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, 2022
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.)**
2882 Sand Hill Road, Suite 106 **Menlo Park, CA**	**94025**
(Address of Principal Executive Offices)	**(Zip Code)**

(650) 460-8308
(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. ☐

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, 2022, was $25.7 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 March 7, 2023 was 697,685,365.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement to be filed with the Securities and Exchange Commission within 120 days after registrant's fiscal year ended December 31, 2022 are incorporated by reference into Part III of this report.

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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 and Section 21E of the Securities Exchange Act of 1934 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 below);
- our ability to raise sufficient additional funds to make payments under the License Agreement (as defined below);
- the timing of and the ability to start and effectively execute clinical development of ivonescimab;
- the timing and conduct of clinical trials for any product candidates;
- the timing of and our ability to seek a partner or a divestiture of ridinilazole (formerly SMT19969), the Company's Phase III product candidate for the treatment of patients with *Clostridioides difficile* infection (formerly known as *Clostridium difficile* infection);
- our ability to advance and conduct, through partners, research and development of SMT-738, the Company's preclinical product candidate for combating multidrug resistant infections, specifically carbapenem-resistant Enterobacteriaceae (“CRE”) infections;
- 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;
- the potential advantages of our new mechanism antibiotics;
- the rate and degree of market acceptance and clinical utility of our new mechanism antibiotics;
- our estimates regarding the potential market opportunity for our new mechanism antibiotics;
- our sales, marketing and distribution capabilities and strategy;
- our ability to establish and maintain arrangements for manufacture of our product candidates;
- our intellectual property position;
- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- the impact of government laws and regulations;
- our competitive position;
- the need to raise additional capital to fund ongoing operations and capital needs; and
- the impact of the novel coronavirus pandemic (“COVID-19”) and the response to it.

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 Report, 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

Summary

Below is a summary of the principal factors that make an investment in Summit Therapeutics Inc. 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

- The License Agreement and the transactions contemplated thereby represent a significant change in the Company's strategic focus, may not achieve intended results and could increase the number of our outstanding shares or amount of outstanding debt.
- We depend heavily on the success of ivonescimab. If we are unable to successfully 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.
- 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 profits from operations or maintain profitability.
- We will need substantial additional capital to fund our operations and to make payments under the License Agreement and the Note Purchase 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. We have substantial indebtedness and may require additional indebtedness in the future. Our existing and future indebtedness will require interest payments and need to be repaid or refinanced and could require us to divert funds identified for other purposes to service our debt, could result in cash demands and impair our liquidity position and could result in financial risk for us.

Risks Related to our Financial and Intellectual Property 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, any of the licenses under the License Agreement, or issues as to intellectual property could have a material adverse effect on our business.
- 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.

Risks Related to Our Industry and Market

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

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.
- Drug discovery and development is a complex, time-consuming and expensive process that is fraught with risk and a high rate of failure.
- Biologics, such as ivonescimab, carry unique risks and uncertainties, which could have a negative impact on our business.
- We have not yet developed, and may never successfully develop, any marketed drugs.

Legal, Tax, Regulatory and Compliance Risks

- Our ability to commercialize any of our product candidates is subject to substantial regulatory and legislative uncertainty, including as to pricing, reimbursement practices or other healthcare initiatives which could harm our business.
- Our business is subject to the risks associated with doing business in China.
- We may face costly legal claims, in particular related to product liability and intellectual property infringement.
- We are subject to certain United States ("U.S."), United Kingdom ("U.K.") and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations. We can face serious consequences for violations.

Risks Related to Our Intellectual Property, Cybersecurity and Data Privacy

- We rely upon patents to protect our technology. We may be unable to protect our intellectual property rights and we may be liable for infringing the intellectual property rights of others.
- Our actual or perceived failure to comply with stringent and changing obligations related to data privacy and security could lead to regulatory investigations and actions, litigation, fines and penalties, disruptions to our business operations, reputational harm, loss of revenue and profits and other adverse business impacts.

Risks Related to Corporate Governance and Employee Relations

- Our future success depends on our ability to retain our Chairman and Chief Executive Officer, our co-Chief Executive Officer, President and member of the Board and other key executives and to attract, retain and motivate qualified personnel.
- Our Chairman and Chief Executive Officer owns more than a majority of the voting power of the outstanding shares of our common stock, and as a result investors may have limited ability to affect either the corporate governance of the Company or the taking of certain major decisions.

Risks Related to Owning 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.
- The prices of our shares of common stock may be volatile and fluctuate substantially, which could result in substantial losses for our stockholders.
- We have received the requisite approvals and if the Board decides to proceed with the reverse stock split, it may decrease the liquidity of the shares of our common stock and could lead to a decrease in our overall market capitalization.

Risks Related to the COVID-19 Pandemic

- The ongoing COVID-19 pandemic continues to evolve and its enduring impact on our business remains uncertain. Our business has and could continue to be adversely affected, directly or indirectly, by the ongoing COVID-19 pandemic.

PART I

Item 1. Business

Overview

We are 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. Our 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.

On December 5, 2022, we entered into a Collaboration and License Agreement (the "License Agreement") with Akeso, Inc. and its affiliates ("Akeso") pursuant to which we are partnering with Akeso to in-license its breakthrough bispecific antibody, ivonescimab. 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 benefits of immunotherapy via a blockade of PD-1 with the anti-angiogenesis benefits of an anti-VEGF into a single molecule. Ivonescimab was engineered to bring two well established oncology targeted mechanisms together. Through the License Agreement, we obtained the rights to develop and commercialize SMT112 in the United States, Canada, Europe, and Japan (the "Licensed Territory"). The License Agreement and transaction closed on January 17, 2023 following customary waiting periods.

The entry into the License Agreement represents a significant change in the Company's strategy. All prior development and marketing activities relating to ridinilazole are being terminated. All business activities related to anti-infectives are being reviewed for partnership opportunities for potential further development. Our future operations will be focused on the development of ivonescimab and other future activities as the Company determines.

On September 28, 2022, we determined that we would seek partners or a divestiture of ridinilazole, our lead product candidate for treating patients suffering from *Clostridioides difficile* infection, also known as *C. difficile* infection, or CDI, as the path forward for the clinical development of the asset. As a result of this determination, we discontinued our only active study for ridinilazole, a pediatric clinical trial evaluating ridinilazole for treating adolescent patients with CDI. We are currently involved in activities related to closeout of ridinilazole clinical trials.

Our other product candidate, SMT-738, has been in development for combating multidrug resistant infections, specifically carbapenem-resistant Enterobacteriaceae ("CRE") infections. SMT-738 is the first of a novel class of precision antibiotics that has been in preclinical development and has been undergoing investigational new drug ("IND") enabling activities. We will continue to pursue partnerships for further development of SMT-738.

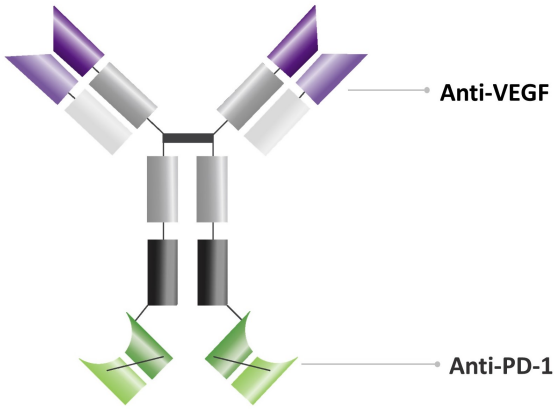
Akeso Collaboration and License Agreement

Our License Agreement with Akeso, as referred to above, calls for Summit to receive the rights to develop and commercialize ivonescimab in the United States, Canada, Europe, and Japan (the "Licensed Territory"). Akeso will retain development and commercialization rights for the rest of the regions including China. In exchange for these rights, Summit made an upfront payment during the first quarter of 2023 comprising 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 the a share transfer agreement. In connection with the License Agreement, the Company has also agreed to enter 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").

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. 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 bispecific antibody, believed to be the most advanced in clinical development. 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 vascular endothelial growth factor ("VEGF") from binding to VEGF receptors. In view of the co-expression of VEGF and PD-1 in the tumor microenvironment, ivonescimab, may block these two pathways more effectively and enhance the antitumor activity, as compared to combination therapy.



Ivonescimab has received Breakthrough Therapy Designation status in China from the National Medical Products Administration ("NMPA") for three indications:

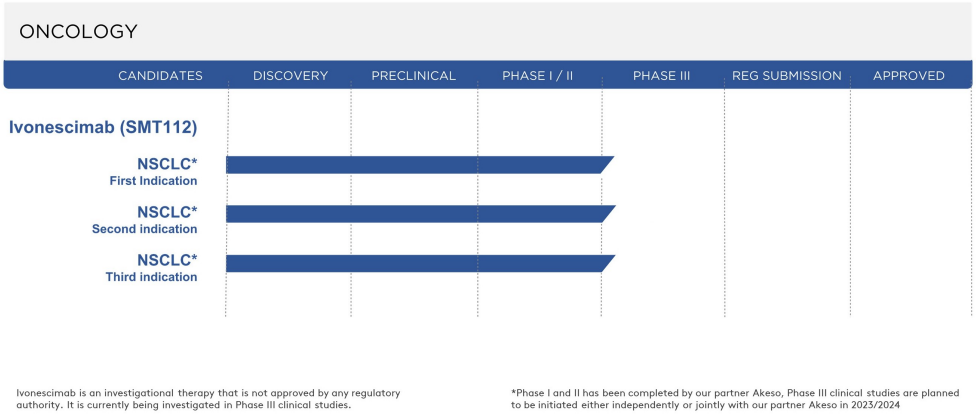
a) ivonescimab combined with chemotherapy for the treatment of EGFR-mutated locally advanced or metastatic NSCLC patients who have progressed after taking an EGFR-TKI treatment
b) ivonescimab as the first-line treatment for locally advanced or metastatic NSCLC patients with positive PD-L1 expression
c) ivonescimab combined with docetaxel for the treatment of locally advanced or metastatic NSCLC patients who have progressed after taking a prior PD-(L)1 inhibitor combined with platinum-based doublet chemotherapy.

Ivonescimab is currently being developed in China and Australia in multiple solid tumors and has been dosed in more than 500 patients. Akeso is currently conducting, in China, a Phase III clinical trial in patients with NSCLC who are positive for an epidermal growth factor receptor ("EGFR") mutation and whose disease has progressed after treatment with an EGFR tyrosine-kinase inhibitor ("TKI"). As presented at ASCO 2022, ivonescimab treatment was associated with an overall response rate (ORR) in a Phase II study in patients with NSCLC who have failed EGFR-TKI's of 68.4% and a median Progression-Free Survival ("mPFS") time period of 8.2 months when combined with combination chemotherapy (pemetrexed and carboplatin). The phase II study, which similarly had patients receiving ivonescimab plus chemotherapy as their first line therapy for metastatic disease, was considered to have demonstrated a tolerable safety profile and a low discontinuation rate for adverse events.

In a separate cohort, in the same phase II study, ivonescimab, combined with docetaxel in patients who have failed PD-(L)1 and chemotherapies, demonstrated a mPFS of 6.6 months. The phase II study, which similarly had patients receiving ivonescimab plus chemotherapy as their first line therapy for metastatic disease, was considered to have demonstrated a tolerable safety profile and a low discontinuation rate for adverse events. Akeso is currently conducting, in China, a phase III clinical trial of ivonescimab monotherapy versus pembrolizumab monotherapy as the first-line treatment for NSCLC patients with positive PD-L1 expression.

Summit has clinical development and commercialization rights for SMT112 in its Licensed Territory (United States, Canada, Europe, and Japan). Summit plans to design and conduct the clinical trial activities for SMT112 in its Licensed Territory, to support and submit relevant regulatory filings. Summit is initiating development activities for ivonescimab and will do so first in NSCLC indications.

Product Pipeline



Ivonescimab is an investigational therapy that is not approved by any regulatory authority. It is currently being investigated in Phase III clinical studies.

*Phase I and II has been completed by our partner Akeso, Phase III clinical studies are planned to be initiated either independently or jointly with our partner Akeso in 2023/2024

Status of Anti-Infectives Pipeline

Discuva Platform

In December 2017, we expanded our activities in the field of infectious diseases with the acquisition of Discuva Limited, a privately held United Kingdom-based company. Through this acquisition, we obtained a bacterial genetics platform and a suite of software-based technologies (collectively termed our "Discuva Platform"), which facilitate the discovery and development of new mechanism antibiotics. Our Discuva Platform can be used to identify new bacterial targets for drug discovery, understand the mechanism of action of small molecules targeting varying types of bacteria and select the most optimal preclinical candidates, including those with the least propensity to develop bacterial resistance.

Our Discuva Platform uses pathogen specific transposons and aligns modified bacterial transposon mutagenesis with next generation sequencing and a proprietary end user interface. Transposons are small segments of DNA that are capable of replicating and inserting copies of DNA at random sites in the same or a different chromosome. Our pathogen specific transposons have three different activating promoters to drive bacterial gene upregulation, to cause gene disruption, or cause the downregulation of bacterial gene expression. There is a single transposon insertion per genome. The density of transposon insertion at the different genomic loci is determined in the whole library with insertion rates potentially being as high as every two to three base pairs.

We believe that our Discuva Platform has three principal uses:

i) Identifying Essential Genes in Bacteria. We are able to use our Discuva Platform to identify genes within bacteria that are essential for their survival. This allows us to identify new bacterial targets against which to develop new antibiotic drugs.

ii) Elucidating Mechanism of Action. We are able to use our Discuva Platform to elucidate the mechanism of action of a compound to be inferred by the genes that are upregulated during experiments when in the presence of a drug. We are able to rapidly identify the mechanism of action of a potential drug and this represents an important capability of our Discuva Platform. We have been able to validate the ability of our Discuva Platform to elucidate mechanisms of action by testing antibiotic compounds representative of known classes whose mechanisms of action are known.

iii) Understanding Emergent Mechanisms of Resistance. We are able to use our Discuva Platform to test a compound's susceptibility towards known mechanisms of antibiotic resistance to allow us to select potential drug candidates with what we believe will be much better resistance profiles. We believe the importance of understanding patients prior to the development of widespread resistance.

On January 20, 2023, we announced that, given the License Agreement that we entered into in December 2022 and the shift in Company's focus to oncology, we will cease further investment in the Discuva platform and evaluate further options for the use of the Discuva Platform. Based on the evaluation of further options for the use of the Discuva Platform, management concluded that this indicated the carrying amount of the acquired Discuva Platform intangible asset may not be recoverable and therefore, performed an impairment assessment to evaluate whether the fair value of the intangible asset was less than its carrying amount. Based on this assessment, an impairment charge of $8.5 million was recognized during the year ended December 31, 2022, representing the aggregate carrying value of the intangible asset. See Note 12 to our consolidated financial statements contained in this Annual Report on Form 10-K for further details.

Enterobacteriaceae Program

We have used our Discuva Platform to identify our DDS-04 series, a novel chemotype active against a clinically unexploited bacterial target that has the potential to treat Enterobacteriaceae infections. The DDS-04 series act *via* a clinically unexploited target, LolCDE, which is involved in the transport of lipoproteins from the inner to outer membrane in Gram-negative bacteria. The cell membrane is crucial for cell viability and the *lol* genes are essential in bacteria such as *E.coli*. In April 2019, we reported data that showed our DDS-04 series to be rapidly bactericidal and highly potent across globally diverse Enterobacteriaceae strains, including multi-drug resistant isolates. Importantly, our DDS-04 series has a low propensity for resistance development and displays no cross resistance with existing classes of antibiotics. In July 2019, we reported initial, positive proof of concept data on an exemplar compound from our DDS-04 series across *in vivo* rodent models of sepsis, urinary tract infection, and pneumonia with further data presented in September 2019.

Our lead preclinical candidate for the Enterobacteriaceae program from the DDS-04 series is SMT026738 (formerly "DIS-0104145" and referred to as "SMT-738"). SMT-738 is a novel small molecule inhibitor of the essential bacterial lipoprotein transport system ("LolCDE") in Gram-negative bacteria, which displays a narrow spectrum of activity towards Enterobacteriaceae, that currently have very limited and failing treatment options due to resistance to existing antibiotic classes. SMT-738 has demonstrated potent in vitro activity against global MDR isolates of *E. coli* and *K. pneumoniae*, including the clinically challenging NDM-carrying CRE isolates where many currently available treatment options have succumbed to clinical resistance including colistin, an antibiotic of last resort. Most importantly, SMT-738 has also shown robust in vivo efficacy in relevant murine models of UTI, pneumonia and sepsis. Preliminary toxicity studies have been conducted, and the data supports the continued clinical development of SMT-738. SMT-738 has the potential to become a first in class antibiotic to treat life-threatening infections. We retain worldwide clinical development and commercial rights to SMT-738. We will continue to pursue partnerships for further development of SMT-738.

Other Material Agreements

The following material agreements relate to our commitments and obligations with respect to ridinilazole and SMT-738 only. The entry into the License Agreement represents a significant change in the Company's strategy. All prior development and marketing activities relating to ridinilazole are being terminated and all business activities related to anti-infectives are being reviewed for partnership opportunities for potential further development.

BARDA

In September 2017, we were awarded a contract from the Biomedical Advanced Research and Development Authority ("BARDA"), part of the Office of the Assistant Secretary for Preparedness and Response at the United States Department of Health and Human Services, to fund, in part, the clinical and regulatory development of ridinilazole for the treatment of infections caused by *C. difficile*. The awarded contract was originally worth up to $62.0 million. In June 2019 and again in January 2020, BARDA increased the value of the contract such that it is now worth up to $72.5 million and brought the total amount of committed funding to $62.4 million. As of December 31, 2022, based on translation of historical foreign currency amounts in the period, the Company has recognized $59.2 million of cumulative income since contract inception. The contract provides for a cost-sharing arrangement under which BARDA funded a specified portion of estimated costs for the continued clinical and regulatory development of ridinilazole for CDI. Under this cost sharing arrangement, we were responsible for a portion of the costs associated with each segment of work, including any costs in excess of the estimated amounts.

The remaining federal government funding is dependent on BARDA in its sole discretion exercising the final independent option work segment, upon the achievement by the Company of certain agreed-upon milestones for ridinilazole. This option work segment was never exercised by BARDA. The contract ran through April 2022 and was extended through December 2022 as a no cost contract, solely to close out open activities. As a result of the Company's decision to not pursue further internal

clinical development of ridinilazole and seek partners or a divestiture related to ridinilazole as a path forward for the clinical development of the asset, the Company recorded expenses for the remaining clinical trial costs associated with the close out activities of ridinilazole and recognized the remainder of the deferred income that had been received from BARDA prior to the expenses being recognized during the third quarter of 2022.

Wellcome Trust

In October 2012, we entered into a translation award funding agreement with the Wellcome Trust Limited, as trustee of the Wellcome Trust, in order to support a Phase I and a Phase II clinical trial of ridinilazole for the treatment of CDI, for which we received $6.3 million. The translation award funding agreement followed an initial funding agreement we and the Wellcome Trust entered into in October 2009, under which we received $3.7 million for preclinical development of CDI antibiotics.

