax attributes may be subject to significant limitations under Sections 382 and 383 of the Code. Under those sections of the Code, if a corporation undergoes an "ownership change" (as defined in Section 382 of the Code), the corporation's ability to use its pre-change NOL carryforwards and other tax attributes may be substantially limited. An ownership change generally occurs if one or more stockholders (or groups of stockholders) who are each deemed to own at least 5% of such corporation's stock change their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. In the event that we were to

undergo an ownership change, utilization of our NOL carryforwards and other tax attributes would be subject to an annual limitation under Section 382 of the Code and Section 383 of the Code (as applicable), determined by multiplying the value of our stock at the time of the ownership change by the applicable long-term tax-exempt rate in effect during the month in which the ownership change occurs, subject to certain adjustments, which could result in a portion of our tax attributes expiring prior to their utilization. Any unused annual limitation may be carried over to later years. Any limitation on our ability to utilize our NOL carryforwards or other tax attributes against income or gain we generate in the future could increase our future tax liabilities and adversely affect our operating results and cash flows.

Furthermore, we are subject to various complex and evolving U.S. federal, state, local and non-U.S. tax laws. U.S. federal, state, local and non-U.S. tax laws, policies, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us, in each case, possibly with retroactive effect. Any significant variance in our interpretation of current tax laws, including as result of the release of final Treasury Regulations or other interpretive guidance implementing, or a successful challenge of one or more of our tax positions by the IRS or other state, local or non-U.S. tax authorities could increase our future tax liabilities and adversely affect our operating results and cash flows.

Laws and regulations affecting government contracts make it more costly and difficult for us to successfully conduct our business. Failure to comply with these laws and regulations could result in significant civil and criminal penalties and adversely affect our business.

We must comply during the term of such government contracts and upon expiration/termination of such contracts, as to continuing obligations, with numerous laws and regulations. These laws, regulations and obligations include, for example, the Federal Acquisition Regulation, compliance regulations, business ethics and public integrity obligations, export and import laws and regulations, etc. Additionally, government agencies routinely audit and investigate government contractors for compliance with the applicable laws and standards. If an audit uncovers improper or illegal activities, we may be subject to civil and criminal penalties including fines, debarment and exclusion from government funding and administrative sanctions, such as long-term monitoring arrangements and exclusion from regulatory approvals. In addition, we could suffer serious reputational harm if allegations of impropriety were made against us, which could jeopardize our other research programs, deter research institutions from engaging with us, and cause our stock price to decrease.

The marketing approval process is expensive, time-consuming and uncertain, and may prevent us from obtaining approvals for the commercialization of some or all of our product candidates. If we are unsuccessful or delayed in obtaining required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.

Our product candidates, including ivonescimab, and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us or our collaborators from commercializing the product candidate.

We have only limited experience in filing and supporting the applications necessary to obtain marketing approvals for product candidates and expect to rely on third-party contract research organizations to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Regulatory authorities may determine that ivonescimab or any of our other product candidates are not effective or only moderately effective, or have undesirable or unintended side effects, toxicities, safety profiles or other characteristics that preclude us from obtaining marketing approval or that prevent or limit commercial use.

The process of obtaining marketing approvals is expensive, may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. If we experience delays in

obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

We also are required to register ongoing clinical trials and post the results of completed clinical trials on a U.S. government-sponsored database, www.ClinicalTrials.gov, within certain timeframes. Failure to comply would violate federal requirements and could result in fines and/or civil and criminal sanctions, which would delay the regulatory approval process and result in adverse publicity.

Our failure to obtain marketing approval in a jurisdiction would prevent our product candidates from being marketed in such jurisdiction, and any approval we are granted for our product candidates in one jurisdiction would not ensure approval of our product candidates in any other jurisdictions.

In order to market and sell ivonescimab and our other product candidates in foreign jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements in those jurisdictions. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ from that required to obtain FDA or EMA/EC approval. The regulatory approval process outside the United States and Europe generally includes all of the risks associated with obtaining FDA and EMA/EC approval. In addition, some countries outside the United States and Europe require approval of the sales price of a drug before it can be marketed. In many countries, separate procedures must be followed to obtain reimbursement. We may not obtain marketing, pricing or reimbursement approvals outside the United States and Europe on a timely basis, if at all. Approval by the FDA or the EMA/EC does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States and Europe does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA or the EMA/EC. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market. Marketing approvals in countries outside the United States and Europe do not ensure pricing approvals in those countries or in any other countries, and marketing approvals and pricing approvals do not ensure that reimbursement will be obtained.

Our ability to obtain and maintain conditional marketing authorizations in the E.U. is limited to specific circumstances and subject to several conditions and obligations. A failure to renew any conditional approval that we obtain prior to full approval for the applicable indication would prevent us from continuing to market our products.

Conditional marketing authorizations based on incomplete clinical data may be granted for a limited number of listed medicinal products for human use, including products designated as orphan medicinal products under E.U. law, if (1) the risk-benefit balance of the product is positive, (2) it is likely that the applicant will be in a position to provide the required comprehensive clinical trial data, (3) unmet medical needs will be fulfilled and (4) the benefit to public health of the immediate availability on the market of the medicinal product outweighs the risk inherent in the fact that additional data are still required. Specific obligations, including with respect to the completion of ongoing or new studies, and with respect to the collection of pharmacovigilance data, may be specified in the conditional marketing authorization. Conditional marketing authorizations are valid for one year and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions. Even if we, or a third-party collaborator, obtain conditional approval for ivonescimab, or any other product candidate, we or they may not be able to renew such conditional approval.

Even if we obtain marketing approvals for our product candidates, the terms of approvals and ongoing regulation of our products may limit how we manufacture and market our products and compliance with such requirements may involve substantial resources, which could materially impair our ability to generate revenue.

Even if marketing approval of a product candidate is granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation, including the potential requirement to implement a risk evaluation and mitigation strategy or to conduct costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. We and our collaborators must also comply with requirements concerning advertising and promotion for any of our product candidates for which we obtain marketing approval. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, neither we nor our collaborators will be able to promote any products we develop for indications or uses for which they are not approved. In addition, manufacturers of approved products and those manufacturers' facilities are required to ensure that quality control and manufacturing procedures conform to cGMP, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We and our contract manufacturers could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMP.

Accordingly, assuming we receive marketing approval for one or more of our product candidates, we and our contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we are not able to comply with post-approval regulatory requirements, we could have the marketing approvals for our products withdrawn by regulatory authorities and our ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Thus, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

Any product candidate for which we obtain marketing approval will be subject to strict enforcement of post-marketing requirements and we could be subject to substantial penalties, including withdrawal of our product from the market, if we fail to comply with all regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include, but are not limited to, restrictions governing promotion of an approved product, submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping.

The FDA and other federal and state agencies, including the DOJ, closely regulate compliance with all requirements governing prescription drug products, including requirements pertaining to marketing and promotion of drugs in accordance with the provisions of the approved labeling and manufacturing of products in accordance with cGMP requirements. The FDA and DOJ impose stringent restrictions on manufacturers' communications regarding off-label use, and if we market our products for unapproved indications, we may be subject to enforcement action for off-label marketing. Violations of such requirements may lead to investigations alleging violations of the Food, Drug and Cosmetic Act and other statutes, including the False Claims Act and other federal and state health care fraud and abuse laws as well as state consumer protection laws. Our failure to comply with all regulatory requirements, and later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, may yield various results, including:

- litigation involving patients taking our products;
- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- holds on clinical trials;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or revocation of marketing approvals;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Non-compliance by us or any future collaborator with regulatory requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with regulatory requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

Non-compliance with E.U. requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with the E.U.'s requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

Our relationships with customers, healthcare providers and professionals and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of any product candidates, including ivonescimab, for which we obtain marketing approval. Our future arrangements with customers, healthcare providers and professionals and third-party payors may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include, and are not limited to, the following:

- The federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federally funded healthcare programs such as Medicare and Medicaid. This statute has been broadly interpreted to apply to manufacturer arrangements with prescribers, purchasers and formulary managers, among others. Several other countries, including the U.K., have enacted similar anti-kickback, fraud and abuse, and healthcare laws and regulations.
- The federal False Claims Act imposes civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, claims for payment of government funds that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. The government and qui tam relators have brought False Claims Act actions against pharmaceutical companies on the theory that their practices have caused false claims to be submitted to the government. There is also a separate false claims provision imposing criminal penalties.
- HIPAA, as amended by the HITECH, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.
- HIPAA also imposes criminal liability for 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.
- The federal Physician Sunshine Act requirements under the ACA require manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to payments and other transfers of value made to or at the request of covered recipients, such as physicians and teaching hospitals, and physician ownership and investment interests in such manufacturers. Payments made to physicians and research institutions for clinical trials are included within the ambit of this law. Failure to submit timely, accurate and required information for all payments, transfers of value and ownership or investment interests may result in civil monetary penalties.
- Analogous state laws and regulations, such as state anti-kickback and false claims laws, 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 some state laws 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 physicians and other health care providers or marketing expenditures. Additionally, some state and local laws require the registration of pharmaceutical sales representatives in the jurisdiction.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. Exclusion, suspension and debarment from government funded healthcare programs would significantly impact our ability to commercialize, sell or distribute any drug. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Inadequate funding for or other disruptions to government agencies could hinder or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of reviewing regulatory agencies, including the FDA, to review and approve new products can be affected by a variety of factors, including government budget and funding levels, the ability to hire and retain key leadership and other personnel and the acceptance of user fees payments, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. If funding is inadequate, a prolonged government shutdown occurs, the FDA is required to furlough review staff or necessary employees, or if the agency operations are otherwise disrupted, it could significantly affect the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our ability to successfully develop and commercialize ivonescimab or any other product candidate in our pipeline. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Current and future legislation may increase the difficulty and cost to obtain marketing approval of and commercialize our product candidates and could affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been and continue to be a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability, or the ability of any future collaborators, to profitably sell any products for which we, or they, obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more limits on reimbursement and additional downward pressure on the price that we, or any future collaborators, may receive for any approved products.

We expect that recently enacted healthcare reforms, as well as 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 as well as impact reimbursement to stakeholders that administer any approved product we might bring to market. Any reductions in reimbursement may negatively impact physicians, hospitals and other provider's ability to purchase and appropriately prescribe our products. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

The costs of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. To date, there have been several U.S. congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products.

In the U.S., the ACA substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The ACA was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers, and impose additional health policy reforms. Since its passage, there have been significant ongoing efforts to modify or eliminate the ACA and potential future legislative, judicial or regulatory actions related to the ACA, and any effects on us, are uncertain.

Other legislative changes have been proposed and adopted since passage of the ACA. These have, among other things, reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers. For example, several healthcare reform initiatives culminated in the enactment of the IRA, which includes several provisions to lower prescription drug costs for Medicare patients and reduce drug spending by the federal government. Among other things, the IRA requires HHS to directly negotiate the selling price of a statutorily specified number of drugs and biologics each year that the U.S. Centers for Medicare and Medicaid Services ("CMS") reimburses under Medicare Part B and Part D. Negotiations will occur for high expenditure single-source biological products that have been on the market for 11 years (seven years for single-source drugs). Revised prices will take effect two years after these negotiations occur. For 2026, the first year in which negotiated prices become effective, CMS selected 10 high-cost Medicare Part D products in 2023, negotiations began in 2024, and the negotiated price for each product has been announced. In addition, CMS has selected and announced the negotiated price for 15 additional Medicare Part D drugs which will become effective in 2027. For 2028, an additional 15 drugs, which may be covered under either Medicare Part B or Part D, the negotiated price will be effective, and for 2029 and subsequent years, 20

Part B or D drug negotiated prices will be effective. The negotiated prices have represented, and will continue to represent, a significant discount from average prices to wholesalers and direct purchasers.

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, and in 2024, CMS finalized regulations for the Medicare Part B and Part D inflation rebates. 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.

The current administration is pursuing policies to reduce regulations and expenditures across government including at HHS, which include the FDA and CMS, and related agencies. For example, on May 12, 2025, President Trump issued an Executive Order that, among other things, required HHS, within 30 days, to establish and communicate to drug manufacturers MFN price targets designed to bring drug prices for American patients in line with those in comparably developed nations. If significant progress towards MFN pricing is not achieved, the Executive Order requires HHS to propose a rulemaking to implement MFN pricing. Recently, on December 23, 2025, CMS issued proposed regulations to establish, under the Center for Medicare and Medicaid Innovation, two mandatory MFN demonstration models under Medicare Parts B and D, respectively. If these rules or other MFN pricing rules are finalized, they are likely to reduce prices of at least some drugs in the United States, if they are also sold in comparator countries. Even if we do not market drugs in such countries, we will be indirectly affected if our drugs competed with drugs whose prices were reduced as a result of MFN pricing initiatives.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care 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. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Legislative and regulatory proposals have also been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us and any future collaborators to more stringent product labeling and post-marketing testing and other requirements.

In the E.U., similar political, economic and regulatory developments may affect our ability to profitably commercialize our products. In addition to continuing pressure on prices and cost containment measures, legislative developments at the E.U. or Member State level may result in significant additional requirements or obstacles that may increase our operating costs. An example of reform measures is the forthcoming EU pharmaceutical legislation revision, which intends to change – among other things – the regulatory data protection regime and the orphan designation regime. The final text of the reform proposal is expected to be endorsed and published in the first half of 2026 and, after a transition period, the new legislation is expected to start to apply from mid-2028.

We are subject to anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses, which could adversely affect our business, results of operations and financial condition.

Our operations are subject to anti-corruption laws, including the FCPA, the U.K. Bribery Act 2010 (the "Bribery Act"), and other anti-corruption laws that apply in countries where we do business and may do business in the future. The FCPA, Bribery Act and these other laws generally prohibit us, our officers, and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. We may in the future operate in jurisdictions that pose a high risk of potential FCPA or Bribery Act violations, and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the FCPA, Bribery Act or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the U.S. and the U.K., and authorities in the E.U., including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations (collectively, the "Trade Control laws").

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the FCPA, the Bribery Act or other legal requirements, including Trade Control laws. If we are not in compliance with the FCPA, the Bribery Act and other anti-corruption laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. Likewise, any investigation of any potential violations of the FCPA, the Bribery Act, other anti-corruption laws or Trade Control laws by U.S., U.K. or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition.

Environmental, social and governance ("ESG") matters may impact our business and reputation.

Governmental authorities, non-governmental organizations, customers, investors, external stakeholders and employees are increasingly aware of ESG concerns, such as climate change, water use, recyclability or recoverability of packaging, and plastic waste. The ESG landscape is uncertain and constantly evolving due to changes in executive action, legislation, regulations and court orders. ESG concerns may lead to new requirements that could result in increased costs associated with developing, manufacturing and distributing our products. Our ability to compete could also be affected by changing customer preferences and requirements or by failure to meet such customer expectations or demand. We risk negative stockholder reaction, including from proxy advisory services, as well as damage to our brand and reputation, if we do not act responsibly, or if we are perceived to not be acting responsibly in key ESG areas. If we do not meet the ESG expectations of government agencies, our investors, customers and other stakeholders, we could experience reduced demand for our products, loss of customers, and other negative impacts on our business and results of operations.

The Company's reputation or relationships with its stakeholders and other third parties could also be adversely impacted as a result of, among other things, (i) stakeholder or third-party perceptions of certain statements, if any, made by the Company, its employees, agents, any industry trade associations, or other third parties; or (ii) public pressure from investors or policy groups to change the Company's policies. Such statements or initiatives with respect to ESG matters are increasingly subject to heightened scrutiny from the public and governmental authorities, as well as other parties. Certain regulators, such as the SEC and various state agencies, as well as nongovernmental organizations and other private actors have filed lawsuits under various securities and consumer protection laws alleging that certain ESG statements, goals or standards were misleading, false or otherwise deceptive. Additionally, certain employment practices and social initiatives are the subject of scrutiny by both those calling for the continued advancement of such policies, as well as those who believe they should be curbed, including government actors, and the complex regulatory and legal frameworks applicable to such initiatives continue to evolve. We cannot be certain of the impact of such regulatory, legal and other developments on our business. More recent political developments could mean that we could face criticism from certain "anti-ESG" parties, including various governmental agencies, if we were to make environmental or social commitments or pursue certain environmental or social initiatives that are alleged to be inherently political or polarizing in nature and could subject the Company to pressure in the media or through other means, which could adversely affect our reputation, business, financial performance, market access and growth.

Risks Related to Our Intellectual Property, Cybersecurity and Data Privacy

If we are unable to obtain and maintain patent protection for our technology and product candidates, our competitors could develop and commercialize technology and drug products similar or identical to ours, and our ability to successfully commercialize our technology and drug product candidates may be impaired.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries for our proprietary technology and products. We seek to protect our proprietary position by filing patent applications in strategic jurisdictions, including the United States, Europe and other key markets. However, this process is inherently costly, time-consuming, and uncertain. We may not successfully identify patentable aspects of our research in a timely manner, potentially missing opportunities to secure meaningful protection. Additionally, challenges such as high costs, delays in prosecution, and changes in the law could compromise our ability to file and prosecute all necessary or desirable applications. These factors may limit the scope of protection we achieve, increasing our vulnerability to competition and undermining the commercial potential of our products.

Moreover, if we license technology or product candidates from third parties in the future, we may have limited control over the preparation, filing, prosecution, or enforcement of the associated patents, leaving us vulnerable to decisions that may not align

with our goals or interests. For example, under the License Agreement, patent prosecution and enforcement in the Licensed Territory are subject to consultation and cooperation with Akeso. Actions or statements during patent prosecution outside of the Licensed Territory could significantly influence the prosecution of any patent application within the Licensed Territory. Additionally, Akeso owned patents and patent applications, which are non-exclusively licensed to Summit under the License Agreement, are under the control of Akeso. Akeso's prosecution, enforcement, and licensing strategies with regard to their owned patents and patent applications may conflict with our objectives.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and is currently the focus of extensive litigation. This unpredictability makes the issuance, scope, validity, enforceability and commercial value of our patent rights highly uncertain. While we strive to secure patents that protect our technology and products, our pending and future patent applications may not yield issued patents that provide meaningful protection. Even when patents are granted, they may fail to effectively prevent competitors from developing and commercializing similar or identical technologies and products. Furthermore, ongoing changes in patent laws or their interpretation due to changing administrations, specifically in the United States and internationally, may diminish the value of our patents, restrict the scope of our patent protection, or complicate our enforcement efforts.

The laws of foreign countries may offer less robust protection for patent rights compared to those in the United States, potentially exposing us to heightened competition. For example, European patent law imposes stricter limitations on the patentability of methods of treatment for the human body when compared with U.S. law, which may leave aspects of our technology and products vulnerable in certain markets. Additionally, differences in national patent laws and enforcement mechanisms may make it more difficult to obtain and maintain comprehensive protection across all major markets. This patchwork of international protection may hinder our ability to prevent the entry of third parties into the market.

Assuming the other requirements for patentability are met, under current U.S. law, the first to file a patent application is generally entitled to the patent. This framework, implemented after March 16, 2013, replaced the previous "first to invent" system which granted rights to the original inventor regardless of the filing date. Unfortunately, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. This lack of clarity makes it difficult to ascertain whether we were the first to make the inventions claimed in our U.S. patents or pending U.S. patent applications. We face similar uncertainties when seeking patent protection outside of the United States, where filing dates are critical to determining patent rights.

Moreover, we may be subject to third-party pre-issuance submissions of prior art to the USPTO or become involved in opposition, derivation, reexamination, reissue, inter parties review, post grant review, interference proceedings or other patent office proceedings, court litigation or International Trade Commission proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. Adverse determinations in any of these proceedings could severely restrict or invalidate our patents, reducing their enforceability and allowing third parties to commercialize similar or identical technologies without compensation to us. Furthermore, when third-party patents are involved, such disputes may result in our inability to manufacture, market, or commercialize our products without infringing on third-party rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened or narrowed by operation of any of the foregoing, such an event could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Third parties may have filed patent applications or received patents and may obtain additional patents and proprietary rights that block or compete with our patents. Resolving intellectual property disputes, such as infringement claims, can be costly and time consuming. Such disputes may force us to design around third-party patents, incurring additional expenses, or seek licenses on terms that may not be commercially reasonable, favorable, or even obtainable. A successful claim of patent or other intellectual property infringement could result in substantial damages, disrupt our operations, or lead to an injunction preventing the manufacture, sale, or use of the affected product. We may choose not to file patents for certain intellectual property to maintain trade secrets or know-how, leaving a risk that third parties may subsequently patent those innovations. Even if our patent applications issue as patents, they may not issue in a form that would provide us with adequate protection against competition. Our competitors may circumvent our owned or licensed patents by developing similar, improved or alternative technologies or products in a non-infringing manner, eroding our competitive advantage.

In addition, other companies may attempt to circumvent any regulatory data protection or market exclusivity, such as orphan drug exclusivity in the United States, which we obtain under applicable legislation, which may require us to allocate significant resources to preventing such circumvention. These efforts can divert attention and financial resources away from other critical business activities, potentially slowing our overall progress. Legal and regulatory developments in the E.U. and elsewhere may also result in clinical trial data submitted as part of a marketing authorization application becoming publicly available. Such

developments could enable other companies to use our clinical trial data to assist in their own product development and to obtain marketing authorizations in the E.U. and in other jurisdictions. Loss of market exclusivity, particularly through the entry of generic or biosimilar competitors, could significantly reduce our revenue and market share. Such developments may also require us to allocate significant resources to prevent other companies from circumventing or violating our intellectual property rights. Despite our best efforts, our attempts to prevent third parties from circumventing our intellectual property and other rights may ultimately be unsuccessful. Additionally, any failure to take the required actions, such as paying necessary maintenance fees or addressing administrative formalities, could jeopardize the longevity and enforceability of our patents, further exposing us to risks of market erosion and reduced exclusivity.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. 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 technology and products, or limit the duration of the patent protection of our technology and products. Future changes in U.S. statutory or case law beyond our control could affect some or all of the foregoing possibilities. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. This could be the case even after giving effect to patent term extensions and data exclusivity provisions preventing third parties from relying on clinical trial data filed by us for regulatory approval in support of their own applications for such approval. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

Competitors may infringe our patents, trademarks, copyrights or other intellectual property rights. To counter infringement or unauthorized use, we may be required to initiate legal claims or enforcement actions, which can be expensive and time-consuming. Such actions are not always successful. Any claims we assert against perceived infringers may prompt these parties to assert counterclaims against us, alleging that we infringe their intellectual property or that our patent and other intellectual property rights are invalid or unenforceable, including counterclaims based on antitrust or other legal theories. In a patent infringement proceeding, a court or administrative body may decide that a patent of ours is invalid or unenforceable, in whole or in part, or may construe the patent's claims narrowly. Such rulings could allow the other party to continue using the disputed technology at issue on the grounds that our patents do not cover the competitor's activities or products. Antitrust considerations may also hinder our ability to settle such matters on favorable terms, as certain types of settlement agreements, particularly in the pharmaceutical sector, are subject to heightened scrutiny by antitrust authorities. In the E.U., for instance, antitrust regulators closely monitor settlement agreements for compliance with competition laws, adding another layer of complexity and potential risk to these proceedings.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies, including our in-licensed drug candidate ivonescimab, without infringing the intellectual property and other proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including interference, derivation, inter parties review, reexamination, reissue or post-grant review proceedings before the USPTO or similar proceedings in other jurisdictions. The risks of being involved in such disputes may increase as our product candidates approach commercialization, and as we gain greater visibility as a publicly traded company in the United States. Third parties may assert infringement claims against us based on their existing or future intellectual property rights, potentially restricting our freedom to operate or delaying our progress. Moreover, they may seek injunctive relief to bar us from practicing our technologies altogether while litigation against us is pending, potentially causing significant disruptions to our operations.

If we are found to infringe third party's intellectual property rights, or if we choose to settle a dispute to avoid prolonged litigation, we may be required to obtain a license to enable us to continue developing and marketing our products and technology. However, obtaining such licenses may be challenging or unattainable on commercially reasonable terms. Even if we were able to obtain a license, it could be non-exclusive, which would enable our competitors access to the same technologies and we may be required to pay substantial upfront or ongoing royalties. Absent a license, we could be forced, including by court order, to cease commercializing the infringing technology or product entirely. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, particularly if we are found to have willfully

infringed a patent or other intellectual property right. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties, or claims that we derived our inventions from another, could have a similar negative impact on our business.

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

Many of our employees were previously employed at universities, research institutions or other biotechnology or pharmaceutical companies, including competitors or potential competitors. Although we take measures to ensure that our employees do not use the proprietary or otherwise confidential information or know-how from former employers, we may be subject to claims that we or our employees have, without authorization, misappropriated intellectual property, trade secrets or other proprietary or confidential information. Litigation may be necessary to defend against these claims.

In addition, while we typically require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us and agreeing to cooperate and assist us with securing and defending our intellectual property, certain risks may arise. We may be unsuccessful in executing such an agreement from all relevant parties who develop intellectual property for us, and certain agreements may not be enforceable under applicable laws or may be subject to challenges from third parties. Furthermore, assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims third parties may bring against us, to determine the ownership of what we regard as our intellectual property.
If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

Intellectual property litigation could cause us to spend substantial resources and could distract our personnel from their normal responsibilities.

Even if we are successful in defending against intellectual property claims, litigation or related legal proceedings can still impose significant financial and operational burdens. These disputes often require us to allocate substantial resources, including legal fees and other expenses, which can strain our finances and reduce funds available for critical business functions like development, sales, and marketing. Moreover, these proceedings can pull key technical and management personnel away from their normal responsibilities, disrupting our operations and slowing our progress.