In October 2017, we entered into a revenue sharing agreement with the Wellcome Trust. Under the terms of the revenue sharing agreement upon commercialization of ridinilazole the Wellcome Trust is eligible to receive a share of the net revenues that we, our affiliates, licensees or third-party collaborators receive from commercial sales, and a one-time milestone payment of a specified amount if cumulative net revenues that we our affiliates, licensees or third-party collaborators receive exceed a specified amount. In addition, if a third party commercializes ridinilazole following the first commercial sale by such third party, the Wellcome Trust is eligible to receive a one-time milestone payment of a share of the aggregate amount of any pre-commercial payments we receive from third-party licensees prior to such commercial sale and in the event of an assignment or sale of the assets or intellectual property pertaining to ridinilazole, the net proceeds we receive from such assignment or sale would be treated as net revenue under the revenue sharing agreement.

Eurofarma Laboratórios S.A.

In December 2017, we entered into an exclusive license and commercialization agreement with Eurofarma, pursuant to which we granted Eurofarma the exclusive right to commercialize ridinilazole in specified countries in South America, Central America and the Caribbean (the licensed territory). We have retained commercialization rights in the rest of the world.

Under the terms of the license agreement, we received an upfront payment of $2.5 million and are entitled to receive additional development milestones upon the achievement of staged patient enrollment targets in the licensed territory in our Ri-CoDIFy 1 and Ri-CoDIFy 2 Phase III clinical trials for ridinilazole. In February 2020, we achieved the first of these patient enrollment targets to trigger a milestone payment of $1.0 million. In September 2021, we reached the second enrollment milestone and earned $1.25 million. In addition, we are eligible to receive an additional $2.5 million in various development milestones, $2.4 million in commercial milestones and up to $18.0 million in sales milestones when cumulative net sales equal or exceed $100.0 million in the Eurofarma licensed territory. Each subsequent achievement of an additional $100.0 million in cumulative net sales will result in Summit receiving additional milestone payments, which, when combined with anticipated product supply transfer payments from Eurofarma paid to us in connection with a commercial supply agreement to be entered into between the two parties, would provide payments estimated to range from a mid-teens to high-teens percentage of cumulative net sales in the Eurofarma licensed territory. We estimate such product supply transfer payments from Eurofarma would range from a high single-digit to low double-digit percentage of cumulative net sales in the licensed territory. With the closeout of ridinilazole clinical trials, at this time, we are not anticipating any future payments from Eurofarma under this agreement.

Under the license agreement, Eurofarma is responsible for all costs related to obtaining regulatory approval of ridinilazole in the licensed territory and is obligated to use commercially reasonable efforts to file applications for regulatory approval in specified countries in the licensed territory within a specified time period after we have filed an application for regulatory approval, or obtained regulatory approval, for ridinilazole in a jurisdiction where we retain commercial rights. We retain sole responsibility for the clinical development of ridinilazole in all countries and are responsible for all costs related to obtaining regulatory approval for ridinilazole outside of the licensed territory.

University College London

On March 23, 2010, we entered into a collaborative research agreement with the School of Pharmacy, University of London which was later novated on November 28, 2011, by the School of Pharmacy to University College London. As part of this agreement, and in consideration of their role in the development of the initial compound series from which ridinilazole was later identified, we agreed to pay the School of Pharmacy (now University College London) a low single-digit share of all revenue received by us with respect to ridinilazole, including any pre-commercial licensing revenue, up to a maximum of $1.2 million. To date, we have paid $0.1 million under this agreement.

CARB-X

In May 2021, we announced the selection of a new preclinical candidate, SMT-738, which originated from the DDS-04 series. SMT-738 has been under development to combat multi-drug resistant infections, specifically Carbapenem-resistant Enterobacteriaceae ("CRE") infections. Simultaneously, Summit has received a sub-award from CARB-X to progress SMT-738 through preclinical development and an option to continue into Phase Ia clinical studies. The award commits initial non-dilutive funding of up to $4.1 million for the preclinical phase, with the potential for a further $3.7 million available for the Phase Ia clinical phase upon successfully achieving key preclinical development milestones. During the quarter ended September 30, 2022, CARB-X announced changes to its funding arrangements and terms and conditions. As a result, the current arrangement concluded as of June 30, 2022 however, we have the ability to recognize revenue for any milestone payments related to work incurred subsequent to this date in accordance with this agreement.

Discuva Limited Acquisition

In December 2017, we entered into a share purchase agreement with the shareholders of Discuva, a private limited company organized under the laws of England and Wales pursuant to which we acquired all of the outstanding share capital of Discuva. Discuva was a discovery-stage company with a bacterial genetics-based platform that facilitates the discovery and development of new mechanism antibiotics.

Under the terms of the share purchase agreement, we paid the Discuva shareholders a total upfront consideration comprised of (A) $6.7 million in cash , (B) $6.7 million of shares of common stock, satisfied by the issue of 586,685 of our fully-paid shares of common stock at a price per share of $11.41 and (C) an additional balancing amount in respect of the closing cash position. .

In addition, the Discuva shareholders are entitled to receive contingent payments from us based on (i) the receipt of potential research and development tax credits to which Discuva may be entitled for the period from April 1, 2015, to the date of the share purchase agreement and (ii) approximately one-half of the economic benefit from any amounts received in connection with certain payments made to us under an existing collaboration agreement between Discuva and F. Hoffman - La Roche Limited, or Roche. We made two contingent payments to the Discuva shareholders in December 2018 and May 2019 totaling $1.0 million with respect to research and development tax credits for the period from April 2015 to December 2017 (when the acquisition occurred). Separately, certain employees, former employees and former directors of Discuva are eligible for further payments from Discuva of up to $10.9 million based on specified development and clinical milestones related to proprietary product candidates developed under the platform.

The share purchase agreement contained customary representations and warranties that we and the selling Discuva shareholders made to each other as of specific dates. The assertions embodied in those representations and warranties were made solely for purposes of the share purchase agreement and may be subject to important qualifications and limitations agreed to by us and the Discuva shareholders in connection with negotiating its terms. Moreover, the representations and warranties may be subject to a contractual standard of materiality that may be different from what may be viewed as material to shareholders or may have been used for the purpose of allocating risk between us and the Discuva shareholders rather than establishing matters as facts. For the foregoing reasons, no person should rely on such representations and warranties as statements of factual information at the time they were made or otherwise.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technologies, knowledge, experience, and scientific resources provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, government agencies, and private and public research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

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. This may have the effect of making branded products less attractive from a cost perspective to buyers. 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.

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.

Competition for ivonescimab (SMT112)

Ivonescimab is a novel, potential first-in-class bispecific antibody combining the effects of immunotherapy via a blockade of PD-1 with the anti-angiogenesis effects associated with blocking of VEGF into a single molecule. Ivonescimab is the most advanced PD-1/VEGF bispecific antibody in clinical development and received Breakthrough Therapy Designation status in China for three indications:

a) ivonescimab combined with chemotherapy for the treatment of EGFR-mutated locally advanced or metastatic NSCLC patients who have progressed after taking an EGFR-TKI treatment
b) ivonescimab as the first-line treatment for locally advanced or metastatic NSCLC patients with positive PD-L1 expression
c) ivonescimab combined with docetaxel for the treatment of locally advanced or metastatic NSCLC patients who have progressed after taking a prior PD-(L)1 inhibitor combined with platinum-based doublet chemotherapy.

Ivonescimab is currently being investigated in Phase III clinical trials in China. Summit is initiating development activities for SMT112 and will do so first in NSCLC indications. Summit plans to start treating patients in clinical studies by the second quarter of 2023.

There are no known approved PD-(L)1/VEGF bispecific antibodies that are further advanced in clinical trial development or approved in the territories in which we have licensed ivonescimab. There are also no known PD-1-based bispecific antibodies approved by the US Food and Drug Administration (“FDA”) or the European Medicines Agency (“EMA”).

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 NSCLC are several immuno-oncology drugs and chemotherapies, administered either as monotherapy or in combination with other approved therapeutics. NSCLC treatment regimens vary due to several factors, including genetic mutations and progression of disease. Several medications have been approved by the FDA for these treatments, including, but not limited to pembrolizumab, atezolizumab, nivolumab and durvalumab. In addition, several potential therapeutics are in various stages of development and clinical trials for the treatment of NSCLC, including Daiichi Sankyo with patritumab deruxtecan, Merck with pembrolizumab and Janssen Research & Development, LLC with their drugs lazertinib and amivantamab.

Manufacturing

We do not own or operate, and currently have no plans to establish, manufacturing facilities for the production of clinical or commercial quantities of ivonescimab, ridinilazole or SMT-738. 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 have also agreed to enter into a supply agreement with Akeso, pursuant to which we agree to purchase a certain portion of drug substance for clinical and commercial supply (the “Supply Agreement”). Akeso shall initially be solely responsible for the manufacture of our requirements of clinical and commercial drug substance for use in the Licensed Territory until such time that we are able to establish second source suppliers or are able to manufacture the drug substance independently. We are using a different third-party supplier for clinical packaging, labeling and distribution of the finalized drug product.

Ridinilazole

We engaged a third-party manufacturer to provide clinical material of the active pharmaceutical ingredient ("API") of ridinilazole with a different supplier responsible for drug product manufacturing services that supplied the final drug product for use in the Phase III clinical program. We used a different third-party supplier for clinical packaging, labeling and distribution of the finalized ridinilazole drug product. We obtain the supplies of our API and drug products from these manufacturers pursuant to agreements that include specific supply timelines and volume expectations.

Intellectual Property

We have obtained and maintain proprietary protection for our antibiotic product candidates, technology and know-how, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. 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.

As of December 31, 2022, we owned or exclusively licensed a total of 6 U.S. patents, 3 U.S. patent applications, 3 European patents and 2 European patent applications, including original filings, continuations, divisional and validation applications, as well as numerous other foreign counterparts to these U.S. and European patents and patent applications. Our patent portfolio currently contains a total of 86 patents and patent applications.

Discuva Platform Technology. Our Discuva Platform technology is currently protected by 14 granted U.S. and foreign patents. We expect patent protection for this portfolio to expire in 2032.

***Ridinilazole Program*.** Our ridinilazole program is currently protected by 23 granted U.S. and foreign patents, with 22 pending patent applications. Our patent portfolio for ridinilazole includes patents and patent applications directed to composition of matter, polymorphic forms, methods of manufacture and use and formulation subject matter. We expect that our existing patents and patent applications (assuming the applications proceed to grant) will provide patent coverage for our ridinilazole program until 2043.

***SMT-738 Program*.** Our SMT738 program currently has 4 granted patents and 23 patent applications pending worldwide, directed to the composition of matter. We anticipate that our existing portfolio (assuming the applications proceed to grant) will provide patent coverage for our SMT738 program until 2042.

In addition to the intellectual property patents and applications owned by the Company, following the completion of the License and Collaboration Agreement with Akeso, Summit has in-licensed the rights to various Akeso patent applications in the Licensed Territory and has rights to control prosecution of such in-licensed intellection property in the Licensed Territory in collaboration with Akeso.

***Patent Term Extension*.** Patent term extensions are available in the U.S. and in some foreign countries to compensate a patentee for patent term lost between patent grant and obtaining marketing approval by a regulatory agency, such as the FDA, for a product that is protected by the patent. In accordance with the patent term extension provision of the Drug Price Competition and Patent Term Restoration Act, better known as the “Hatch-Waxman Act”, an extension of time may be granted for one of Summit’s patents protecting ridinilazole, for example, which patent was granted several years before we may obtain marketing approval for the drug product. This extension may provide up to an additional five years of patent term. Similarly, patent extensions called supplementary protection certificates (“SPCs”) may be obtained in some foreign countries for patents granted in advance of obtaining market authorization. SPCs may also provide up to an additional five years of patent term. Summit will submit applications for patent term extensions in all countries where such extensions are available to extend patent protection for ridinilazole, as well as for future patents granted that are directed to Summit’s other drug programs in development. The expiration dates referred to above are without regard to any potential patent term extension or other extension that may be available in the U.S. or any other market.

***Pediatric Exclusivity*.** Pediatric exclusivity is another type of marketing exclusivity in the U.S. that, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, as well as any patent term that is listed in the FDA “Orange Book” for the corresponding drug product. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data

does not need to show the product to be effective in the pediatric population studied; rather if the pediatric clinical trial is deemed to fairly respond to the FDA's request, and reports of the requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, the additional six months exclusivity is granted. A six-month pediatric extension of a SPC may also be obtained in some foreign countries, subject to carrying out an agreed pediatric investigation plan and compliance with other regulatory requirements of that country.

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. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors 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. Summit, in working with Akeso, is in the process of selecting a name for ivonescimab, which we will pursue protection for as a trademark in Licensed Territories. 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 that we infringe or otherwise violate the intellectual property rights of third parties. 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 the FDA under the Federal Food, Drug, and Cosmetic Act ("FDCA") and its implementing regulations, as well as other regulatory bodies in the United States, Europe and other countries. 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, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

Review and Approval of Drugs in the United States

In the United States, the FDA regulates drugs under the FDCA, and implementing regulations. The failure 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 refusal by the FDA to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of letters, product recalls, product seizures, total or partial suspension of production 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 product in the United States must typically undertake the following:

- completion of preclinical 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"), which must take effect before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, approving each clinical study before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with current good clinical practices ("GCP"), to establish the safety and efficacy of the proposed drug product for each indication;
- preparation and submission to the FDA of a new drug application ("NDA") or Biologic Licensing Application ("BLA");

- 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 assure 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 assure compliance with GCPs and the integrity of the clinical data;
- payment of user fees and securing FDA approval of the NDA/BLA; 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.

Preclinical Studies

Before an applicant begins testing a compound with potential therapeutic value in humans, the product candidate enters the preclinical testing stage. Preclinical studies include laboratory evaluation of the purity and stability of the API, and the formulated drug or 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. 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. 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 and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the 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 Institutional Review Board ("IRB") Processes

An IND is an exemption from the FDCA that allows an unapproved drug to be shipped in interstate commerce for use in an investigational clinical trial and 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, applicants 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 filing 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 whenever 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, or 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. A partial clinical hold is a delay or suspension of only part of the clinical work requested under the IND. For example, a specific protocol or part of a protocol or new patient enrollment is not allowed to proceed, while other protocols or already enrolled patients may continue.

Following issuance of a clinical hold or partial clinical hold, an investigation 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, on April 28, 2008, the FDA amended its regulations governing the acceptance of foreign clinical studies not conducted under an investigational new drug application as support for an IND or a new drug application. The final rule provides that such studies must be conducted in accordance with good clinical practice, or GCP, including review and approval by an independent ethics committee, or IEC, and informed consent from subjects. The GCP requirements in the final rule encompass both ethical and data integrity standards for clinical studies. The FDA's regulations 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 the clinical trial 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 organized by the trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access that only the group maintains to available data from the study. Suspension or termination of development during any phase of clinical trials can occur if it is determined 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 clinical trials must be submitted within specific timeframes to the National Institutes of Health ("NIH"), for public dissemination on its ClinicalTrials.gov website. Similar requirements for posting clinical trial information are present in the European Union (EudraCT) website: https://eudract.ema.europa.eu/ and other countries, as well.

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 an IND by the company or the treating physician for treatment purposes on a case-by-case basis 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 under a treatment protocol or Treatment IND Application.

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.

On December 13, 2016, the 21st Century Cures Act established (and the 2017 Food and Drug Administration Reauthorization Act later amended) a requirement that sponsors of one or more investigational drugs for the treatment of a serious disease(s) or condition(s) make publicly available their policy for evaluating and responding to requests for expanded access for individual patients. Although these requirements were rolled out over time, they have now come into full effect. This provision requires drug and biologic companies to make publicly available their policies for expanded access for individual patient access to products intended for serious diseases. Sponsors are required to make such policies publicly available upon the earlier of initiation of a Phase II or Phase III study; or 15 days after the drug or biologic receives designation as a breakthrough therapy, fast track product, or regenerative medicine advanced therapy. Running clinical trials that can support regulatory approvals is

the best way to ultimately ensure wide access for patients to our product candidates. At this point in the development, we cannot support any use of our product candidates outside of clinical trials.

In addition, on May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act, but the manufacturer must develop an internal policy and respond to patient requests according to that policy.

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 informed consent in writing 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 safety and the effectiveness criteria to be evaluated.

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

Phase I. 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 II. 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 III. The investigational drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough 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 presents the data that the FDA or other relevant regulatory agency will use to determine the primary basis of whether or not to approve a product candidate.

Progress reports of the clinical trials must be submitted at least annually to the FDA and more frequently 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 I, Phase II and Phase III clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA/HA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, 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 drug has been associated with unexpected serious harm to patients. The FDA/HA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted.

Under the Pediatric Research Equity Act ("PREA") of 2003, an NDA or supplement thereto must contain data that are adequate 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. With enactment of the Food and Drug Administration Safety and Innovation Act ("FDASIA"), in 2012, sponsors must also submit pediatric study plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests and other information required 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 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. Additional requirements and procedures relating to deferral requests and requests for extension of deferrals are contained in FDASIA.

The FDA Reauthorization Act of 2017 established new requirements to govern certain molecularly targeted cancer indications. Any company that submits an NDA/BLA three years after the date of enactment of that statute 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 testing 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/BLA requesting approval to market the drug product for one or more indications. Under federal law, the submission of most NDAs/BLAs is subject to an application user fee, which for federal fiscal year 2022 is $3,117,218 for an application requiring clinical data. The sponsor of the approved NDA/BLA is also subject to an annual program fee, which for the fiscal year 2022 is $369,413. 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 certain small businesses.

Following submission of an application, the FDA conducts a filing review of an NDA/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 request additional information rather than accept an NDA/BLA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review.

The FDA has agreed to certain performance goals in the review process of NDAs/BLAs. Under that agreement, 90% of applications seeking approval of new molecular entities ("NMEs"), are meant to be reviewed within ten months from the date on which FDA accepts the NDA for filing, and 90% of applications for NMEs that have been designated for "priority review" are meant to be reviewed within six months of the acceptance 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.

Before approving an NDA/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 assure consistent production of the product within required specifications. Additionally, before approving an NDA/BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Under the FDA Reauthorization Act of 2017, the FDA must implement a protocol to expedite review of responses to inspection reports pertaining to certain applications, including applications for products in shortage or those for which approval is dependent on remediation of conditions identified in the inspection report.

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 assure 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, Priority Review and Regenerative Advanced Therapy Designations

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, priority review designation and regenerative advanced therapy designation.

Specifically, the FDA may designate a product for fast-track review 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/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 time period goal for reviewing a fast-track application does not begin until the last section of the NDA/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.

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 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.

Finally, with passage of the 21st Century Cures Act, or Cures Act, in December 2016, Congress authorized the FDA to accelerate review and approval of antibacterial products *via* the limited-population antibacterial drug ("LPAD") pathway. The LPAD pathway provides a unique mechanism for the Food and Drug Administration to review and approve new antibacterial drugs that address unmet medical needs for specific, limited populations of patients - those with serious and life-threatening bacterial infections that are resistant to current treatments. This targeted approach would make antibiotic development more feasible by allowing for smaller clinical development programs that are focused on the limited, high-risk populations that would use these new antibiotics, instead of on more general populations that can be treated with existing medicines. LPAD would also make antibiotic development more feasible by enabling FDA to assess these drugs based on the unique balance of benefits they offer versus risks they present to the limited number of patients they are intended to treat - specifically, patients who have few or no other treatment options. Product candidates that qualify for LPAD review may simultaneously qualify for one or more of FDA's expedited review programs.

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.

Limited Population Antibacterial Drug Pathway

With passage of the Cures Act, Congress authorized the FDA to approve an antibacterial or antifungal drug, alone or in combination with one or more other drugs, as a "limited population drug". To qualify for this approval pathway, the drug must be intended to treat a serious or life-threatening infection in a limited population of patients with unmet needs; the standards for approval of drugs and biologics under the FDCA and the Public Health Service Act ("PHSA"), must be satisfied; and the FDA must receive a written request from the sponsor to approve the drug as a limited population drug pursuant to this provision. The FDA's determination of safety and effectiveness for such a product must reflect the benefit-risk profile of such drug in the intended limited population, taking into account the severity, rarity, or prevalence of the infection the drug is intended to treat and the availability or lack of alternative treatment in such a limited population.

Any drug or biologic approved under this pathway must be labeled with the statement "Limited Population" in a prominent manner and adjacent to the proprietary name of the drug or biological product. The prescribing information must also state that the drug is indicated for use in a limited and specific population of patients and copies of all promotional materials relating to the drug must be submitted to the FDA at least 30 days prior to dissemination of the materials. If the FDA subsequently approves the drug for a broader indication, the agency may remove any post-marketing conditions, including requirements with respect to labeling and review of promotional materials applicable to the product. Nothing in this pathway to approval of a limited population drug prevents sponsors of such products from seeking designation or approval under other provisions of the FDCA, such as accelerated approval.

The FDA's Decision on an NDA/BLA

On the basis of the FDA's evaluation of the NDA/BLA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may 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/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. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

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 with 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 products, as well as new application fees for supplemental applications with clinical data.

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 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 state agencies. The drug manufacturers are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process 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 and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution 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 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 generally may not be promoted for uses that are not approved by the FDA, as reflected in the product's 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 the promotion of off-label uses. It may be permissible, under very specific, narrow conditions, for a manufacturer to engage in

nonpromotional, non-misleading communication regarding off-label information, such as distributing scientific or medical journal information.

If a company is found to have promoted off-label uses, it may become subject to 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. This 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. The federal government has levied large civil and criminal fines against companies for alleged improper promotion, and has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

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.

Pediatric Exclusivity

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent and orphan exclusivity. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly respond 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 additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

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 regulatory review while the patent is in force. 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.

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, 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 Directive 2001/20/EC, the Directive 2005/28/EC on Good Clinical Practice ("GCP"), and the related national implementing provisions of the individual E.U. Member States govern the system for the approval of clinical trials in the European Union. Under this system, an applicant must obtain prior approval from the competent national authority of the E.U. Member States in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial at a specific study site after the competent ethics committee has issued a favorable opinion. The clinical trial application must be accompanied by, among other documents, an investigational medicinal product dossier (the Common Technical Document) with supporting information prescribed by Directive 2001/20/EC, Directive 2005/28/EC, where relevant the implementing national provisions of the individual E.U. Member States and further detailed in applicable guidance documents.

In April 2014, the new Clinical Trials Regulation, (E.U.) No 536/2014 (Clinical Trials Regulation) was adopted. The Regulation was published on June 16, 2014, but has not yet become effective. The Clinical Trials Regulation will be directly applicable in all the E.U. Member States, repealing the current Clinical Trials Directive 2001/20/EC and replacing any national legislation that was put in place to implement the Directive. Conduct of all clinical trials performed in the European Union will continue to be bound by currently applicable provisions until the new Clinical Trials Regulation becomes applicable. The extent to which ongoing clinical trials will be governed by the Clinical Trials Regulation will depend on when the Clinical Trials Regulation becomes applicable and on the duration of the individual clinical trial. If a clinical trial continues for more than three years from the day on which the Clinical Trials Regulation becomes applicable, the Clinical Trials Regulation will at that time begin to apply to the clinical trial.

The new Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the European Union. The main characteristics of the regulation include: a streamlined application procedure *via* a single entry point, the "E.U. Portal and Database;" 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. Part I is assessed by the appointed reporting Member State, 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 (Concerned Member States). 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 European Union (EudraCT) website: https://eudract.ema.europa.eu/ 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. Regulation (EC) No 1901/2006 provides that prior to obtaining a marketing authorization in the European Union, 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.

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 European Union 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") 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 European Union, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops, when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated 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 it is possible that the CHMP can revert to the standard time limit for the centralized procedure if it considers 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”. 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, 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. 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” prior to obtaining the comprehensive clinical data required for an application for a full marketing authorization. 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.

The E.U. medicines rules expressly permit 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. 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.

Regulatory Data Protection in the European Union

In the European Union, innovative medicinal products approved on the basis of a complete independent data package qualify for eight years of data exclusivity upon 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 (abridged) application for a period of eight years. During an additional two-year period of market exclusivity, a generic marketing authorization application 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.

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, 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 case of 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 European Union, 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 a marketing authorization application 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 European Union 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 European Union's stringent pharmacovigilance or safety reporting rules must be ensured. 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 2003/94/EC, Regulation (EC) No 726/2004 and the European Commission Guidelines for Good Manufacturing Practice. 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 European Union with the intention to import the active pharmaceutical ingredients into the European Union;
- The marketing and promotion of authorized drugs, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the European Union notably under Directive 2001/83EC, as amended, and E.U. Member State laws. Direct-to- consumer advertising of prescription medicines is prohibited across the European Union.

General Data Protection Regulation

The collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the European Union, including personal health data, is subject to the E.U. General Data Protection Regulation ("GDPR"), which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union, including the U.S., and 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. The GDPR also 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. Compliance with the GDPR will be a rigorous and time-intensive process that may increase the cost of doing business or require companies to change their business practices to ensure full compliance.

Pricing Decisions for Approved Products

In the European Union, 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 European Union 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 European Union have increased the amount of discounts 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 European Union. 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.

Patent Term Extension

In order to compensate the patentee for delays in obtaining a marketing authorization for a patented product, a supplementary certificate ("SPC") may be granted extending the exclusivity period for that specific product by up to five years. 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 European Union (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 member states of the European Union.

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 with 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, or 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, and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- Foreign Corrupt Practices Act, or 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, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services, or 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 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 manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures. 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 not preempted by HIPAA, thus complicating compliance efforts.

Pharmaceutical Coverage and Reimbursement

In the United States and markets in 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.

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. 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 assure 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.

The containment of health care costs also has become a priority of federal, state and foreign governments and the prices of products have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products.

Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States. In March 2010, the United States Congress enacted the Affordable Care Act, or ACA, which, among other things, includes changes to the coverage and payment for drug products under government health care programs. Among the provisions of the ACA of importance to our potential product candidates are:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices;
- addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- expanded the types of entities eligible for the 340B drug discount program;
- established the Medicare Part D coverage gap discount program by requiring manufacturers to provide a 70% as of January 1, 2019 point-of-sale-discount off the negotiated price of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments, will remain in effect through 2027 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

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 health care 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 additional pricing pressures. The demand for our products is predicated on our clinical trial strategy of attempting to achieve superiority against the standard-of-care. If there are not adequate reimbursement levels, our business and results of operations could be adversely affected.

Human Capital

In order to be a competitive, innovative and successful Company, we believe it is critical to attract, engage, motivate and retain a dedicated, talented and innovative team of employees. As part of these efforts, we strive to foster a diverse, equitable and inclusive community, invest in continuous learning and development, offer a competitive compensation and benefits program and provide a safe and healthy workplace. Our success starts and ends with having the best talent and, as a result, we are focused on attracting, developing, and engaging our employees. In 2022, we continued to strengthen the team by attracting a number of world class leaders with successful track records into the Company, all of our executive positions are now filled with proven leaders.

As of December 31, 2022, we had 76 full-time employees and 77 total employees. Of our total workforce, approximately 62% work in research and development, and 38% work in finance, legal, information technology, general management and other administrative functions. Approximately 62% and 38% of our workforce is located in the U.S. and the U.K., respectively.

In 2022, we once again made challenging demands of our employees and they have responded with dedication and enthusiasm. In August 2022, Summit launched an engagement survey, in which 80% of employees responded. The results of this survey showed our employees to be well engaged, with a strong team spirit and strongly aligned to the Company's mission.

Compensation and Benefits

We provide robust compensation and benefits programs to attract, motivate and retain our employees. In addition to competitive compensation, we provide generous benefits including employer contributions to pension/401k plans, an employee stock purchase plan, insurance benefits, healthcare programs and paid vacation. We are committed to ensuring that our total compensation packages are competitive while supporting our business plans and strategies.

Diversity, Equity and Inclusion

We are committed to embedding a culture of diversity, equity and inclusion across our Company. We believe that diversity of gender, age, ethnicity, sexual orientation, culture, education, background and experience fuels innovation and enables our employees to succeed. This includes ensuring opportunity for all and embraces the positive effect that our diverse workforce brings. We do not tolerate any form of discrimination and our employment policies and practices focus on ensuring that all our employment processes are free from discrimination or harassment on any grounds. Approximately 63% of our employees are female and 62% of our executive team is female.

Learning and Development

We are committed to investing in learning and development for our employees. Our employees have access to online training courses which cover a wide range of technical and business topics to help them develop their professional skills and explore other areas as they plan for their career and personal growth. Our performance management process includes timely performance feedback and career development discussions which are critical to each employee's continued growth and development within the organization.

Workplace Health and Safety

We are committed to the health and safety of all of our employees. We accomplish this through strict compliance with applicable workplace safety laws and regulations, continuous risk assessment and expeditious action. We have again had no reportable health and safety issues in 2022.

Our Corporate Information

Summit Therapeutics Inc. was incorporated in Delaware on July 17, 2020. Our principal executive office is located at 2882 Sand Hill Road, Suite 106, Menlo Park, California and our phone number is (650) 460-8308. 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 Report 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 Report are the property of their respective owners. Solely for convenience, some of the trademarks, service marks, and trade names referred to in this Report 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 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, and amendments to these reports in a timely manner after we provide them to the Securities and Exchange Commission ("SEC").

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 report and our other filings with the Securities and Exchange Commission.

Risks Related to our Financial Position and Need for Additional Capital

The License Agreement and the transactions contemplated thereby represent a significant change in the Company's strategic focus, may not achieve intended results and could increase the number of our outstanding shares or amount of outstanding debt.

As the Company previously announced, on September 28, 2022, we determined that we would seek partners or a divestiture of ridinilazole, our lead product candidate for treating patients suffering from CDI, as the path forward for the clinical development of the asset. As a result of this determination, we discontinued our only active study for ridinilazole, a pediatric clinical trial evaluating ridinilazole for treating adolescent patients with CDI. We are currently involved in activities related to closeout of ridinilazole clinical trials.

On December 5, 2022 we entered into the License Agreement with Akeso pursuant to which Akeso granted the Company an in-license to its breakthrough bispecific antibody, ivonescimab, in the Licensed Territory. The entry into the License Agreement and potential partnership or divestiture of ridinilazole represents a significant change in the Company's strategy. All prior development and marketing activities relating to ridinilazole are being terminated and our future operations will be heavily dependent on the License Agreement and other future activities as the Company determines.

The success of this transaction will depend, in part, on the clinical success of ivonescimab as well as the success of our collaboration with Akeso. This transaction 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. Our Company has no prior history of a successful product candidate and, as discussed above, we determined that we would seek partners or a divestiture for our prior lead product candidate, ridinilazole, and will continue to pursue partnerships for further development of SMT-738. We will also require significant additional financing to fund the clinical development plan and certain payments contemplated by the License Agreement that could result in an increase in the number of our outstanding shares or the aggregate amount of our debt. If we are unable to raise capital to fund these additional payments, it may cause a material adverse effect on our business.

Given the License Agreement that we entered into in December 2022 and shift in focus to oncology, the Company decided it will cease further investment in the Discuva platform and evaluate further options for the use of the Discuva Platform.

We depend heavily on the success of ivonescimab. If we are unable to successfully 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.

We plan to invest 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 will depend on a number of factors, including the following:

- Ability to use data of patients from Akeso's clinical trials in China in seeking regulatory approval;
- successful completion of clinical development;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing supply chain and commercial manufacturing arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity;
- protecting 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 adequate pricing and a reimbursement profile;
- ensuring no disruption in supply or lack of sufficient quantities of ivonescimab;
- effectively competing with other therapies; and

- maintaining a continued acceptable safety profile of ivonescimab, following approval.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize ivonescimab, which would materially harm our business.

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 profits from operations or maintain profitability.

We are a development-stage company and we cannot assure profitability. 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. Since inception, we have incurred significant operating losses. During the year ended December 31, 2022, we incurred a net loss of $78.8 million, and cash flows used in operating activities was $41.6 million. As of December 31, 2022 we had an accumulated deficit of $378.3 million, cash and cash equivalents of $348.6 million, restricted cash of $300,000, research and development tax credits of $5.8 million and accounts receivable of $0.3 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 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 our ability to successfully complete development of any product candidates which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We have not yet demonstrated our 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.

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 the Note Purchase 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 and 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 we are not planning to have commercially available for several years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. In addition, we may

seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. Additional financing may not be available to us on acceptable terms, or 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 these 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 obtain substantial additional funding in connection with our continuing operations. 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.

Our primary future capital requirements will be related to our obligations under the License Agreement.

We expect to continue to generate operating losses for the foreseeable future. The License Agreement calls for initial consideration payments of $500 million (which have been paid), as well as total contingent payments by the Company of up to $5.0 billion, as Akeso will be eligible to receive regulatory milestones of up to $1.05 billion and commercial milestones of up to $3.45 billion, many of which will be due before the Company anticipates generating any revenue from the License Agreement. We entered into the Note Purchase Agreement to fund the initial consideration payments and we will need additional capital to fund our operations and payments under the License Agreement and the Note Purchase Agreement. We may anticipate the need for further capital raises to repay the remaining $100 million principal balance under the Note Purchase Agreement. We also anticipate further capital raises to repay the remaining borrowings under the Note Purchase Agreement. We do not have any committed external sources of funds with respect to SMT112.

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

We have substantial indebtedness and may require additional indebtedness in the future, which may require us to use a substantial portion of our cash flow to service debt and limit our financial and operating flexibility.

We have substantial indebtedness and may require additional indebtedness in the future. As of March 7, 2023, we had a total of $100 million of indebtedness outstanding under the Note Purchase Agreement. Further, the License Agreement calls for certain additional future payment obligations and we may require additional indebtedness to fund those obligations. Our existing and future indebtedness will require interest payments and need to be repaid or refinanced and could require us to divert funds identified for other purposes to service our debt, could result in cash demands and impair our liquidity position and could result in financial risk for us. Diverting funds identified for other purposes for debt service may adversely affect our growth prospects. If we cannot generate sufficient cash flow from operations to service our debt, we may need to refinance our debt, dispose of assets, or issue equity to obtain necessary funds. We do not know whether we would be able to take any of these actions on a timely basis, on terms satisfactory to us, or at all.

The Company's failure to comply with the terms and obligations of the Note Purchase Agreement, including as a result of events beyond our control, may result in an event of default.

The Note Purchase Agreement requires us to comply with certain repayment obligations, representations and covenants. A breach of any of these obligations, representations or covenants or the occurrence of certain other specified events could result in an event of default under the Note Purchase Agreement. Upon the occurrence of any event of default under the Note Purchase Agreement, the outstanding balance on the corresponding Note will, at the option of such lender, become immediately and automatically due and payable in cash and a default interest rate of an additional 2% per annum will apply on all outstanding obligations during the occurrence and continuance of an event of default.

We may not be able to maintain compliance with these repayment obligations and covenants in the future and, if we fail to do so, that we may not able to obtain waivers from the lenders and/or amend the covenants. Our failure to comply with the repayment obligations and covenants described above could result in an event of default, which, if not cured or waived, and if lender accelerates, would result in us being required to repay these borrowings before their due date. If we are forced to refinance these borrowings on less favorable terms or if we are unable to refinance these borrowings, our business, financial condition, and results of operations could be materially adversely affected.

Risks Related to our Financial and Intellectual Property 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, any of the licenses under the License Agreement, or issues as 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 product candidates with the use of Akeso's 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, patent prosecution and commercialization. If we are unable to meet our obligations, some or all of our rights under the agreement may be restricted or terminated.

Our primary product candidate, ivonescimab, is subject to a license from Akeso, which is revocable in certain circumstances, including in the event we do not achieve certain payment deadlines. Without the license, 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 us 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. Akeso may also terminate the agreement upon written notice upon the Company's bankruptcy.

We may not continue to be able to make the various payment obligations under the License Agreement, including certain significant payments due upon satisfaction of pre-commercialization milestones. If the License Agreement were to be terminated by Akeso for any reason, we would lose our most significant asset and primary product candidate, and would likely not be able to develop ivonescimab, which would have a material adverse effect on our operations.

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 Akeso or other third parties that are not subject to the License Agreement;
- whether Akeso had the right to grant the licenses under 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 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;
- our involvement in and ability to align on the prosecution and enforcement of the licensed patents and patent applications and Akeso's overall patent prosecution, intellectual property protection and enforcement strategies; and
- the impact on payments and costs associated with commercialization if there is blocking intellectual property in or costs associated with prosecution, maintenance and enforcement 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 will be reliant on Akeso for knowledge transfer relating to manufacturing of our product candidate. 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 our product candidate.

We have entered into the License Agreement and will enter into a Supply Agreement with Akeso for information and drug substance that we will rely on to be used in our product candidate, and the termination or Akeso's breach of these agreements could have a material adverse effect on our business.

Further, failure of Akeso to adequately transfer knowledge to the Company to continue to produce 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 have to develop alternative processes and delay manufacturing. The product may not comply with the FDA quality requirements and/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 start of clinical trials.

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 agreement with Eurofarma 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 collaboration likely will pose, numerous risks to us, including 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 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 us 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.

Use of third parties to manufacture our product candidates may increase the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable 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, or API, in our product candidates. Our strategy is to outsource all manufacturing of our product candidates and products to third parties.