In addition, public announcements of the outcomes of hearings, motions or other interim proceedings or developments could have far reaching consequences. If securities analysts or investors interpret these developments negatively, it could have a substantial adverse effect on the price of our shares of common stock. Beyond the reputational impact, such litigation or proceedings could severely impact our business by diverting critical resources away from development, sales, marketing, and distribution efforts. Our ability to manage these legal challenges effectively may be constrained by limited financial and operational resources, especially when compared to competitors with deeper financial reserves who may weather such disputes more effectively. As a result, the cumulative costs, management distraction, and lingering uncertainties stemming from patent litigation or similar proceedings could substantially impair our ability to compete and succeed in the marketplace.

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

In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary and confidential information, to maintain our competitive position. To safeguard these trade secrets, we employ non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. However, despite these reasonable measures, we cannot guarantee that we have executed these agreements with each party that may have or have had access to our trade secrets or that the agreements we have executed will provide adequate protection. Even with these protections, any party with whom we have executed such an agreement may breach their obligations and disclose our proprietary or confidential information, including our trade secrets unlawfully. We may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. Additionally, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no legal recourse to prevent them from using this information to compete with us. If any of our trade secrets, particularly unpatented know-how, were to be obtained or independently developed by a competitor, our competitive position would be harmed.

We operate in the biotechnology sector and rely heavily on information technology. Any interruption, malfunction, or lapse related to that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.

We rely on both internal information technology systems and those of third parties to process and store sensitive data, including confidential research, business plans, financial information, intellectual property and personal data that may be subject to legal protection, and ensure the continuity of the Company's operations. As of the date of this Annual Report on Form 10-K, though the Company and our service providers have experienced certain cybersecurity incidents, we are not aware of any previous cybersecurity incidents that have materially affected or are reasonably likely to materially affect the Company. Any such cybersecurity incidents could result in a material compromise of our systems or the systems of our third-party vendors, and the information stored there could be accessed, publicly disclosed, lost, stolen, corrupted or rendered, permanently or temporarily, inaccessible. Furthermore, the Company or its service providers may not promptly discover a system intrusion. Cybersecurity incidents could have a material impact on our business, operations or financial results. Any access, disclosure or other loss of information, including Company data being compromised within the systems of our third-party providers, could result in legal claims or proceedings, liability under laws that protect the privacy of personal information or personal health information, disrupt our operations and damage our reputation, which could adversely affect our business. We also may need to make a material ransom payment to unencrypt, re-access, or preserve the confidentiality of our data or systems. We could be required to spend significant financial and other resources to respond to and remedy the damage caused by such an incident, including the costs to recover data or to repair or replace networks and information technology systems, increased cybersecurity protection costs and increased insurance premiums.

If our information technology systems or data, or those of third parties upon whom we rely or interact, are or were compromised, we could experience material adverse consequences resulting from such compromise.

In the ordinary course of our business, we and the third parties we rely on collect, receive, store, use, transfer, make accessible, dispose of, transmit, disclose or otherwise process proprietary, confidential and sensitive information, personal information, personal health information, participant-study-health-related data, proprietary information, intellectual property, and trade secrets (collectively, the "sensitive data"). In addition, we rely on service providers to establish and maintain appropriate information technology and data security protections to operate critical business systems (such as cloud-based infrastructure and systems, personnel email, as well as data storage and management systems). However, except for contractual protections, which may prove ineffective, we have limited ability to control the safeguards implemented and actions taken by such third parties. These service providers may not maintain adequate information security measures. We may share or receive sensitive data with or from third parties whose information security measures may not be adequate.

The risk of cybersecurity incidents may be heightened as a result of our some of our employees utilizing a remote working environment, which may be less secure and more susceptible to cybersecurity incidents. Additionally, the prevalent use of mobile devices that access our sensitive data increases the risk of data breaches. Advances in computer capabilities, discoveries in the field of artificial intelligence, cryptography, inadequate facility security or other developments may result in a compromise or breach of the technology we use to safeguard sensitive information.

Our information technology systems, including in our remote work environment, and those of parties upon which we rely, are vulnerable to evolving threats. These threats are prevalent, continue to increase and come from a variety of sources such as hackers; external or internal bad actors; personnel (such as through theft, error and misuse); sophisticated nation-states and nation-state-supported actors; and others. These threats include, but are not limited to, outages, social-engineering attacks, malicious code or intrusions, malware, denial-of-service attacks, personnel misconduct or errors, ransomware attacks, supply-chain attacks, software bugs, computer viruses, server malfunctions, software and hardware failures, misdirected wire transfers, theft or loss of data and other information technology assets, adware, natural disasters, terrorism, war, as well as telecommunication and electrical failures. In particular, ransomware attacks are becoming increasingly prevalent and severe and can lead to significant disruptions to operations, loss of data and income, reputational harm and diversion of funds. If we were to experience such an attack, ransom payments might alleviate some of the negative impacts of a ransomware attack but we might be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Any of these threats may result in unauthorized, unlawful or accidental loss, corruption, access, modification, destruction, alteration, acquisition or disclosure of sensitive data (including without limitation clinical trial data). The costs to us to attempt to protect against such cybersecurity incidents and breaches are significant and could potentially require us to modify our business (including without limitation non-clinical and clinical trial activities). While we have implemented security measures designed to protect our information technology systems and to identify and remediate potential vulnerabilities, such measures may not be successful. We may not be able to detect vulnerabilities in our information technology systems because such threats and techniques used by threat actors change frequently, are sophisticated in nature and may not be detected until after a security incident has occurred. In addition, we may not have adequate insurance coverage to remediate or provide compensation for any losses associated with such events.

If we or our third-party partners upon whom we rely experience or are perceived to have experienced a breach, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits and inspections), interruptions in our operations (including disruptions to our clinical trials), interruptions or restrictions on processing sensitive data (which could result in delays in obtaining, or our inability to obtain, regulatory approvals and significantly increase our costs to recover or reproduce the sensitive data), reputational harm, litigation (including class-action claims), indemnification obligations, monetary fund diversions, financial loss and other harms. In addition, such a breach may require notification of the breach to relevant stakeholders, certain state agencies or the media. Such disclosures are costly and the disclosure or the failure to comply with such requirements could lead to adverse consequences.

Many of our contracts with relevant stakeholders include obligations relating to safeguarding sensitive data and a breach or other cybersecurity incident could lead to claims against us by such stakeholders. There can be no assurance that the limitations of liability or other protections in our contracts would be enforceable or adequate or would otherwise protect us from liabilities, damages or claims relating to our data privacy and security obligations.

In addition, failure to maintain effective internal accounting controls related to data security breaches and cybersecurity in general could impact our ability to produce timely and accurate financial statements and could subject us to regulatory and private party scrutiny.

We are subject to stringent and changing obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to material adverse consequences.

In the ordinary course of business, we process personal data and other sensitive data (including proprietary and confidential business information, trade secrets, intellectual property, clinical trial data, and other sensitive third-party data). We are subject to or affected by numerous data privacy and security obligations such as various federal, state, local and foreign laws, regulations, and guidance; industry standards; external and internal privacy and security notices and policies; contracts; and other obligations governing the processing of personal data by us and on our behalf. These obligations may change, are subject to differing interpretations and may be inconsistent across jurisdictions. The global data protection landscape is rapidly evolving and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. This evolution may create uncertainty in our business, affect us or our collaborators', service providers' and others' ability to operate in certain jurisdictions or to collect, store, transfer (including across jurisdictional borders), use, share, and otherwise process personal data, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these obligations is high and is likely to increase in the future. These obligations may necessitate changes to our information technologies, systems and practices and to those of any service providers that process personal data on our behalf. In addition, these obligations may require us to change our business plans.

An increasing number of laws, regulations and industry standards apply to data privacy and security. For example, the E.U.'s GDPR, imposes strict requirements on the processing of personal data. Under the E.U. GDPR, government regulators may impose temporary or definitive bans on personal data processing as well as fines of up to 20 million Euros or 4% of the annual global revenues of the noncompliant company, whichever is greater. Additionally, the Personal Information Protection Law ("PIPL") of the People's Republic of China may apply to certain personal data processed by us, our collaborators or others on our behalf. Similar to the E.U. GDPR, PIPL imposes strict requirements on the processing of personal data and allows for statutory fines and penalties.

Certain jurisdictions, including the U.K., E.U., and China have enacted data localization laws and cross-border personal data transfer laws which make it more difficult to transfer information across jurisdictions (such as transferring or receiving personal data that originates in the U.K. or in other foreign jurisdictions). Existing mechanisms that facilitate cross-border personal data transfers may change or be invalidated. The processing of sensitive personal data, such as physical health conditions, is a topic of active interest among regulators. As we expand into countries and jurisdictions outside the U.S., we will be subject to additional laws and regulations that may affect how we conduct business in relation to the personal data or personal health information we or our third-party partners process. For example, in relation to cross-border personal data laws, if we cannot maintain a valid compliance mechanism for cross-border personal data transfers, we may face increased exposure to regulatory actions, fines and injunctions against the transferring of personal data from the U.K., Europe, China and elsewhere. We may have to increase our personal data processing capabilities and infrastructure in foreign jurisdictions at significant expense.

Likewise, we expect that there will continue to be new laws, regulations and industry standards relating to data privacy and security in the U.S. For example, the California Consumer Privacy Act, as amended by the California Privacy Rights Act (the "CCPA"), imposes obligations on business to which it applies. These obligations include, but are not limited to, providing

specific disclosures in privacy notices and affording California residents certain rights related to their personal data. The CCPA allows for statutory fines for noncompliance (up to $7,500 per violation). While the CCPA contains limited exceptions for clinical trial data, the CCPA's implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. In addition, the CCPA establishes a new California Privacy Protection Agency to implement and enforce the CCPA which could increase the risk of an enforcement action. Other states (such as Colorado, Virginia, Delaware, Texas and others) have also enacted data privacy laws. If we become subject to new data privacy laws, the risk of enforcement actions or class-action litigation brought against us could increase because we may become subject to additional obligations and the number of individuals or entities that can initiate actions against us may increase (including individuals, via a private right of action, and state agencies).

Further, there are regulations related to data privacy and security that are specific to our industry. For example, the U.S. Department of Health and Human Services has issued rules governing the use, disclosure, and security of protected health information, and the FDA has issued further guidance concerning cybersecurity for medical devices. HIPAA, as amended by HITECH, and their respective implementing regulations impose significant obligations on covered entities and business associates to safeguard the privacy, security, and integrity of individually identifiable health information, also known as protected health information.

On April 8, 2025, the U.S. Department of Justice implemented a final rule carrying out Executive Order 14117, "Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons (the "Rule"), which places restrictions on certain bulk data transactions involving "Countries of Concern" (China, Hong Kong, Iran, Cuba, Russia, North Korea, and Venezuela) and covered individuals (i.e., individuals and entities located in or controlled by individuals or entities located in those jurisdictions). The Rule's restrictions could significantly impact some of our business activities, such as clinical related vendor engagements and collaborations and partnerships. If there is no lawful manner, including applicable exemptions under the Rule, for us to transfer sensitive personal information of U.S. persons to persons or entities located in Countries of Concern, we may face significant business disruptions, including needing to change our operations by re-locating portions of our business, personnel and/or data processing activities to other jurisdictions (such as the United States) and having to engage with vendors and partners located outside Countries of Concern.

Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail to do so or may be perceived to have failed to do so. Moreover, despite our efforts, we may not be successful in achieving compliance if our personnel or third parties we rely on fail to comply with such obligations, which could negatively impact our business operations and compliance posture. For example, any failure by a service provider to comply with applicable data privacy and security obligations could result in adverse effects, including inability to operate our business and proceedings against us by governmental entities or others. If we fail, or are perceived to have failed, to address or comply with data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions (e.g., investigations, fines, penalties, audits, inspections and similar activities); litigation (including class-related claims); additional reporting requirements and oversight; bans on processing personal data; orders to destroy or not use personal data; individual, media or agency notifications, including without limitation notice to the Department of Health and Human Services; and imprisonment of company officials. Any of these events could have a material adverse effect on our reputation, business or financial condition, including but not limited to: interruptions or stoppages in our business operations (including, as relevant, our clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to comply as well as to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations. Moreover, trial participants or research subjects as well as the providers who share their information with us, may contractually limit our ability to use and disclose the information, and we may face significant liability for failing to abide by such limitations.

Risks Related to Operations

Our future success depends on our ability to retain our Co-Chief Executive Officers, Chief Operating Officer and other key executives.

We are highly dependent on the principal members of our executive and scientific teams, including Mr. Robert W. Duggan and Dr. Mahkam Zanganeh, our Co-Chief Executive Officers, and Mr. Manmeet Soni, our Chief Operating Officer and Chief Financial Officer, all of whom are at-will employees. They may terminate their employment with us at any time. Mr. Duggan and Dr. Zanganeh have also been married since December 18, 2024. We do not maintain "key person" insurance on any of our executive officers. The unplanned loss of the services of any of these persons could materially impact the achievement of our research, development and commercialization objectives.

We or the third parties we rely on may be adversely affected by social unrest or terrorism.

Social instability, disruption, or widespread destruction in areas where we operate or in significant markets could have a negative impact on our business. Events, including war, terrorism, riot, civil insurrection or social unrest, regardless of cause, could result in material adverse effects on our ability to operate, the ability of our suppliers to operate, and macroeconomic conditions. Such negative impacts may adversely affect the Company's business, results of operations and financial condition.

We or the third parties we rely on may be adversely affected by natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

The changing nature, frequency, and severity of natural disasters and extreme weather events such as tornadoes, hurricanes flooding, extreme heat, and wildfires pose a risk to Company facilities, assets, and programs, as well as those of third parties on whom we rely. Natural disasters could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage, or other event occurred that prevented us, or a third party on whom we rely, from using offices or other facilities, or if a disaster damaged infrastructure critical to such offices or facilities, or if a disaster otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for extended periods period of time. In addition to operational impacts, natural disasters could significantly affect clinical trial participants, institutions, doctors, and supporting staff. For participants, a disruption in trial operations could delay access to investigational therapies, compromise ongoing treatment regimens, or create uncertainty about trial continuity. Institutions and medical personnel and staff could face logistical challenges, including damage to clinical trial sites, limited availability of resources, and interrupted communication channels. Key staff may be unable to perform their duties due to displacement, injury, or other disaster-related issues, leading to trial delays and operational challenges. Such disruptions may result in increased costs, delays in regulatory submissions, and reputational harm. Our existing disaster recovery and business continuity plans may not fully mitigate these risks, and unanticipated gaps in communication during emergencies may hinder our decision making and response efforts. We may incur substantial expenses to address and recover from such disruptions, which could further strain our financial and operational resources.

Widespread health concerns, pandemics or epidemics, and other outbreaks of illness may negatively affect the Company's ability to maintain operations and execute its business plan.

Widespread health concerns, pandemics, epidemics and other outbreaks of illness can have evolving and uncertain impacts on our business. As a result of any widespread health concern, pandemic, or other outbreaks of illness, including the COVID-19 pandemic, the Company has in the past and may experience disruptions that severely impact our business, commercialization, third party vendor operations, including foreign and domestic supply chains, or delays in clinical trial activities, including:

- delays or difficulties in initiating clinical trial sites;
- disruption to and delays in preclinical research and analysis activities due to an extended temporary closure of contract lab facilities;
- disruptions in supply, logistics or other activities related to the procurement of materials, which could have a negative impact on the Company's ability to conduct preclinical studies, initiate or complete clinical trials or commercialize product candidates;
- diversion of healthcare resources away from conducting clinical trials;
- interruption of key preclinical studies and clinical trial activities, due to limitations on travel imposed or recommended by federal, state, provincial or municipal governments, employers and others;
- limitations in resources that would otherwise be focused on the conduct of the Company's business or current or planned preclinical studies or clinical trials, including due to sickness, restrictions on travel, prolonged stay-at-home or shelter-in-place orders and other pandemic related concerns;
- slowed enrollment in and delayed execution of clinical trials due to hospital closures to clinical trials or patient hesitation to enroll in clinical trials;
- impact of infection of patients on the outcomes of clinical trials; and
- changes in regulations as part of a response to the future pandemic or epidemic may require the Company to change the ways in which the preclinical studies and clinical trials are conducted and incur unexpected costs, or requires the Company to discontinue our preclinical research or clinical trials altogether.

Our employees may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We may be exposed to the risk of employee fraud or other misconduct, including intentional failures to (i) comply with FDA or Office of Inspector General regulations or similar regulations of comparable non-U.S. regulatory authorities, (ii) provide

accurate information to the FDA or comparable non-U.S. regulatory authorities, (iii) comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable non-U.S. regulatory authorities, (iv) report financial information or data accurately or (v) disclose unauthorized activities to us. 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, or a request for the reimbursement of expenses that were not incurred. 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 be in compliance with such laws, standards 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 significant impact on our business and results of operations, including the imposition of significant fines and other sanctions.

Key personnel have been, and may continue to be, difficult to attract and retain.

Our ability to maintain and grow our business is directly related to the service of our employees in each area of our business, as we consider talent to be a key asset. Our performance is directly tied to our ability to hire, train, motivate and retain qualified personnel, including highly skilled technical, operational and program managerial, clinical, medical, analytical and legal or financial personnel. There is significant competition for personnel in the clinical sciences marketplace, particularly in certain geographies where we are located, including but not limited to the United States, where we plan to expand our physical presence, as well as Europe. Also, employees in our industry are increasingly able to work remotely, which could increase employee mobility and turnover, making it more difficult for us to attract and retain employees. In addition, many of our clinical development, operational and program management positions require deep technical expertise, and it can be particularly challenging to identify and attract candidates and retain employees possessing such expertise. We have experienced, and may continue to experience, attrition across the company. If we are unable to hire sufficient numbers of qualified employees or retain and motivate existing employees, our business and operating results would be harmed.

Additionally, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development, and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

Risks Related to Owning Our Common Stock

Our principal stockholder and Co-Chief Executive Officer maintains the ability to control or significantly influence all matters submitted to stockholders for approval.

As of December 31, 2025, Mr. Duggan beneficially owned, in the aggregate, shares of common stock representing over 70% of our outstanding capital stock. Mr. Duggan is able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, Mr. Duggan is able to control or influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire. As a member of the board of directors, Mr. Duggan will adhere to the corporate governance standards adopted by the company.

As a "controlled company" under the listing requirements of the Nasdaq Stock Market, we have an exemption from certain corporate governance requirements, which could adversely affect our stockholders by denying them certain rights and protections.

Mr. Duggan owns more than a majority of the voting power of our outstanding shares of common stock. Under the Nasdaq Stock Market listing requirements, a company of which more than 50% of the voting power is held by an individual, group, or another company is a "controlled company". We have in the past, and we expect in the future, to rely on the "controlled company" exemptions under the Nasdaq Stock Market listing requirements. For example, in the past, a majority of the members of our board of directors were not independent directors, and our compensation and nominating and corporate governance committees did not consist entirely of independent directors. Accordingly, during the period we remain a controlled company and during any transition period following a time when we are no longer a controlled company, you may not have the same protections afforded to stockholders of companies that are subject to all of the corporate governance requirements of the Nasdaq Stock Market.

The price of our shares of common stock have in the past, and may continue to be volatile and fluctuate substantially, which could result in substantial losses for our stockholders.

The market prices of our shares of common stock on the Nasdaq Global Market have in the past and may continue to be volatile and fluctuate substantially. The stock market in general and the market for smaller pharmaceutical and biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, stockholders may not be able to sell their shares of common stock at or above the price at which they were purchased.

The market price for our shares of common stock may be influenced by many factors, including:

- the success of competitive products or technologies;
- results of clinical trials of ivonescimab and any other product candidate that we develop;
- results of clinical trials of product candidates of our competitors;
- the acquisition activity and licensing and collaboration efforts of our competitors and large biopharmaceutical companies;
- changes or developments in laws or regulations applicable to ivonescimab and any other product candidates that we develop;
- our entry into, and the success of, any collaboration agreements with third parties;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates, products or technologies;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the biotechnology and pharmaceutical sectors;
- regulatory or legal developments in the United States and other countries;
- the societal and economic impact of public health epidemics and pandemics, and government efforts to slow their spread;
- general economic, industry and market conditions;
- the trading volume of the shares on the Nasdaq Global Market; and
- the other factors described in this “Risk Factors” section.

Additionally, the stock market historically has experienced significant price and volume fluctuations. These fluctuations are often unrelated to the operating performance of particular companies. These broad market fluctuations may cause declines in the trading price and market value of our common stock.

Substantial future sales of our shares of common stock in the public market, or the perception that these sales could occur, could cause the price of the shares to decline significantly, even if our business is doing well.

Sales of a substantial number of our shares of common stock in the public market could occur at any time. These sales, or the perception in the market that these sales could occur, could cause the market price of the shares to decline. Following the domestication, all of our outstanding shares of common stock were freely tradeable in the public market without restriction, unless held by our affiliates. Our principal stockholder and Co-Chief Executive Officer, Mr. Duggan, holds a substantial number of shares. Mr. Duggan’s shares have been registered for resale pursuant to an effective registration statement on Form S-3. If he sells, or indicates an intention to sell, substantial amounts of shares in the public market, the trading price of our shares could decline.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our shares of common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or Section 404, or any subsequent

testing by our independent registered public accounting firm, as and when required, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our shares of common stock.

We are required to disclose changes made in our internal controls and procedures on a quarterly basis, and our management is required to assess the effectiveness of these controls annually. Now that we have transitioned from a "non-accelerated filer" and "smaller reporting company" to a "large accelerated filer," our independent registered public accounting firm is required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. Pursuant to Section 404(a) of the Sarbanes-Oxley Act, we are required to furnish a report by our management on our internal controls over financial reporting. In order to comply with Section 404(a) of the Sarbanes-Oxley Act, we expect to incur additional expenses and devote increased management effort including documenting and evaluating our internal controls over financial reporting. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Our restated certificate of incorporation designates the Court of Chancery of the State of Delaware and the federal district courts of the U.S. as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers and employees.

Our restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware does not have jurisdiction, the federal district court for the District of Delaware) will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, employees or stockholders to our company or our stockholders;
- any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law ("DGCL") or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware; or
- any action asserting a claim arising pursuant to any provision of our certificate of incorporation or bylaws (in each case, as they may be amended from time to time) or governed by the internal affairs doctrine.

These choice of forum provisions will not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the U.S. shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any claims arising under the Securities Act. 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. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive forum provisions may limit the ability of our stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees. If a court were to find the either exclusive forum provision contained in our restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving such action in other jurisdictions, all of which could materially adversely affect our business, financial condition and operating results.

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

We have never declared or paid cash dividends on our shares of common stock. We currently intend to retain all of our future earnings to fund the development and expansion of our business. Any determination to pay dividends in the future will be at the discretion of our board of directors. As a result, capital appreciation of our shares of common stock, if any, will be the sole source of gain for our stockholders for the foreseeable future.

If equity research analysts stop publishing research or reports about our business or if they issue unfavorable commentary or downgrade our shares of common stock, the price of the shares could decline.

The trading market for our shares of common stock relies in part on the research and reports that equity research analysts publish about us and our business. We do not control these analysts. The price of our shares of common stock could decline if one or more equity research analysts downgrades such securities or if analysts issue other unfavorable commentary about us or our business. In addition, if one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause the trading prices and trading volumes of our shares of common stock to decline.

We are exposed to risks related to currency exchange rates.

We conduct a portion of our operations in the U.K and rely on third parties across the globe. Exchange rate fluctuations between local currencies and the U.S. dollar create risk in several ways, including the following: weakening of the U.S. dollar may increase the U.S. dollar cost of overseas research and development expenses and the cost of sourced product components outside the United Kingdom; strengthening of the U.S. dollar may decrease the value of our revenues denominated in other currencies; the exchange rates on non-dollar transactions and cash deposits can distort our financial results; and commercial pricing and profit margins are affected by currency fluctuations.

We have broad discretion in the use of our cash and cash equivalents and may not use them effectively.

Our management has broad discretion in the use of our cash and cash equivalents and could spend our cash in ways that do not improve our results of operations or enhance the value of our shares of common stock. If our management team were to fail to apply these funds effectively, such failure could result in financial losses that could have a material adverse effect on our business, cause the market price of our shares of common stock to decline and delay the development of our product candidates.

We may complete a future acquisition that may not achieve intended results or could increase the number of our outstanding shares or amount of outstanding debt or result in a change of control.

In addition to the License Agreement and the transactions contemplated thereby, we may pursue business development opportunities to expand or enhance our pipeline of drug candidates, including without limitation, through potential acquisitions of and/or collaborations with other entities. Any such transaction could happen at any time, could be material to our business and could take any number of forms, including, for example, an acquisition, merger or a collaboration with other entities.

Evaluating potential transactions and integrating completed ones may divert the attention of our management from ordinary operating matters. The success of these potential transactions will depend, in part, on our ability to realize the anticipated growth opportunities through the successful integration of the businesses we acquire with our existing business, as well as the success of the underlying business or intellectual property that we acquire or otherwise obtain rights to. Even if we are successful in integrating the acquired businesses, these integrations may not result in the realization of the full benefit of any anticipated growth opportunities or these benefits may not be realized within the expected time frames. In addition, acquired businesses may have unanticipated liabilities or contingencies.

If we complete an acquisition, investment or other strategic transaction, we may require additional financing that could result in an increase in the number of our outstanding shares or the aggregate amount of our debt.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

We have implemented a risk-based approach to identify and assess the cybersecurity threats that could affect our business and information systems. We use recognized commercially reasonable measures, tools and methodologies designed to manage cybersecurity risk that are tested on a regular cadence. We also monitor and evaluate our cybersecurity posture on an ongoing basis through regular vulnerability scans, penetration tests and third-party reviews. We rely on third-party service providers to provide the systems required to effectively run our clinical trials and endeavor to require third-party service providers that have access to personal, confidential or proprietary information to implement and maintain cybersecurity practices. Specific controls that are used in appropriate portions of our environment include endpoint threat detection and response, identity and access management, privileged access management, logging and monitoring involving the use of security information and event management, multi-factor authentication, firewalls and intrusion detection and prevention, and vulnerability and patch management. Our cybersecurity risk management processes are integrated into our enterprise risk management program.