We have agreements with third-party manufacturers for the long-term clinical or commercial supply of our product candidates. We have supply agreements with Akeso for supply of ivonescimab for use in clinical trials as well as for commercial supply. We are in the process of setting up agreements with third party manufacturers for the long-term clinical and commercial supply of ivonescimab. 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. We may be unable to conclude agreements for commercial supply with third-party manufacturers, or may be unable to do so on acceptable terms.

Even if we are able to establish and maintain arrangements with third-party manufacturers, reliance on third-party manufacturers 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 misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Third-party manufacturers may not be able to comply with current good manufacturing practice, or cGMP, regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, 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 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 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 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 novel 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.

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 Good Clinical Practice, or GCP, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity of data and confidentiality of clinical trial participants are protected. The EMA imposes similar requirements on us for products that are the subject of clinical trials in the European Union, including the United Kingdom.

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.

Risks Related to Our Industry and Market

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 candidates 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 non-small cell lung cancer ("NSCLC"), and several additional companies are developing products for the treatment of NSCLC. Currently, the most commonly used treatments for NSCLC are several immuno-oncology drugs and chemotherapies, administered either as monotherapy or in combination with other approved therapeutics. NSCLC treatment regimens vary due to several factors, including genetic mutations and progression of disease. Several medications have been approved by FDA for these treatments, including, but not limited to pembrolizumab, atezolizumab, nivolumab and durvalumab. In addition several potential therapeutics are in various stages of development and clinical trials for treatment of NSCLC.

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.

Many of our competitors may have significantly greater financial 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.

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.

Risks Related to the Development and Commercialization of our Product Candidates

If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of the U.S. Food and Drug Administration, or the FDA, or the European Medicines Agency, or the EMA, or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of ivonescimab or any other product candidate.

In connection with obtaining marketing approval from regulatory authorities 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. To date, we have not conducted a clinical trial for ivonescimab and cannot predict the results of such trials.

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 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;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower 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, such as the novel coronavirus;
- 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;
- 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 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 cost of clinical trials of our product candidates may be greater than we anticipate;
- 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, such as the novel coronavirus; and
- 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.

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

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, if we are unable 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 or illnesses, such as the novel coronavirus.

Patient enrollment is affected by other factors, including:

- 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;
- 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 serious adverse or inappropriate side effects are identified during the development of ivonescimab or any other 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.

Even if ivonescimab or any other 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 European Union and other jurisdictions.

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 market 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.

We do not have a sales or marketing infrastructure and have no experience as a company in the sale or marketing of pharmaceutical products, although certain employees do have experience in the sale and marketing of pharmaceutical products. To achieve commercial success for any approved product, we must either develop a sales and marketing organization 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 and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. 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 prematurely or unnecessarily 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;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe any future products;
- 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.

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, which could have a negative impact on 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 biologic, 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.

Legal, Tax, Regulatory and Compliance Risks

Even if we are able to commercialize ivonescimab or any other product candidate that we develop, the product may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which would 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. 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. A primary trend in the U.S. and E.U. healthcare industries and elsewhere is cost containment.

Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products.

We cannot be sure that coverage and reimbursement will be available for 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 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. In the United States, third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. In the European Union, reference pricing systems and other measures may lead to cost containment and reduced prices. Our inability to promptly obtain 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.

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

In some countries, particularly the member states of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of 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 European Union member states and parallel distribution, or arbitrage between low-priced and high-priced 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; and
- difficulties in managing foreign relationships and operations generally.

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 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. It is unknown whether and to what extent new tariffs, laws or regulations will be adopted that increase the cost or feasibility of importing and/or 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 and customers is unknown and difficult to predict. As additional new tariffs, legislation and/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.

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 could materially adversely affect our company and holders of our shares of common stock.

We are unable to predict what tax changes may be enacted in the future or what effect such changes would have on our business, but such changes could affect our effective tax rates in countries where we have operations and could have an adverse effect on our overall tax position in the future, along with increasing the complexity, burden and cost of tax compliance.

United States

Recent changes in tax law may adversely affect our business or financial condition. On December 22, 2017, the U.S. government enacted the Tax Cuts and Jobs Act, or the TCJA, which significantly reformed the U.S. Internal Revenue Code of 1986, as amended, or the Code. The TCJA, among other things, contained significant changes to corporate taxation, including the limitation of the tax deduction for net interest expense to 30% of adjusted taxable income (except for certain small businesses), the limitation of the deduction for net operating losses arising in taxable years beginning after December 31, 2017 to 80% of current year taxable income, the allowance of net operating losses arising in taxable years beginning after December 31, 2017 to be carried forward indefinitely, the allowance of immediate deductions for certain new investments instead of deductions for depreciation expense over time, and the modification or repeal of many business deductions and credits.

Beginning with costs incurred in 2022, the TCJA also eliminated the option to deduct research and development expenditures currently and requires taxpayers to capitalize and amortize them over five or fifteen years pursuant to Internal Revenue Code Section 174. This does not increase our effective tax rate or our cash tax payable in 2022. However, if the requirement to capitalize Section 174 expenditures is not modified, it may also impact our effective tax rate and our cash tax liability in future years.

United Kingdom

Recent announcements of changes in the UK R&D regime are likely to impact the level of cash benefit that the Company will be able to receive in respect of the R&D activity. As a result of a reduction in rates applied in the SME regime, the cash credit that the Company will be able to obtain is likely to reduce if the qualified spending remains consistent. This will be partly offset by an increase in the RDEC regime. In addition, there is a refocus of relief towards UK activity and therefore costs outside the UK are expected to be restricted going forward with further changes anticipated following a government consultation being launched with the intention of merging the SME and RDEC schemes.

Our ability to use our U.S. federal, U.S. state and foreign net operating losses and other tax attributes may be limited.

Our ability to use our U.S. federal, U.S. state and foreign net operating losses to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our net operating losses.

Unused U.S. federal tax losses for tax years beginning before January 1, 2018 and prior tax years will carry forward to offset future taxable income, if any, until such unused losses expire. Unused U.S. federal tax losses generated for tax year beginning after December 31, 2017 will not expire and may be carried forward indefinitely, and generally may not be carried back to prior taxable years, except that, under the CARES Act, net operating losses generated in 2018, 2019 and 2020 may be carried back to each of the five tax years preceding the tax years of such losses. Additionally, for taxable years beginning after December 31, 2020, the deductibility of such U.S. federal net operating losses is limited to 80% of our taxable income in any future taxable year. In addition, both our current and our future unused U.S. federal and state tax losses and unused U.S. federal and state research and development tax credits may be subject to limitation under Sections 382 and 383 of the Internal Revenue Code ("IRC" or "the Code") of 1986, as amended, if we undergo an “ownership change,” generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a rolling three-year period. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of shifts in our stock ownership, some of which are outside our control. As of December 31, 2022 and 2021, we reported U.S. federal and state gross operating loss carryforwards of approximately $18.9 million and $10.9 million, respectively, and federal research and development tax credit carryforwards of $1.7 million and $0.9 million, respectively. Our ability to utilize those net operating loss carryforwards could be limited by an “ownership change” as described above, which could result in increased tax liability to us.

As of December 31, 2022, we reported foreign gross operating loss carryforwards of $199.1 million. Our ability to utilize those net operating loss carryforwards are dependent upon our generation of future taxable income.

Laws and regulations affecting government contracts, such as BARDA and CARB-X , 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.

Even if we complete the necessary clinical trials, 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 not able to obtain, or if there are delays 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 foreign jurisdictions would prevent our product candidates from being marketed in these other jurisdictions, and any approval we are granted for our product candidates in the United States and Europe would not assure approval of our product candidates in 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 approval. The regulatory approval process outside the United States and Europe generally

includes all of the risks associated with obtaining FDA and EMA 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 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. 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 European Union 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 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 Department of Justice, or 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 do not market our products for their approved 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;
- 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 withdrawal 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 European Union'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 United Kingdom, 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, to the federal government, claims for payment 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.
- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, 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 Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, referred to together as the Affordable Care Act, 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.

Current and future legislation may increase the difficulty and cost for us and any future collaborators to obtain marketing approval of and commercialize our product candidates and affect the prices we, or they, 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 rigorous coverage criteria and in 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 and/or the

level of reimbursement physicians receive for administering any approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or administered. 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 has 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.

More recently, in August 2022, President Biden signed into law the Inflation Reduction Act of 2022 (the "IRA"). Among other things, the IRA has multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the United States. Starting in 2023, a manufacturer of a drug or biological product covered by Medicare Parts B or D must pay a rebate to the federal government if the drug product's price increases faster than the rate of inflation. This calculation is made on a drug product by drug product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, starting in payment year 2026, the U.S. Centers for Medicare and Medicaid Services ("CMS"), will negotiate drug prices annually for a select number of single source Part D drugs without generic or biosimilar competition. CMS will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease.

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 European Union, 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 European Union or member state level may result in significant additional requirements or obstacles that may increase our operating costs.

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 U.S. Foreign Corrupt Practices Act, or FCPA, the U.K. Bribery Act 2010, or 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 United States and the United Kingdom, and authorities in the European Union, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, collectively referred to as 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.

The Committee on Foreign Investment in the United States ("CFIUS") or other regulatory agencies may modify, delay or prevent the transactions contemplated by the License Agreement.

The Committee on Foreign Investment in the United States ("CFIUS") has authority to review direct or indirect foreign investments in U.S. companies. Among other things, CFIUS is empowered to require certain foreign investors to make mandatory filings, to charge filing fees related to such filings and to self-initiate national security reviews of foreign direct and indirect investments in U.S. companies if the parties to that investment choose not to file voluntarily. In the case that CFIUS determines an investment to be a threat to national security, CFIUS has the power to unwind or place restrictions on the investment. Whether CFIUS has jurisdiction to review an acquisition or investment transaction depends on, among other factors, the nature and structure of the transaction, including the level of beneficial ownership interest and the nature of any information or governance rights involved. For example, investments that result in "control" of a U.S. business by a foreign person always are subject to CFIUS jurisdiction. CFIUS's expanded jurisdiction under the Foreign Investment Risk Review Modernization Act of 2018 and implementing regulations that became effective on February 13, 2020 further includes investments that do not result in control of a U.S. business by a foreign person but afford certain foreign investors certain information or governance rights in a U.S. business that has a nexus to "critical technologies," "critical infrastructure" and/or "sensitive personal data".

We believe that no mandatory filing was required in connection with the License Agreement but we have not yet determined whether we will make a voluntary filing. CFIUS may decide to modify or delay our proposed business combination, impose conditions with respect to such business combination, request the President of the United States to order us to divest all or a portion of the assets we acquired without first obtaining CFIUS approval or prohibit the License Agreement entirely. If it is determined that a mandatory filing was required to be made, it is possible that a material penalty could be assessed against the Company.

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, or if the scope of our patent protection is not sufficiently broad, 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 with respect to our proprietary technology and products. We seek to protect our proprietary position by filing patent applications in the United States, in Europe and in certain additional foreign jurisdictions related to our novel technologies and product candidates that are important to our business. This process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, if we license technology or product candidates from third parties in the future, these license agreements may not permit us to control the preparation, filing and prosecution of patent applications, or to maintain or enforce the patents, covering the licensed technology or product candidates. These agreements could also give our licensors the right to enforce the licensed patents without our involvement, or to decide not to enforce the patents at all. Therefore, in these circumstances, these patents and applications may not be prosecuted or enforced in a manner consistent with the best interests of our business. For example, while under the collaboration and license agreement with Akeso for ivonescimab, we have the right, after a set period of time, to take control of the prosecution, maintenance and enforcement of certain patent applications licensed under the agreement in the License Territory, prosecution is subject to consultation and cooperation with Akeso, except with regard

to patent extension. If the parties cannot align this could impact patentability of the licensed intellectual property. Additionally, as actions or statements during prosecution in other territories (i.e., the non-License Territory) can impact the validity of any patent obtained in the License Territory, Akeso prosecution of its patent applications in the non-License Territory, can have an impact on patent prosecution and validity of applications/patents that we are prosecuting, maintaining or enforcing in the License Territory. Additionally, Akeso owned patents and patent applications, non-exclusively licensed to Summit under the agreement, are under the control of Akeso, Akeso's prosecution and/or licensing strategies with regard to these patents and/or patent application may impact our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents, narrow the scope of our patent protection or make enforcement more difficult or uncertain.

The laws of foreign countries may not protect our patent rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. In addition, for the foregoing reasons, we may not pursue or obtain patent protection in all major markets or may not obtain protection that enables us to prevent the entry of third parties into the market.

Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. 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. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our U.S. patents or pending U.S. patent applications, or that we were the first to file for patent protection of such inventions outside the United States or, since March 16, 2013, within the United States.

Moreover, we may be subject to a third party pre-issuance submission 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. An adverse determination in any such submission, proceeding or litigation concerning our patent rights could reduce the scope of or prevent the enforceability of, or invalidate, our patent rights, allowing third parties to commercialize our technology or products, or equivalent or similar technology or products, and so to compete directly with us, without payment to us, or, where such proceedings involve third-party patents, result in our inability to manufacture or commercialize products without infringing third-party patent 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 an intellectual property infringement claim can be costly and time consuming and may require Summit to design around the claims of patents covering our products that may have been issued by third parties or to obtain a license, either of which would could cause us to incur additional expenses. Summit cannot guarantee that it would be able to obtain license agreements on commercially reasonable terms. A successful claim of patent or other intellectual property infringement could subject Summit to significant damages or an injunction preventing the manufacture, sale, or use of the affected product We may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property. Even if our patent applications issue as patents, they may not issue in a form that will provide us with adequate protection to prevent competitors from competing with us or otherwise to provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar, improved or alternative technologies or products in a non-infringing manner.

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. Legal and regulatory developments in the European Union 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 European Union and in other jurisdictions. Such developments may also require us to

allocate significant resources to prevent other companies from circumventing or violating our intellectual property rights. Our attempts to prevent third parties from circumventing our intellectual property and other rights may ultimately be unsuccessful. We may also fail to take the required actions or pay the necessary fees to maintain our patents.

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. To counter infringement or unauthorized use, we may be required to file claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke 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 for anti-trust reasons. As a result, 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 and so refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the competitor technology in question. Even if we are successful in a patent infringement action, the unsuccessful party may subsequently raise antitrust issues and bring a follow-on action thereon. Antitrust issues may also provide a bar to settlement or constrain the permissible settlement terms. Further, settlement agreements in the pharmaceutical sector are the subject of ongoing review by the antitrust authorities in the European Union.

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 the success of 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. The risks of being involved in such litigation and office proceedings may also 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 existing or future intellectual property rights and so restrict our freedom to operate. Third parties may also seek injunctive relief against us, whereby they would attempt to prevent us from practicing our technologies altogether pending outcome of any litigation against us.

If we are found to infringe a third party's intellectual property rights, or in order to avoid or settle litigation, we could be required to obtain a license to enable us to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies as are licensed to us, and could require us to make substantial payments. Absent a license, we could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent 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 or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary or otherwise confidential information or know-how of others in their work for us, we may be subject to claims that we or these employees have without authorization used or disclosed intellectual property, including trade secrets or other proprietary or confidential information, of any such employee's former employer. 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, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their 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 they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property 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 resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our shares of common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development, sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Accordingly, costs and lost management time, as well as uncertainties resulting from the initiation and continuation of patent litigation or other proceedings, could have a material adverse effect on our ability to compete 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. We seek to protect these trade secrets, in part, by entering into 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, 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. Any party with whom we have executed such an agreement may breach that agreement and disclose our proprietary or confidential information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or 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.

If our information technology systems or data, or those of third parties upon whom we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including, but not limited to, regulatory investigations and actions; litigation (including class claims); fines and penalties; a disruption of our business operations such as our clinical trials; reputational harm; loss of revenue and profits; and other adverse consequences.

In the ordinary course of our business, we (and third parties upon whom we rely) may collect, receive, store, use, transfer, make accessible, protect, secure, dispose of, transmit, disclose or otherwise process proprietary, confidential and sensitive information (including personal data (such as health-related data and participant study related data), intellectual property, and trade secrets (collectively, sensitive data). In addition, we rely on service providers to establish and maintain appropriate information

technology and data security protections over the information technology systems they provide to us to operate our 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, we have limited ability to control their safeguards and actions related to such matters and 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. In particular, the COVID-19 pandemic has caused us to modify our information technology practices including that our employees may work remotely which increases the risk of data breaches. Additionally, the prevalent use of mobile devices that access our sensitive data increases the risk of data breaches.

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/or misuse); sophisticated nation states and nation-state-supported actors; and others. These threats include, but are not limited to, 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, 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, extortion 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 (such as clinical trial data). The costs to us to attempt to protect against such breaches is significant and could potentially require us to modify our business (including 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 provide compensation for any losses associated with such events.

If we or others 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. 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 the safeguard of sensitive data and a breach could lead to claims against us by such stakeholders. There can be no assurance that the limitations of liability 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 regulatory investigations and actions; litigation; fines and penalties; disruptions to our business operations; reputational harm; loss of revenue and profits; and other adverse business impacts.

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 guidances; 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 among 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, 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.

Outside the U.S., an increasing number of laws, regulations and industry standards apply to data privacy and security. For example, the European Union's General Data Protection Regulation (GDPR) (EU) 2016/679, or the EU GDPR, imposes strict requirements on the processing of personal data. Under the EU 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 EU GDPR, PIPL imposes strict requirements on the processing of personal data and allows for statutory fines and penalties.

Certain jurisdictions, including the United Kingdom, EU, 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 UK 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 may be subject to additional laws and regulations that may affect how we conduct business in relation to the personal data we process. For example, in relation to these 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 UK, 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 proposed laws, regulations and industry standards relating to data privacy and security in the U.S. For example, the California Consumer Privacy Act, as amended, 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, as amended, 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 and Virginia) have also enacted data privacy laws. If we become subject to new data privacy laws, at the state level, the risk of enforcement action 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 actors).

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 upon whom we rely 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/or oversight; bans on processing personal data; orders to destroy or not use personal data; 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.

Risks Related to Corporate Governance and Employee Relations

Our future success depends on our ability to retain our Chief Executive Officer, our co-Chief Executive Officer, President and member of the Board and other key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the principal members of our executive and scientific teams, including Mr. Robert W. Duggan, our Executive Chairman and Chief Executive Officer, and Dr. Mahkam Zanganeh, our co-Chief Executive Officer, President and member of the Board. We do not have employment agreements with Mr. Duggan or Dr. Zanganeh. They may terminate their employment with us at any time. 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.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel, including in the United States where we plan to continue to expand our physical presence, will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous biotechnology and pharmaceutical companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our 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.

Our principal stockholder and chief executive officer maintains the ability to control or significantly influence all matters submitted to stockholders for approval.

As of December 31, 2022, Mr. Duggan beneficially owned, in the aggregate, shares of common stock representing approximately 81.8% 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.

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 are exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with FDA or Office of Inspector General regulations or similar regulations of comparable non-U.S. regulatory authorities, provide accurate information to the FDA or comparable non-U.S. regulatory authorities, 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, report financial information or data accurately or 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 or other sanctions.

Risks Related to Owning Our Common Stock

The prices of our shares of common stock may 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 may 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;
- 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, such as the ongoing COVID-19 pandemic, 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, such as those caused by the COVID-19 pandemic, may cause declines in the trading price and market value of our common stock.

Our shares of common stock do not trade on any exchange outside of the United States.

Our shares of common stock are listed only in the United States on The Nasdaq Global Market, and we have no plans to list our shares in any other jurisdiction. As a result, a holder of our shares of common stock outside of the United States may not be able to effect transactions in our shares as readily as the holder may if our shares were listed on an exchange in that holder’s home jurisdiction.

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 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.

We are a "smaller reporting company" and the reduced disclosure requirements applicable to smaller reporting companies may make our shares of common stock less attractive to investors.

We are a "smaller reporting company," as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended. We would cease to be a smaller reporting company if we have a public float in excess of $250 million or have annual revenues in excess of $100 million and a public float in excess of $700 million, determined on an annual basis.

We expect to continue to take advantage of some or all of the exemptions available to us as a smaller reporting company. We cannot predict whether investors will find our shares of common stock less attractive if we rely on these exemptions. If some investors find our shares of common stock less attractive as a result, there may be a less active trading market for the shares and the market price of the shares may be more volatile.

We incur increased costs as a result of operating as a company with shares of common stock that are publicly traded in the United States, and our management is required to devote substantial time to compliance initiatives.

As a company with shares of common stock that are publicly traded in the United States, and particularly after we are no longer a "smaller reporting company," we have incurred and will continue to incur significant legal, accounting and other expenses that we did not previously incur. In addition, the Sarbanes-Oxley Act, the Dodd-Frank Act, the listing requirements of the Nasdaq Stock Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly.

However, for as long as we remain a smaller reporting company, we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not smaller reporting companies as described in the preceding risk factor.

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. However, for as long as we are a "smaller reporting company", our independent registered public accounting firm will not be 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.

We have received the requisite approvals and if the Board decides to proceed with the reverse stock split, it may decrease the liquidity of the shares of our common stock and could lead to a decrease in our overall market capitalization.

On January 6, 2023, the Company held a Special Meeting of Stockholders in which the stockholders approved: (i) an amendment to the Company's restated certificate of incorporation to increase the number of authorized shares of our common stock by 650,000,000 (from 350,000,000 to 1,000,000,000), and (ii) an amendment to authorize the Board to amend our restated certificate of incorporation to effect a reverse stock split of all of the outstanding shares of our common stock, at a ratio in the range of 1-for-5 to 1-for-10. The Board reserves the right to adopt the proposal described in clause (ii) at any time prior to January 6, 2024. The liquidity of the shares of our common stock may be affected adversely by such reverse stock split given the reduced number of shares of our common stock that will be outstanding following such reverse stock split, especially if the market price of our common stock does not increase as a result of such reverse stock split. In addition, such reverse stock split may increase the number of stockholders who own odd lots (less than 100 shares) of our common stock, creating the potential for such stockholders to experience an increase in the cost of selling their shares of common stock and greater difficulty effecting such sales.

We expect that the proposed reverse stock split, if effected, will increase the per share trading price of our common stock. However, the market price per share of our common stock after the reverse stock split may not rise (or remain constant) in proportion to the reduction in the number of shares of common stock outstanding before the reverse stock split. We cannot predict the effect of the reverse stock split on the per share trading price of our common stock, and the history of reverse stock splits for other companies is varied, particularly since some investors may view a reverse stock split negatively. Our total market capitalization after the reverse stock split, if approved and effective, may be lower than our total market capitalization before the reverse stock split.

If our common stock trades below $1.00, we may fail to meet the continued listing requirements of the Nasdaq Global Market and our common stock may be delisted.

Our common stock is subject to certain continued listing standards set by the Nasdaq Global Market, including a requirement to maintain a minimum bid price of at least $1.00 per share. If our common stock fails to meet such standards, it could be delisted from the Nasdaq Global Market. This would have a negative impact on the liquidity of our common stock.

Our restated certificate of incorporation designates the Court of Chancery of the State of Delaware and the federal district courts of the United States of America 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 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 United States of America 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 or on Summit Therapeutics plc's ordinary shares. 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 significant portion of our operations in the United Kingdom. Because our financial statements are presented in U.S. dollars, changes in currency exchange rates have had and could have a significant effect on our operating results when our operating results are translated into pounds sterling. 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. The failure by our management to apply these funds effectively 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.

Risks Related to the COVID-19 Pandemic

The ongoing COVID-19 pandemic continues to evolve and its enduring impact on our business remains uncertain. Our business has and could continue to be adversely affected, directly or indirectly, by the ongoing COVID-19 pandemic.

The continual spread of COVID-19 and the emergence of new variants has caused a broad impact globally, adversely affecting the economies and financial markets of many countries and resulting in an economic downturn. These adverse economic effects, as well as the uncertainty regarding the duration, spread and intensity of the pandemic have led to labor shortages, supply restrictions and inflationary pressures. As a result of the COVID-19 pandemic, governmental authorities across the world implemented and may continue to implement safety precautions. These measures may disrupt normal business operations and may continue to have significant negative impacts on businesses and financial markets worldwide. We continue to monitor our operations and applicable government recommendations, and we have made modifications to our normal operations because of the COVID-19 pandemic, including flexible working arrangements. Changes in flexible working arrangements

could impact employee retention, employees' productivity and morale, strain our technology resources and introduce operational risks. Additionally, the risk of cyber-attacks or other privacy or data security incidents may be heightened as a result of our moving increasingly towards a remote working environment, which may be less secure and more susceptible to hacking attacks. The COVID-19 pandemic could affect the health and availability of our workforce as well as those of the third-parties we rely on. Furthermore, any delays and disruptions due to the COVID-19 pandemic experienced by our collaborators or other third-parties, including regulatory agencies, such as the FDA, could adversely impact the ability of such parties to fulfill their obligations.

The disruptions caused by COVID-19, including limitations on in-person meetings with existing or potential stakeholders may result in inefficiencies, delays and additional costs in our product development, sales, marketing, product implementation and customer service efforts that we may not be able to fully mitigate through remote work arrangements. We have previously experienced, and may experience in the future, patient enrollment at clinical trial sites at a slower pace than expected. Our ability to undertake clinical trials may be adversely affected, directly or indirectly, by the COVID-19 pandemic. While we do not currently anticipate significant interruptions in our clinical supply chain, quarantines, travel restrictions and other measures may significantly impact the ability of employees of our third-party suppliers to get to their places of work to manufacture and deliver additional clinical supplies, which could cause the results from our clinical trials to be delayed even further.

While it is not possible at this time to estimate the entirety of the continued impact the COVID-19 pandemic will have on our business, operations, employees, customers, suppliers or collaboration partners, continued spread of COVID-19, measures taken by governments, actions taken to protect employees and the broad impact of the pandemic on all business activities may materially and adversely affect our business, supply chain, results of operations and financial condition.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

The following table provides information concerning Summit's principal leased facilities as of December 31, 2022:

We maintain the following leased properties:

Type/Uses	Location	Size	Lease Expiration
Executive office	Oxfordshire, United Kingdom	6,781 square feet	February 2027
Executive office	Menlo Park, California, United States	5,777 square feet	December 2025
Laboratory and office	Sawston, United Kingdom	7,644 square feet	October 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. We are not currently subject to any material legal proceedings.

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. Prior to that date, there was no public market for our common stock. On September 21, 2020, Summit Therapeutics plc became our wholly-owned subsidiary and we became the holding company and successor issuer to Summit Therapeutics plc (the predecessor registrant and former holding company) and its subsidiaries. Such succession occurred pursuant to a statutory scheme of arrangement under U.K. law pursuant to which all Summit Therapeutics plc’s outstanding ordinary shares were exchanged on a five-for-one basis for newly issued shares of our common stock. Summit Therapeutics plc's American Depositary Shares ("ADSs") had traded on the Nasdaq Global Market under the symbol "SMMT" since March 2015 and its ordinary shares previously traded on AIM, a sub-market of the London Stock Exchange plc, under the symbol “SUMM”. Each ADS represented five ordinary shares of Summit Therapeutics plc. We canceled the admission of the ordinary shares to trading on AIM on February 24, 2020.

Holders of Record

As of March 7, 2023, there were approximately 308 holders of record of our common stock. The actual number of stockholders is greater than this number of holders of record and includes 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

On July 17, 2020, in connection with our incorporation, we issued an aggregate of 100 shares of our common stock to a nominee stockholder for $1.00. The shares were offered and issued pursuant to Section 4(2) of the Securities Act of 1933, as amended, or the "Securities Act".

On September 18, 2020, we issued an aggregate of 67,231,903 shares of our common stock in exchange for the entire issued share capital of Summit Therapeutics plc in a transaction exempt from registration pursuant to Section 3(a)(10) of the Securities Act. No cash was paid for these shares.

On November 6, 2020, in connection with the closing of a private placement for an aggregate purchase price of $50 million in cash, we issued an aggregate of 14,970,060 shares of our common stock to three investors: our Executive Chairman and Chief Executive Officer Mr. Duggan, the Mahkam Zanganeh Revocable Trust and Polar Capital Funds plc - Biotechnology Fund. The shares were sold to each of the foregoing investors at a price of $3.34 per share of common stock. The common stock was offered and sold pursuant to an exemption from the registration requirements under Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder.

On March 24, 2021, Mr. Duggan entered into a Note Purchase Agreement (the "Initial Purchase Agreement") pursuant to which he loaned the Company $55.0 million in exchange for the issuance by the Company of an unsecured promissory note (the “Initial Note”) in the amount of $55.0 million. The Note accrues interest at a rate per annum equal to 150% of the applicable 10 Year US Treasury rate, as adjusted monthly. The rate is initially estimated to be approximately 2.4%. The Company may prepay any portion of the Note at its option without penalty. The Note will mature and become due upon the earlier of (i) the

consummation of a registered public offering with net proceeds of no less than $55.0 million, or (ii) 13 months from the date of issuance of the Note. The Note was issued to Mr. Duggan in a private placement in reliance Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder. On April 20, 2021, the Company determined, with Mr. Duggan's agreement, to rescind both the Initial Purchase Agreement and the Initial Note issued thereunder, and repaid the principal amount of the Initial Note in full, without interest or penalty, as such the Company recognized imputed interest of $0.1 million within additional paid in capital.

On April 20, 2021, subsequent to the repayment of the Initial Note, Mr. Duggan entered into a second Note Purchase Agreement (the "Second Purchase Agreement") pursuant to which he loaned the Company $55.0 million in exchange for the issuance by the Company of an unsecured promissory note (the "Second Note") in the amount of $55.0 million. The Second Note accrued interest at a rate per annum equal to 150% of the applicable 10 Year US Treasury rate, as adjusted monthly (initially estimated to be approximately 2.4%). The Company was permitted to prepay any portion of the Second Note at its option without penalty. Pursuant to the terms of the Second Note, following consummation of the 2021 Rights Offering, the Second Note matured and all principal and interest thereunder was repaid by the Company using a portion of the proceeds of the 2021 Rights Offering.

On March 10, 2022, the Company's Chairman and Chief Executive Officer, Mr. Duggan, entered into a Note Purchase Agreement (the "2022 Note"), pursuant to which he has loaned the Company $25.0 million in exchange for the issuance by the Company of an unsecured promissory note in the amount of $25.0 million. The 2022 Note is to accrue interest at a rate per annum equal to the prime rate as reported in the *Wall Street Journal*, which is 3.25% as of the effective date. The 2022 Note becomes due upon the earlier of (i) the consummation of a registered public offering with net proceeds of no less than $25.0 million or (ii) 18 months from the date of issuance of the 2022 Note and was repaid on August 10, 2022.

On December 5, 2022, the Company entered into the License Agreement with Akeso. The License Agreement closed on January 17, 2023, and both Akeso and Summit entered into the Common Stock Issuance Agreement ("Issuance Agreement"). Pursuant to the License Agreement and Issuance Agreement, Akeso elected to receive 10 million shares of Company common stock in lieu of cash and was paid $274.9 million in cash as the initial upfront payment. The remaining $200 million of the upfront payment was paid on March 6, 2023. As regulatory approval for ivonescimab has not yet been granted, the Company will record in-process research and development expenses in the first quarter of 2023 for the cash payments of $474.9 million and for the fair market value of the 10 million shares issued to Akeso.

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 million. Pursuant to the Note Purchase Agreement, the Company 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 would mature and become 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 will mature and become due on September 15, 2023. The maturity dates of the December 2022 Notes could be 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 shall consummate 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 shall 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 million (the "Rights Offering"), 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 (i) the net proceeds of such capital raise or (ii) 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 accrue interest at an initial rate of 7.5%. All interest on the Notes shall be paid on the date of signing for the period through February 15, 2023. Such prepaid interest shall be paid in a number of shares of the Company's 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 the Company entered into the Note Purchase Agreement, plus $.01), which was 9,720,291 shares. For all applicable periods following the February 15, 2023, interest shall accrue 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. On February 15, 2023, the $20 million Zanganeh Note matured and the Company repaid the outstanding principal balance. In connection with the closing of the Rights Offering, the $400 million Duggan Promissory Note matured and became due, and the Company repaid all principal and accrued interest thereunder using a portion of the proceeds from the Rights Offering.

The intended use of proceeds generated from the transactions described above includes funding the Company's activities to support clinical and regulatory development of its assets and general corporate purposes.

Issuer Purchases of Equity Securities

Not applicable.

Item 6. Selected Financial Data

Reserved.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in "Item 1A. Risk Factors" of this Annual Report on Form 10-K, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

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, 2022 compared to the same period in the prior year.

Company Overview

We are 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. Our 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.

On December 5, 2022, we entered into a Collaboration and License Agreement (the "License Agreement") with Akeso, Inc. and its affiliates ("Akeso") pursuant to which we are partnering with Akeso to in-license its breakthrough bispecific antibody, ivonescimab. 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 benefits of immunotherapy via a blockade of PD-1 with the anti-angiogenesis benefits of an anti-VEGF into a single molecule. Ivonescimab was engineered to bring two well established oncology targeted mechanisms together. Through the License Agreement, we obtained the rights to develop and commercialize SMT112 in the United States, Canada, Europe, and Japan (the "Licensed Territory"). The License Agreement and transaction closed on January 17, 2023 following customary waiting periods.

The entry into the License Agreement represents a significant change in the Company's strategy. All prior development and marketing activities relating to ridinilazole are being terminated. All business activities related to anti-infectives are being reviewed for partnership opportunities for potential further development. Our future operations will be focused on the development of ivonescimab and other future activities as the Company determines.

On September 28, 2022, we determined that we would seek partners or a divestiture of ridinilazole, our lead product candidate for treating patients suffering from *Clostridioides difficile* infection, also known as *C. difficile* infection, or CDI, as the path forward for the clinical development of the asset. As a result of this determination, we discontinued our only active study for

ridinilazole, a pediatric clinical trial evaluating ridinilazole for treating adolescent patients with CDI. We are currently involved in activities related to closeout of ridinilazole clinical trials.

Our other product candidate, SMT-738, has been in development for combating multidrug resistant infections, specifically carbapenem-resistant Enterobacteriaceae ("CRE") infections. SMT-738 is the first of a novel class of precision antibiotics that has been in preclinical development and has been undergoing investigational new drug ("IND") enabling activities. We will continue to pursue partnerships for further development of SMT-738.

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.

As a result, we will need to seek additional funding in the future to fund operations. 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 may be unable to raise sufficient funds through equity or debt financings, or other arrangements when needed based on our liquidity needs acceptable terms, or at all.

Recent Developments

In addition to the events detailed in the Company Overview section above, the following other recent developments have occurred.

On February 15, 2023, the $20 million Zanganeh Note matured and the Company repaid the outstanding principal balance.

On March 1, 2023, we closed our Rights Offering, which was fully subscribed. We received aggregate gross proceeds from the Rights Offering of $500 million from the sale of 476,190,471 shares of our common stock at a price per share of $1.05. Issuance costs associated with the Rights Offering were approximately $0.5 million. In connection with the closing of the Rights Offering, a promissory note with the principal amount of $400 million, issued by us to our Executive Chairman and Chief Executive Officer, Mr. Duggan, matured and became due and we repaid the principal amounts and all outstanding accrued interest thereunder using a portion of the proceeds from the Rights Offering.

In conjunction with the significant change in our strategy and shift in focus to the therapeutic area of oncology, the Company is re-prioritizing its investments and financial resources towards the development of ivonescimab. This could result in reduced investment in our infectious diseases programs, including, subject to local legal process and approvals, reducing research and development employee compensation-related costs and facility-related costs incurred with respect to our laboratory and office space.

Key Components of our Results of Operations

Revenue

Revenue consists of amounts received from the license and commercialization agreement with Eurofarma Laboratórios S.A. ("Eurofarma"). We have not generated any revenue from product sales.

Under the terms of the license and commercialization agreement with Eurofarma, we received an upfront payment of $2.5 million in December 2017. In February 2020, we achieved the first enrollment milestone and received $1.0 million. In September 2021, we achieved the second enrollment milestone and received $1.3 million. The terms of the contract have been assessed under ASC 606 and currently only the upfront payment and the first two milestone payments are included in the transaction price. These payments were initially reported as deferred revenue in the balance sheet and were recognized as revenue ratably over the determined performance period.

Revenue recognized during the years ended December 31, 2022 and 2021 related to the upfront payment and the first two enrollment milestones earned in accordance with our revenue recognition policy. The revenue was recognized ratably over the determined performance period to reflect the transfer of control to the customer occurring over the time period that the research

and development services were provided. This output method is, in management's judgment, the best measure of progress towards satisfying the performance period.

Other Operating Income

Other operating income includes income received and recognized from grants and clinical trial support from government entities, philanthropic, non-government and not-for-profit organizations.

In September 2017, we were awarded a funding contract from the Biomedical Advanced Research and Development Authority ("BARDA"), part of the Office of the Assistant Secretary for Preparedness and Response at the United States Department of Health and Human Services, in support of our Ri-CoDIFy clinical trials and clinical development of ridinilazole. The awarded contract was originally worth up to $62.0 million. In June 2019 and again in January 2020, BARDA increased the value of the contract such that it is now worth up to $72.5 million and brought the total amount of committed funding to $62.4 million.

The remaining federal government funding is dependent on BARDA in its sole discretion exercising the final independent option work segment, upon the achievement by the Company of certain agreed-upon milestones for ridinilazole. This option work segment was never exercised by BARDA. The contract ran through April 2022 and was extended through December 2022 as a no cost contract, solely to close out open activities. As of December 31, 2022, based on translation of historical foreign currency amounts in the period, an aggregate of $59.2 million of cumulative income has been recognized since contract inception. As a result of our decision to not pursue further internal clinical development of ridinilazole and seek partners or a divestiture related to ridinilazole as a path forward for the clinical development of the asset, we recognized the remainder of the deferred income for BARDA during the third quarter of 2022.