To manage our material risks from cybersecurity threats and to protect against, detect, and prepare to respond to cybersecurity incidents, we endeavor to:

- Monitor emerging data protection laws and implement changes to our processes to comply;
- Conduct annual cybersecurity management and incident training for employees that process sensitive data;
- Conduct onboarding and cybersecurity training for all employees on an ongoing basis;
- Conduct regular phishing email simulations for all employees; and
- Carry cybersecurity risk insurance meant to provide protection against the potential losses arising from a cybersecurity incident.

In addition, we engage several third-party consultants in connection with our risk assessment and risk management, and we have established separate processes and procedures to oversee and identify cybersecurity risks associated with third parties. All third parties involved in our cybersecurity risk assessments and risk management are required to provide reports designed to allow us to monitor and assess such third parties' security controls.

Our incident response plan coordinates the activities that we and our third-party cybersecurity provider take to respond and recover from cybersecurity incidents, which include processes to triage, assess severity, investigate, escalate, contain, and remediate an incident, as well as to comply with legal obligations and attempt to mitigate brand and reputational damage. We have business continuity plans that we periodically review and update in line with our evolving applications architecture.

Our cybersecurity leadership team is responsible for assessing and managing cybersecurity risks and is made up of experienced professionals with an extensive background in information security, risk management, and incident response. This team is led by our Head of Information Technology. The Head of Information Technology is a senior technology strategist and thought leader with over two decades of experience in the bio pharma, life sciences, and high-tech sectors.

Our Board of Directors provides oversight to our cybersecurity efforts to ensure effective governance in assessing and managing risks associated with cybersecurity threats. Our Head of Information Technology provides periodic updates to senior management and quarterly updates to the Board of Directors regarding our cybersecurity program, including information about cyber risk management governance, status updates on various projects intended to enhance the overall cybersecurity posture of the Company, and information about the prevention, detection, mitigation and remediation of any cybersecurity incidents, as appropriate.

As of the date of this Annual Report on Form 10-K, we are not aware of any previous cybersecurity incidents that have materially affected or are reasonably likely to materially affect the Company. However, we acknowledge that cybersecurity threats are continually evolving, and the possibility of future cybersecurity incidents remains. Despite the implementation of our cybersecurity processes, our security measures cannot guarantee that a significant cyberattack will not occur. While we devote resources to security measures designed to protect our systems and information, these measures cannot provide absolute security. No security measure is infallible. A successful attack on our information technology systems or on the systems of our third-party vendors could have material consequences on our business. We describe whether and how risks from cybersecurity threats have or are reasonably likely to affect our financial position, results of operations and cash flows, under the heading

"Risks Related to Our Intellectual Property, Cybersecurity and Data Privacy" included as part of Part 1, Item 1A, Risk Factors of this Annual Report on Form 10-K, which disclosures are incorporated by reference herein.

Item 2. Properties

The following table provides information concerning Summit's principal leased facilities as of December 31, 2025:

We maintain the following leased properties:

Type/Uses	Location	Size	Lease Expiration
Headquarters	Miami, Florida	9,425 square feet	April 2029
Executive office	Palo Alto, CA	36,406 square feet	October 2033
Executive office	Princeton, NJ	8,857 square feet	August 2028
Executive office	Oxfordshire, United Kingdom	6,781 square feet	February 2027
Executive office	Menlo Park, California	11,523 square feet	May 2026

We believe our facilities are suitable and adequate to meet our needs.

Item 3. Legal Proceedings

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. Except as described below, we are not aware of any legal proceedings arising outside the ordinary course of business.

Litigation Relating to the December 2022 Notes Entered into in Connection with the License Agreement

On March 17, 2025, Rainaldi Revocable Trust, a purported stockholder of the Company, filed a derivative lawsuit in the Delaware Court of Chancery against certain of the Company's current and former directors and the Company, solely as a nominal defendant, concerning the December 2022 Notes entered into by the Company, Mr. Duggan and Dr. Zanganeh in connection with the License Agreement. The suit asserts claims for breach of fiduciary duty and unjust enrichment and seeks, among other things, unspecified damages, rescission of the shares that Mr. Duggan and Dr. Zanganeh received as part of prepaid interest payments under the December 2022 Notes, as well as attorneys' fees and costs.

Pursuant to the December 2022 Notes, the Company obtained $520 million in bridge financing through three unsecured promissory notes: (1) a $400 million note issued to Mr. Duggan due on February 15, 2023; (2) a $20 million note issued to Dr. Zanganeh due on February 15, 2023; and (3) a $100 million note issued to Mr. Duggan due on September 15, 2023 (the "$100 Million Note"). The notes had an interest rate of 7.5% through February 15, 2023, with prepaid interest through that date paid in shares valued at $0.7913 per share. For periods after February 15, 2023, interest would accrue at the U.S. prime interest rate plus 50 basis points for three months, and thereafter at the U.S. prime rate plus 300 basis points. The notes contained no warrant coverage and no security interests. The Company announced the 2023 Rights Offering on December 6, 2022, which ran from February 7 through March 1, 2023. The 2023 Rights Offering was fully subscribed, with stockholders purchasing 476,190,471 shares of the Company's common stock at $1.05 per share, raising $500 million in gross proceeds. Mr. Duggan and Dr. Zanganeh fully subscribed to their basic subscription rights, with Mr. Duggan participating by purchasing 376,489,880 shares for approximately $395.31 million. Following the Company's fully subscribed $500 million 2023 Rights Offering, Dr. Zanganeh's $20 million note was repaid on February 15, 2023, and Mr. Duggan's $400 million note was repaid. In the interest of minimizing stockholders dilution, the $100 Million Note was extended, and eventually the $75.5 million repayment was funded through the proceeds of the September 2024 Private Placement in which Mr. Duggan purchased 3,325,991 shares for an aggregate purchase price of $75.5 million as a participant in the September 2024 Private Placement at a purchase price of $22.70 per share, and the remaining $24.5 million was repaid in full on October 1, 2024, along with $7.3 million in accrued interest. Defendants' motion to dismiss the complaint was filed on May 16, 2025 (the "Motion to Dismiss"). Plaintiff filed a motion to certify certain constitutional questions to the Delaware Supreme Court on May 29, 2025 (the "Motion to Certify"). Defendants agreed to a stipulation staying briefing on the Motion to Certify and the Motion to Dismiss pending the Delaware Supreme Court's decision in another case involving substantially the same constitutional questions. On June 18, 2025, the Court granted such stipulation.

European Patent Opposition

On June 18, 2025, an unknown third party filed a notice of opposition against the Company's in-licensed EP3882275B1 patent (the "'275 patent") in the European Opposition Division of the European Patent Office ("EPO"). The '275 patent covers Ivonescimab. The notice primarily asserts that the '275 patent lacks inventive step. The Company contests these assertions and worked with its collaboration partner, Akeso, to timely file a response before the European Opposition Division of the EPO on January 2, 2026.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market Information

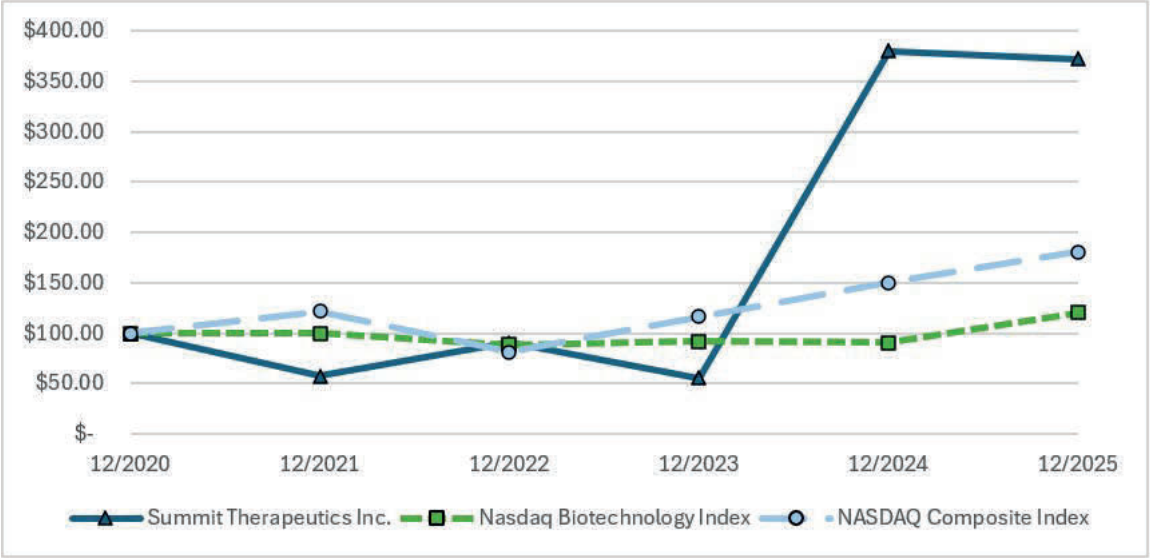
Our common stock has been publicly traded on the Nasdaq Global Market under the symbol "SMMT" since September 21, 2020.

Stock Performance Graph

The following performance graph shall not be deemed "soliciting material" or to be "filed" with the SEC for purposes of the Exchange Act or otherwise subject to the liabilities under that section and shall not be deemed to be incorporated by reference into any filing of Summit Therapeutics Inc. under the Securities Act or the Exchange Act.

The following graph illustrates a comparison for the five years ended December 31, 2025 of the cumulative total return for our common stock, the Nasdaq Biotechnology Index and the Nasdaq Composite Index each of which assumes an initial investment of $100. Such returns are based on historical results and are not intended to suggest future performance.

The comparison shown in the graph below are based upon historical data. We caution that the stock price performance shown in the graph below is not necessarily indicative of, nor is it intended to forecast, the potential future performance of our common stock.



Holders of Record

As of February 17, 2026, there were approximately 123 holders of record of our common stock, which number does not include stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividends

We have never declared or paid cash dividends on our common stock or ordinary shares. We currently intend to retain all available funds and any future earnings to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination to declare and pay dividends will be made at the discretion of our Board of Directors and will depend on then-existing conditions, including our results of operations, financial condition, contractual restrictions, capital requirements, business prospects, and other factors our Board of Directors may deem relevant.

Recent Sales of Unregistered Securities

There were no unregistered sales of equity securities sold during the period covered by this Annual Report on Form 10-K that were not previously included in a Quarterly Report on Form 10-Q or in a Current Report on Form 8-K.

Issuer Purchases of Equity Securities

Not applicable.

Item 6. [RESERVED]

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

The following discussion and analysis of our financial condition and results of operations is for the year ended December 31, 2025 compared with the year ended December 31, 2024. This comparison should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under "Risk Factors" included in Part I, Item 1A or in other parts of this Annual Report on Form 10-K. For a discussion and analysis of our financial condition and results of operations for the year ended December 31, 2024 compared to December 31, 2023, see Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in the 2024 Annual Report on Form 10-K, filed with the Securities and Exchange Commission on February 24, 2025.

The Management's Discussion and Analysis of Financial Condition and Results of Operations, or MD&A, describes principal factors affecting the results of our operations, financial condition and liquidity, as well as our critical accounting policies and estimates that require significant judgment and thus have the most significant potential impact on our Consolidated Financial Statements. This section provides an analysis of our financial results for the year ended December 31, 2025 compared to the same period in the prior year.

Company Overview

Summit Therapeutics Inc. ("we", "Summit" or the "Company") is a biopharmaceutical company focused on the discovery, development, and commercialization of patient-, physician-, caregiver- and societal-friendly medicinal therapies intended to improve quality of life, increase potential duration of life, and resolve serious unmet medical needs. The Company's pipeline of product candidates is designed with the goal to become the patient-friendly, new-era standard-of-care medicines, in the therapeutic area of oncology.

The Company's current lead development candidate is ivonescimab, a novel, potential first-in-class bispecific antibody intending to combine the effects of immunotherapy via a blockade of PD-1 with the anti-angiogenesis effects of an anti-VEGF compound into a single molecule. On December 5, 2022, the Company entered into the License Agreement with Akeso pursuant to which the Company has in-licensed intellectual property rights related to ivonescimab (as amended, the "License Agreement"). Through the License Agreement, the Company obtained the rights to develop and commercialize ivonescimab in the United States, Canada, Europe, and Japan. The License Agreement and transaction closed in January 2023 following customary waiting periods. On June 3, 2024, the Company entered into the Second Amendment with Akeso to expand its territories covered under the License Agreement to also include Latin America, including Mexico and all countries in Central America and South America, the Middle East and Africa. The Company's operations are focused on the development of ivonescimab and other future activities, as the Company determines.

The Company is developing ivonescimab in NSCLC and CRC, specifically conducting Phase III clinical trials in the following proposed indications:

(a) ivonescimab combined with chemotherapy in patients with EGFR-mutated, locally advanced or metastatic non-squamous NSCLC who were previously treated with a third-generation EGFR TKI ("HARMONi");

(b) ivonescimab combined with chemotherapy in patients with first-line metastatic NSCLC (including separate statistical analyses planned for patients with squamous NSCLC and non-squamous NSCLC) ("HARMONi-3");

(c) ivonescimab monotherapy in patients with first-line metastatic NSCLC whose tumors have high PD-L1 expression ("HARMONi-7"); and

(d) ivonescimab combined with chemotherapy in patients with first-line unresectable metastatic CRC ("HARMONi-GI3").

In October 2024, the Company completed enrollment in its HARMONi clinical trial. In May 2025, we announced topline results from our multiregional, double-blinded, placebo-controlled, Phase III study HARMONi. At the prespecified primary data analysis, ivonescimab in combination with chemotherapy demonstrated a statistically significant improvement in PFS, the magnitude of which we believe to be clinically meaningful, with a hazard ratio of 0.52 (95% CI: 0.41 – 0.66; p<0.00001) compared to placebo in combination with chemotherapy; median PFS was 6.8 months for those patients receiving ivonescimab plus chemotherapy compared to 4.4 months for those receiving chemotherapy. PFS was assessed by BICR.

We believe the PFS hazard ratio that was observed in both Asian and Western sub-populations to be clinically meaningful. The primary analysis demonstrated the consistency of the magnitude of the PFS benefit between patients randomized in Asian and Western territories, as well as the consistency in a single-region study (HARMONi-A) with this multiregional study.

In a longer-term follow-up of PFS, which included all Western patients and at least six months of follow-up time for all patients, ivonescimab plus chemotherapy demonstrated a consistent hazard ratio in PFS as the primary PFS analysis observed HR = 0.57; 95% CI: 0.46 – 0.71). With the longer-term follow-up analysis, consistency of the magnitude of PFS benefit was demonstrated between patients randomized in Asia and Western patients when measured by hazard ratio. This longer-term follow-up analysis of PFS was performed at the time of the primary OS analysis.

Ivonescimab in combination with chemotherapy showed a positive trend in OS in the primary analysis without achieving a statistically significant benefit with a hazard ratio of 0.79 (95% CI: 0.62 – 1.01; p=0.057). This trend provides further support for its use in EGFRm NSCLC post-TKI therapy, a setting where high unmet need continues to exist with limited approved options in the United States and other western territories. Currently there are no FDA-approved regimens that have demonstrated a statistically significant OS benefit in this patient setting. Both Asian and North American patients demonstrated a positive trend in OS. The results of the primary analysis in this multiregional study were consistent with that of the single-region randomized Phase III HARMONi-A study, which demonstrated a statistically significant OS benefit with a hazard ratio of 0.74 in the primary OS analysis in a similar patient population.

In September 2025, an additional ad hoc OS analysis was performed for the HARMONi study, whereby the Western patients were followed for a longer period of time (Asian patients were locked at the time of the primary analysis). In this analysis that included longer-term follow-up of Western patients (median follow-up time of Western patients of 13.7 months), a hazard ratio consistent with the primary analysis was observed with an improved nominal p-value (HR=0.78; 95% CI: 0.62 – 0.98; nominal p=0.0332). Median OS for this analysis remained the same in both arms as was observed in the primary analysis. Median OS in Western patients receiving ivonescimab was 17.0 months compared to 14.0 months for those receiving placebo (HR=0.84); median OS in North American patients, specifically, had not yet been reached in the ivonescimab arm compared to 14.0 months in the placebo arm (HR=0.70). The hazard ratios for Western patients in totality, as well as patients from the North American and European regions individually, improved from the primary OS analysis to the analysis with longer-term follow-up of Western patients. Consistent benefit was observed across pre-defined subgroups.

The dual primary endpoints were allocated separate alpha levels and tested individually. The alpha was recycled from the PFS to the OS analysis upon the successful achievement of the PFS endpoint.

Based on the results of the HARMONi clinical trial, we submitted a BLA in the fourth quarter of 2025 in order to seek approval for ivonescimab plus chemotherapy for this proposed indication. The positive results of the multiregional Phase III study are detailed further under "Product Pipeline" below. As previously disclosed, the FDA noted that a statistically significant OS benefit is necessary to support marketing authorization in this setting. After careful consideration of the safety and efficacy profile of the current FDA-approved options for patients in this setting, the positive results of the Phase III multiregional study, including regional consistency, as well as discussions with key opinion leaders and those physicians who have administered ivonescimab to patients in a clinical study setting, we believe that the safety and efficacy data generated in the HARMONi study demonstrates that the ivonescimab regimen offers a potential treatment option for patients impacted by EGFR-mutant NSCLC in this setting with a favorable benefit-risk profile despite the lack of a statistically significant OS benefit. Summit announced in January 2026 that the FDA accepted for filing the BLA seeking approval for ivonescimab in combination with chemotherapy for this proposed indication. The FDA noted it intends to perform a complete review of the accepted and filed BLA, including planned mid-cycle and wrap-up meetings, and, subject to major deficiencies not being identified during the FDA's review, proposed labeling, prior to the Prescription Drug User Fee Act goal action date of November 14, 2026.

Key Components of our Results of Operations

Research and Development Expenses

Research and development expenses consist of all costs associated with our research and development activities.

These include:

- costs incurred in conducting our preclinical studies and clinical trials through contract research and development organizations, including, but not limited to, preclinical toxicology, pharmacology, formulation and manufacturing work, as well as regulatory, operational, drug supply and treatment costs related to conducting the study;
- laboratory and vendor expenses incurred in relation to our preclinical, non-clinical and clinical studies;
- costs incurred in supply chain development and scale up activities to support product registration;
- employee related expenses, which include salary, benefits and stock-based compensation, for our research and development staff;
- costs incurred in development and conduct of training and education related our development candidates; and
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies.

We utilize our employee and infrastructure resources across multiple research projects. We track expenses related to our clinical programs and certain preclinical programs on a per project basis. We expect our research and development expenses to continue to be significant as we initiate our planned clinical trials of ivonescimab, and continue our activities to initiate preclinical programs for future product candidates. The timing and amount of these expenses will depend upon the outcome of our clinical trials and the associated costs. The timing and amount of these expenses will also depend on the costs associated with potential future clinical trials of our product candidates and the related expansion of our research and development organization, regulatory requirements, advancement of our preclinical programs and product candidate manufacturing costs.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and benefits related to our executive, finance, business development, human resources, legal and other support functions. Other general and administrative expenses include stock-based compensation expenses, market research costs, facility-related costs, consulting costs and expenses associated with the requirements of being a publicly traded company in the United States, including insurance, legal, audit and taxation services fees.

We anticipate that our general and administrative expenses will continue to increase in the future as we increase our headcount to support our planned clinical trials of ivonescimab, continued research and development and potential commercialization of our product candidates. We also anticipate continued accounting, audit, regulatory, compliance, insurance and investor and public relations expenses associated with being a publicly traded company in the United States.

Other Income, Net

Other income, net primarily consists of foreign currency net gains and losses and investment income related to investments in money market funds and U.S. treasury securities. All highly liquid investments with a maturity date of 90 days or less at the date of purchase are considered to be cash equivalents and the related investment income is recognized in net loss. The appropriate classification of investments in securities is determined by the Company at the time of purchase.

Interest Expense

Interest expense consists of cash and imputed interest expense incurred related to our promissory notes to related parties. Imputed interest is calculated as the difference between the expected interest payable and the deemed market rate of interest and is recorded as a debt discount at inception of the note payable with a credit to additional paid-in capital for notes payable to related parties. The debt discount is amortized to interest expense using an effective interest rate method.

Taxation

As a U.S. tax resident trading entity, we are subject to U.S. corporate taxation. Our U.K. resident trading subsidiaries are individually subject to U.K. corporate taxation. Due to the nature of our business, we have generated losses since inception. We

have recorded a full valuation allowance against the deferred tax assets with respect to these tax losses in excess of our deferred tax liabilities in each jurisdiction because we do not consider it more likely than not that there will be suitable taxable profits in the foreseeable future based on the evidence available against which to offset these losses.

Results of Operations

For a discussion and analysis of our financial condition and results of operations for the year ended December 31, 2024 compared to December 31, 2023, please refer to Item 7 of Part II, "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2024, which was filed with the SEC on February 24, 2025, and is available on the SEC's website at www.sec.gov and our Investor Relations website at www.smmttx.com/investor-information.

Amounts reported in millions within this Annual Report on Form 10-K are computed based on the amounts in thousands, and therefore, the sum of components may not equal the total amount reported in millions due to rounding.

Comparison of the Year Ended December 31, 2025 to the Year Ended December 31, 2024

	Year Ended December 31,		
(in millions)	2025	2024	$ Change
Operating expenses:			
Research and development	$ 537.7	$ 150.8	$ 386.9
Acquired in-process research and development	—	15.0	(15.0)
General and administrative	556.7	60.2	496.5
Total operating expenses	1,094.4	226.0	868.4
Other income, net	14.8	13.4	1.4
Interest expense	—	(8.7)	8.7
Net loss	$ 1,079.6	$ 221.3	$ 858.3

Research and Development Expenses

The table below summarizes our research and development expenses by category for the year ended December 31, 2025 and 2024, respectively.

	Year Ended December 31,		
(in millions)	2025	2024	$ Change
Oncology clinical trial related costs	$ 266.4	$ 100.9	$ 165.5
Acquired in-process research and development	—	15.0	(15.0)
Compensation related costs, excluding stock-based compensation	52.7	33.9	18.8
Stock-based compensation	218.6	16.0	202.6
Total	$ 537.7	$ 165.8	$ 371.9

The entry into the License Agreement represents a significant change in our strategy from anti-infectives to the therapeutic area of oncology. We invested our resources in the clinical development of ivonescimab in the periods presented.

Oncology clinical trial related costs represent our investment in the clinical development of ivonescimab, known as SMT112 in the Licensed Territory.

Research and development expenses increased by $371.9 million during the year ended December 31, 2025, compared to the same period in the prior year. This increase was in part due to the increase in stock-based compensation expense of $202.6 million for the year ended December 31, 2025, as a result of the modification to our performance-based stock option awards during the second quarter of 2025. In addition, our continued investment in oncology expenses for ivonescimab, known as SMT112 in our Licensed Territory, resulted in an increase of $165.5 million for the year ended December 31, 2025, primarily due to adding new clinical trials and expanding current clinical trials from last year. We expect oncology-related research and development costs to continue to increase as we progress with the development of ivonescimab.

In June 2024, we entered into a second amendment (the "Second Amendment") to the License Agreement with Akeso to expand the Licensed Territory to include Latin America, Middle East and Africa regions. Considered an extension of the original License Agreement, we agreed to make an upfront payment to Akeso in the amount of $15.0 million for these expanded territories which we paid in the third quarter of 2024. This was recorded in our consolidated statement of operations and comprehensive loss as acquired in process research and development expenses for the year ended December 31, 2024.

General and Administrative Expenses

The table below summarizes our general and administrative expenses by category for the year ended December 31, 2025 and 2024, respectively.

	Year Ended December 31,		
(in millions)	2025	2024	$ Change
Compensation related costs, excluding stock-based compensation	$ 22.9	$ 14.7	$ 8.2
Stock-based compensation	513.8	35.0	478.8
Legal fees and professional services	11.2	4.8	6.4
Other general and administrative expenses	8.8	5.7	3.1
Total	$ 556.7	$ 60.2	$ 496.5

General and administrative expenses increased by $496.5 million for the year ended December 31, 2025, compared to the same period in the prior year. The increase was primarily due to the increase in stock-based compensation expense of $478.8 million for the year ended December 31, 2025, as a result of the modification to our performance-based stock option awards during the second quarter of 2025. In addition, compensation related costs, excluding stock-based compensation, increased by $8.2 million, for the year ended December 31, 2025, compared to the same period in the prior year, as the Company is focused on building its executive management team and legal fees and professional services increased by $6.4 million for the year ended December 31, 2025, compared to the same period in the prior year to continue supporting the development of ivonescimab. We expect general and administrative expenses to continue to increase as we scale our infrastructure and management to support development of ivonescimab.

Other Income, Net

The table below summarizes our other income, net by category for the year ended December 31, 2025 and 2024, respectively.

	Year Ended December 31,		
(in millions)	2025	2024	$ Change
Foreign currency loss	$ (0.6)	$ (0.1)	$ (0.5)
Investment income	15.5	13.5	2.0
Other	(0.1)	—	(0.1)
Total	$ 14.8	$ 13.4	$ 1.4

Other income, net increased by $1.4 million for the year ended December 31, 2025, compared to the same period in the prior year, primarily due to an increase of $2.0 million in interest income due to the higher cash equivalents and short-term investments balance.