We have also received income from research and development ("R&D") tax credits, which consist of the R&D tax credit received in the United Kingdom ("U.K."). We benefit from two U.K. research and development tax credit cash rebate regimes: Small and Medium Enterprise Program ("SME Program") and the Research and Development Expenditure Credit Program ("RDEC Program"). Qualifying expenditures largely comprise employment costs for research staff, consumables, a proportion of relevant, permitted sub-contract costs and certain internal overhead costs incurred as part of research projects for which we do not receive income. Tax credits related to the SME Program and RDEC Program are recorded as other operating income in the consolidated statements of operations and other comprehensive loss. Under both schemes, we receive cash payments that are not dependent on our pre-tax net income levels.

Based on criteria established by His Majesty's Revenue and Customs ("HMRC"), a portion of expenditures being carried out in relation to our pipeline research and development, clinical trials management and third-party manufacturing development activities are eligible for the SME regime and we expect such elements of research and development expenditure incurred in our UK entities will also continue to be eligible for the SME regime for future periods.

In May 2021, we announced the selection of a new preclinical candidate, SMT-738, from the DDS-04 series for development in the fight against multi-drug resistant infections, specifically Carbapenem-resistant Enterobacteriaceae ("CRE") infections. Simultaneously, we received an award from the Trustees of Boston University under the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator program ("CARB-X") to progress this candidate through preclinical development and Phase Ia clinical trials. The award commits initial funding of up to $4.1 million with the possibility of up to another $3.7 million based on the achievement of future milestones. As of December 31, 2022, based on translation of historical foreign currency amounts in the period, $2.9 million of cumulative income has been recognized since contract inception. During the quarter ended September 30, 2022, CARB-X announced changes to its funding arrangements and terms and conditions. As a result, the current arrangement concluded as of June 30, 2022, however we have the ability to recognize reimbursements for any milestone payments related to work incurred subsequent to this date in accordance with this agreement.

Operating Expenses

The majority of our operating expenses since inception have consisted of research and development activities and general and administrative costs.

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 organizations, including preclinical toxicology, pharmacology, formulation and manufacturing work;
- laboratory and vendor expenses incurred in relation to our preclinical and non-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; 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 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 expense, net

Other expense, net primarily consists of foreign currency net gains and losses, cash and imputed interest expense incurred related to our promissory notes to related parties, investment income related to our money market fund and investments in highly liquid U.S. treasury securities and interest income on restricted cash.

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. 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.

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 probable that there will be suitable taxable profits in the foreseeable future based on the evidence available against which to offset these losses.

Jumpstart Our Business Startups Act of 2021

As of January 1, 2021, we are no longer an “emerging growth company” as defined in the Jumpstart our Business Startups Act of 2012, or the JOBS Act. Formerly, as an emerging growth company, we were able to take advantage of specified reduced reporting and other burdens that are otherwise applicable generally to public companies. The last day of the fiscal year following the fifth anniversary of our initial public offering in March 2015 was December 31, 2020, hence we have ceased to be an emerging growth company.

Results of Operations

Comparison of the Year Ended December 31, 2022 to the Year Ended December 31, 2021

(in millions)	Year Ended		
	December 31, 2022	December 31, 2021	$ Change
Revenue	$ 0.7	$ 1.8	$ (1.1)
Operating expenses:			
Research and development	52.0	85.4	(33.4)
General and administrative	26.7	23.6	3.1
Impairment of intangible assets	8.5	—	8.5
Total operating expenses	87.2	109.0	(21.8)
Other operating income	14.4	21.0	(6.6)
Operating loss	(72.1)	(86.2)	14.1
Other expense, net	(6.7)	(2.4)	(4.3)
Loss before income taxes	(78.8)	(88.6)	9.8
Net loss	$ (78.8)	$ (88.6)	$ 9.8

Revenue

Revenue for the years ended December 31, 2022 and 2021 relates to revenue from our license and commercialization agreement with Eurofarma Laboratórios S.A ("Eurofarma"). This revenue was recognized ratably over the performance period the research and development services were provided. The decrease for the year ended December 31, 2022 compared to the same period in the prior year is attributed to the achievement of a milestone related to this agreement in September of 2021. The total milestone of $1.3 million was recognized ratably over the determined performance period the research and development service were provided.

Operating Expenses

Research and Development Expenses

(in millions)	Year Ended		
	December 31, 2022	December 31, 2021	$ Change
CDI program	$ 25.3	$ 53.9	$ (28.6)
Antibiotic pipeline research and development costs	3.3	1.9	1.4
Other research and development expenses	23.4	29.6	(6.2)
Total	$ 52.0	$ 85.4	$ (33.4)

Investment in our CDI program decreased by $28.6 million for the year ended December 31, 2022, compared to the same period in the prior year, primarily due to a decrease in clinical and manufacturing activity spend associated with the ridinilazole Phase III clinical program as a result of our decision to seek partners or a divestiture related to ridinilazole as the path forward for the clinical development of the asset.

Investment in our antibiotic pipeline development activities increased by $1.4 million for the year ended December 31, 2022, compared to the same period in the prior year, primarily due to increased development activity spend, specifically IND-enabling activities, associated with the development of our preclinical candidate, SMT-738, from the DDS-04 series for development in the fight against multi-drug resistant infections, specifically Carbapenem-resistant Enterobacteriaceae ("CRE") infections.

Other research and development expenses are comprised of the following:

(in millions)	Year Ended		
	December 31, 2022	December 31, 2021	$ Change
Compensation related costs	$ 16.3	$ 19.4	$ (3.1)
Stock-based compensation	4.3	5.9	(1.6)
Other research and development costs	2.8	4.3	(1.5)
Total	$ 23.4	$ 29.6	$ (6.2)

Other research and development expenses decreased by $6.2 million for the year ended December 31, 2022, compared to the same period in the prior year, primarily due to a decrease of $3.1 million in compensation related costs, a decrease of $1.6 million in stock-based compensation due to a lower headcount as compared to the same period in the prior year, and recognition of a $1.3 million gain on the remeasurement of assumed contingent liabilities.

General and Administrative Expenses

(in millions)	Year Ended		
	December 31, 2022	December 31, 2021	$ Change
Compensation related costs	$ 11.5	$ 9.7	$ 1.8
Stock-based compensation	7.6	6.9	0.7
Legal and professional fees	3.7	2.6	1.1
Other general and administrative expenses	3.9	4.4	(0.5)
Total	$ 26.7	$ 23.6	$ 3.1

General and administrative expenses increased by $3.1 million, compared to the same period in the prior year, primarily due to an increase of $1.8 million in compensation related costs and an increase of $0.7 million in stock-based compensation as the Company is focused on building our executive management team to support the growth of the Company, and an increase of $1.1 million in legal and professional fees to support our financings and business development efforts during the year.

Impairment of Intangible Assets

In December 2017, we expanded our activities in the field of infectious diseases with the acquisition of Discuva Limited, a privately held United Kingdom-based company. Through this acquisition, we obtained a bacterial genetics platform and a suite of software-based technologies (collectively termed our “Discuva Platform”), which facilitates the discovery and development of new mechanism antibiotics. In conjunction with the significant change in the Company’s strategy and shift in focus to the therapeutic area of oncology, the Company determined that it will cease further investment in the Discuva Platform and evaluate further options for the use of the Discuva Platform. Management have concluded that this indicated the carrying amount of the acquired Discuva Platform intangible asset may not be recoverable and hence performed an assessment using a probability-weighted approach to determine the undiscounted cash flows of the asset, which indicated that an impairment exists. Based on the assessment to compare the fair value of the asset to its carrying amount, an impairment charge of $8.5 million was recognized during the year ended December 31, 2022, representing the aggregate carrying amount of the intangible asset. This impairment charge is presented as impairment of intangible assets in the consolidated statements of operations and comprehensive loss.

Other Operating Income

Other operating income is comprised of the following:

(in millions)	Year Ended		
	December 31, 2022	December 31, 2021	$ Change
Funding income from BARDA	$ 8.1	$ 4.6	$ 3.5
Research and development tax credits	4.5	15.2	(10.7)
Grant income from CARB-X	1.8	1.2	0.6
Total	$ 14.4	$ 21.0	$ (6.6)

Funding income from BARDA increased by $3.5 million for the year ended December 31, 2022, compared to the same period in the prior year, primarily due to the accrual of the remaining clinical trial costs associated with ridinilazole as a result of our decision to seek partners or a divestiture related to ridinilazole as the path forward for the clinical development of the asset. The recognition of the remaining clinical trial costs resulted in the acceleration of deferred other income for costs that had been billed and collected from BARDA prior to the expense being recognized.

U.K. research and development tax credits decreased by $10.7 million for the year ended December 31, 2022, compared to the same period in the prior year, due to a decrease in clinical and manufacturing activity spend associated with the ridinilazole Phase III clinical program, which was ceased during the third quarter of 2022, and resulted in a decrease in tax credits claimed, coupled with a decrease in eligible expenses claimed due to recent changes in tax legislation.

Grant income received from CARB-X increased by $0.6 million for the year ended December 31, 2022, compared to the same period in the prior year due to an increase in spend to progress the preclinical candidate SMT-738 from the DDS-04 series for development in the fight against multidrug resistant infections, specifically CRE infections.

Other Expense, Net

Other expense, net is comprised of the following:

(in millions)	Year Ended		
	December 31, 2022	December 31, 2021	$ Change
Foreign currency loss	$ (4.1)	$ (2.1)	$ (2.0)
Interest expense on promissory notes payable to related parties	(4.4)	(0.2)	(4.2)
Investment income	1.5	—	1.5
Other income (expense), net	0.3	(0.1)	0.4
Total	$ (6.7)	$ (2.4)	$ (4.3)

Other expense, net primarily increased by $4.3 million for the year ended December 31, 2022, compared to the same period in the prior year, due to unfavorable changes in foreign currency of $2.0 million, increase in loan interest expense of $4.2 million related to the $25.0 million and $520.0 million promissory notes issued to related parties during the year (as described below), partially offset by $1.5 million of investment income related to increased balances and yields in our money-market fund and highly liquid U.S. government treasury securities.

Liquidity and Capital Resources

Sources of Liquidity

To date, we have financed our operations primarily through issuances of our common stock, payments to us under license, collaboration, and commercialization arrangements, for example, our license and commercialization agreement with Eurofarma Laboratórios SA, or Eurofarma, and development funding and other assistance from government entities, philanthropic, non-government and not-for-profit organizations for our product candidates. In particular, we have received funding from BARDA, CARB-X, Innovate UK, Wellcome Trust and a number of not-for-profit organizations.

On March 24, 2021, pursuant to an unsecured promissory note we received net proceeds of $55.0 million. Such note was later repaid without interest or penalty, rescinded and replaced by a new note on April 20, 2021, pursuant to a second unsecured promissory note we received net proceeds of $55.0 million. Subsequently, on May 12, 2021, we received proceeds of $75.0 million in the aggregate from the sale of 14,312,976 shares of Common Stock at a price per share of $5.24 from our 2021 rights offering ("2021 Rights Offering), the proceeds of which were used in part to repay amounts outstanding on the second unsecured promissory note. On March 10, 2022, we received net proceeds of $25.0 million from the issuance of an unsecured promissory notes. On August 8, 2022, we received net proceeds of $99.9 million from the sale of 103,092,783 share of Common Stock at a price of $0.97 per share from our 2021 Rights Offering, the proceeds of which were used in part to repay amounts outstanding on the March 2022 Note.

On December 6, 2022, the Company entered into a 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 million. Pursuant to the Note Purchase Agreement, the Company issued to Mr. Duggan and Dr. Zanganeh the unsecured Duggan February Note in the amount of $400 million and $20 million Zanganeh Note, respectively, which would mature and become due on February 15, 2023 and an unsecured Duggan September Note to Mr. Duggan in the amount of $100 million, which will mature and become due on September 15, 2023. The maturity dates of the December 2022 Notes could be 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 shall consummate 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 shall 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 million (the "Rights Offering"), 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 (i) the net proceeds of such capital raise or (ii) the full amount outstanding of the Duggan September Note. Following the issuance of 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 Notes. The Notes accrue interest at an initial rate of 7.5%. All interest on the Notes shall be paid on the date of signing for the period through February 15, 2023. Such prepaid interest shall be 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 $.01), which was 9,720,291 shares. For all applicable periods following the February 15, 2023, interest shall accrue 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. On February 15, 2023, the $20 million Zanganeh Note matured and the Company repaid the outstanding principal balance. In connection with the closing of the Rights Offering, the $400 million Duggan Promissory Note matured and became due, and the Company repaid all principal and accrued interest thereunder using a portion of the proceeds from this Rights Offering. Following the repayment of this note, only the $100 million Duggan September Note remains outstanding.

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, 2022, we incurred a net loss of $78.8 million, and cash flows used in operating activities was $41.6 million. As of December 31, 2022 we had an accumulated deficit of $378.3 million, cash and cash equivalents of $348.6 million, restricted cash of $300.0 million, research and development tax credits of $5.8 million and accounts receivable of $0.3 million. These losses could continue for the next several years as we invest in clinical development of ivonescimab. We believe that our financial resources as of December 31, 2022, after considering the payments made to Akeso in January and March 2023 totaling $474.9 million, the net proceeds of $499.5 million from the Rights Offering that closed on March 1, 2023, and repayments of the promissory notes payable to related parties in February and March 2023 totaling $420 million, will fund our operating costs and working capital needs for our planned clinical trials for ivonescimab into the second half of 2024. In addition to the payments already made to Akeso, under the License Agreement there are additional potential milestone payments of $4.5 billion, as Akeso will be eligible to receive regulatory milestones of up to $1.05 billion and commercial milestones of up to $3.45 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 our Licensing Agreement 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.

Cash Flows

The following table summarizes the results of our cash flows for the years ended December 31, 2022 and 2021.

(in millions)	Year Ended December 31, 2022	Year Ended December 31, 2021
Net cash used in operating activities	$ (41.6)	$ (72.6)
Net cash used in investing activities	$ (0.6)	$ (0.3)
Net cash provided by financing activities	$ 620.2	$ 77.9

Operating Activities

Net cash used in operating activities for the year ended December 31, 2022 was $41.6 million and resulted from a net loss of $78.8 million, which included non-cash charges of $37.2 million, which is primarily comprised of $11.9 million of stock-based compensation, $8.5 million impairment charge, $4.3 million non-cash interest expense, $2.5 million of amortization and depreciation charges, $2.6 million unrealized foreign exchange loss and a $8.6 million net decrease in working capital. The net decrease in working capital was primarily due to a $8.4 million decrease in the research and development tax credit receivable, a $4.8 million increase in accrued liabilities and accrued compensation, a $5.1 million decrease in prepaid expenses, partially offset by a $7.3 million decrease in deferred revenue and other income and a $4.1 million decrease in accounts payable.

Net cash used in operating activities for the year ended December 31, 2021 was $72.6 million and resulted from a net loss of $88.6 million, which included non-cash charges of $16.1 million, which is primarily comprised of $12.8 million of stock-based compensation, and a $0.1 million net increase in working capital. The net increase in working capital was primarily due to a $6.0 million increase in the research and development tax credit receivable, a $1.7 million decrease in accounts payable, a $1.1 million increase in accounts receivable, a $1.1 million decrease in lease liabilities and a $0.8 million decrease in deferred revenue, partially offset by a $8.2 million increase in accrued liabilities and accrued compensation and a $2.3 million decrease in prepaid expenses.

Investing Activities

Net cash used in investing activities for the years ended December 31, 2022 and 2021of $0.6 million and $0.3 million, respectively, was for the purchase of property and equipment.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2022 was $620.2 million and primarily resulted from net proceeds of $99.9 million from the rights offering in August 2022, proceeds from promissory notes from related parties of $545.0 million, partially offset by the repayment of a promissory note from a related party of $25.0 million and $0.4 million of net proceeds from the exercise of stock options.

Net cash provided by financing activities for the year ended December 31, 2021, was $77.9 million and primarily resulted from net proceeds of $74.8 million from the rights offering in May 2021, proceeds from the promissory notes from a related party of $110.0 million, partially offset by repayments of the promissory notes from a related party of $110.0 million and $3.1 million of net proceeds received from the exercise of stock options.

Contractual Obligations and Commitments

Fixed asset purchase commitments

At December 31, 2022 and 2021, we had no capital commitments.

Lease commitments

The following table summarizes our lease contractual obligations as of December 31, 2022.

	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	$4.9	$1.5	$3.4	$ —	$ —

Debt commitments

December 2022 Promissory Notes

On December 6, 2022, we entered into 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 the Duggan February Note and the Zanganeh Note, respectively, which would mature and become due on February 15, 2023 and the Duggan September Note to Mr. Duggan, which will mature and become due on September 15, 2023.

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 regarding prepayment terms. Please see "Liquidity and Capital Resources-Sources of Liquidity" section for further details of the Company's debt commitments.

On February 15, 2023, the $20 million Zanganeh Note matured and the Company repaid the outstanding principal balance. In connection with the closing of the Rights Offering, the $400 million Duggan Promissory Note matured and became due, and the Company repaid all principal and accrued interest thereunder using a portion of the proceeds from this Rights Offering.

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, 2022, total contractual commitments, excluding leases

commitments and debt commitments, are estimated to be approximately $11.5 million and the majority of these commitments are due within one year.

We have certain commitments under our agreements with Akeso, Wellcome Trust, the University College London and certain employees, former employees and former directors of Discuva, pursuant to which we will be required to pay royalties or make milestone payments. The License Agreement with Akeso also contains certain manufacturing and purchase commitments. As of December 31, 2022, 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.

Indemnifications

Our certificate of incorporation provides that it will indemnify the directors and officers to the fullest extent permitted by Delaware law. In addition, we have entered into indemnification agreements with all of the directors and executive officers. These indemnification agreements may require us, among other things, to indemnify each such director or executive officer for some expenses, including attorneys' fees, judgments, fines, and settlement amounts incurred by him or her in any action or proceeding arising out of his or her service as one of our directors or executive officers. We believe the fair value for these indemnification obligations is minimal. Accordingly, we have not recognized any liabilities relating to these obligations as of December 31, 2022.

Legal Proceedings

We are not currently subject to any material legal proceedings.

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 revenue recognition, intangible assets, 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:

Revenue Recognition

The Company accounts for revenue using Accounting Standards Codification ("ASC") 606 ("ASC 606"). This standard applies to all contracts with customers, except for contracts that are within the scope of other standards.

The Company enters into out-licensing agreements within the scope of ASC 606 under which it licenses certain rights to its product candidates to third parties. Such agreements may include the transfer of intellectual property rights in the form of licenses, transfer of technological know-how, delivery of drug substances, research and development services, and participation on certain committees with the counterparty. Payments made by the customers may include one or more of the following: non-refundable, up-front license fees; development, regulatory, and commercial milestone payments; payments for manufacturing supply services the Company provides through its contract manufacturers; and royalties on net sales of licensed products if they are successfully approved and commercialized. Each of these payments may result in license, collaboration, or other revenue, except revenue from royalties on net sales of licensed products, which would be classified as royalty revenue.