Interest Expense

Interest expense decreased for the year ending December 31, 2025 compared to the same period in the prior year, due to the repayment in full of the promissory note in October 2024.

Liquidity and Capital Resources

Sources of Liquidity

To date, we have financed our operations primarily through issuances of our common stock, including our most recent private placements issued in October 2025 and September 2024 for gross proceeds of $500.0 million and $235.0 million, respectively, and the raise of $150.7 million gross proceeds from our ATM Agreement since inception, issuance of debt, and receipt of payments to us under license and collaboration arrangements.

We have devoted substantially all of our efforts to research and development, including clinical trials. We have not completed the development of any drugs. We expect to continue to incur significant expenses and increasing operating losses for at least the next few years. The net losses we incur may fluctuate significantly from quarter to quarter and year to year, due to the nature and timing of our research and development activities. We expect that our research and development and general and administrative expenses will continue to be significant in connection with our ongoing research and development efforts. In addition, if we obtain marketing approval for any of our product candidates in the United States or other jurisdictions where we retain commercial rights, and if we choose to retain those rights, we would expect to incur significant sales, marketing, distribution and outsourced manufacturing expenses, as well as ongoing research and development expenses. In addition, our expenses will increase if and as we:

- invest in clinical development of ivonescimab in our Licensed Territory;
- conduct research and continue development of additional product candidates;
- maintain and augment our intellectual property portfolio and opportunistically acquire complimentary intellectual property;
- seek further regulatory advancement for ivonescimab;
- invest in our manufacturing capabilities for ivonescimab and any other products for which we may obtain regulatory approval;
- seek marketing approvals for any product candidates that successfully complete clinical development;
- ultimately establish a sales, marketing and distribution infrastructure in jurisdictions where we have retained commercialization rights and scale up external manufacturing capabilities to commercialize any product candidates for which we receive marketing approval;
- perform our obligations under our collaboration agreements;
- pursue business development opportunities, including investing in other businesses, products and technologies;
- experience any delays or encounter any issues with any of the above, including but not limited to failed studies, complex results, safety issues or other regulatory challenges;
- hire additional clinical, regulatory, scientific and administrative personnel;
- expand our physical presence;
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and
- borrow capital to fund our resources and have to pay interest expenses on such borrowings.

During the year ended December 31, 2025, we incurred a net loss of $1,079.6 million, and cash flows used in operating activities was $322.9 million. As of December 31, 2025 we had an accumulated deficit of $2,294.2 million, cash and cash equivalents and short-term investments of $713.4 million. We expect to continue to generate operating losses for the foreseeable future.

During the year ended December 31, 2025, the Company raised gross proceeds of $500,037 from a private placement and $106,498 from the Company's at-the-market sales agreement. With these recent financings, the Company has evaluated and concluded that its cash, cash equivalents and short-term investments provide sufficient cash to fund its operating cash needs for at least the next 12 months from the date of issuance of these consolidated financial statements.

From time to time, we may raise additional equity or debt capital through both registered offerings off of a shelf registration, including ATM offerings, and private offerings of securities. On February 20, 2024, we filed a shelf registration statement on Form S-3 with the SEC, which the SEC declared effective on February 27, 2024. Through our shelf registration statement we may, from time to time, sell up to an aggregate of $450.0 million of our common stock, preferred stock, debt securities, depository shares, warrants, subscription rights, purchase contracts, or units. Of the $450.0 million of liquidity available to us under this shelf registration statement, on May 13, 2024, we had established an ATM offering program with J.P. Morgan Securities LLC, as sales agent, in the amount of up to $90.0 million.

On August 11, 2025, we entered into an amendment (the "Amendment") to the distribution agreement, which amended that certain distribution agreement, dated May 13, 2024, by and between us and sales agent (the "Original Distribution Agreement" and, as amended by the Amendment, the "Distribution Agreement"). Pursuant to the Amendment, the Original Distribution Agreement was amended to, among other things, increase the aggregate offering price of shares of the Company's common stock, par value $0.01 per share, from time to time, through the sales agent, by up to an additional $360.0 million. The remaining gross proceeds available under the Distribution Agreement as of December 31, 2025 was approximately $299.3 million.

In addition to the payments already made to Akeso, under the License Agreement and Second Amendment, there are additional potential milestone payments of $4.56 billion, as Akeso will be eligible to receive regulatory milestones of up to $1.05 billion and commercial milestones of up to $3.51 billion. In addition, Akeso will be eligible to receive low double-digit royalties on net sales. Until we can generate substantial revenue and achieve profitability, we will need to raise additional capital to fund ongoing operations and capital needs, including the payment of the milestone payments referenced above.

We have based the foregoing estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. This estimate assumes, among other things, that we do not obtain any additional funding through grants and clinical trial support or through new collaboration arrangements. Our future capital requirements will depend on many factors, including:

- the costs, timing and outcome of clinical trials required for clinical development of ivonescimab;
- the number and development requirements of other future product candidates that we pursue;
- the costs, timing and outcome of regulatory review of ivonescimab and/or our other product candidates we develop;
- the costs and timing of commercialization activities, including product sales, marketing, distribution and manufacturing, for any of our product candidates that receive marketing approval;
- the extent to which we become liable for milestone payments under the License Agreement and Second Amendment for ivonescimab;
- subject to receipt of marketing approval, revenue received from commercial sales of any product candidates;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against any intellectual property-related claims;
- our ability to establish and maintain collaborations, licensing or other arrangements and the financial terms of such arrangements;
- the extent to which we acquire or invest in other businesses, products and technologies;
- the rate of the expansion of our physical presence; and
- the extent to which we change our physical presence.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of some, or all, of the following: equity and debt offerings, collaborations, strategic alliances, grants and clinical trial support from government entities, philanthropic, non-government and not-for-profit organizations, and marketing, distribution or licensing arrangements.

We will need to seek additional funding in the future to fund operations. Additional capital, when needed, may not be available to us 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 existing stockholders may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders. Additional debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends or other distributions. If we raise additional funds through collaborations, strategic alliances or marketing, distribution, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us.

If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves, which could materially adversely affect our business, operating results and financial condition and our ability to continue operations.

Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2025 and 2024.

	Year Ended December 31,	
(in millions)	**2025**	**2024**
Net cash used in operating activities	$ (322.9)	$ (142.1)
Net cash used in investing activities	$ (174.3)	$ (205.3)
Net cash provided by financing activities	$ 617.5	$ 381.2

Operating Activities

Net cash used in operating activities for the year ended December 31, 2025 was $322.9 million and primarily consisted of net loss of $1,079.6 million and a $31.4 million net change in operating assets and liabilities, partially offset by non-cash charges of $725.2 million. The non-cash charges primarily consisted of $732.4 million of stock-based compensation driven by the modification to outstanding performance-based stock option awards which removed the performance-based vesting criteria, partially offset by $7.0 million relating to amortization of the discount on short-term investments in U.S. Treasury securities. The net change in working capital is primarily due to a $15.3 million increase in accounts payable, a $12.9 million increase in accrued liabilities and other current liabilities, a $4.9 million decrease in prepaid expenses and other current assets, a $2.9 million increase in accrued compensation, partially offset by a $4.9 million increase in other assets.

Net cash used in operating activities for the year ended December 31, 2024 was $142.1 million and primarily resulted from a net loss of $221.3 million, which included an adjustment of $15.0 million in cash payments related to investing activities for the purchase of in-process research and development from Akeso under the terms of the License Agreement and the associated direct transaction costs, non-cash charges of $48.7 million and a net change in operating assets and liabilities of $15.5 million. Non-cash charges primarily include $51.0 million of stock-based compensation, partially offset by $2.6 million related to the amortization of discount on short-term investments. The net change in operating assets and liabilities is primarily due to an $11.9 million increase in accrued liabilities and other current liabilities, a $6.6 million increase in accrued compensation, a $2.5 million decrease in other assets, and a $2.0 million increase in accounts payable, partially offset by a $7.4 million increase in prepaid expenses and other current assets.

Investing Activities

Net cash used in investing activities for the years ended December 31, 2025 was $174.3 million and primarily consisted of net purchases of short-term investments of $173.7 million.

Net cash used in investing activities for the years ended December 31, 2024 was $205.3 million and was primarily due to $190.2 million of net purchases of short-term investments and $15.0 million of cash payments made to Akeso pursuant to the License Agreement.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2025 was $617.5 million and primarily consisted of proceeds from a private placement of $500.0 million, $104.5 million net proceeds from our current Distribution Agreement, $7.3 million of proceeds received related to the exercise of warrants and proceeds received of $5.7 million related to employee stock awards and purchase plans.

Net cash provided by financing activities for the year ended December 31, 2024 was $381.2 million and was primarily due to $434.9 million of proceeds from various private placements, $43.0 million net proceeds from our current ATM Agreement, and proceeds received of $2.7 million related to employee stock awards, partially offset by a $100.0 million early principal payment on promissory notes payable to a related party.

Contractual Obligations and Commitments

Fixed asset purchase commitments

At December 31, 2025 and 2024, we had no capital commitments.

Lease commitments

The following table summarizes our lease contractual obligations as of December 31, 2025:

	Payment due by period				
(in millions)	Total	Less than 1 year	Between 1 and 3 years	Between 3 and 5 years	More than 5 years
Operating lease obligations [1]	$ 27.3	$ 3.5	$ 8.2	$ 6.4	$ 9.2

[1] For additional information, please see Note 11 to our consolidated financial statements contained in this Annual Report on Form 10-K.

Debt commitments

On December 6, 2022, we entered into a Note Purchase Agreement (the "Note Purchase Agreement"), with Mr. Duggan and Dr. Zanganeh, pursuant to which we agreed to sell to each of Mr. Duggan and Dr. Zanganeh unsecured promissory notes in the aggregate amount of $520 million. Pursuant to the Note Purchase Agreement, we issued to Mr. Duggan and Dr. Zanganeh unsecured promissory notes in the amount of $400 million (the "Duggan February Note") and $20 million (the "Zanganeh Note"), respectively, which matured and became due on February 15, 2023 and an unsecured promissory note to Mr. Duggan in the amount of $100 million (the "Duggan September Note" and together with the Duggan February Note and the Zanganeh Note, the "December 2022 Notes"), which was originally due on September 15, 2023. The maturity dates of the December 2022 Notes could have been extended one or more times at our election, but in no event to a date later than September 6, 2024. In addition, if we consummated a public offering, then upon the later to occur of (i) five business days after we receive the net cash proceeds therefrom or (ii) May 15, 2023, the Duggan February Note and the Zanganeh Note were to be prepaid by an amount equal to the lesser of (a) 100% of the amount of the net proceeds of such offering and (b) the outstanding principal amount on such Notes. On January 19, 2023, we provided notice to extend the term of the Duggan February Note and Duggan September Note to a maturity date of September 6, 2024.

Furthermore, on January 19, 2023, we and Mr. Duggan rectified the Duggan February Note and Duggan September Note in order to correctly reflect the parties' intent that we may only prepay (i) the Duggan February Note following the completion of a public rights offering to be conducted by us in the approximate amount of $500 million, or a similar capital raise, in an amount equal to the lesser of (x) the net proceeds of the 2023 Rights Offering or such capital raise or (y) the full amount outstanding of the Duggan February Note, and (ii) the Duggan September Note following the completion of a capital raising transaction subsequent to the 2023 Rights Offering (as defined in Note 17 Stockholders' Equity to the consolidated financial statements included under Item 15 Exhibits, Financial Statement Schedules) in an amount equal to the lesser of (A) the net proceeds of such capital raise or (B) the full amount outstanding of the Duggan September Note. Following the issuance of the two new Promissory Notes (the "Duggan Promissory Notes"), the Duggan February Note and Duggan September Note were marked as "cancelled" on their face and replaced in their entirety by the Duggan Promissory Notes (together with the Zanganeh Note, the "Notes"). The Notes accrued interest at an initial rate of 7.5%. All interest on the Notes was paid on the date of signing for the period through February 15, 2023. Such prepaid interest was paid in a number of shares of our common stock, par value $0.01 ("Common Stock") equal to the dollar amount of such prepaid interest, divided by $0.7913 (the consolidated closing bid price immediately preceding the time we entered into the Note Purchase Agreement, plus $.01), which was 9,720,291 shares. For all applicable periods following February 15, 2023, interest accrued on the outstanding principal balance of the Notes at the US prime interest rate, as reported in the *Wall Street Journal,* plus 50 basis points, as adjusted monthly, for three months immediately following February 15, 2023, and thereafter at the US prime rate plus 300 basis points, as adjusted monthly. Accrued interest was paid in cash, quarterly in arrears, on each of March 31, June 30, September 30 and December 31.

On February 15, 2023, the $20 million Zanganeh Note matured and we repaid the outstanding principal balance. In connection with the closing of the 2023 Rights Offering, the $400 million Duggan Promissory Note matured and became due, and we satisfied all principal and accrued interest thereunder using a combination of a portion of the cash proceeds from the 2023 Rights Offering and the extinguishment of a portion of the amount due equal to the subscription price of shares subscribed by Mr. Duggan in the 2023 Rights Offering.

On February 17, 2024 the Duggan February Note was amended to extend the maturity date from September 6, 2024 to April 1, 2025. For all applicable periods commencing February 17, 2024, interest accrued on the outstanding principal balance at the greater of 12% or the US prime interest rate, as reported in the *Wall Street Journal* plus 350 basis points, as adjusted monthly, compounded quarterly. Interest was paid upon maturity of the loan.

As of October 1, 2024, the Company repaid the Duggan September Note in full, resulting in principal payments in the aggregate amount of $100.0 million and accrued cash interest of $7.3 million.

Other commitments

We enter into contracts in the normal course of business with various third parties for clinical trials, preclinical research studies and testing, manufacturing and other services and products for operating purposes. Most contracts provide for termination upon notice, and therefore are cancellable contracts. As of December 31, 2025, total unconditional purchase obligations, excluding lease commitments, are estimated to be approximately $18.0 million.

We have certain commitments under our agreements with Akeso. The License Agreement with Akeso also contains certain manufacturing and purchase commitments. As of December 31, 2025, we are unable to estimate the amount, timing or likelihood of achieving the milestones, making future product sales or assessing estimated forecasts for manufacturing and supplied materials which these contingent payment obligations relate to. For additional information about the License Agreement with Akeso, refer to Note 4, "Akeso License and Collaboration Agreement" to the Consolidated Financial Statements included under Item 15, "Exhibits, Financial Statement Schedules."

Legal Proceedings

Litigation Relating to the December 2022 Notes Entered into in Connection with the License Agreement

On March 17, 2025, Rainaldi Revocable Trust, a purported stockholder of the Company, filed a derivative lawsuit in the Delaware Court of Chancery against certain of the Company's current and former directors and the Company, solely as a nominal defendant, concerning the December 2022 Notes entered into by the Company, Mr. Duggan and Dr. Zanganeh in connection with the License Agreement. The suit asserts claims for breach of fiduciary duty and unjust enrichment and seeks, among other things, unspecified damages, rescission of the shares that Mr. Duggan and Dr. Zanganeh received as part of prepaid interest payments under the December 2022 Notes, as well as attorneys' fees and costs.

Pursuant to the December 2022 Notes, the Company obtained $520 million in bridge financing through three unsecured promissory notes: (1) a $400 million note issued to Mr. Duggan due on February 15, 2023; (2) a $20 million note issued to Dr. Zanganeh due on February 15, 2023; and (3) a $100 million note issued to Mr. Duggan due on September 15, 2023 (the "$100 Million Note"). The notes had an interest rate of 7.5% through February 15, 2023, with prepaid interest through that date paid in shares valued at $0.7913 per share. For periods after February 15, 2023, interest would accrue at the U.S. prime interest rate plus 50 basis points for three months, and thereafter at the U.S. prime rate plus 300 basis points. The notes contained no warrant coverage and no security interests. The Company announced the 2023 Rights Offering on December 6, 2022, which ran from February 7 through March 1, 2023. The 2023 Rights Offering was fully subscribed, with stockholders purchasing 476,190,471 shares of the Company's common stock at $1.05 per share, raising $500 million in gross proceeds. Mr. Duggan and Dr. Zanganeh fully subscribed to their basic subscription rights, with Mr. Duggan participating by purchasing 376,489,880 shares for approximately $395.31 million. Following the Company's fully subscribed $500 million 2023 Rights Offering, Dr. Zanganeh's $20 million note was repaid on February 15, 2023, and Mr. Duggan's $400 million note was repaid. In the interest of minimizing stockholders dilution, the $100 Million Note was extended, and eventually the $75.5 million repayment was funded through the proceeds of the September 2024 Private Placement in which Mr. Duggan purchased 3,325,991 shares for an aggregate purchase price of $75.5 million as a participant in the September 2024 Private Placement at a purchase price of $22.70 per share, and the remaining $24.5 million was repaid in full on October 1, 2024, along with $7.3 million in accrued interest. Defendants' motion to dismiss the complaint was filed on May 16, 2025 (the "Motion to Dismiss"). Plaintiff filed a motion to certify certain constitutional questions to the Delaware Supreme Court on May 29, 2025 (the "Motion to Certify"). Defendants agreed to a stipulation staying briefing on the Motion to Certify and the Motion to Dismiss pending the Delaware Supreme Court's decision in another case involving substantially the same constitutional questions. On June 18, 2025, the Court granted such stipulation.

European Patent Opposition

On June 18, 2025, an unknown third party filed a notice of opposition against the Company's in-licensed EP3882275B1 patent (the "'275 patent") in the European Opposition Division of the European Patent Office ("EPO"). The '275 patent covers Ivonescimab. The notice primarily asserts that the 275 patent lacks inventive step. The Company contests these assertions and worked with its collaboration partner, Akeso, to timely file a response before the European Opposition Division of the EPO on January 2, 2026.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued research and development expenses, stock-based compensation and income taxes. We base our estimates on historical experience, known trends and events, and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following critical accounting policies affect the most significant judgments, assumptions and estimates we use in preparing the consolidated financial statements:

Acquired In-Process Research and Development

The Company may enter into agreements with collaboration partners for the development and commercialization of its products. These arrangements may include payments contingent on the occurrence of certain events such as development, regulatory or sales-based milestones. The Company considers the unique nature, terms and facts and circumstances of each transaction. The Company considers whether or not the assets acquired have a future alternative use.

The fair value associated with acquired in-process research and development which does not have an alternative future use is expensed and is recorded as research and development expense. Any development or commercial milestone payments are recognized when the achievement of the associated milestone becomes probable and will either be expensed or capitalized depending upon whether or not regulatory approval has been obtained.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred to discover, research and develop product candidates, including personnel expenses, stock-based compensation expense, allocated facility-related and depreciation expenses, third-party license fees and external costs of outside vendors engaged to conduct preclinical and clinical development activities and clinical trials as well as to manufacture clinical trial materials. Non-refundable prepayments for goods or services that will be used or rendered for future research and development activities are recorded as prepaid expenses. Such amounts are recognized as an expense as the goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered, or the services rendered. The significant estimates in our accrued research and development expenses include the costs incurred for services performed by our vendors in connection with research and development activities for which we have not yet been invoiced. Milestone and other payments made to third-parties with respect to in-process research and development, in accordance with the Company's license, acquisition and other similar agreements are expensed when determined to be probable and estimable.

The Company has entered into various research and development contracts with other companies. These agreements are generally cancellable, and related payments are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research and development costs or prepaid expenses where the payments made exceed the estimated costs. These amounts are determined based on the estimated costs to complete each study or activity, the estimation of the current stage of completion and the invoices received, as well as predetermined milestones which are not reflective of the current stage of development for prepaid expenses. Actual results could differ from the Company's estimates. In all cases, the full cost of each study or activity is expensed by the time the final report or where applicable, product, has been received. The Company's historical estimates have not been materially different from the actual costs.

Stock-Based Compensation

The Company measures and recognizes compensation expense for all stock option and restricted stock unit awards based on the estimated fair value of the award on the grant date. The Company uses the Black-Scholes option pricing model to estimate the fair value of stock option awards. Additionally, the Company uses a Monte Carlo simulation model to calculate the estimated fair value on the date of grant related to awards with market-based service conditions. The fair value is recognized as expense, over the requisite service period, which is generally the vesting period of the respective award, on a straight-line basis for each separately vesting portion of the award when the only condition to vesting is continued service. If vesting is subject to a market or performance condition, recognition is based on the derived service period of the award. Expense for awards with

performance conditions is estimated and adjusted on a quarterly basis based upon the assessment of the probability that the performance condition will be met. Use of the Black-Scholes option-pricing model requires management to apply judgment under subjective assumptions. These assumptions include:

- Expected term—The expected term of stock options represents the weighted-average period the stock options are expected to be outstanding. The Company uses the simplified method for estimating the expected term as provided by the Securities and Exchange Commission. The simplified method calculates the expected term as the average of the time-to-vesting and the contractual life of the options.
- Expected volatility—The expected volatility is calculated based on historical volatility of the Company's share price.
- Risk-free interest rate—The risk-free rate assumption is based on the U.S. Treasury instruments, the terms of which were consistent with the expected term of the Company's stock options.
- Expected dividend—The expected dividend assumption is based on the Company's history and expectation of dividend payouts. The Company has not paid and does not intend to pay dividends.

The Company uses a Monte Carlo simulation model to estimate the fair value of Performance and Market-based Stock Options at the date of grant. Key assumptions used in the model include the risk-free interest rate, which reflects the US Treasury Constant Maturity Yield with a term commensurate with the contractual term of the award, and stock price volatility, which is derived based on the historical volatility of the Company's stock.

The Company estimates expected forfeitures at the time of grant instead of accounting for forfeitures as they occur. Stock option awards have been granted at fair value to non-employees, in connection with research and consulting services provided to the Company, to non-employees in connection with corporate activities, and to employees, in connection with Stock Purchase and Restriction Agreements. Equity awards generally vest over terms of 3 or 4 years.

The Company classifies stock-based compensation expense in the consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified.

Income Taxes

The provision for income taxes is determined using the asset and liability approach. Tax laws may require items to be included in tax filings at different times than the items are reflected in the financial statements. A current asset or liability is recognized for the estimated taxes receivable or payable for the current year. Deferred taxes represent the future tax consequences expected to occur when the reported amounts of assets and liabilities are recovered or paid. Deferred taxes are initially recognized at enacted tax rates in force at the time of initial recognition and are subsequently adjusted for any enacted changes in tax rates and tax laws. Subsequent changes to deferred taxes originally recognized in equity are recognized in income. Valuation allowances are recorded to reduce deferred tax assets when it is more likely than not that a tax benefit will not be realized. The Company has recorded a full valuation allowance against the deferred tax assets in excess of its deferred tax liabilities, as the deferred tax liability represents future reversals of existing taxable temporary differences. The Company records interest and penalties related to income tax matters as part of income tax expense.

The Company accounts for uncertain tax positions taken in its tax filings by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities having full knowledge of the facts and applicable tax rules. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed as the amount of benefit to recognize in the consolidated financial statements. The amount of benefits that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate, as well as the related net interest and penalties. At December 31, 2025, 2024, and 2023 the Company had unrecognized tax positions of $3.9 million, $2.1 million, and $1.1 million, respectively. Due to the Company's full valuation allowance, the unrecognized tax benefits are not expected to materially impact the Company's effective tax rate when recognized or significantly increase or decrease in the next 12 months. In addition, the Company's policy is to recognize interest and penalties related to uncertain tax positions as part of its income tax provision.

Recent Accounting Pronouncements

For a discussion of recent accounting pronouncements, please see Note 2 to our consolidated financial statements contained in this Annual Report on Form 10-K.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Our primary exposures to market risk are liquidity risk and foreign currency risk.

Liquidity Risk

We have funded our operations since inception primarily through the issuance of equity and debt securities. We have also received funding from our license and collaboration arrangements. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity or debt financings or other sources. Adequate additional financing may not be available to us on acceptable terms, or at all. Our inability to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy.

Foreign Currency Exchange Rate Risk

Foreign currency exchange rate risk refers to the risk that the value of a financial commitment or recognized asset or liability will fluctuate due to changes in foreign currency rates. Our net loss and financial position, as expressed in U.S. dollars, are exposed to movements in foreign exchange rates against the pound sterling and the euro. The main trading currencies are the pound sterling, the U.S. dollar, Japanese Yen, and the euro. We are exposed to foreign currency exchange rate risk as a result of entering into operating transactions denominated in currencies other than the functional currency of our subsidiaries, particularly in relation to our monetary assets and liabilities relating to intercompany transactions, supplier liabilities and the translation of foreign cash balances. Operating transaction foreign currency gains and losses are included in the determination of net loss in our statements of operations and comprehensive loss. We monitor our exposure to foreign currency exchange rate risk. Exposures are generally managed through natural hedging via the currency denomination of cash balances and any impact currently is not material to us.

Interest Rate Risk

We hold our cash, cash equivalents and short-term investments for working capital purposes. Some of the securities we invest in are subject to market risk. This means that a change in prevailing interest rates may cause the principal amount of such investments to fluctuate. To minimize this risk, we maintain our portfolio of cash, cash equivalents and short-term investments which are invested in a variety of short term securities, including money market funds, certificates of deposit and U.S. treasury securities. Due to the short-term nature of these instruments, we believe that we do not have any material exposure to changes in the fair value of our investment portfolio as a result of changes in interest rates. Declines in interest rates, however, would reduce future interest income. The effect of a hypothetical 10% increase or decrease in overall interest rates would not have had a material impact on our operating results or the total fair value of our portfolio.

Credit Risk

We consider all of our material counterparties to be creditworthy. We consider the credit risk for each of our counterparties to be low and do not have a significant concentration of credit risk at any of our counterparties. We have $0.9 million of research and development tax credits outstanding at December 31, 2025. Given that these receivables relate to U.K. research and development tax credit cash rebate regimes and given our history of collection, it is highly unlikely that these amounts will not be collected.

Item 8. Financial Statements and Supplementary Data

The financial statements required to be filed pursuant to this Item 8 are included in this Annual Report on Form 10-K. An index of those financial statements is found in Item 15, “Exhibits, Financial Statement Schedules.”

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We have performed an evaluation of the effectiveness of our disclosure controls and procedures under the supervision and the participation of the company's management, including our Co-Chief Executive Officers (our Principal Executive Officers) and our Chief Operating Officer and Chief Financial Officer (our Principal Financial Officer). The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. There are inherent limitations to the effectiveness of any system of disclosure controls and procedures, including the possibility of human error and the circumvention or overriding of the controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives. Based upon our evaluation of our disclosure controls and procedures as of December 31, 2025, our Co-Chief Executive Officer and Executive Chairman and our Co-Chief Executive Officer, President and Director (our Principal Executive Officers), and our Chief Operating Officer, Chief Financial Officer and Director (our Principal Financial Officer) concluded that, as of such date, our disclosure controls and procedures were effective at a reasonable level of assurance.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting is a process designed, under the supervision of the Co-Chief Executive Officers (our Principal Executive Officers), and our Chief Operating Officer and Chief Financial Officer (our Principal Financial Officer), to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external reporting purposes in accordance with generally accepted accounting principles.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of the effectiveness of internal control to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management has assessed the effectiveness of internal control over financial reporting as of December 31, 2025, based on the "Internal Control—Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in 2013. Based on this assessment, management concluded that, as of December 31, 2025, our internal control over financial reporting is effective based on the COSO internal control criteria.

The effectiveness of the Company's internal control over financial reporting as of December 31, 2025 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in its report included in Item 15, "Exhibits, Financial Statement Schedules" of this Annual Report on Form 10-K.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Rule 10b5-1 Trading Plans.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required in response to this item will be set forth in our definitive proxy statement for the 2026 annual meeting of stockholders and is incorporated herein by reference.

Item 11. Executive Compensation

The information required in response to this item will be set forth in our definitive proxy statement for the 2026 annual meeting of stockholders and is incorporated herein by reference.

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

The information required in response to this item will be set forth in our definitive proxy statement for the 2026 annual meeting of stockholders and is incorporated herein by reference.

Item 13. Certain Relationships and Related Party Transactions

The information required in response to this item will be set forth in our definitive proxy statement for the 2026 annual meeting of stockholders and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services

The information required in response to this item will be set forth in our definitive proxy statement for the 2026 annual meeting of stockholders and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(1) **Financial Statements**

As part of this Annual Report on Form 10-K, the consolidated financial statements are listed in the accompanying index to financial statements on page 92.

(2) **Financial Statement Schedules**

All financial statement schedules have been omitted because they are not applicable, not required, or the information required is shown in the consolidated financial statements or the notes thereto.

(3) **Exhibits**

The exhibits filed as part of this Annual Report on Form 10-K are listed below.

Exhibit No.	Description
3.1	Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-36866), filed with the Securities and Exchange Commission on September 18, 2020)
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K (File No. 001-36866), filed with the Securities and Exchange Commission on September 18, 2020)
3.3	Amendment to Restated Certificate of Incorporation of Summit Therapeutics Inc., as filed with the Delaware Secretary of State on July 27, 2022 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-36866), filed with the Securities and Exchange Commission on July 29, 2022
3.4	Amendment No. 2 to Restated Certificate of Incorporation of Summit Therapeutics Inc., dated January 19, 2023 (incorporated by reference to Exhibit 5.1 to the Company's Current Report on Form 8-K (File No. 001-36866), filed with the Securities and Exchange Commission on January 20, 2023
4.1	Registration Rights Agreement, dated January 9, 2019, by and among Summit Therapeutics plc and Robert W. Duggan (incorporated by reference to Exhibit 2.1 to the Company's Report on Form 6-K (File No. 001-36866), filed with the Securities and Exchange Commission on January 10, 2019)
4.2	Form of Consultant Warrant (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K (File No. 001-36866), filed with the Securities and Exchange Commission on September 18, 2020)
4.3	Form of Investor Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K (File No. 001-36866), filed with the Securities and Exchange Commission on September 18, 2020)
4.4	Description of Securities Registered Under Section 12 of the Exchange Act (incorporated by reference to the description of securities contained in the Company's Current Report on Form 8-K12B (File No. 001-36866), filed with the Securities and Exchange Commission on September 18, 2020)
4.5	Registration Rights Agreement, dated November 6, 2020, by and among Summit Therapeutics Inc., Polar Capital Funds plc - Biotechnology Fund and the Mahkam Zanganeh Revocable Trust (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K (File No. 001-36866), filed with the Securities and Exchange Commission on November 6, 2020)
10.1#	2005 Enterprise Management Incentive Scheme (incorporated by reference to Exhibit 4.3 to the Company's Transition Report on 20-F (File No. 333-36866), as amended, filed with the Securities and Exchange Commission on April 30, 2020)
10.2#	2016 Long Term Incentive Plan (incorporated by reference to Exhibit 4.22 to the Company's Annual Report on Form 20-F (File No. 001-36866), filed with the Securities and Exchange Commission on May 12, 2016)
10.3	Lease, dated February 17, 2017, by and among MEPC Milton Park No. 1 Limited, MEPC Milton Park No. 2 Limited and Summit Therapeutics plc (incorporated by reference to Exhibit 4.25 to the Company's Annual Report on Form 20-F (File No. 001-36866), filed with the Securities and Exchange Commission on March 30, 2017)
10.4	Lease, dated December 22, 2017, by and between Merrifield Centre Ltd and Discuva Limited (incorporated by reference to Exhibit 4.31 to the Company's Annual Report on Form 20-F (File No. 001-36866), filed with the Securities and Exchange Commission on April 13, 2018)
10.5#	Form of Non-Executive Director Restricted Stock Unit (RSU) Agreement (incorporated by reference to Exhibit 4.33 to the Company's Annual Report on Form 20-F (File No. 001-36866), filed with the Securities and Exchange Commission on April 13, 2018)
10.6(1)	Securities Purchase Agreement, dated October 2, 2020, by and between Summit Therapeutics Inc. and Robert W. Duggan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-36866) filed with the Securities and Exchange Commission on October 5, 2020)
10.7#*	Form of Indemnification Agreement between Summit Therapeutics Inc. and each of its Executive Officers and Directors
10.8#	2020 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K (File No. 001-36866), filed with the Securities and Exchange Commission on September 18, 2020)
10.9#	Form of Option Award under 2020 Stock Incentive Plan (incorporated by reference to Exhibit 10.28 to the Company's Current Report on Form 8-K (File No. 001-36866), filed with the Securities and Exchange Commission on September 29, 2020)
10.10#	Form of Restricted Stock Unit Agreement under 2020 Stock Incentive Plan (incorporated by reference to Exhibit 10.29 to the Company's Current Report on Form 8-K (File No. 001-36866), filed with the Securities and Exchange Commission on September 29, 2020)

Exhibit No.	Description
10.11#	2020 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K (File No. 001-36866), filed with the Securities and Exchange Commission on September 18, 2020)
10.12	Sublease Agreement, dated March 26, 2021, by and between Maky Zanganeh & Associates Inc. and Summit Therapeutics Sub Inc. (incorporated by reference to Exhibit 10.36 to the Company's Annual Report on Form 10-K (File No. 001-36866), filed with the Securities and Exchange Commission on March 31, 2021)
10.13(1)	Note Purchase Agreement, dated March 10, 2022, by and between Summit Therapeutics Inc. and Robert W. Duggan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File. No. 001-36866), filed with the Securities and Exchange Commission on March 11, 2022)
10.14	Promissory Note, dated March 10, 2022, in the name of Robert W. Duggan (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K (File. No. 001-36866), filed with the Securities and Exchange Commission on March 11, 2022)
10.15	Note Purchase Agreement, dated December 6, 2022, by and among Summit Therapeutics Inc., Robert W. Duggan, and Dr. Mahkam Zanganeh (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-36866), filed with the Securities and Exchange Commission on December 6, 2022)
10.16†	Collaboration and License Agreement, dated December 5, 2022, by and between Akeso, Inc. and its affiliates and Summit Therapeutics Sub Inc. (incorporated by reference to Exhibit 10.1 to the Company's Form S-3 (File No. 333-268932) filed with the Securities and Exchange Commission on December 21, 2022)
10.17	Amendment No. 1 to Collaboration and License Agreement Amendment, dated January 16, 2023, by and among Summit Therapeutics Inc. and Akeso, Inc. (incorporated by reference to Exhibit 10.1 of Form 8-K filed by the Company on January 20, 2023, File No. 001-36866)
10.18	Common Stock Issuance Agreement, dated January 17, 2023, by and among Summit Therapeutics Inc. and Akeso, Inc. (incorporated by reference to Exhibit 10.2 of Form 8-K filed by the Company on January 20, 2023, File No. 001-36866)
10.19	Promissory Notes, dated January 19, 2023, by and among Summit Therapeutics Inc. and Robert W. Duggan (incorporated by reference to Exhibit 10.3 of Form 8-K filed by the Company on January 20, 2023, File No. 001-36866)
10.20#	Amended and Restated 2020 Stock Incentive Plan, dated July 27, 2022 (incorporated by reference to Exhibit 10.45 to the Company's Annual Report on Form 10-K (File No. 001-36866), filed with the Securities and Exchange Commission on March 9, 2023)
10.21†	First Amendment to Sublease Agreement, dated July 25, 2022, by and among Summit Therapeutics Inc. and Maky Zanganeh and Associates, Inc. (incorporated by reference to Exhibit 10.45 to the Company's Annual Report on Form 10-K (File No. 001-36866), filed with the Securities and Exchange Commission on March 9, 2023)
10.22†	Second Amendment to Sublease Agreement, dated July 29, 2022, by and among Summit Therapeutics Inc. and Maky Zanganeh and Associates, Inc. (incorporated by reference to Exhibit 10.45 to the Company's Annual Report on Form 10-K (File No. 001-36866), filed with the Securities and Exchange Commission on March 9, 2023)
10.23#	Amended Employment Agreement, dated October 31, 2023 by and between Summit Therapeutics Inc. and Mahkam Zanganeh. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q (File No. 001-36866), filed with the Securities and Exchange Commission on May 1, 2024)
10.24#	Employment Agreement, dated October 13, 2023, by and between Summit Therapeutics Inc. and Manmeet Soni (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q (File No. 001-36866), filed with the Securities and Exchange Commission on November 7, 2023)
10.25	Securities Purchase Agreement, dated October 13, 2023, by and between Summit Therapeutics Inc. and Manmeet Soni (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q (File No. 001-36866), filed with the Securities and Exchange Commission on November 7, 2023)
10.26	Amended and Restated Promissory Note, dated February 17, 2024, by and between Summit Therapeutics Inc. and Robert W. Duggan (incorporated by reference to Exhibit 10.51 to the Company's Annual Report on Form 10-K (File No. 001-36866), filed with the Securities and Exchange Commission on February 20, 2024).
10.27	Lease Agreement, dated January 8, 2024 by and between Brickell Key Center, LLC and Summit Therapeutics, Inc (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q (File No. 001-36866), filed with the Securities and Exchange Commission on May 1, 2024)
10.28	Distribution Agreement, dated May 13, 2024, by and between Summit Therapeutics Inc. and J.P. Morgan Securities LLC (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K (File No. 001-36866), filed with the Securities and Exchange Commission on May 13, 2024)

Exhibit No.	Description
10.29+	Securities Purchase Agreement, dated June 3, 2024, by and among the Company and the Investors named therein (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-36866), filed with the Securities and Exchange Commission on June 3, 2024)
10.30+	Registration Rights Agreement, dated June 3, 2024, by and among the Company and the Investors named therein (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K (File No. 001-36866), filed with the Securities and Exchange Commission on June 3, 2024)
10.31†	Amendment No. 2 to Collaboration and License Agreement Amendment, dated June 3, 2024, by and among Summit Therapeutics Sub, Inc. and Akeso, Inc. and its affiliates (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q (File No. 001-36866), filed with the Securities and Exchange Commission on August 6, 2024.
10.32†	Sublease, dated June 27, 2024, by and between Summit Therapeutics Inc. and Duggan Investments Research LLC (incorporated by reference to Exhibit 10.5 of the Company's Quarterly Report on Form 10-Q (File No. 001-36866), filed with the Securities and Exchange Commission on August 6, 2024)
10.33†	Sublease, dated June 27, 2024, by and between Summit Therapeutics Inc. and Genius 24C Inc. (incorporated by reference to Exhibit 10.6 of the Company's Quarterly Report on 10-Q (File No. 001-36866), filed with the Securities and Exchange Commission on August 6, 2024)
10.34†	Third Amendment to Sublease, dated August 2, 2024, by and between Summit Therapeutics Sub, Inc. and Zanganeh & Associates Inc. (incorporated by reference to Exhibit 10.7 of the Company's Quarterly Report on 10-Q (File No. 001-36866), filed with the Securities and Exchange Commission on August 6, 2024)
10.35+	Securities Purchase Agreement, dated September 11, 2024, by and among Summit Therapeutics Inc. and the Investors named therein (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed (File No. 001-36866), filed with the Securities and Exchange Commission on September 12, 2024)
10.36+	Registration Rights Agreement, dated September 11, 2024, by and among Summit Therapeutics Inc. and the Investors named therein (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed (File No. 001-36866), filed with the Securities and Exchange Commission on September 12, 2024)
10.37†	Sub-Sublease Agreement, dated June 2, 2025, by and between Summit Therapeutics Inc. and Ascendis Pharma, Inc. (incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed (File No. 001-36866), filed with the Securities and Exchange Commission on August 11, 2025)
10.38	Amendment to Distribution Agreement, dated August 11, 2025, by and between Summit Therapeutics Inc. and J.P. Morgan Securities LLC (incorporated by reference to Exhibit 1.2 of the Company's Current Report on Form 8-K filed (File No. 001-36866), filed with the Securities and Exchange Commission on August 11, 2025)
10.39+	Form of Securities Purchase Agreement by and between Summit Therapeutics Inc. and certain Investors (incorporated by reference to Exhibit 1.1 of the Company's Current Report on Form 8-K filed (File No. 001-36866), filed with the Securities and Exchange Commission on October 22, 2025)
10.40+	Form of Registration Rights Agreement and between Summit Therapeutics Inc. and certain Investors (incorporated by reference to Exhibit 1.2 of the Company's Current Report on Form 8-K filed (File No. 001-36866), filed with the Securities and Exchange Commission on October 22, 2025)
14.1*	Code of Business Conduct and Ethics of Summit Therapeutics Inc.
19.1	Insider Trading Policy
21.1*	List of Significant Subsidiaries
23.1*	Consent of PricewaterhouseCoopers LLP, an independent registered public accounting firm
31.1*	Certification of Chief Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to §302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Co-Chief Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to §302 of the Sarbanes-Oxley Act of 2002
31.3*	Certification of Chief Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to §302 of the Sarbanes-Oxley Act of 2002
32.1**	Certification pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002
97.1	Summit Therapeutics, Inc. Incentive-based Compensation Clawback Policy (incorporated by reference to Exhibit 97.1 to the Company's Annual Report on Form 10-K (File No. 001-36866), filed with the Securities and Exchange Commission on February 20, 2024)
101.INS*	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document

Exhibit No.	Description
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

*	Filed herewith.
**	Furnished herewith.
†	Portions of this exhibit have been omitted in compliance with Regulation S-K Item 601(b)(10)(iv) because the Registrant has determined that the information is not material and is the type that the Registrant treats as private or confidential.
+	Certain of the exhibits and schedules to this exhibit have been omitted in accordance with Regulation S-K Item 601(a)(5). The Company agrees to furnish supplementally a copy of all omitted exhibits and schedules to the SEC upon its request.
(1)	The schedules and exhibits have been omitted. A copy of any omitted schedule or exhibit will be furnished to the SEC upon request.
#	Indicates management contract or compensatory plan or arrangement.

Item 16. Report Summary

None.

SIGNATURES

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

SUMMIT THERAPEUTICS INC.

By:	/s/ Robert W. Duggan
Name:	Robert W. Duggan
Title:	Co-Chief Executive Officer and Executive Chairman (Principal Executive Officer)
By:	/s/ Mahkam Zanganeh
Name:	Dr. Mahkam Zanganeh
Title:	Co-Chief Executive Officer, President and Director (Principal Executive Officer)
By:	/s/ Manmeet S. Soni
Name:	Manmeet S. Soni
Title:	Chief Operating Officer, Chief Financial Officer and Director (Principal Financial Officer)

Date: February 23, 2026

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

Name	Title	Date
/s/ Robert W. Duggan Robert W. Duggan	Co-Chief Executive Officer and Executive Chairman (*Principal Executive Officer*)	February 23, 2026
/s/ Mahkam Zanganeh Dr. Mahkam Zanganeh	Co-Chief Executive Officer, President and Director (*Principal Executive Officer*)	February 23, 2026
/s/ Manmeet S. Soni Manmeet S. Soni	Chief Operating Officer, Chief Financial Officer and Director *(Principal Financial Officer)*	February 23, 2026
/s/ Bhaskar Anand Bhaskar Anand	Head of Finance and Chief Accounting Officer *(Principal Accounting Officer)*	February 23, 2026
/s/ Robert F. Booth Dr. Robert F. Booth	Director	February 23, 2026
/s/ Alessandra Cesano Dr. Alessandra Cesano	Director	February 23, 2026
/s/ Kenneth Clark Kenneth Clark	Director	February 23, 2026
/s/ Jeff Huber Jeff Huber	Director	February 23, 2026
/s/ Mostafa Ronaghi Mostafa Ronaghi	Director	February 23, 2026
/s/ Yu Xia Dr. Yu Xia	Director	February 23, 2026

SUMMIT THERAPEUTICS INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Summit Therapeutics Inc.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Summit Therapeutics Inc. and its subsidiaries (the "Company") as of December 31, 2025 and 2024, and the related consolidated statements of operations and comprehensive loss, of stockholders' equity and of cash flows for each of the three years in the period ended December 31, 2025, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2025, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2025 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2025, based on criteria established in Internal Control - Integrated Framework (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements 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. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Emphasis of Matter

As discussed in Note 1 to the consolidated financial statements, the Company has incurred net losses from operations and cash outflows from operating activities. Management's evaluation of the events and conditions and management's plans to mitigate these matters are also described in Note 1.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and

expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

External Research and Development Costs

The Company's research and development expense for the year ended December 31, 2025 was $537.7 million, of which a portion relates to external research and development costs. As described in Note 2 to the consolidated financial statements, research and development costs are expensed as incurred. Research and development expenses consist of costs incurred to discover, research and develop product candidates, including third-party license fees and external costs of outside vendors engaged to conduct preclinical and clinical development activities and clinical trials as well as to manufacture clinical trial materials. Management has entered into various research and development contracts with other companies. These agreements are generally cancellable, and related payments are recorded as research and development expenses as incurred.

The principal consideration for our determination that performing procedures relating to external research and development costs is a critical audit matter is a high degree of auditor effort in performing procedures related to the Company's external research and development costs.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls related to the research and development costs process. These procedures also included, among others, testing external research and development costs on a sample basis by (i) evaluating costs incurred to underlying agreements with outside vendors, invoices received, and underlying payments made for costs incurred on the contract; and (ii) evaluating the classification as research and development costs.

/s/ PricewaterhouseCoopers LLP

San Jose, California
February 23, 2026

We have served as the Company's auditor since 2021.

Summit Therapeutics Inc.
Consolidated Balance Sheets
(in thousands, except share and per share data)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 225,266	$ 104,862
Restricted cash	316	325
Short-term investments	488,182	307,487
Prepaid expenses and other current assets	6,537	11,076
Total current assets	720,301	423,750
Non-current assets:		
Property and equipment, net	1,059	254
Operating lease right-of-use assets	20,616	7,144
Goodwill	2,001	1,864
Other assets	7,205	2,548
Total assets	$ 751,182	$ 435,560
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 20,292	$ 4,636
Accrued liabilities	32,100	19,554
Accrued compensation	14,925	11,977
Operating lease liabilities, current portion	3,388	3,765
Other current liabilities	2,283	1,797
Total current liabilities	72,988	41,729
Non-current liabilities:		
Operating lease liabilities, net of current portion	17,502	3,453
Other non-current liabilities	1,832	1,630
Total liabilities	92,322	46,812
Commitments and contingencies (Note 16)		
Stockholders' equity:		
Preferred stock, $0.01 par value, 20,000,000 shares authorized; none issued and outstanding at December 31, 2025 and 2024, respectively	—	—
Common stock, $0.01 par value: 1,000,000,000 shares authorized; 775,371,200 and 737,626,004 shares issued and outstanding at December 31, 2025 and 2024, respectively	7,754	7,376
Additional paid-in capital	2,947,805	1,598,230
Accumulated other comprehensive loss	(2,540)	(2,285)
Accumulated deficit	(2,294,159)	(1,214,573)
Total stockholders' equity	658,860	388,748
Total liabilities and stockholders' equity	$ 751,182	$ 435,560

The accompanying notes are an integral part of the consolidated financial statements

Summit Therapeutics Inc.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	Year Ended December 31,		
	2025	**2024**	**2023**
Operating expenses:			
Research and development [1]	$ 537,674	$ 150,777	$ 59,471
Acquired in-process research and development	—	15,007	520,915
General and administrative	556,750	60,214	29,264
Total operating expenses	1,094,424	225,998	609,650
Other income, net	14,838	13,369	11,183
Interest expense	—	(8,686)	(16,461)
Net loss	$ (1,079,586)	$ (221,315)	$ (614,928)
Net loss per share:			
Basic and diluted	$ (1.44)	$ (0.31)	$ (0.99)
Weighted average common shares outstanding:			
Basic and diluted	747,702,265	718,541,896	619,646,180
Other comprehensive income (loss):			
Foreign currency translation adjustments	(327)	60	(172)
Reclassification of unrealized loss on short-term investments to other income, net	—	3	—
Reclassification of cumulative currency translation gain to other income, net	—	—	(419)
Unrealized gain on short-term investments	72	100	36
Comprehensive loss	$ (1,079,841)	$ (221,152)	$ (615,483)

[1] Refer to Note 15 – Related Party Transactions for expenses incurred.

The accompanying notes are an integral part of the consolidated financial statements.

Summit Therapeutics Inc.
Consolidated Statements of Stockholders' Equity
(in thousands, except share data)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Total Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2022	211,091,425	$ 2,110	$ 504,767	$ (1,893)	$ (378,330)	$ 126,654
2023 Rights Offering of common stock, net of offering costs of $619 [(2)]	476,190,471	4,762	494,619	—	—	499,381
Issuance of common stock under employee stock purchase plans and exercise of stock options	596,472	7	922	—	—	929
Issuance of common stock in lieu of cash for Akeso upfront payment	10,000,000	100	45,800	—	—	45,900
Private placement of common stock	2,976,190	30	4,970	—	—	5,000
Exercise of warrants [(2)]	805,495	8	1,195	—	—	1,203
Stock-based compensation	—	—	14,108	—	—	14,108
Net other comprehensive loss	—	—	—	(555)	—	(555)
Net loss	—	—	—	—	(614,928)	(614,928)
Balance at December 31, 2023	701,660,053	$ 7,017	$1,066,381	$ (2,448)	$ (993,258)	$ 77,692
Private placement of common stock, net of offering costs of $140 [(2)]	32,574,640	326	434,534	—	—	434,860
Issuance of common stock under stock purchase plans and exercise of stock options and warrants	1,584,218	15	3,319	—	—	3,334
Proceeds from at-the-market offering, net of commissions and offering costs of $1,190	1,807,093	18	43,015	—	—	43,033
Stock-based compensation	—	—	50,981	—	—	50,981
Net other comprehensive gain	—	—	—	163	—	163
Net loss	—	—	—	—	(221,315)	(221,315)
Balance at December 31, 2024	737,626,004	$ 7,376	$1,598,230	$ (2,285)	$ (1,214,573)	$ 388,748
Private placement of common stock [(2)]	26,682,846	267	499,770	—	—	500,037
Issuance of common stock under stock purchase plans and exercise of stock options and warrants	5,723,011	58	12,910	—	—	12,968
Proceeds from at-the-market offering, net of commissions and offering costs of $1,969	5,339,339	53	104,475	—	—	104,528
Stock-based compensation	—	—	732,420	—	—	732,420
Net other comprehensive loss	—	—	—	(255)	—	(255)
Net loss	—	—	—	—	(1,079,586)	(1,079,586)
Balance at December 31, 2025	775,371,200	$ 7,754	$2,947,805	$ (2,540)	$ (2,294,159)	$ 658,860

(2) Refer to Note 13 – Stockholders' Equity for related party transactions.

The accompanying notes are an integral part of the consolidated financial statements.