In determining the appropriate amount of revenue to be recognized as the Company fulfills its obligations under each of its out-licensing agreements, the following steps are performed: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. Revenue is then recognized in respect of the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. As part of the accounting for these arrangements, the Company must use significant judgment to determine: (a) the performance obligations based on the determination under step (ii) above; (b) the transaction price under step (iii) above; and (c) the standalone selling price for each performance obligation identified in the contract for the allocation of transaction price in step (iv) above. The Company also uses judgment to determine whether milestone payments or other variable consideration, except for royalties and sales-based milestones, should be included in the transaction price, as described below. The transaction price is allocated to each performance obligation based on the relative standalone selling price of each performance obligation in the contract, and the Company recognizes revenue based on those amounts when, or as, the performance obligations under the contract are satisfied.

Exclusive Licenses

If the license to the Company's intellectual property is determined to be distinct from the other promises or performance obligations identified in the arrangement, the Company recognizes revenue from nonrefundable, upfront fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. In assessing whether a promise or performance obligation is distinct from the other promises, the Company considers factors such as the research, development, manufacturing and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. In addition, the Company considers whether the collaboration partner can benefit from a promise for its intended purpose without the receipt of the remaining promises, whether the value of the promise is dependent on the unsatisfied promises, whether there are other vendors that could provide the remaining promises, and whether it is separately identifiable from the remaining promises. For licenses that are combined with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined

performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of progress and related revenue recognition. The measure of progress, and the resulting periods over which revenue should be recognized, are subject to estimates by management and may change over the course of the research, development and licensing arrangement. Such a change could have a material impact on the amount of revenue the Company records in future periods. Under the Company's existing license and collaboration agreements, the Company has concluded that the transfer of control to the customer occurs over the time period that the research and development services are to be provided by the Company, and this output method is, in management's judgment, the best measure of progress towards satisfying the performance obligation.

Milestone Payments

At the inception of each arrangement that includes potential research, development or regulatory milestone payments, the Company evaluates whether the milestones are considered likely to be met and estimates the amount to be considered for inclusion in the transaction price using the most-likely-amount method. If it is probable that a significant reversal in the amount of cumulative revenue recognized would not occur, the associated milestone payment value is included in the transaction price. For milestone payments due upon events that are not within the control of the Company or the licensee, such as regulatory approvals, the Company is not able to assert that it is likely that the regulatory approval will be granted and that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur until those approvals are received. In making this assessment, the Company evaluates factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the particular milestone. There is considerable judgment involved in determining whether it is probable that a significant reversal in the amount of cumulative revenue recognized would not occur. At the end of each subsequent reporting period, the Company reevaluates the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price of the arrangement. Any such adjustments are recorded on a cumulative catch-up basis, which would affect the amounts of revenue and earnings in the period of adjustment.

Royalties

For arrangements that include sales-based royalties, including milestone payments due upon first commercial sales or based on a level of sales, that are the result of a customer-vendor relationship and for which the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) the occurrence of the related sales or (ii) the date upon which the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied. To date, the Company has not recognized any royalty revenue from any of its licensing arrangements.

Intangible Assets

Intangible assets are estimated by management based on the fair value of assets acquired. These include acquired technology, patents, licenses, an option over non-financial assets and a research and development discovery platform ("Discuva Platform"). Intangible assets are amortized from one to eighteen years on a straight-line basis which represents the estimated periods of benefit and the expected pattern of consumption.

Our intangible assets are recorded at fair value at the time of their acquisition, assigned an estimated useful life, and amortized primarily on a straight-line basis over their estimated useful lives or over the period of the relevant agreement for an option over non-financial assets. Intangible assets are stated in our consolidated balance sheets net of accumulated amortization and impairments, if applicable.

The Company evaluates the recoverability of its intangible and long-lived assets whenever events and changes in circumstances indicate that the carrying amount of an asset may not be fully recoverable. If events and circumstances indicate that the carrying amount may not fully be recoverable, the carrying values of the asset are evaluated in relation to their operating performance and future undiscounted cash flows of the underlying business. If the future undiscounted cash flows are less than their carrying value, impairment exists. The impairment is measured as the difference between the carrying value and the fair value of the underlying asset. Fair values are based on estimates of market prices and assumptions concerning the amount and timing of estimated future cash flows and assumed discount rates, reflecting varying degrees of perceived risk.

Amortization of intangible assets is included as part of the research and development expense line shown on the face of the consolidated statement of operations and comprehensive loss.

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 exceeds the estimated costs. When evaluating the adequacy of these balances, the Company analyzes progress of the studies, including 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 highly 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 estimates expected forfeitures at the time of grant instead of accounting for forfeitures as they occur. Stock option and restricted stock unit 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 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.

Recent Accounting Pronouncements

For a discussion of recent accounting pronouncements, please see Note 5 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, collaboration, and commercialization arrangements, for example, our license and commercialization agreement with Eurofarma, as well as philanthropic, non-government and not-for-profit organizations and grant funding from government entities, including BARDA, CARB-X, Innovate UK, Wellcome Trust and a number of not-for-profit organizations. 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, 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 income in our statements of operations. 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 which is invested in a variety of short term securities, including money market funds and investments in highly liquid 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.

We are exposed to market risks related to fluctuations in interest rates related to our promissory notes payable to related parties. As of December 31, 2022, the principal balance payable was $520 million, the outstanding principal balance is subject to a variable interest rate from February 15, 2023. As of March 7, 2023, the principal balance payable was $100 million. For all applicable periods following the February 15, 2023, interest shall accrue on the outstanding principal balance at the United States 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 United States prime rate plus 300 basis points, as adjusted monthly.

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 a $5.8 million of research and development tax credits outstanding at December 31, 2022. Given that these receivables related 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.

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 carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) under the supervision and the participation of the company's management, which is responsible for the management of the internal controls, and which includes our Chief Executive Officer (our Principal Executive Officer and Principal Financial Officer). The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, 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 Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission'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 Securities Exchange Act of 1934 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, 2022, our Chief Executive Officer and Co-Chief Executive Officer (our Principal Executive Officers), and our Chief Financial Officer (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 and Attestation Report of Registered Public Accounting Firm

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 Chief Executive Officer and Co-Chief Executive Officer (our Principal Executive Officers), and our 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 all misstatements. Moreover, projections of any evaluation of the effectiveness of internal control to future periods are subject to a risk that controls may become inadequate because of changes in conditions and 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, 2022, based on the Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) 2013. Based on this assessment, our management has concluded that our internal control over financial reporting as of December 31, 2022, was effective.

This report does not include an attestation report of our registered public accounting firm as we are a non-accelerated filer and a smaller reporting company.

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, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

The Compensation Committee of the Company's Board of Directors reviewed and approved employee 2022 bonuses. A discretionary cash bonus of $202,500 and an extraordinary bonus of $250,000 was paid to Dr. Zanganeh, the Company's co-Chief Executive Officer, President and member of the Board, on January 10, 2023. A discretionary cash bonus of $131,918 and an extraordinary bonus of $250,000 was paid to Ankur Dhingra, the Company's Chief Financial Officer on January 10, 2023.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item is incorporated herein by reference to the information that will be included in our proxy statement related to the 2023 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K.

Item 11. Executive Compensation

The information required by this Item is incorporated herein by reference to the information that will be included in our proxy statement related to the 2023 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K.

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

The information required by this Item is incorporated herein by reference to the information that will be included in our proxy statement related to the 2023 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K.

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

The information required by this Item is incorporated herein by reference to the information that will be included in our proxy statement related to the 2023 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K.

Item 14. Principal Accounting Fees and Services

The information required by this Item is incorporated herein by reference to the information that will be included in our proxy statement related to the 2023 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(1) **Financial Statements**

As part of this Report, the consolidated financial statements are listed in the accompanying index to financial statements on page 88.

(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 Report are listed below.

Exhibit No.	Description
2.1	Scheme of Arrangement, dated September 18, 2020 (incorporated by reference to Exhibit 99.1 to the Company's Report on Form 6-K (File No. 001-36866), filed with the Securities and Exchange Commission on July 27, 2020)
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 of Form 8-K filed by the Company on July 29, 2022, File No. 001-36866)
3.4	Amendment No. 2 to Restated Certificate of Incorporation, dated January 19, 2023 (incorporated by reference to Exhibit 5.1 of Form 8-K filed by the Company on January 20, 2023, File No. 001-36866)
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 Specimen Stock Certificate (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 29, 2020)
4.3	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)
4.4	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)
4.5	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-K (File No. 001-36866), filed with the Securities and Exchange Commission on September 18, 2020)
4.6	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)
4.7	Form of Subscription Rights Certificate (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 April 21, 2021)
10.1†	Translation Award Funding Agreement, entered into as of October 19, 2012, by and between the Wellcome Trust Limited and Summit Therapeutics plc (incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form F-1 (File No. 333-201807), as amended, filed with the Securities and Exchange Commission on February 27, 2015)
10.2	Service Agreement, effective as of January 14, 2015, by and between Cambridge Innovation Center and Summit Therapeutics Inc. (incorporated by reference to Exhibit 10.10 to the Company's Registration Statement on Form F-1 (File No. 333-201807), as amended, filed with the Securities and Exchange Commission on February 20, 2015)
10.3#	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)
10.4#	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)

Exhibit No.	Description
10.5†	License and Collaboration Agreement, dated October 3, 2016, by and between Summit (Oxford) Ltd. and Sarepta Therapeutics, Inc. (incorporated by reference to Exhibit 4.23 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)
10.6	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)
10.7†	Agreement, dated September 5, 2017, by and between Summit (Oxford) Limited and the U.S. Department of Health and Human Services Biomedical Advanced Research and Development Authority (BARDA) (incorporated by reference to Exhibit 4.26 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)
10.8†	Amendment of Solicitation/Modification of Contract (0001), dated June 19, 2018, to Agreement, dated September 5, 2017, by and between Summit (Oxford) Limited and the U.S. Department of Health and Human Services Biomedical Advanced Research and Development Authority (BARDA) (incorporated by reference to Exhibit 4.13 to the Company's Transition Report on 20-F (File No. 333-36866) filed with the Securities and Exchange Commission on March 29, 2019)
10.9+	Amendment of Solicitation/Modification of Contract (0002), dated August 14, 2018, to Agreement, dated September 5, 2017, by and between Summit (Oxford) Limited and the U.S. Department of Health and Human Services Biomedical Advanced Research and Development Authority (BARDA) (incorporated by reference to Exhibit 4.14 to the Company's Transition Report on 20-F(File No. 333-36866) filed with the Securities and Exchange Commission on March 29, 2019)
10.10+	Amendment of Solicitation/Modification of Contract (0003), dated February 14, 2019, to Agreement, dated September 5, 2017, by and between Summit (Oxford) Limited and the U.S. Department of Health and Human Services Biomedical Advanced Research and Development Authority (BARDA) (incorporated by reference to Exhibit 4.15 to the Company's Transition Report on 20-F (File No. 333-36866), filed with the Securities and Exchange Commission on March 29, 2019)
10.11†	License and Commercialization Agreement, dated December 18, 2017, by and between Summit (Oxford) Ltd. and Eurofarma Laboratórios S.A. (incorporated by reference to Exhibit 4.27 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)
10.12†[(1)]	Share Purchase Agreement, dated December 23, 2017, by and among Summit Therapeutics plc and the shareholders of Discuva Limited (incorporated by reference to Exhibit 4.28 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)
10.13†	Transfer Incentive Agreement, dated December 23, 2017, by and among Discuva Limited and certain of its managers (incorporated by reference to Exhibit 4.29 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)
10.14	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)
10.15†	Equity and Revenue Sharing Agreement, dated October 16, 2017, by and between Summit (Oxford) Limited and the Wellcome Trust Limited (incorporated by reference to Exhibit 4.32 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)
10.16	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)
10.17	Securities Purchase Agreement, dated December 14, 2018, by and among Summit Therapeutics plc and Robert W. Duggan (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 6-K (File No. 001-36866), filed with the Securities and Exchange Commission on December 17, 2018)

Exhibit No.	Description
10.18+	Amendment of Solicitation/Modification of Contract (0004), dated June 17, 2019, to Agreement, dated September 5, 2017, by and between Summit (Oxford) Limited and the U.S. Department of Health and Human Services Biomedical Advanced Research and Development Authority (BARDA) (incorporated by reference to Exhibit 4.24 to the Company's Transition Report on 20-f (File No. 333-36866) filed with the Securities and Exchange Commission on April 30, 2020)
10.19	Securities Purchase Agreement, dated December 6, 2019, by and among Summit Therapeutics plc and Robert W. Duggan (incorporated by reference to Exhibit 4.1 to the Company's Report on Form 6-K (File No. 001-36866), filed with the Securities and Exchange Commission on December 6, 2019)
10.20	Placing Agreement, December 6, 2019, by and between Summit Therapeutics plc and Nplus1 Singer Advisory LLP (incorporated by reference to Exhibit 4.2 to the Company's Report on Form 6-K (File No. 001-36866), filed with the Securities and Exchange Commission on December 6, 2019)
10.21	Consulting Agreement, dated December 6, 2019, by and between Summit Therapeutics plc and Maky Zanganeh & Associates, Inc. (incorporated by reference to Exhibit 4.4 to the Company's Report on Form 6-K (File No. 001-36866), filed with the Securities and Exchange Commission on December 6, 2019)
10.22	Relationship Agreement, dated December 14, 2018, by and among Summit Therapeutics plc, Robert W. Duggan and Cairn Financial Advisers LLP (incorporated by reference to Exhibit 10.2 to the Company's Report on Form 6-K (File No. 001-36866), filed with the Securities and Exchange Commission on December 17, 2018)
10.23	Deed of Termination, dated December 6, 2019, by and among Summit Therapeutics plc, Robert Duggan and Cairn Financial Advisers LLP (incorporated by reference to Exhibit 4.3 to the Company's Report on Form 6-K (File No. 001-36866), filed with the Securities and Exchange Commission on December 6, 2019)
10.24+	Amendment of Solicitation/Modification of Contract (0005), dated January 21, 2020, to Agreement, dated September 5, 2017, by and between Summit (Oxford) Limited and the U.S. Department of Health and Human Services Biomedical Advanced Research and Development Authority (BARDA) (incorporated by reference to Exhibit 4.36 to the Company's Transition Report on 20-F (File No. 333-36866) filed with the Securities and Exchange Commission on April 30, 2020)
10.25(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)
10.26(1)	Securities Purchase Agreement, dated November 6, 2020, by and between Summit Therapeutics Inc. and Polar Capital Fund plc - Biotechnology Fund (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 November 6, 2020)
10.27(1)	Securities Purchase Agreement, dated November 6, 2020, by and between Summit Therapeutics Inc. and Mahkam Zanganeh Revocable Trust (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 November 6, 2020)
10.28#	Form of Indemnification Agreement between Summit Therapeutics Inc. and each of its Executive Officers and Directors (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 September 18, 2020)
10.29#	Offer of Employment, dated May 21, 2020, by and between Summit Therapeutics Inc. and Michael Donaldson (incorporated by reference to Exhibit 10.25 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)
10.30#	Contract of Employment, dated May 29, 2020, by and between Summit Therapeutics Inc. and Ventzislav Stefanov (incorporated by reference to Exhibit 10.26 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)
10.31#	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)
10.32#	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)

Exhibit No.	Description
10.33#	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)
10.34#	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)
10.35#	Contract of Employment, dated November 22, 2020, by and between Summit Therapeutics Inc. and Mahkam Zanganeh (incorporated by reference to Exhibit 10.35 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)
10.36	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)
10.37	Exit Agreement, dated May 28, 2021, by and between Summit Therapeutics Inc. and Michael Donaldson (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 May 28, 2021)
10.38(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)
10.39	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)
10.40	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)
10.41†	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)
10.42	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)
10.43	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)
10.44	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)
10.45#*	Amended and Restated 2020 Stock Incentive Plan, dated July 27, 2022
10.46†*	First Amendment to Sublease Agreement, dated July 25, 2022, by and among Summit Therapeutics Inc. and Maky Zanganeh and Associates, Inc.
10.47†*	Second Amendment to Sublease Agreement, dated July 29, 2022, by and among Summit Therapeutics Inc. and Maky Zanganeh and Associates, Inc.
10.48#*	Contract of Employment, dated April 15, 2022, by and between Summit Therapeutics Inc. and Ankur Dhingra
16.1	Letter from PwC to the Securities and Exchange Commission, dated May 26, 2021 (incorporated by reference to Exhibit 16.1 to the Company's Current Report on Form 8-K (File No. 001-36866), filed with the Securities and Exchange Commission on May 26, 2021)
21.1*	List of Significant Subsidiaries
23.1*	Consent of PricewaterhouseCoopers LLP, a Delaware limited liability partnership
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

Exhibit No.	Description
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
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
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.
†	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 portions of this exhibit have been omitted because they are not material and would likely cause competitive harm to the registrant if disclosed.
(1)	The schedules and exhibits have been omitted. A copy of any omitted schedule or exhibit will be furnished to the Securities and Exchange Commission 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:	Chief Executive Officer and Executive Chairman; Principal Executive Officer
By:	/s/ Mahkam Zanganeh
Name:	Dr. Mahkam Zanganeh
Title:	Co-Chief Executive Officer, President and member of the Board; Principal Executive Officer
By:	/s/ Ankur Dhingra
Name:	Ankur Dhingra
Title:	Chief Financial Officer; Principal Financial Officer

Date: March 9, 2023

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	Chief Executive Officer and Executive Chairman (*Principal Executive Officer*)	March 9, 2023
/s/ Mahkam Zanganeh Dr. Mahkam Zanganeh	Co-Chief Executive Officer, President and member of the Board (*Principal Executive Officer*)	March 9, 2023
/s/ Ankur Dhingra Ankur Dhingra	Chief Financial Officer *(Principal Financial Officer)*	March 9, 2023
/s/ Robert F. Booth Dr. Robert F. Booth	Director	March 9, 2023
/s/ Alessandra Cesano Dr. Alessandra Cesano	Director	March 9, 2023
/s/ Kenneth Clark Kenneth Clark	Director	March 9, 2023
/s/ Ujwala Mahatme Ujwala Mahatme	Director	March 9, 2023
/s/ Manmeet Soni Manmeet Soni	Director	March 9, 2023
/s/ Yu Xia Dr. Yu Xia	Director	March 9, 2023

Summit Therapeutics Inc.

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Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Summit Therapeutics Inc. and its subsidiaries (the "Company") as of December 31, 2022 and 2021, and the related consolidated statements of operations and comprehensive loss, of stockholders' equity and of cash flows for the years then ended, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the years then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Emphasis of Matter

As discussed in Note 17 to the consolidated financial statements, the Company has a note payable with a principal amount of $100 million maturing in September 2024. Management's evaluation of the events and conditions related to future funding are described in Note 3.

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.