Summit Therapeutics Inc.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,		
	2025	**2024**	**2023**
Cash flows used in operating activities:			
Net loss	$ (1,079,586)	$ (221,315)	$ (614,928)
Adjustments to reconcile net loss to net cash used in operating activities:			
Non-cash interest expense	—	—	6,253
Amortization of discount on short-term investments	(7,006)	(2,576)	(1,924)
Unrealized foreign exchange loss (gain)	(320)	229	(812)
Reclassification of currency translation gain	—	—	(419)
Impairment of fixed assets	—	—	474
Depreciation	146	89	198
Stock-based compensation	732,420	50,981	14,108
Loss on disposal of assets	—	—	(109)
Acquired in-process research and development expense	—	15,007	520,915
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	4,866	(7,370)	3,613
Other assets	(4,875)	2,470	(3,421)
Accounts payable	15,303	2,015	2,263
Accrued liabilities and other current liabilities	12,930	11,879	(2,377)
Accrued compensation	2,909	6,557	(235)
Other long-term liabilities	80	95	—
Operating lease right-of-use assets and lease liabilities, net	203	(167)	(359)
Net cash used in operating activities	(322,930)	(142,106)	(76,760)
Cash flows used in investing activities:			
Maturities and sales of short-term investments	311,340	489,837	208,165
Purchase of short-term investments	(484,993)	(680,032)	(321,022)
Purchase of property and equipment	(657)	(139)	(128)
Proceeds from sale of property, plant and equipment	—	—	226
Payments to Akeso for upfront milestone payments and associated direct transaction	—	(15,007)	(475,015)
Net cash used in investing activities	(174,310)	(205,341)	(587,774)
Cash flows provided by financing activities:			
Proceeds from the issuance of common stock via private placements, net of offering costs [2]	500,037	434,860	5,000
Proceeds from the issuance of common stock under at-the-market offering, net of commissions and offering costs	104,528	43,033	—
Proceeds from exercise of warrants [2]	7,315	598	1,203
Proceeds received related to employee stock purchase plan and exercise of stock	5,653	2,736	929
Proceeds from the issuance of common stock for rights offering [2]	—	—	104,686
Transaction costs from the issuance of common stock for rights offering	—	—	(619)
Re-payment of related party promissory notes	—	(100,000)	(24,686)
Net cash provided by financing activities	617,533	381,227	86,513
Effect of exchange rates on cash and cash equivalents	102	(18)	839
Increase (decrease) in cash, cash equivalents and restricted cash	120,395	33,762	(577,182)
Cash, cash equivalents and restricted cash at beginning of period	105,187	71,425	648,607
Cash, cash equivalents and restricted cash at end of period	$ 225,582	$ 105,187	71,425
Supplemental Disclosure of Cash Flow Information:			
Cash paid for interest on related party promissory note	$ —	$ 8,806	$ 10,650
Cash paid for income taxes	$ —	$ —	$ 52
Supplemental Disclosure of Non-Cash Investing and Financing Activities:			
Leased assets obtained in exchange for operating lease liabilities	$ 17,056	$ 4,216	$ 4,245
Unpaid amounts related to purchase of property, plant and equipment	$ 291	$ —	$ —
Consideration for the issuance of common stock for rights offering used to satisfy a portion of a related party promissory note (Note 12)	$ —	$ —	$ 395,314
Issuance of common stock pursuant to the Akeso License Agreement (Note 4)	$ —	$ —	$ 45,900

[2] Refer to Note 13 – Stockholders' Equity for related party transactions.

The accompanying notes are an integral part of the consolidated financial statements.

1. Organization

Summit Therapeutics Inc. ("we", "Summit" or the "Company") is a biopharmaceutical company focused on the discovery, development, and commercialization of patient-, physician-, caregiver- and societal-friendly medicinal therapies intended to improve quality of life, increase potential duration of life, and resolve serious unmet medical needs. The Company's pipeline of product candidates is designed with the goal to become the patient-friendly, new-era standard-of-care medicines, in the therapeutic area of oncology.

The Company's current lead development candidate is ivonescimab, a novel, potential first-in-class bispecific antibody intending to combine the effects of immunotherapy via a blockade of PD-1 with the anti-angiogenesis effects of an anti-VEGF compound into a single molecule. On December 5, 2022, the Company entered into the License Agreement with Akeso, Inc. and its affiliates (collectively, "Akeso") pursuant to which the Company has in-licensed intellectual property rights related to ivonescimab (as amended, the "License Agreement"), as further described in Note 4. Through the License Agreement, the Company obtained the rights to develop and commercialize ivonescimab in the United States, Canada, Europe, and Japan. The License Agreement and transaction closed in January 2023 following customary waiting periods. On June 3, 2024, the Company entered into an amendment to the License Agreement (the "Second Amendment") with Akeso to expand its territories covered under the License Agreement to also include Latin America, including Mexico and all countries in Central America and South America, the Middle East and Africa (collectively, and as expanded, the "Licensed Territory") . The Company's operations are focused on the development of ivonescimab and other future activities, as the Company determines.

Basis of Presentation

The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") and pursuant to the rules and regulations of the U.S. Securities and Exchange Commission. Any reference in these notes to applicable guidance is meant to refer to authoritative U.S. GAAP as found in the Accounting Standards Codification ("ASC") and as amended by Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB"). Certain reclassifications have been made to the prior years' financial statements to conform to current year presentation.

Use of Estimates

The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the reported amounts of income and expenses during the reporting period. On an on-going basis, management evaluates its estimates and judgments, including those related to accrued research and development expenses, stock-based compensation, and income taxes. Management bases its estimates and judgments on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Liquidity and Capital Resources

During the year ended December 31, 2025, the Company incurred a net loss of $1,079,586 and cash used in operating activities was $322,930. As of December 31, 2025, the Company had an accumulated deficit of $2,294,159, and cash and cash equivalents of $225,266 and short-term investments of $488,182. The Company expects to continue to generate operating losses for the foreseeable future.

During the year ended December 31, 2025, the Company raised gross proceeds of $500,037 from a private placement and $106,498 from the Company's at-the-market sales agreement, both described further in Note 13. With these recent financings, the Company has evaluated and concluded that its cash, cash equivalents and short-term investments provide sufficient cash to fund its operating cash needs for at least the next 12 months from the date of issuance of these consolidated financial statements.

Until the Company can generate substantial revenue and achieve profitability, the Company will need to raise additional capital to fund its ongoing operations and capital needs. The Company continues to evaluate options to further finance its operating

cash needs for its product candidates through a combination of some, or all, of the following: equity and debt offerings, collaborations, strategic alliances, grants and clinical trial support from government entities, philanthropic, non-government and not-for-profit organizations, and marketing, distribution or licensing arrangements. There is no assurance, however, that additional financing will be available when needed or that management of the Company will be able to obtain financing on terms acceptable to the Company. If the Company is unable to obtain funding when required in the future, the Company could be required to delay, reduce, or eliminate research and development programs, product portfolio expansion, or future commercialization efforts, which could adversely affect its business prospects.

2. Summary of Significant Accounting Policies and Recent Accounting Pronouncements

The significant accounting policies adopted by the Company in the preparation of these consolidated financial statements are set out below. These policies have been consistently applied to all the years presented, unless otherwise stated.

Principles of Consolidation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the U.S. GAAP and pursuant to the rules and regulations of the U.S. Securities and Exchange Commission. The consolidated financial statements reflect the accounts of Summit Therapeutics Inc. and its wholly owned subsidiaries. Intercompany balances and transactions are eliminated in consolidation.

Foreign Currency Translation

The financial statements of the Company's subsidiaries with functional currencies other than the U.S. dollar are translated into U.S. dollars using period-end exchange rates for assets and liabilities, historical exchange rates for stockholders' equity and weighted average exchange rates for operating results. Translation gains and losses are included in accumulated other comprehensive (loss) income in stockholders' equity. Foreign currency transaction gains and losses are included in other income, net in the consolidated statements of operations and comprehensive loss. The Company recorded realized and unrealized foreign currency transaction (loss) gain of ($610), $(97) and $613 for the years ended December 31, 2025, 2024 and 2023, respectively, which is included in other income, net in the consolidated statements of operations and comprehensive loss.

Net Loss Per Share

Basic net loss per share is computed by dividing the net loss by the weighted-average number of common shares outstanding for the period. Diluted net loss per share is computed by dividing the diluted net loss by the weighted-average number of common shares outstanding for the period, including potentially dilutive common shares. The dilutive effect of share options and warrants are determined under the treasury stock method using the average market price for the period. In addition, the assumed proceeds under the treasury stock method include the average unrecognized compensation expense of stock options and warrants that are in-the-money.

Goodwill

Goodwill represents the excess of the consideration transferred over the fair value of net assets acquired. Goodwill is assigned to reporting units at the time of acquisition or when there is a change in the reporting structure and bases that allocation on which reporting units will benefit from the acquired assets and liabilities. Reporting units are defined as operating segments or one level below an operating segment, referred to as a component. Typically acquisitions related to a single reporting unit do not require the allocation of goodwill to multiple reporting units. If the net assets obtained in an acquisition are assigned to multiple reporting units, the goodwill is distributed to the respective reporting units as part of the purchase price allocation process.

The Company assesses goodwill for impairment on an annual basis as of December 31 or more frequently when events and circumstances occur indicating that the recorded goodwill may be impaired. The Company regularly monitors current business conditions and other factors including, but not limited to, adverse industry or economic trends and lower projections of

profitability that may impact future operating results. The process of evaluating the potential impairment of goodwill requires significant judgment. In performing the Company's annual goodwill impairment test, the Company is permitted to first assess qualitative factors to determine whether it is more likely than not that the fair value of the Company's reporting unit is less than its carrying amount, including goodwill. In performing the qualitative assessment, the Company considers certain events and circumstances specific to the reporting unit and to the entity as a whole, such as macroeconomic conditions, industry and market considerations, overall financial performance and cost factors when evaluating whether it is more likely than not that the fair value of the reporting unit is less than its carrying amount. The Company is also permitted to bypass the qualitative assessment and proceed directly to the quantitative test. If the Company chooses to undertake the qualitative assessment and concludes that it is more likely than not that the fair value of the reporting unit is less than its carrying amount, the Company would then proceed to the quantitative impairment test. In the quantitative assessment, the Company compares the fair value of the reporting unit to its carrying amount, which includes goodwill. If the fair value exceeds the carrying value, no impairment loss exists. If the fair value is less than the carrying amount, a goodwill impairment loss is measured and recorded.

Leases

The Company has operating leases for real estate. The Company does not have any finance leases. A contract is or contains a lease when the lessee has the right to control the use of an identified asset. The Company determines if an arrangement is a lease at inception of the contract, which is the date on which the terms of the contract are agreed to and the agreement creates enforceable rights and obligations. The lease term used to calculate the lease liability include options to extend or terminate the lease when it is reasonably certain that the option will be exercised.

At the lease commencement date, the Company measures and recognizes a lease liability and a right-of-use asset in the financial statements. Lease liabilities are recognized based on the present value of the future lease payments over the lease term at commencement date. The right-of use asset is measured by taking the present value of future lease payments, plus any incremental direct costs incurred, less any lease incentives received. As most of the Company's leases do not provide an implicit rate, the Company uses an estimated incremental borrowing rate based on the lease term and the economic environment of the lease at the lease commencement date, which is then utilized to determine the present value of future lease payments. Lease expense for minimum lease payments are recognized on a straight-line basis over the lease term, with variable lease payments recognized in the periods in which they are incurred.

The Company has existing lease agreements with lease and non-lease components, has elected to account for the lease and non-lease components as a single lease component, and has allocated all of the contract consideration to the lease component only.

Leases with an initial lease term of 12 months or less are not recorded on the balance sheet. The Company recognizes lease expense for its short-term leases on a straight-line basis over the lease term.

Acquired In-Process Research and Development

The Company may enter into agreements with collaboration partners for the development and commercialization of its products. These arrangements may include payments contingent on the occurrence of certain events such as development, regulatory or sales-based milestones. The Company considers the unique nature, terms and facts and circumstances of each transaction. The Company considers whether or not the assets acquired have an alternative future use.

The fair value associated with acquired in-process research and development which does not have an alternative future use is expensed and is recorded as research and development expense. Any development or commercial milestone payments are recognized when the achievement of the associated milestone becomes probable and will either be expensed or capitalized depending upon whether or not regulatory approval has been obtained.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred to discover, research and develop product candidates, including personnel expenses, stock-based compensation expense, allocated facility-related and depreciation expenses, third-party license fees and external costs of outside vendors engaged to conduct preclinical and clinical development activities and clinical trials as well as to manufacture clinical trial materials. Non-

refundable prepayments for goods or services that will be used or rendered for future research and development activities are recorded as prepaid expenses. Such amounts are recognized as an expense as the goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered, or the services rendered. Milestone and other payments made to third-parties with respect to in-process research and development, in accordance with the Company's license, acquisition and other similar agreements are expensed when determined to be probable and estimable.

The Company has entered into various research and development contracts with other companies. These agreements are generally cancellable, and related payments are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research and development costs or prepaid expenses where the payments made exceed the estimated costs. These amounts are determined based on the estimated costs to complete each study or activity, the estimation of the current stage of completion and the invoices received, as well as predetermined milestones which are not reflective of the current stage of development for prepaid expenses. Actual results could differ from the Company's estimates. In all cases, the full cost of each study or activity is expensed by the time the final report or where applicable, product, has been received. The Company's historical estimates have not been materially different from the actual costs.

Stock-Based Compensation

The Company measures and recognizes compensation expense for all stock option awards based on the estimated fair value of the award on the grant date. The Company uses the Black-Scholes option pricing model to estimate the fair value of stock option awards. Additionally, the Company uses a Monte Carlo simulation model to calculate the estimated fair value on the date of grant related to awards with market-based service conditions. The fair value is recognized as expense, over the requisite service period, which is generally the vesting period of the respective award, on a straight-line basis for each separately vesting portion of the award when the only condition to vesting is continued service. If vesting is subject to a market or performance condition, recognition is based on the derived service period of the award. Expense for awards with performance conditions is estimated and adjusted on a quarterly basis based upon the assessment of the probability that the performance condition will be met. Use of the Black-Scholes option-pricing model requires management to apply judgment under subjective assumptions. These assumptions include:

- Expected term—The expected term of stock options represents the weighted-average period the stock options are expected to be outstanding. The Company uses the simplified method for estimating the expected term as provided by the SEC. The simplified method calculates the expected term as the average of the time-to-vesting and the contractual life of the options.
- Expected volatility—The expected volatility is calculated based on historical volatility of the Company's share price.
- Risk-free interest rate—The risk-free rate assumption is based on the U.S. Treasury instruments, the terms of which were consistent with the expected term of the Company's stock options.
- Expected dividend—The expected dividend assumption is based on the Company's history and expectation of dividend payouts. The Company has not paid and does not intend to pay dividends.

The Company uses a Monte Carlo simulation model to estimate the fair value of Performance and Market-based Stock Options at the date of grant which utilizes multiple input variables to estimate the probability that the market condition will be achieved. Key assumptions used in the model include the risk-free interest rate, which reflects the US Treasury Constant Maturity Yield with a term commensurate with the contractual term of the award, and stock price volatility, which is derived based on the historical volatility of the Company's stock.

The Company estimates expected forfeitures at the time of grant instead of accounting for forfeitures as they occur. Stock option awards have been granted at fair value to non-employees in connection with research and consulting services provided to the Company. Equity awards generally vest over terms of 3 or 4 years.

The Company classifies stock-based compensation expense in the consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified.

Income Taxes

The provision for income taxes is determined using the asset and liability approach. Tax laws may require items to be included in tax filings at different times than the items are reflected in the financial statements. A current asset or liability is recognized

for the estimated taxes receivable or payable for the current year. Deferred taxes represent the future tax consequences expected to occur when the reported amounts of assets and liabilities are recovered or paid. Deferred taxes are initially recognized at enacted tax rates in force at the time of initial recognition and are subsequently adjusted for any enacted changes in tax rates and tax laws. Subsequent changes to deferred taxes originally recognized in equity are recognized in income. Valuation allowances are recorded to reduce deferred tax assets when it is more likely than not that a tax benefit will not be realized. The Company has recorded a full valuation allowance against the deferred tax assets in excess of its deferred tax liabilities, as the deferred tax liabilities represent future reversals of existing taxable temporary differences. The Company records interest and penalties related to income tax matters as part of income tax expense.

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents, restricted cash and short-term investments. The Company's cash is comprised of short-term cash deposits at a variety of financial institutions which the Company believes are of high credit ratings in amounts that may exceed federally insured limits. The Company has not experienced any losses on such accounts. Cash balances maintained during the year have been principally held with U.S.-based and U.K.-based banks. The Company does not believe it is exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

The Company relies, and expects to continue to rely, on a number of vendors to conduct its clinical trials and preclinical studies, manufacture drug product and supply clinical trial and preclinical study materials for its development programs. These programs could be adversely affected by a significant interruption in these services or the availability of materials.

Fair Value Measurements

In accordance with the provisions of fair value accounting, a fair value measurement assumes that the transaction to sell an asset or transfer a liability occurs in the principal market for the asset or liability or, in the absence of a principal market, the most advantageous market for the asset or liability and defines fair value based on the exit price model.

The fair value measurement guidance establishes a fair value hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The guidance describes three levels of inputs that may be used to measure fair value:

Level 1
Quoted prices in active markets for identical assets or liabilities as of the reporting date. Active markets are those in which transactions for the asset or liability occur in sufficient frequency and volume to provide pricing information on an ongoing basis.

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 2 assets and liabilities include debt securities with quoted prices that are traded less frequently than exchange-traded instruments or securities or derivative contracts that are valued using a pricing model with inputs that are observable in the market or can be derived principally from or corroborated by observable market data.

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. Level 3 assets and liabilities include financial instruments whose value is determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant management judgment or estimation.

In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, the Company categorizes such assets and liabilities based on the lowest level input that is significant to the fair value measurement in its entirety. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment and considers factors specific to the asset.

(in thousands, except share and per share data)

Cash and Cash Equivalents

The Company considers only those investments that are highly liquid, readily convertible to cash and that mature within 90 days or less from date of purchase to be cash equivalents. As of December 31, 2025, cash equivalents were comprised of money market funds and U.S. treasury securities. As of December 31, 2024, cash equivalents were comprised of money market funds.

Restricted Cash

Restricted cash represents amounts which are legally restricted to withdrawal or usage and is presented in the consolidated balance sheet as restricted cash. As of December 31, 2025 the Company has $316 of restricted cash associated with an irrevocable letter of credit required by the landlord to enter into the lease for Company's corporate office.

The Company's total cash, cash equivalents and restricted cash balances were as follows:

	Year Ended December 31,		
	2025	2024	2023
Cash and cash equivalents	$ 225,266	$ 104,862	$ 71,425
Restricted cash	316	325	—
Total cash, cash equivalents and restricted cash	$ 225,582	$ 105,187	$ 71,425

Short-term Investments

Short-term investments consist of marketable securities with original maturities greater than ninety days from the date of acquisition. The Company classifies marketable securities with original maturities of greater than 90 days and less than one year as short-term, based on the liquid nature of the marketable securities and because such marketable securities represent the investment of cash that is available for current operations. The Company considers its investment portfolio of marketable securities as available-for-sale. Accordingly, these investments are recorded at fair value, which is based on quoted market prices or other observable inputs. Unrealized gains and losses are recorded as a component of other comprehensive income (loss). Realized gains and losses are determined on a specific identification basis and are included in other income, net. Amortization and accretion of discounts and premiums are also recorded in other income, net.

When the fair value is below the amortized cost of the asset, an estimate of expected credit losses is made. This estimate is limited to the amount by which fair value is less than amortized cost. The credit-related impairment amount is recognized in the consolidated statements of operations and comprehensive loss and the remaining impairment amount and unrealized gains are reported as a component of accumulated other comprehensive income (loss) in stockholders' equity. Credit losses are recognized through the use of an allowance for credit losses account and subsequent improvements in expected credit losses are recognized as a reversal of the allowance account. If the Company has the intent to sell the security or it is more likely than not that the Company will be required to sell the security prior to recovery of its amortized cost basis the allowance for credit loss is written off and the excess of the amortized cost basis of the asset over its fair value is recorded in the consolidated statements of operations and comprehensive loss.

Recently Issued Accounting Pronouncements

In December 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update "ASU" 2023-09, "Improvements to Income Tax Disclosures", which requires disclosure of disaggregated income taxes paid, prescribes standard categories for the components of the effective tax rate reconciliation, and modifies other income tax-related disclosures. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024 and allows for adoption on a prospective basis, with a retrospective option. Early adoption is permitted. The Company adopted ASU 2023-09 for the year ended December 31, 2025 using a retrospective approach. The adoption of ASU-2023-09 did not have a material impact on the Company's consolidated financial statements and related disclosures.

In November 2024, the FASB issued ASU 2024-03, "Disaggregation of Income Statement Expenses", which requires disclosures about specific types of expenses included in the expense captions presented on the face of the income statement as

(in thousands, except share and per share data)

well as disclosures. The guidance is to be applied prospectively, with the option for retrospective application and is effective for public business entities for fiscal years beginning after December 15, 2026, and interim periods beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the impact of the adoption of this standard on the Company's consolidated financial statements and related disclosures.

In December 2025, the FASB issued ASU 2025-11, "Narrow-Scope Improvements", which is intended to improve the navigability of the guidance in ASC 270 and clarify when the guidance is applicable. ASU 2025-11 is effective for interim reporting periods within annual reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the impact of the adoption of this standard on the Company's consolidated financial statements and related disclosures.

Other recent authoritative guidance issued by the FASB (including technical corrections to the FASB ASC), the American Institute of Certified Public Accountants, and the SEC did not or are not expected to have a material impact on the Company's consolidated financial statements and related disclosures.

3. Segment Reporting

The Company's chief operating decision makers (the "CODM function"), which are the Company's Co-Chief Executive Officers, Mr. Duggan and Dr. Zanganeh, and Chief Operating Officer and Chief Financial Officer, Mr. Soni, utilize consolidated net loss that is reported on the consolidated statement of operations and comprehensive loss to make decisions about allocating resources and assessing performance for the entire Company. The CODM function approves of key operating and strategic decisions, including key decisions in clinical development and clinical operating activities, entering into significant contracts, such as revenue contracts and collaboration agreements and approves the Company's consolidated operating budget. The CODM function views the Company's operations and manages its business on a consolidated basis and as a single reportable operating segment. The CODM function is regularly provided with the following significant segment expenses:

	Year Ended December 31,		
	2025	2024	2023
Oncology clinical trial related costs	$ 266,439	$ 100,937	$ 35,224
Acquired in-process research and development	—	15,007	520,915
Compensation related costs, excluding stock-based compensation	75,575	48,295	31,371
Stock-based compensation	732,420	50,981	14,108
Other expenses [1]	19,990	10,778	8,032
Total segment expenses	1,094,424	225,998	609,650
Other income, net	14,838	13,369	11,183
Interest expense	—	(8,686)	(16,461)
Net loss	$ (1,079,586)	$ (221,315)	$ (614,928)

[1] Other expenses include general and administrative expenses excluding compensation and stock-based compensation.

As of December 31, 2025 and 2024, substantially all of our long-lived assets are located in the United States.

4. Akeso License and Collaboration Agreement

On December 5, 2022, the Company entered into the License Agreement with Akeso pursuant to which the Company is in-licensing its breakthrough bispecific antibody, ivonescimab. The License Agreement and transaction closed in January 2023 following customary waiting periods.

Ivonescimab, known as AK112 in China and Australia, and also as SMT112 in the United States, Canada, Europe, and Japan, is a novel, potential first-in-class bispecific antibody intending to combine the effect of immunotherapy via a blockade of PD-1 with the anti-angiogenesis effects of an anti-VEGF into a single molecule. Ivonescimab was engineered to bring two well established oncology targeted mechanisms together. Ivonescimab is currently in clinical development and, pursuant to the terms

(in thousands, except share and per share data)

of the License Agreement, Summit will design and conduct the clinical trial activities to support regulatory filings in the Licensed Territory that Summit will submit.

Pursuant to the terms of the License Agreement, Summit will have final decision making authority with respect to clinical development strategy and execution in the Licensed Territory. For co-joined studies in which both Summit and Akeso participate, mutual agreement is required for material decisions; Summit retains the exclusive decision making with respect to participating in, and continuing its participation in, co-joined studies. Pursuant to the terms of the License Agreement, Summit will have final decision-making authority with respect to commercial strategy, pricing and reimbursement and other commercialization matters in the Licensed Territory. In connection with the License Agreement, the Company agreed to purchase a certain portion of drug substance and/or drug product for clinical and commercial supply and to enter into a supply agreement with Akeso. Summit is not assuming any liabilities (including contingent liabilities), acquiring any physical assets or trade names, or hiring or acquiring any employees from Akeso in connection with the License Agreement. Through the License Agreement, the Company obtained the rights to develop and commercialize ivonescimab in the United States, Canada, Europe, and Japan.

In exchange for the rights obtained, the Company made an upfront payment of $500,000 to Akeso, of which $274,900 was paid in cash and, pursuant to the License Agreement and Issuance Agreement, Akeso elected to receive 10,000,000 shares of the Company's common stock, par value $0.01 per share ("common stock") in lieu of $25,100 in cash. The remaining $200,000 amount of the upfront payment was paid on March 6, 2023.

Effective June 3, 2024, the Company and Akeso entered into the Second Amendment to the License Agreement to expand the Company's territories covered under the License Agreement to include the Latin America, Middle East and Africa regions. Pursuant to the Second Amendment, the Company paid an upfront payment to Akeso of $15,000 in the third quarter of 2024. Akeso will also be eligible to receive up to an additional $55,000 upon the achievement of certain commercial milestones. Except as specifically modified by the Second Amendment, the terms and conditions of the License Agreement remain in full force and effect.

The Company has accounted for the License Agreement and Second Amendment to acquire the rights to develop and commercialize ivonescimab as the acquisition of an asset. All of the consideration relates to ivonescimab and technological feasibility of the asset has not yet been established since ivonescimab is in clinical development. As such, the Company has expensed the consideration as acquired in-process research and development upon closing of the transaction in the consolidated statement of operations and comprehensive loss. Acquired in-process research and development expense for the year ended December 31, 2025 was nil. Acquired in-process research and development expense for the year ended December 31, 2024, was $15,007 which is comprised of the upfront payment and immaterial transaction costs. For the year ended December 31, 2023, acquired in-process research and development expense totaled $520,915 pursuant to the License Agreement, which was comprised of the $474,900 paid in cash, the fair value of the 10,000,000 shares of common stock on the date of closing the transaction of $45,900, and $115 of direct transactions costs incurred.

In addition to the payments already made to Akeso, under the License Agreement and Second Amendment, there are additional potential milestone payments of up to $4,555,000, as Akeso will be eligible to receive regulatory milestones of up to $1,050,000 and commercial milestones of up to $3,505,000. In addition, Akeso will be eligible to receive low double-digit royalties on net sales.

5. Other Income, Net

The following table sets forth the components of other income, net:

	Year Ended December 31,		
	2025	**2024**	**2023**
Foreign currency (loss) gain	$ (610)	$ (97)	$ 613
Investment income [1]	15,501	13,466	10,403
Reclassification of cumulative currency translation gain [2]	—	—	419
Other expense, net	(53)	—	(252)
	$ 14,838	$ 13,369	$ 11,183

(1) Investment income relates to the Company's money market funds and short-term investments in U.S. treasury securities. Refer to Note 9 for details.

(2) The reclassification of cumulative currency translation gain related to the reclassification of cumulative foreign currency translation gains from accumulated other comprehensive loss due to the dissolution of certain dormant entities.

(in thousands, except share and per share data)

6. Income Tax

The Company is primarily subject to corporation taxes in the U.S. and the U.K. The calculation of the Company's tax provision involves the application of both U.S. and U.K. tax law and requires judgment and estimates. The Company has also assessed the applicability of the OECD/G20 Inclusive Framework on Base Erosion and Profit Shifting (BEPS) Pillar 2 rules, which establish a global minimum tax rate. Based on the Company's current financial position and revenue it does not meet the thresholds for Pillar 2 to apply. Therefore, the provisions and requirements under Pillar 2 do not impact our financial statements for the reporting period.

The provision for income taxes is determined using the asset and liability approach. Tax laws may require items to be included in tax filings at different times than the items are reflected in the financial statements. A current asset or liability is recognized for the estimated taxes receivable or payable for the current year.

Deferred taxes represent the future tax consequences expected to occur when the reported amounts of assets and liabilities are recovered or paid. Deferred taxes are initially recognized at enacted tax rates in force at the time of initial recognition and are subsequently adjusted for any enacted changes in tax rates and tax laws. Subsequent changes to deferred taxes originally recognized in equity are recognized in income.

Valuation allowances are recorded to reduce deferred tax assets when it is more likely than not that a tax benefit will not be realized. The Company has recorded a full valuation allowance against the deferred tax assets in excess of its deferred tax liabilities, as the deferred tax liabilities represent future reversals of existing taxable temporary differences. The Company records interest and penalties related to income tax matters as part of income tax expense.

Uncertain Tax Positions

The Company accounts for uncertain tax positions taken in its tax filings by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities having full knowledge of the facts and applicable tax rules. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed as the amount of benefit to recognize in the consolidated financial statements. The amount of benefits that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate, as well as the related net interest and penalties.

Due to the Company's full valuation allowance, the unrecognized tax benefits are not expected to materially impact the Company's effective tax rate when recognized or significantly increase or decrease in the next 12 months. In addition, the Company's policy is to recognize interest and penalties related to uncertain tax positions as part of its income tax provision. However, for the years ended December 31, 2025 and 2024, the Company had no interest or penalties related to unrecognized tax benefits because any potential disallowance would not result in current tax but only result in a reduction to the Company's net operating loss carryforwards.

Loss Before Income Taxes

The components of the Company's loss before income taxes are as follows:

	Year Ended December 31,		
	2025	2024	2023
Foreign	$ (326,729)	$ (199,040)	$ (499,810)
United States	(752,857)	(22,275)	(115,118)
Loss before income taxes	$ (1,079,586)	$ (221,315)	$ (614,928)

(in thousands, except share and per share data)

Deferred Income Taxes

The Company has not recognized a current or deferred provision for federal, state or non-United States income taxes in either of the years ending December 31, 2025 or December 31, 2024.

Deferred taxes are recognized for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes.

The major components of deferred tax assets and liabilities are as follows:

	Year Ended December 31,	
	2025	2024
Deferred tax assets:		
Net operating loss carryforward	$ 73,583	$ 59,413
Research and development credit carryforward	16,092	7,869
Stock-based compensation	32,158	14,001
Section 174 Research and Development Capitalization	11,034	14,167
Other	711	475
Total deferred tax assets	133,578	95,925
Deferred tax liabilities:		
Other	(417)	(337)
Total deferred tax liabilities	(417)	(337)
Net deferred tax assets before valuation allowance	133,161	95,588
Valuation allowance	(133,161)	(95,588)
Deferred tax, net	$ —	$ —

For the year ended December 31, 2025 and 2024, the Company recorded a deferred tax asset of $133,578 and $95,925, respectively.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize its deferred tax assets, which are comprised primarily of net operating loss carryforwards, research and development credits, stock-based compensation expense, and research and development costs capitalized for tax purposes. Management has considered the Company's history of cumulative net losses in each taxing jurisdiction, estimated future taxable income, as well as prudent and feasible tax planning strategies, and has concluded that it is more likely than not that the Company will not realize the tax benefits in each jurisdiction. Accordingly, a full valuation allowance has been established against these net deferred tax assets as of December 31, 2025 and 2024, respectively. The Company reevaluates the positive and negative evidence at each reporting period.

The changes in the valuation allowance during the years ended December 31, 2025, 2024 and 2023 primarily related to net operating loss carryforwards and capitalized research and development expenses.

The change in the valuation allowance was as follows:

	Year Ended December 31,		
	2025	2024	2023
Valuation allowance as of beginning of year	$ (95,588)	$ (84,751)	$ (64,016)
Net increases recorded to income tax provision	(37,573)	(10,837)	(20,735)
Valuation allowance as of end of year	$ (133,161)	$ (95,588)	$ (84,751)

Net Operating Loss and Tax Credit Carryforwards

As of December 31, 2025 and 2024, the Company had U.S. Federal gross operating loss carryforwards of approximately $93,210 and $44,270, respectively, which may be available to offset future income tax liabilities. The 2017 Tax Cuts and Jobs Act ("TCJA") will generally allow losses incurred after 2017 to be carried over indefinitely but generally limits the net operating loss deduction to the lesser of the net operating loss carryover or 80% of a corporation's taxable income (subject to Section 382 of the Internal Revenue Code of 1986, as amended). In addition, the Company has approximately $21,335 in U.S. State gross loss carryforwards which expire through various dates through 2044.

As of December 31, 2025, the Company had an estimated U.S. federal and state research and development tax credit carryforwards of $15,565 and $5,002, respectively, which may be available to offset future tax liabilities, and each begin to expire in 2041 and 2037, respectively.

As of December 31, 2025 and 2024, the Company had U.K. gross operating loss carryforwards of approximately $211,096 and $198,653 respectively, which may be available to offset future income tax liabilities. To the extent that U.K. taxable profits exceed £5,000 in each year, the loss available to utilize against profits in excess of £5,000 will be restricted to 50%. The U.K. loss carryforwards do not lapse and therefore, the full amount will be relieved over time provided there are sufficient profits against which the losses can be utilized.

Utilization of the U.S. net operating loss carryforwards and research and development tax credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986 due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50% over a three-year period. The Company has not completed a study to assess whether a change of ownership has occurred, or whether there have been multiple ownership changes since its formation. Any limitation may result in the loss of a portion of the net operating loss carryforwards or research and development tax credit carryforwards before utilization.

U.K. tax losses are subject to additional restrictions where there is a change in ownership in the business and certain other conditions are met. An ownership change of a U.K. tax resident company would occur where (directly or indirectly) a single person acquires more than half of the ordinary share capital of a company, or two or more persons each acquire a holding of at least 5% of the ordinary share capital of a company and these holdings together amount to more than half the ordinary share capital of a company. Where a change in ownership has occurred, and within three years prior to that change in ownership and five years afterwards, there is a major change in the nature and conduct of trade of that company or the trade of that business becomes small or negligible, any losses carried forward will be extinguished from the point of the change in ownership. In addition, losses accrued subsequent to April 1, 2017 will be extinguished on a change of ownership when there is a major change in the nature or conduct of a company's business, or where there is a major change in the scale of that business, or a company ceases to carry on a particular trade or business. The Company has not completed a study to assess whether a change of ownership has occurred since its formation, or whether there has been a major change in the Company's business that would restrict the U.K. tax losses. Any limitation may result in the loss of a portion of the net operating loss carryforwards before utilization.

Deemed U.S. Income Inclusions

The TCJA created a requirement that US corporations include in income earnings of certain controlled foreign corporations under the global intangible low taxed income ("GILTI") regime. Pursuant to the FASB Staff Q&A, Topic 740 No.5. Accounting for Global Intangible Low-taxed Income, the Company is allowed to make an accounting policy election to either recognize deferred taxes for temporary basis differences expected to reverse as GILTI in future years or to provide for the tax expense related to GILTI in the year the tax is incurred as period expense only. The Company has elected to account for GILTI in the year the tax is incurred and include the current tax impact of GILTI in the effective tax rate. Given the Company's loss position in the U.S. and the valuation allowance recorded against its U.S. net deferred tax assets, these provisions have not had a material impact on the Company's consolidated financial statements.

(in thousands, except share and per share data)

Annual Effective Tax Rate Reconciliation

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

	Year Ended December 31,					
	2025		2024		2023	
Tax at federal statutory rate	(226,702)	21.0 %	(46,476)	21.0 %	(129,048)	21.0 %
State income tax, net of federal tax benefit	—	— %	(17)	— %	—	— %
Research and development credits	(6,828)	0.6 %	(4,782)	2.2 %	(2,275)	0.4 %
Nontaxable or nondeductible Items						
Stock-based compensation	134,033	(12.4) %	(130)	0.1 %	2,978	(0.5) %
Other	299	— %	77	— %	521	(0.1) %
Foreign Tax Effects						
Cayman Islands Statutory income tax rate differential	67,969	(6.3) %	41,570	(18.8) %	104,282	(17.0) %
Other foreign jurisdictions	644	(0.1) %	229	(0.1) %	678	(0.1) %
Changes in unrecognized tax benefits	1,357	(0.1) %	956	(0.4) %	800	(0.1) %
Change in valuation allowance	29,228	(2.7) %	8,573	(4.0) %	22,064	(3.6) %
Total	$ —	— %	$ —	— %	$ —	— %

Unrecognized Tax Benefit Reconciliation

The Company records unrecognized tax benefits in accordance with ASC 740-10, Income Taxes. ASC 740-10 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of uncertain tax positions taken or expected to be taken in the Company's income tax return and also provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. As of December 31, 2025, 2024, and 2023, the Company had total unrecognized tax benefits of $3,903, $2,122, and $1,064, respectively.

A reconciliation of unrecognized tax benefits from continuing operations is as follows:

	Year Ended December 31,		
	2025	2024	2023
Unrecognized tax benefits, beginning of year	$ 2,122	$ 1,064	$ —
Increases related to prior year tax positions	592	122	610
Increases related to current year tax positions	1,189	936	454
Unrecognized tax benefits, end of year	$ 3,903	$ 2,122	$ 1,064

Audit Examinations

In the U.S., the Company files a Federal consolidated income tax return and income tax returns in various states. In the U.S., the filings for tax years from 2020 remain subject to examination by the U.S. Internal Revenue Service and state tax authorities. The Company is not currently under examination by the Internal Revenue Service or any other jurisdiction for years 2020 through present. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may be adjusted upon examination by the Internal Revenue Service or state tax authorities to the extent utilized in a future period. In the U.K., tax returns for the year ended December 31, 2023 remains subject to examination by HMRC.

Legislative Impacts

On July 4, 2025, H.R. 1, a U.S. budget reconciliation bill, was signed into law. The Company has assessed the provisions of the new legislation and has integrated the resulting impacts into its effective income tax rate. Management has concluded that the bill does not have an impact on the Company's consolidated financial statements for the current period.

(in thousands, except share and per share data)

7. Net Loss per Share

The following table sets forth the computation of basic and diluted net loss per share:

	Year Ended December 31,		
	2025	2024	2023
Net loss	$ (1,079,586)	$ (221,315)	$ (614,928)
Basic and diluted weighted average number of shares of common stock outstanding	747,702,265	718,541,896	619,646,180
Basic net loss per share	$ (1.44)	$ (0.31)	$ (0.99)
Diluted net loss per share	$ (1.44)	$ (0.31)	$ (0.99)

Basic net loss per share is computed by dividing the net loss by the weighted-average number of common shares outstanding for the period. Diluted net loss per share is computed by dividing the diluted net loss by the weighted-average number of common shares outstanding for the period, including potentially dilutive common shares. Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share for all periods, as the inclusion of all potential common share equivalents outstanding would have been antidilutive.

Because the 2023 Rights Offering (see Note 13) exercise price of $1.05 per share was less than the closing price of $1.82 per share on March 1, 2023, the expiration, the Company has retroactively adjusted earnings per share and the weighted average number of shares outstanding for the bonus element for the year ended December 31, 2023.

The following potentially dilutive securities were excluded from the computation of the diluted net loss per share of common stock for the periods presented because their effect would have been anti-dilutive:

	Year Ended December 31,		
	2025	2024	2023
Options to purchase common stock	115,614,728	68,920,334	54,209,289
Warrants	—	4,629,988	5,015,642
Shares expected to be purchased under employee stock purchase plan	65,905	86,550	155,163
Total	115,680,633	73,636,872	59,380,094

Stock options that are outstanding and contain improbable vesting criteria are excluded from the presentation of common stock equivalents outstanding in the table above.

8. Goodwill

In December 2017, the Company expanded its activities in the field of infectious diseases with the acquisition of Discuva Limited, a privately held United Kingdom-based company. Through this acquisition, the Company obtained a bacterial genetics platform and a suite of software-based technologies, which facilitates the discovery and development of new mechanism antibiotics. This resulted in the recognition of goodwill of £1.5 million, which is translated into U.S. dollars at each reporting period.

As of December 31, 2025 and 2024, goodwill was $2,001 and $1,864, respectively. Changes year over year are the result of changes in foreign currency.

The Company assesses goodwill for impairment on an annual basis as of December 31 or more frequently when events and circumstances occur indicating that recorded goodwill may be impaired. As of December 31, 2025, the Company performed its annual impairment assessment of goodwill and determined that it is more likely than not that the fair value of the reporting unit exceeds its carrying amount. The Company has recorded no goodwill impairment charges to date.

(in thousands, except share and per share data)

9. Fair Value Measurements and Short-Term Investments

The following tables sets forth the Company's fair value hierarchy for its assets and liabilities that are measured at fair value on a recurring basis as of December 31, 2025 and 2024:

		December 31, 2025				
	Fair Value Hierarchy Level	Amortized Cost	Unrealized Gain	Unrealized (Loss)	Credit (Loss)	Fair Value
Financial assets included within cash and cash equivalents:						
Money market funds	Level 1	$ 163,588	$ —	$ —	$ —	$ 163,588
U.S. Government treasury bills	Level 2	45,300	12	—	—	45,312
Financial assets included within short-term investments:						
Certificate of deposit	Level 2	25,000	—	—	—	25,000
U.S. Government treasury bills	Level 2	463,022	160	—	—	463,182
Total		$ 696,910	$ 172	$ —	$ —	$ 697,082

		December 31, 2024				
	Fair Value Hierarchy Level	Amortized Cost	Unrealized Gain	Unrealized (Loss)	Credit (Loss)	Fair Value
Financial assets included within cash and cash equivalents:						
Money market funds	Level 1	$ 88,599	$ —	$ —	$ —	$ 88,599
Financial assets included within short-term investments:						
U.S. Government treasury bills	Level 2	307,387	100	—	—	307,487
Total		$ 395,986	$ 100	$ —	$ —	$ 396,086

The tables above do not include cash at December 31, 2025 and 2024 of $16,366 and $16,263, respectively.

The Company believes that the carrying amounts of prepaid expenses, other current assets, accounts payable, and accrued expenses approximates their fair values due to the short-term nature of those instruments.

Realized gain (loss) on short-term investments for the years ended December 31, 2025 and 2024 were immaterial, respectively.

10. Research and Development Prepaid Expenses and Accrued Liabilities

Included within prepaid expenses and other current assets at December 31, 2025 and 2024 is $3,996 and $8,338, respectively, of prepayments relating to research and development expenditures. Included within accrued liabilities at December 31, 2025 and 2024 is $31,498 and $17,441, respectively, relating to research and development expenditures.

These amounts are determined based on the estimated costs to complete each study or activity related to the ongoing clinical trials for ivonescimab, the estimation of the current stage of completion and the invoices received, as well as predetermined milestones which are not reflective of the current stage of development for prepaid expenses. However, accrued liabilities increase as the activities progress. The key sensitivity is the estimated current stage of completion of each study or activity, which is based on information received from the supplier and the Company's operational knowledge of the work completed under those contracts.

(in thousands, except share and per share data)

11. Leases

The Company has operating leases for real estate. The Company does not have any finance leases.

The Company leases its offices and facilities in Miami, FL, Palo Alto, CA, Princeton, NJ, Oxford, U.K., and Menlo Park, CA under non-cancellable operating lease agreements. The lease agreements for the Company's offices and facilities in Miami, FL, Palo Alto, CA, Princeton, NJ and Oxford, U.K., expire in April 2029, October 2033, August 2028, and February 2027, respectively. The remaining lease agreement for the Company's office and facility in Menlo Park, CA expires in May 2026. Under the terms of the lease agreements, the Company is responsible for certain repair and maintenance, utilities, licensing and permit fees.

During the year ended December 31, 2025, the Company recorded $17,056 of operating right-of-use assets and operating lease liabilities related to new leases for office space for its Palo Alto, CA and Princeton, NJ locations. Total future lease payments as of December 31, 2025 are approximately $23,117 on an undiscounted basis. The Palo Alto lease commenced on December 1, 2025 and has a term of approximately 8 years. The Princeton, NJ lease commenced on August 18, 2025 and has a term of 3 years. The Company recorded $4,216 of right-of-use assets during the year ended December 31, 2024 related to its Miami, Florida headquarters.

The carrying value of the right-of-use assets as of December 31, 2025 and 2024 is $20,616 and $7,144, respectively.

The elements of lease expense were as follows:

	Year Ended December 31,		
	2025	**2024**	**2023**
Fixed lease costs	$ 3,853	$ 3,461	$ 2,214
Variable lease costs	225	48	83
Total lease cost	$ 4,078	$ 3,509	$ 2,297

The weighted average discount rate and the weighted average remaining lease term were 7.6% and 6.7 years, respectively, as of December 31, 2025. The weighted average discount rate and the weighted average remaining lease term were 6.9% and 2.8 years, respectively, as of December 31, 2024. The Company made cash payments related to lease liabilities of $3,741 and $2,568 for the years ended December 31, 2025 and 2024, respectively.

Future lease payments under non-cancelable leases as of December 31, 2025 are detailed as follows:

Year Ending December 31,	
2026	$ 3,492
2027	4,052
2028	4,158
2029	3,349
2030	3,073
Thereafter	9,205
Total lease payments	27,328
Less: imputed interest	6,438
Total operating lease liabilities	$ 20,890
Less: Operating lease liabilities, current portion	3,388
Operating lease liabilities, net of current portion	$ 17,502

12. Promissory Note Payable to Related Parties

December 2022 Promissory Notes

On December 6, 2022, the Company entered into a Note Purchase Agreement (the "Note Purchase Agreement"), with Mr. Duggan and Dr. Zanganeh, pursuant to which the Company agreed to sell to each of Mr. Duggan and Dr. Zanganeh unsecured promissory notes in the aggregate amount of $520,000. Pursuant to the Note Purchase Agreement, the Company issued to Mr. Duggan and Dr. Zanganeh unsecured promissory notes in the amount of $400,000 (the "Duggan February Note") and $20,000 (the "Zanganeh Note"), respectively, which matured and became due on February 15, 2023 and an unsecured promissory note to Mr. Duggan in the amount of $100,000 (the "Duggan September Note" and together with the Duggan February Note and the Zanganeh Note, the "December 2022 Notes"), which was originally due on September 15, 2023. The maturity dates of the December 2022 Notes could have been extended one or more times at the Company's election, but in no event to a date later than September 6, 2024. In addition, if the Company consummated a public offering, then upon the later to occur of (i) five business days after the Company receives the net cash proceeds therefrom or (ii) May 15, 2023, the Duggan February Note and the Zanganeh Note were to be prepaid by an amount equal to the lesser of (a) 100% of the amount of the net proceeds of such offering and (b) the outstanding principal amount on such Notes.

On January 19, 2023, the Company provided notice to extend the term of the Duggan February Note and Duggan September Note to a maturity date of September 6, 2024. Furthermore, on January 19, 2023, the Company and Mr. Duggan rectified the Duggan February Note and Duggan September Note in order to correctly reflect the parties' intent that the Company may only prepay (i) the Duggan February Note following the completion of a public rights offering to be conducted by Summit in the approximate amount of $500,000, or a similar capital raise, in an amount equal to the lesser of (x) the net proceeds of the rights offering or such capital raise or (y) the full amount outstanding of the Duggan February Note, and (ii) Duggan September Note following the completion of a capital raising transaction subsequent to the rights offering in an amount equal to the lesser of (A) the net proceeds of such capital raise or (B) the full amount outstanding of the Duggan September Note. Following the issuance of the two new Promissory Notes (the "Revised Duggan February Note" and the "Revised Duggan September Note", respectively), the Duggan February Note and Duggan September Note were marked as "cancelled" on their face and replaced in their entirety by the Revised Duggan February Note and the Revised Duggan September Note (together with the Zanganeh Note, the "Notes").

On February 15, 2023, the $20,000 Zanganeh Note matured and the Company repaid the outstanding principal balance. In connection with the closing of the rights offering in 2023 (the "2023 Rights Offering"), the $400,000 Revised Duggan February Note matured and became due, and the Company repaid all principal and accrued interest thereunder using a combination of a portion of the cash proceeds from the 2023 Rights Offering and the extinguishment of a portion of the amount due equal to the subscription price of shares subscribed by Mr. Duggan in the 2023 Rights Offering.

The Notes accrued interest at an initial rate of 7.5%. All interest on the Notes was paid on the date of signing for the period through February 15, 2023. Such prepaid interest was paid in a number of shares of the Company's common stock equal to the dollar amount of such prepaid interest, divided by $0.7913 (the consolidated closing bid price immediately preceding the time the Company entered into the Note Purchase Agreement, plus $0.01), which was 9,720,291 shares. For all applicable periods following February 15, 2023, interest accrued on the outstanding principal balance of the Notes at the U.S. prime interest rate, as reported in the *Wall Street Journal,* plus 50 basis points, as adjusted monthly, for three months immediately following February 15, 2023, and thereafter at the U.S. prime rate plus 300 basis points, as adjusted monthly. Accrued interest was paid in cash, quarterly in arrears, on each of March 31, June 30, September 30 and December 31. Debt issuance costs associated with the Notes were $44 and were capitalized as part of the carrying value of the promissory notes payable to related parties.

On February 17, 2024, the Revised Duggan February Note was amended to extend the maturity date from September 6, 2024 to April 1, 2025. For all applicable periods commencing February 17, 2024, interest accrued on the outstanding principal balance at the greater of 12% or the U.S. prime interest rate, as reported in the *Wall Street Journal* plus 350 basis points, as adjusted monthly, and compounded quarterly. Interest was paid upon maturity of the loan. The debt discount was amortized to interest expense using an effective interest rate method. The effective interest rate of the Revised Duggan February Note and Zanganeh Note was 8.9% and the effective interest rate of the Revised Duggan September Note was 11.3%.

On September 16, 2024, the Company used some of the proceeds raised from the September 2024 Private Placement (see Note 13 for further details) to repay $75,500 in principal on the Revised Duggan September Note. On October 1, 2024, the Company repaid the remaining outstanding balance of the Revised Duggan September Note in full, resulting in principal payments of $24,500 and accrued cash interest of $7,305.

As of December 31, 2025 and 2024, the Company had no debt. During the year ended December 31, 2025, the Company incurred no interest expense. During the year ended December 31, 2024, the Company incurred interest expense of $8,686 related to the Revised Duggan September Note.

13. Stockholders' Equity

Preferred Stock

As of December 31, 2025 and December 31, 2024, the Company had 20,000,000 shares of preferred stock, par value $0.01 authorized and no shares issued and outstanding.

Common Stock

As of December 31, 2025 and December 31, 2024, the Company had authorized 1,000,000,000 shares of common stock, par value $0.01 (the "Common Stock"). As of December 31, 2025 and December 31, 2024, the Company had 775,371,200 shares and 737,626,004 shares of Common Stock issued and outstanding, respectively.

On December 6, 2022, the Company announced the 2023 Rights Offering for its existing shareholders to participate in the purchase of additional shares of its Common Stock for $1.05 per share. The 2023 Rights Offering commenced on February 7, 2023 and the associated subscription rights expired on March 1, 2023. Aggregate gross proceeds from the 2023 Rights Offering were $500,000 from the sale of 476,190,471 shares of the Company's Common Stock and issuance costs were $619. Mr. Duggan and Dr. Zanganeh fully subscribed to their respective basic subscription rights at a price of $1.05 per share. To satisfy the $395,314 subscription price for the shares subscribed by Mr. Duggan in the 2023 Rights Offering, Mr. Duggan agreed with the Company to extinguish a portion of the amount due and payable to him by the Company at the closing of the 2023 Rights Offering pursuant to the $400,000 Duggan Promissory Note in an amount equal to the subscription price (see also Note 12).

On January 19, 2023, the Company filed Amendment No. 2 to the Restated Certificate of Incorporation (the "Amendment No. 2") with the Secretary of State of the State of Delaware to increase the number of authorized shares of its Common Stock by 650,000,000 (from 350,000,000 to 1,000,000,000), which became effective on such date.

On March 17, 2023, the Company filed a registration statement on Form S-3 to register for resale the following shares of the Company's Common Stock at $0.01 par value: (i) 10,000,000 shares of Common Stock issued on January 17, 2023 in connection with the License Agreement (as defined in Note 4) with Akeso pursuant to which the Company issued Akeso such shares; and (ii) the 9,346,434 and 373,857 shares of Common Stock issued in December 2022 to Mr. Duggan and Dr. Zanganeh, respectively, as payment of prepaid interest in connection with the Note Purchase Agreement dated December 6, 2022 between Mr. Duggan, Dr. Zanganeh and the Company. On April 27, 2023, the SEC issued the Company a Notice of Effectiveness for the registration statement on Form S-3.

Mr. Soni entered into a share purchase agreement with the Company to purchase $5,000 of its Common Stock via a private placement. The transaction was effective October 13, 2023 with a closing price of $1.68, resulting in the purchase of 2,976,190 shares of the Company's Common Stock.

June 2024 PIPE (Private Investment in Public Equity)

On June 3, 2024, the Company entered into a securities purchase agreement (the "Purchase Agreement") with 667, L.P. and Baker Brothers Life Sciences, L.P., affiliates of Baker Bros. Advisors, L.P., for the sale by the Company in a private placement (the "June 2024 Private Placement") of 22,222,222 shares (the "Shares") of Common Stock, at a purchase price of $9.00 per share, for an aggregate purchase price of approximately $200,000.

The closing of the June 2024 Private Placement was June 6, 2024. The Purchase Agreement contained customary representations, warranties and covenants by the Company, customary indemnification obligations of the Company, including for liabilities under the Securities Act of 1933, other obligations of the parties and termination provisions. The representations, warranties and covenants contained in the Purchase Agreement were made only for purposes of the Purchase Agreement and as of specific dates, were solely for the benefit of the parties to such agreements and were subject to limitations agreed upon by the contracting parties.

On June 3, 2024, in connection with the Purchase Agreement, the Company entered into a Registration Rights Agreement with certain investors (the "Registration Rights Agreement"). The Registration Rights Agreement provides, among other things, that the Company will as soon as reasonably practicable, file with the SEC a registration statement registering the resale of the shares. The Company agreed to use its reasonable best efforts to have such registration statement declared effective as soon as practicable after the filing thereof. The Company filed the registration statement on August 6, 2024, which was automatically effective upon filing.

September 2024 PIPE

On September 11, 2024, the Company entered into securities purchase agreements (the "September 2024 Purchase Agreements") with multiple biotech institutional investors and individual accredited investors, for the sale by the Company in a private placement (the "September 2024 Private Placement") for an aggregate of 10,352,418 shares of the Company's Common Stock, par value $0.01 per share of Common Stock, at purchase price of $22.70 per share, which was the closing price of the Common Stock on September 11, 2024, for aggregate gross proceeds to the Company of approximately $235,000, with offering costs of $140.

All of the Company's Section 16 officers participated in the capital raise. A total of $79,000 was raised by the Company's Co-Chief Executive Officer ("CEO"), Executive Chairman and majority stockholder, its CEO and the President and member of the Company's Board of Directors (the "Board"), its Chief Operating Officer ("COO"), Chief Financial Officer ("CFO"), and member of the Board, its Chief Accounting Officer ("CAO"), and a member of the Board, who invested via a controlled entity. The remaining $156,000 was raised with multiple leading biotech institutional investors. Refer to Note 15 Related Party Transactions for further details regarding related parties' participation.

The closing of the September 2024 Private Placement was September 13, 2024. The September 2024 Purchase Agreements contain customary representations, warranties and covenants by the Company, customary indemnification obligations of the Company, including for liabilities under the Securities Act, as amended (the "Securities Act"), other obligations of the parties and termination provisions. The representations, warranties and covenants contained in the September 2024 Purchase Agreements were made only for purposes of the September 2024 Purchase Agreements and as of specific dates, were solely for the benefit of the parties to such agreements and were subject to limitations agreed upon by the contracting parties.

On September 11, 2024, in connection with the September 2024 Purchase Agreements, the Company entered into Registration Rights Agreements with certain investors (the "September 2024 Registration Rights Agreements"). The September 2024 Registration Rights Agreements provide, among other things, that the Company will as soon as reasonably practicable file with the SEC a registration statement registering the resale of the shares. The Company filed the registration statement on September 19, 2024, which was automatically effective upon filing.

October 2025 PIPE

On October 21, 2025, the Company entered into securities purchase agreements (the "October 2025 Purchase Agreements") with multiple biotech institutional investors and individual accredited investors, for the sale by the Company in a private placement for an aggregate of 26,682,846 shares of the Company's Common Stock, par value $0.01 per share of Common Stock, at purchase price of $18.74 per Share, which was the closing price of the Common Stock on October 21, 2025, for aggregate gross proceeds to the Company of approximately $500,037, with immaterial offering costs. The private placement transaction was completed in October 2025.

All of the Company's Section 16 officers participated in the capital raise. The Company's Co-CEO, Executive Chairman and majority stockholder, its Co-CEO and the President and member of the Board, its COO, CFO, and member of the Board, its CAO, and certain non-executive employees and other related persons purchased an aggregate of 14,514,402 shares of Common

Stock for gross proceeds of approximately $272,000. Additionally, Akeso purchased 533,617 shares of Common Stock for gross proceeds of approximately $10,000. The remaining $218,037 was raised with multiple leading biotech institutional investors.

The October 2025 Purchase Agreements contain customary representations, warranties and covenants by the Company, customary indemnification obligations of the Company, including for liabilities under the Securities Act, as amended (the "Securities Act"), other obligations of the parties and termination provisions. The representations, warranties and covenants contained in the October 2025 Purchase Agreements were made only for purposes of the October 2025 Purchase Agreements and as of specific dates, were solely for the benefit of the parties to such agreements and were subject to limitations agreed upon by the contracting parties.

On October 21, 2025, in connection with the October 2025 Purchase Agreements, the Company entered into Registration Rights Agreements with the Investors (the "October 2025 Registration Rights Agreements"). The October 2025 Registration Rights Agreements provide, among other things, that the Company will as soon as reasonably practicable, and in any event by no later than December 19, 2025, file with the SEC a registration statement registering the resale of the shares. The Company filed the registration statement on October 29, 2025, which was automatically effective upon filing.

At-the-Market Offering (ATM Offering)

On May 13, 2024, the Company entered into an at-the-market ("ATM") sales agreement (the "Original Distribution Agreement") pursuant to which the Company may, subject to the terms and conditions set forth in the agreement offer and sell, from time to time, through or to the agents, acting as agents or principal, shares of the Company's Common Stock, par value $0.01, having an aggregate offering price of up to $90,000. On August 11, 2025, the Company entered into an amendment to the Original Distribution Agreement (as amended, the "Distribution Agreement"), which among other things, increased the aggregate offering price of Common Stock that the Company may offer and sell from time to time through the sales agent under the Distribution Agreement by an additional $360,000.

From the date of the Original Distribution Agreement through December 31, 2025, the Company sold 7,146,432 shares of Common Stock under the ATM at a weighted-average price of $21.09 per share, for gross proceeds of $150,721, with commissions and fees of approximately $3,160. The remaining gross proceeds available under the Distribution Agreement as of December 31, 2025 was approximately $299,279. The Company plans to use the net proceeds from this offering for working capital and general corporate purposes.

Warrants

As of December 31, 2025, the Company had no outstanding warrants. As of December 31, 2024, the Company had outstanding and exercisable warrants of 4,629,988 with a weighted average exercise price of $1.58. During the year ended December 31, 2025, 4,629,988 warrants were exercised with a weighted average exercise price of $1.58.

14. Stock-Based Compensation

2016 Long Term Incentive Plan

Upon the effectiveness of the 2020 Stock Incentive Plan (the "2020 Plan"), no additional grants will be made under the 2016 Long Term Incentive Plan, (the "2016 Plan") and any outstanding awards continue with their original terms.

2020 Stock Award Plan

In September 2020, the Company's Board of Directors approved the 2020 Stock Incentive Plan, which became effective on September 21, 2020. The 2020 plan provides for the grant of incentive stock options, non-qualified stock options, stock appreciation rights, restricted stock, restricted stock units and other stock-based awards.

A total of 8,000,000 shares of Common Stock were initially reserved for issuance under the 2020 Plan. Additionally, up to 5,000,000 shares of Common Stock, including RSUs can be added to the 2020 Plan for future issuance from options that expire,

lapse or are terminated from the 2016 Plan or any other predecessor plans. The number of shares of Common Stock that may be issued under the 2020 Plan will automatically increase on each January 1, beginning in 2021 and continuing for each fiscal year until, and including, the fiscal year ending December 31, 2030, equal to the lesser of (i) 6,400,000 shares of Common Stock, (ii) 4% of the common shares outstanding on the final day of the immediately preceding calendar year and (iii) an amount as determined by the Company's Board of Directors.

As of December 31, 2025, there are 2,643,200 shares available to be issued under the 2020 Plan. The Company currently grants stock options to employees and directors under the 2020 Stock Incentive Plan (the "2020 Plan") and formerly, the Company granted stock options under the 2016 Long Term Incentive Plan (the "2016 Plan"). The 2020 Plan is administered by the Compensation Committee of the Company's Board of Directors. The 2020 Plan is intended to attract and retain employees and directors and provide an incentive for these individuals to assist the Company to achieve long-range performance goals and to enable these individuals to participate in the long-term growth of the Company.

Based on the provisions of the 2020 Plan, the number of shares of common stock available for issuance under the 2020 Plan increased by 6,400,000 shares on January 1, 2025. On September 18, 2025, the Board approved an increase of 8,000,000 shares of common stock available for issuance under the 2020 Plan (the "Incremental Pool"), subject to the approval of the holders of a majority of the shares voting at the Company's stockholder meeting. As of December 31, 2025, there are 3,082,075 shares available to be issued under the Incremental Pool. The Company's consolidated financial statements have treated the grant date of such stock options as the date Board approval was obtained.

On May 3, 2024, the Board adopted the 2024 Inducement Pool (the "Inducement Pool"), which mirrors the terms of the 2020 Plan, with a total of 2,000,000 shares of Common Stock reserved for issuance under the Inducement Pool. Effective January 22, 2025, the number of shares of common stock available under the Inducement Pool increased by 2,000,000 shares. The Inducement Pool provides for the grant of non-qualified stock options and was approved by the Compensation Committee of the Board without stockholder approval pursuant to Rule 5635(c)(4) of the Nasdaq Listing Rules.

The Inducement Pool is administered by the Compensation Committee of the Board. In accordance with Rule 5635(c)(4) of the Nasdaq Listing Rules, non-qualified stock options under the Inducement Pool may only be made to an employee who has not previously been an employee of the Company or member of the Board (or any parent or subsidiary of the Company), if he or she is granted such non-qualified stock options in connection with his or her commencement of employment with the Company or a subsidiary and such grant is an inducement material to his or her entering into employment with the Company or such subsidiary. As of December 31, 2025, there were 1,936,452 shares available for grant under the Inducement Pool.

2020 Employee Stock Purchase Plan

The 2020 Employee Stock Purchase Plan (the "2020 ESPP") was adopted by the Board of Directors and approved by the Company's shareholders on July 17, 2020 and approved by the predecessor company shareholders on August 19, 2020 and is qualified under Section 423 of the Internal Revenue Code. The 2020 ESPP initially authorized the issuance of up to 1,000,000 shares of Common Stock to participating employees. The number of common shares that may be issued under the 2020 ESPP automatically increases on each fiscal year commencing January 1, 2021 and continuing for each fiscal year until, and including the fiscal year commencing on, January 1, 2030 equal to the lesser of (i) 1,600,000 shares of Common Stock, (ii) 1% of the common shares outstanding on such date and (iii) an amount as determined by the Company's Board of Directors. As of December 31, 2025, there were 1,743,682 shares available to be issued under the 2020 ESPP.

The 2020 ESPP is comprised of purchase periods of six months in duration and commence immediately preceding the end of the previous offering period, unless otherwise determined by the Board of Directors or Compensation Committee.

Under the 2020 ESPP, eligible employees can purchase shares of Common Stock through payroll deductions of up to 15% of their compensation received during the plan period or such shorter period during which deductions from payroll are made, up to a defined maximum amount. The option price is determined based on the lesser of the closing price of Common Stock on (i) the first business day of the plan period or (ii) the exercise date, or shall be based solely on the closing price of the Common Stock on the exercise date; provided that such option price shall be at least 85% of the applicable closing price. In the absence of a determination by the Board of Directors or the Compensation Committee, the option price is 85% of the lesser of the closing price of the Common Stock on (i) the first business day of the plan period or (ii) the exercise date.

(in thousands, except share and per share data)

The closing price is the (a) the closing price (for the primary trading session) on the Nasdaq Global Select Market or (b) the average of the closing bid and asked prices in the over-the-counter-market, whichever is applicable, as published in the *Wall Street Journal* or another source selected by the Board or the Committee.

During the fiscal year ended December 31, 2025 and 2024, 139,459 and 353,578 shares, respectively, were issued under the 2020 ESPP Plan.

Stock Options

The Company estimates the fair value of stock options granted to employees and directors using the Black-Scholes valuation model. Stock options granted under the 2016 and 2020 Plans generally vest over three or four years and expire after ten years. This valuation methodology utilizes several key assumptions as highlighted below.

The assumptions used in the Company's valuation are summarized as follows, presented on a weighted average basis:

	Year Ended December 31,		
	2025	**2024**	**2023**
Risk-free interest rate	3.8% - 3.9%	4.2 %	4.6 %
Expected term (in years)	2.5 - 6.2	6.2	4.8
Expected volatility	124.9% -142.5%	107.8 %	98.1 %
Expected annual dividends per share	— %	— %	— %

The following table summarizes the Company's stock option activity for the year ended December 31, 2025:

	Number of share options	**Weighted average exercise price**	**Weighted average remaining contractual term (years)**	**Aggregate intrinsic value**
Outstanding at December 31, 2024*	108,136,310	$ 2.34	8.6	$ 1,677,748
Granted*	13,297,732	19.20		
Forfeited	(1,015,750)	10.12		
Exercised	(953,564)	3.99		
Outstanding at December 31, 2025	119,464,728	$ 4.14	7.8	$ 1,618,734
Vested and expected to vest at December 31, 2025	110,536,687	$ 3.86	7.7	$ 1,527,454
Exercisable at December 31, 2025	64,834,314	$ 2.32	7.4	$ 983,902

* The stock option activity in the table above includes performance-based options outstanding as of December 31, 2024 of 48,220,320 of which 39,013,976 options were unvested and converted to time-based vesting. During the three months ended March 31, 2025, the company granted 5,475,000 performance-based options which were modified to time-based vesting during the three months ended June 30, 2025.

During the second quarter of 2025, the Compensation Committee of the Board of Directors approved a modification to the Company's outstanding unvested performance-based stock option awards for certain employees and executives that will require only the service-based vesting requirements to continue to be satisfied in order to become fully vested, subject to employee consent. The Company accounted for this change as a Type III modification (improbable-to-probable) in accordance with the requirements of Accounting Standards Codification Topic 718 (ASC 718). As a result, 44,488,976 options were valued on the modification date. The Company is recognizing the newly assessed measurement date fair value of the awards as compensation expense over the remaining vesting period. During the year ended December 31, 2025, the Company recognized expense of $650,959 associated with the modification. As of December 31, 2025, the unrecognized compensation cost associated with the modification was $214,295 and is expected to be expensed over a weighted-average recognition period of approximately 1.6 years.

(in thousands, except share and per share data)

The weighted-average grant-date fair value of stock options granted during the years ended December 31, 2025, 2024 and 2023 was $17.10, $3.40 and $1.41, per share, respectively. The aggregate intrinsic value of stock options exercised during the years ended December 31, 2025, 2024 and 2023 was $15,212, $863, and $474, respectively. The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock.

As of December 31, 2025, there was $345,387 total unrecognized compensation cost related to unvested stock option grants. The unvested amount is expected to be recognized over a weighted average period of approximately 1.8 years.

Stock-Based Compensation

Stock-based compensation expense related to stock options is recorded within the consolidated statements of operations and comprehensive loss as follows:

	Year Ended December 31,		
	2025	2024	2023
Research and development	$ 218,564	$ 16,007	$ 4,408
General and administrative	513,856	34,974	9,700
Total stock-based compensation	$ 732,420	$ 50,981	$ 14,108

The following table summarizes stock-based compensation expense associated with each of our stock-based compensation arrangements:

	Year Ended December 31,		
	2025	2024	2023
Time-based stock options	$ 731,358	$ 39,349	$ 12,606
Performance and market-based stock options	—	11,033	1,318
Employee stock purchase plan	1,062	599	184
Total stock-based compensation	$ 732,420	$ 50,981	$ 14,108

15. Related Party Transactions

Leases

July 25, 2022 First Amendment to Sublease Agreement with Maky Zanganeh and Associates, Inc.

On July 25, 2022 the Company entered into a first amendment, dated July 19, 2022, to its existing sublease agreement with Maky Zanganeh and Associates, Inc. ("MZA"), an entity owned by Maky Zanganeh, consisting of 4,500 square feet of office space at 2882 Sand Hill Road, Menlo Park, California. The existing sublease term, which was set to expire on September 30, 2022, was extended for a period of thirty-nine months from October 1, 2022 through December 31, 2025. The rent payable under the terms of the sublease is equivalent to the proportionate share of the net payable by MZA to the third-party landlord, based on the square footage of office space sublet by the Company, and no mark-up has been applied. The agreement was further amended to include additional space, as noted below under the August 2, 2024 Third Amendment to Sublease Agreement with Maky Zanganeh and Associates, Inc. During the years ended December 31, 2025, 2024 and 2023, payments of $834, $795, and $762, respectively, were made pursuant to the first and third amendments to the Sublease Agreement.

July 29, 2022 Second Amendment to Sublease Agreement with Maky Zanganeh and Associates, Inc.

On July 29, 2022, the Company entered into a second amendment to its existing sublease agreement with MZA, described above. The second amendment was effective as of August 1, 2022 and expires on December 31, 2025. The second amendment includes an additional 1,277 square feet of office space at 2882 Sand Hill Road, Menlo Park, California. The rent payable under the terms of the sublease is equivalent to the proportionate share of the net payable by MZA to the third-party landlord, based

on the square footage of office space sublet by the Company, and no mark-up has been applied. During the years ended December 31, 2025, 2024 and 2023, payments of $232, $224 and $218, respectively, were made pursuant to the second amendment to the Sublease Agreement.

April 1, 2024 Miami Sublease Agreements

On April 1, 2024, the Company entered into two sublease agreements of its Miami headquarters location, one with Genius 24C Inc. ("Genius"), an affiliate of the Company's Co-CEO, Robert W. Duggan (the "Genius Sublease Agreement") and one with Duggan Investments Research LLC ("Investments Research"), also an affiliate of the Company's Co-CEO, Robert W. Duggan (the "Investments Research Sublease Agreement"). Pursuant to the Genius Sublease Agreement, Genius sublet from the Company 848 square feet of office space in the Miami HQ for a sixty-two month term for total rental payments of approximately $446. Pursuant to the Investments Research Sublease Agreement, Investments Research sublet from the Company 848 square feet of office space in the Miami HQ for a sixty-two month term for total rental payments of approximately $446. During the years ended December 31, 2025 and 2024, the Company recognized $186 and $156, respectively, of sublease income recorded net of operating lease expenses.

August 2, 2024 Third Amendment to Sublease Agreement with Maky Zanganeh and Associates, Inc.

On August 2, 2024, the Company entered into a third amendment to its existing sublease agreement with MZA. The third amendment was effective August 1, 2024 and included an additional space of 145 square feet of office space located at 2882 Sand Hill Road, Menlo Park, California. The Company continues to be obligated to pay its proportionate share of the net payable by MZA to the third-party landlord, which is revised to 93.6% as of the effective date, based on the square footage of office space sublet by the landlord.

Promissory Note Payable to Related Parties

Refer to Note 12 for disclosure of the promissory note payable to related parties issued December 6, 2022 and fully repaid as of October 1, 2024.

Akeso Agreements

Upon the closing of the License Agreement, the Board appointed Dr. Yu (Michelle) Xia to serve as a member of the Board pursuant to the terms of the License Agreement. Dr. Xia is the founder of Akeso, and has been the chairwoman, president and CEO of Akeso since its inception in 2012. Furthermore, in connection with the License Agreement, the Company also entered into a Supply Agreement with Akeso, pursuant to which Summit agreed to purchase a certain portion of drug substance for clinical and commercial supply (the "Supply Agreement"). Refer to Note 4 for details on the License Agreement and Second Amendment. In addition to the License and Second Amendment and supply agreements, the Company also entered into various clinical services agreements with Akeso. During the years ended December 31, 2025, 2024 and 2023, the Company incurred research and development expenses of $46,133, $24,635 and $6,207, respectively, under these agreements with Akeso. As of December 31, 2025 and 2024 the Company included in accrued expenses, related to Akeso, $1,215 and $3,956, respectively.

2023 Rights Offering

Refer to Note 13 for a discussion on the 2023 Rights Offering.

Private Placements

October 2023 PIPE

Refer to Note 13 for a discussion on the participation by related parties in October 2023 PIPE.

September 2024 PIPE

Refer to Note 13 for a discussion on the participation by related parties in September 2024 PIPE.

October 2025 PIPE

Refer to Note 13 for a discussion on the participation by related parties in October 2025 PIPE.

Warrants Exercise

In March 2025, Mr. Duggan, the Company's Co-Chief Executive Officer, exercised 2,936,221 of the 3,985,055 warrants which he received in connection with a private placement completed by the Company with Mr. Duggan and other investors on December 24, 2019, resulting in the purchase of 2,936,221 shares of common stock at an exercise price of $1.58.

On April 8, 2025, Mr. Duggan completed the exercise of the remaining warrants received in the December 24, 2019 private placement, resulting in the purchase of 1,048,834 shares of common stock at an exercise price of $1.58.

In October 2024, the Shaun Zanganeh Irrevocable Trust exercised a warrant to purchase 315,681 shares of Common Stock. Refer to Note 13 for the warrants exercise activity for the year ended December 31, 2025.

Professional Services

During the year ended December 31, 2025, the Company engaged the law firm Wilson Sonsini Goodrich & Rosati P.C. ("WSGR"), where Mr. Kenneth A. Clark, a member of the Board, is a partner. Payments to be made by the Company to WSGR were approved by the Audit Committee in accordance with its Related Party Transaction Policy. For the year ended December 31, 2025, the Company incurred expenses for legal services rendered by WSGR totaling approximately $1.4 million included in general and administrative expenses.

16. Commitments and Contingencies

Fixed asset purchase commitments

At December 31, 2025 and 2024, the Company had no capital commitments.

Lease commitments

Refer to Note 11 for a discussion of the Company's lease commitments.

Other commitments

The Company enters into contracts in the normal course of business with various third parties for clinical trials, preclinical research studies and testing, manufacturing and other services and products for operating purposes. Most contracts provide for termination upon notice, and therefore are cancellable contracts. The majority of these commitments are due within one year. As of December 31, 2025, total unconditional purchase obligations, excluding leases commitments, are estimated to be approximately $17,976.

The Company has certain commitments under its agreements with Akeso. The License Agreement also contains certain manufacturing and purchase commitments. As of December 31, 2025, the Company is unable to estimate the amount, timing or likelihood of achieving the milestones, making future product sales or assessing estimated forecasts for manufacturing and supplied materials which these contingent payment obligations relate to.

Legal Proceedings

Litigation Relating to the December 2022 Notes Entered into in Connection with the License Agreement

On March 17, 2025, Rainaldi Revocable Trust, a purported stockholder of the Company, filed a derivative lawsuit in the Delaware Court of Chancery against certain of the Company's current and former directors and the Company, solely as a nominal defendant, concerning the December 2022 Notes entered into by the Company, Mr. Duggan and Dr. Zanganeh in connection with the License Agreement. The suit asserts claims for breach of fiduciary duty and unjust enrichment and seeks, among other things, unspecified damages, rescission of the shares that Mr. Duggan and Dr. Zanganeh received as part of prepaid interest payments under the December 2022 Notes, as well as attorneys' fees and costs. Defendants' Motion to Dismiss

the complaint was filed on May 16, 2025. Plaintiff filed the Motion to Certify certain constitutional questions to the Delaware Supreme Court on May 29, 2025. Defendants agreed to a stipulation staying briefing on the Motion to Certify and the Motion to Dismiss pending the Delaware Supreme Court's decision in another case involving substantially the same constitutional questions. On June 18, 2025, the Court granted such stipulation. Defendants believe that Plaintiff's allegations are without merit and plan to vigorously defend against its claims

Named Executive Officers

Robert W. Duggan
Co-Chief Executive Officer & Chairman of the Board; Chief Executive Officer of Duggan Investments, Inc

Mahkam Zanganeh
Co-Chief Executive Officer, President & Director; Founder and Chief Executive Officer of Maky Zanganeh and Associates

Manmeet Soni
Chief Operating Officer, Chief Financial Officer & Director

Board of Directors

Kenneth A. Clark
Member of Wilson Sonsini Goodrich & Rosati, P.C., and Partner, TCG Labs Management, L.P.

Robert Booth
Retired Executive and Professor; Board Member

Alessandra Cesano
Board Member

Yu (Michelle) Xia
Chief Executive Officer and Chairwoman of Akeso, Inc.

Mostafa Ronaghi
Co-Founder and Executive Board Member of Cellanome

Jeff Huber
Co-Founder and Managing Partner of Triatomic Capital Private L.P.