Accrued and Prepaid Research and Development Costs

As described in Notes 4 and 15 to the consolidated financial statements, included within prepaid expenses as of December 31, 2022 is $0.4 million of prepayments relating to research and development expenditures. Included within accrued liabilities as of December 31, 2022 is $8.9 million relating to research and development expenditures. 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 by management 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. However, prepaid expenses decrease, and accrued liabilities increase as the activities progress, and if actual costs incurred exceed the prepaid expense, an accrual will be recorded for the liability. 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 management's operational knowledge of the work completed under those contracts.

The principal considerations for our determination that performing procedures relating to accrued and prepaid research and development costs is a critical audit matter are the significant judgment by management when determining the estimated research and development costs, which in turn led to significant auditor judgment, subjectivity, and effort in performing procedures and evaluating audit evidence related to estimated current stage of completion of each study or activity.

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, among others, (i) evaluating management's process on a sample basis for determining the current stage of completion of each study or activity; (ii) reading a sample of research and development contracts; (iii) evaluating the reasonableness of progress towards completion for a sample of research and development activities and the associated incurred cost based on invoices, external confirmations or other information received from the supplier; and (iv) testing the completeness and accuracy of the underlying data including total costs included within contracts and actual billed amounts for a sample of contracts.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts
March 9, 2023

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, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 348,607	$ 71,791
Restricted cash	300,000	—
Accounts receivable	349	1,464
Prepaid expenses	1,504	7,161
Other current assets	486	1,201
Research and development tax credit receivable	5,766	15,695
Total current assets	656,712	97,312
Non-current assets:		
Property and equipment, net	906	694
Right-of-use assets	4,175	2,790
Goodwill	1,798	2,009
Intangible assets, net	—	10,399
Other assets	577	170
Total assets	$ 664,168	$ 113,374
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 355	$ 4,374
Accrued liabilities	10,664	7,197
Accrued compensation	5,641	4,125
Lease liabilities	1,690	1,091
Deferred revenue and other income	—	7,939
Other current liabilities	662	897
Promissory note payable to related parties	19,770	—
Total current liabilities	38,782	25,623
Non-current liabilities		
Lease liabilities, net of current portion	2,763	1,691
Other non-current liabilities	1,429	2,776
Promissory notes payable to related parties	494,540	—
Total liabilities	537,514	30,090
Commitments and contingencies (Note 21)		
Stockholders' equity:		
Preferred stock, $0.01 par value, 20,000,000 shares authorized; none issued and outstanding at December 31, 2022 and 2021, respectively	—	—
Common stock, $0.01 par value: 350,000,000 shares authorized; 211,091,425 and 98,039,540 shares issued and outstanding at December 31, 2022 and 2021, respectively	2,110	980
Additional paid-in capital	504,767	384,049
Accumulated other comprehensive loss	(1,893)	(2,197)
Accumulated deficit	(378,330)	(299,548)
Total stockholders' equity	126,654	83,284
Total liabilities and stockholders' equity	$ 664,168	$ 113,374

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, 2022	Year Ended December 31, 2021
Revenue	$ 705	$ 1,809
Operating expenses:		
Research and development	51,999	85,352
General and administrative	26,743	23,611
Impairment of intangible assets	8,468	—
Total operating expenses	87,210	108,963
Other operating income	14,416	20,968
Operating loss	(72,089)	(86,186)
Other expense, net	(6,693)	(2,416)
Loss before income tax	(78,782)	(88,602)
Net loss	$ (78,782)	$ (88,602)
Net loss per share:		
Basic and diluted	$ (0.41)	$ (0.67)
Weighted average common shares outstanding:		
Basic and diluted	193,336,063	131,714,225
Other comprehensive income (loss):		
Foreign currency translation adjustments	304	1,597
Comprehensive loss	$ (78,478)	$ (87,005)

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, 2020	82,575,064	$ 826	$ 293,367	$ (3,794)	$ (210,946)	$ 79,453
2021 Rights Offering of common stock, net of offering costs of $159	14,312,976	143	74,698	—	—	74,841
Issuance on common stock from exercise of share options	1,151,500	11	3,077	—	—	3,088
Stock-based compensation	—	—	12,804	—	—	12,804
Imputed interest expense on promissory note payable to a related party	—	—	103	—	—	103
Foreign currency translation adjustment	—	—	—	1,597	—	1,597
Net loss	—	—	—	—	(88,602)	(88,602)
Balance at December 31, 2021	98,039,540	$ 980	$ 384,049	$ (2,197)	$ (299,548)	$ 83,284
2022 Rights Offering of common stock, net of offering costs of $111	103,092,783	1,031	98,858	—	—	99,889
Issuance of common stock in lieu of interest to related parties	9,720,291	97	7,497	—	—	7,594
Issuance of common stock under stock purchase plans and exercise of stock options	238,811	2	397	—	—	399
Stock-based compensation	—	—	11,948	—	—	11,948
Imputed interest expense on promissory notes payable to related parties	—	—	2,018	—	—	2,018
Foreign currency translation adjustment	—	—	—	304	—	304
Net loss	—	—	—	—	(78,782)	(78,782)
Balance at December 31, 2022	211,091,425	$ 2,110	$ 504,767	$ (1,893)	$ (378,330)	$ 126,654

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

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

	December 31, 2022	December 31, 2021
Cash flows used in operating activities:		
Net loss	$ (78,782)	$ (88,602)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on remeasurement of liabilities	(1,265)	—
Non-cash interest expense	4,303	196
Unrealized foreign exchange loss	2,614	326
Amortization of operating right-of-use assets	1,251	1,108
Depreciation	349	330
Amortization of intangible assets	914	1,017
Impairment of intangible assets	8,468	—
Stock-based compensation	11,948	12,804
Other adjustments	2	301
Changes in operating assets and liabilities:		
Accounts receivable	975	(1,138)
Prepaid expenses	5,107	2,345
Other current and long-term assets	215	104
Research and development tax credit receivable	8,437	(6,015)
Deferred revenue and other income	(7,278)	(813)
Accounts payable	(4,132)	(1,711)
Accrued liabilities	4,782	5,075
Accrued compensation	1,609	3,154
Operating lease liabilities	(1,099)	(1,068)
Net cash used in operating activities	(41,582)	(72,587)
Cash flows used in investing activities:		
Purchase of property and equipment	(624)	(306)
Net cash used in investing activities	(624)	(306)
Cash flows provided by financing activities:		
Proceeds from the issuance of common stock	100,000	75,000
Transaction costs from the issuance of common stock	(111)	(118)
Proceeds from related party promissory notes	545,000	110,000
Re-payment of related party promissory notes	(25,000)	(110,000)
Payments of related party promissory notes issuance costs	(44)	(54)
Proceeds from exercise of share options	399	3,088
Net cash provided by financing activities	620,244	77,916
Effect of exchange rates on cash and restricted cash	(1,222)	351
Increase in cash, cash equivalents and restricted cash	576,816	5,374
Cash at beginning of period	71,791	66,417
Cash, cash equivalents and restricted cash at end of period	$ 648,607	$ 71,791
Supplemental Disclosure of Cash Flow Information		
Cash paid for interest on related party promissory note	$ 434	$ 85
Debt issuance costs in accrued expenses	$ 31	$ —
Transaction costs included in accrued expenses	$ —	$ 41
Deferred transaction costs included in other non-current assets	$ 425	$ —
Leased assets obtained in exchange for operating lease liabilities	$ 2,860	$ 3,389

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

Notes to Consolidated Financial Statements

1. Nature of Business and Operations and Recent Events

Nature of Business and Operations

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.

Recent Events

On September 28, 2022, the Company determined that it would seek partners or a divestiture of ridinilazole, the Company's lead product candidate for treating patients suffering from Clostridioides difficile infection, also known as C. difficile infection, or CDI, as the path forward for the clinical development of the asset. As a result of this determination, the Company discontinued its only active study for ridinilazole, a pediatric clinical trial evaluating ridinilazole for treating adolescent patients with CDI. The Company is currently involved in activities related to closeout of ridinilazole clinical trials.

On December 5, 2022, the Company entered into a Collaboration and License Agreement (the “License Agreement”) with Akeso, Inc. and its affiliates (“Akeso”) pursuant to which we are partnering with Akeso to in-license its breakthrough bispecific antibody, ivonescimab. 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 power of immunotherapy via a blockade of PD-1 with the anti-angiogenesis benefits of an anti-VEGF into a single molecule. Ivonescimab was engineered to bring two well established oncology targeted mechanisms together. Through the License Agreement, the Company obtained the rights to develop and commercialize SMT112 in the United States, Canada, Europe, and Japan. In exchange for these rights, an upfront payment of $500,000 is payable to Akeso, $300,000 of which was payable within the later of 15 days after execution of the License Agreement or upon the earliest date on which the parties have actual knowledge that all applicable waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 and any comparable extension periods with respect to the transactions contemplated by the License Agreement have expired or been terminated (the “Antitrust Clearance Date”) and $200,000 of which is payable within the later of (i) 90 days after execution of the License Agreement or (ii) the Antitrust Clearance Date. In connection with the first payment, up to 16 million shares of Company common stock may be issued in lieu of cash at Akeso’s election (the “Share Transfer”), with the value of such shares based on the ten (10) day volume-weighted average price for the five-trading day period prior to and the five-trading day period after the execution of the License Agreement. The total of the upfront payment and potential milestone payments is $5,000,000, as Akeso will be eligible to receive regulatory milestones of up to $1,050,000 and commercial milestones of up to $3,450,000. In addition, Akeso will be eligible to receive low double-digit royalties on net sales. The License Agreement closed on January 17, 2023, and both Akeso and Summit entered into the Common Stock Issuance Agreement (“Issuance Agreement”). Pursuant to the License Agreement and Issuance Agreement, Akeso elected to receive 10 million shares of Company common stock in lieu of cash and was paid $274,900 dollars in cash as the initial upfront payment. The remaining $200,000 amount of the upfront payment was paid on March 6, 2023.

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. For further details see Note 17.

On January 6, 2023, the Company held a Special Meeting of Stockholders (the “Shareholder Special Meeting”), whereby the following matters were submitted to a vote of the Company’s stockholders: (i) an amendment to the Company’s Restated Certificate of Incorporation, dated September 18, 2020, as amended on July 27, 2022 (the “Restated Certificate”), to increase the number of authorized shares of common stock by 650,000,000 (from 350,000,000 to 1,000,000,000); and (ii) an amendment to the Restated Certificate to effect, as needed, a reverse stock split of all of the outstanding shares of the Company’s common stock at a ratio in the range of 1-for-5 to 1-for-10.

Each of the matters submitted to a vote of the Company's stockholders at the Special Meeting was approved by the requisite vote of the Company's stockholders in accordance with the recommendation of the Company's Board of Directors. The final decision of whether to proceed with the amendments may be determined by the Company's Board of Directors, in its discretion, at any time prior to January 6, 2024.

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 February 7, 2023, the Company commenced its previously announced rights offering ("Rights Offering"). On March 1, 2023, the Company closed the Rights Offering, which was fully subscribed. The Company received aggregate gross proceeds from the Rights Offering of $500,000 from the sale of 476,190,471 shares of our common stock at a price per share of $1.05. Issuance costs associated with the Rights Offering were approximately $500. In connection with the closing of the Rights Offering, $400,000 of the unsecured promissory notes, issued by us to Mr. Duggan, matured and became due and the Company repaid the principal amount and all outstanding accrued interest thereunder using a portion of the proceeds from this Rights Offering.

On February 15, 2023, $20,000 of the unsecured promissory notes, issued by us to Dr. Zanganeh, matured and the Company repaid the outstanding principal balance.

2. Basis of Presentation and Use of Estimates

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"). The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an on-going basis, management evaluates its estimates and judgments, including those related to revenue recognition, accrued research and development expenses, stock-based compensation, intangible assets, goodwill, other long-lived assets 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.

The progression of the COVID-19 pandemic continues to evolve and its enduring impact on the Company's business remains uncertain. Management believes the estimates and assumptions underlying its financial statements are reasonable and supportable based on the information available as of December 31, 2022, however, the extent to which the COVID-19 pandemic impacts the Company's financial results beyond December 31, 2022 will depend on future developments that are highly uncertain and cannot be predicted at this time.

3. Liquidity and Capital Resources

During the year ended December 31, 2022, the Company incurred a net loss of $78,782 and cash flows used in operating activities was $41,582. As of December 31, 2022, the Company had an accumulated deficit of $378,330, cash and cash equivalents of $348,607, restricted cash of $300,000, research and development tax credit receivable of $5,766 and accounts receivable of $349. The Company expects to continue to generate operating losses for the foreseeable future.

Based on the Company's existing cash, cash equivalents and U.K. research and development tax credits, after considering the payments made to Akeso in January and March 2023 totaling $474,900, the net proceeds of $499,500 from the Rights Offering that closed on March 1, 2023, and repayments of the promissory notes payable to related parties in February and March 2023

totaling $420,000, the Company has the ability to fund its operating costs and working capital needs for its planned clinical trials for ivonescimab for a period of at least twelve 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. While the Company believes that funds would be available in this manner before 2024, 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.

The accompanying consolidated financial statements are prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of the business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classifications of liabilities that might result from the outcome of this uncertainty.

4. Summary of Significant Accounting Policies

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 United States of America (“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 United States ("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 shareholders’ equity. Foreign currency transaction gains and losses are included in other expense, net in the results of operations. The Company recorded realized and unrealized foreign currency transaction losses of $4,109 and $2,135 for the years ended December 31, 2022 and 2021, respectively, which is included in other expense, net in the statements of operations and comprehensive loss.

Revenue Recognition

The Company accounts for revenue using ASC 606. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards.

The Company enters into out-licensing agreements within the scope of ASC 606 under which it licenses certain rights to its product candidates to third parties. Such agreements may include the transfer of intellectual property rights in the form of licenses, transfer of technological know-how, delivery of drug substances, research and development services, and participation on certain committees with the counterparty. Payments made by the customers may include one or more of the following: non-refundable, up-front license fees; development, regulatory, and commercial milestone payments; payments for manufacturing supply services the Company provides through its contract manufacturers; and royalties on net sales of licensed products if they are successfully approved and commercialized. Each of these payments may result in license, collaboration, or other revenue, except revenue from royalties on net sales of licensed products, which would be classified as royalty revenue.

In determining the appropriate amount of revenue to be recognized as the Company fulfills its obligations under each of its out-licensing agreements, the following steps are performed: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. Revenue is then recognized in respect of the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. As part of the accounting for these arrangements, the Company must use significant judgment to determine: (a) the performance obligations based on the determination under step (ii) above; (b) the transaction price under step (iii) above; and (c) the standalone selling price for each performance obligation identified in the contract for the allocation of transaction price in step (iv) above. The Company also uses judgment to determine whether milestone payments or other variable consideration, except for royalties and sales-based milestones, should be included in the transaction price, as described below. The transaction price is allocated to each performance obligation based on the relative standalone selling price of each performance obligation in the contract, and the Company recognizes revenue based on those amounts when, or as, the performance obligations under the contract are satisfied.

Exclusive Licenses

If the license to the Company's intellectual property is determined to be distinct from the other promises or performance obligations identified in the arrangement, the Company recognizes revenue from nonrefundable, upfront fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. In assessing whether a promise or performance obligation is distinct from the other promises, the Company considers factors such as the research, development, manufacturing and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. In addition, the Company considers whether the collaboration partner can benefit from a promise for its intended purpose without the receipt of the remaining promises, whether the value of the promise is dependent on the unsatisfied promises, whether there are other vendors that could provide the remaining promises, and whether it is separately identifiable from the remaining promises. For licenses that are combined with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of progress and related revenue recognition. The measure of progress, and the resulting periods over which revenue should be recognized, are subject to estimates by management and may change over the course of the research, development and licensing arrangement. Such a change could have a material impact on the amount of revenue the Company records in future periods. Under the Company's existing license and collaboration agreements, the Company has concluded that the transfer of control to the customer occurs over the time period that the research and development services are to be provided by the Company, and this output method is, in management's judgment, the best measure of progress towards satisfying the performance obligation.

Milestone Payments

At the inception of each arrangement that includes potential research, development or regulatory milestone payments, the Company evaluates whether the milestones are considered likely to be met and estimates the amount to be considered for inclusion in the transaction price using the most-likely-amount method. If it is probable that a significant reversal in the amount of cumulative revenue recognized would not occur, the associated milestone payment value is included in the transaction price. For milestone payments due upon events that are not within the control of the Company or the licensee, such as regulatory approvals, the Company is not able to assert that it is likely that the regulatory approval will be granted and that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur until those approvals are received. In making this assessment, the Company evaluates factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the particular milestone. There is considerable judgment involved in determining whether it is probable that a significant reversal in the amount of cumulative revenue recognized would not occur. At the end of each subsequent reporting period, the Company reevaluates the probability of achievement of all milestones subject to constraint

and, if necessary, adjusts its estimate of the overall transaction price of the arrangement. Any such adjustments are recorded on a cumulative catch-up basis, which would affect the amounts of revenue and earnings in the period of adjustment.

Royalties

For arrangements that include sales-based royalties, including milestone payments due upon first commercial sales or based on a level of sales, that are the result of a customer-vendor relationship and for which the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) the occurrence of the related sales or (ii) the date upon which the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied. To date, the Company has not recognized any royalty revenue from any of its licensing arrangements.

Other Operating Income

The Company generates income from government contracts that reimburse the Company for certain allowable costs for funded projects. For contracts with government agencies where the funding arrangement is considered central to the Company's ongoing operations, the Company classifies the recognized funding received as other operating income.

Income from government grants is recognized as the qualifying expenses related to the contracts are incurred, provided that there is reasonable assurance of recoverability. If the government agency approves the project proposed by the Company, the government agency funds the project upon receipt of the support for the costs incurred up to the contract limit. Income recognized upon incurring qualifying expenses in advance of billing is recorded as unbilled receivable, a component of other current assets, in the consolidated balance sheet.

Grant income is not recognized as deductions of research and development costs because the Company acts as the principal in conducting the research and development activities and these contracts are central to its ongoing operations. The funds received through these means are held as deferred income in the consolidated balance sheets and are released to the consolidated statement of operations and comprehensive loss, classified as other operating income, as the underlying expenditure is incurred and to the extent the conditions of the grant are met. The related costs incurred by the Company are included in research and development expense in the Company's consolidated statements of operations and comprehensive loss.

The Company benefits from two U.K. research and development ("R&D") tax credit cash rebate regimes: Small and Medium Enterprise ("SME") Program and the Research and Development Expenditure Credit ("RDEC") Program. Each reporting period, management evaluates which tax relief programs the Company is expected to be eligible for and records as other operating income the portion of the expense that it expects to qualify under the programs, that it plans to submit a claim for, and it has reasonable assurance that the amount will ultimately be realized. Based on criteria established by HM Revenue and Customs ("HMRC"), management of the Company expects a proportion of expenditures being undertaken in relation to its pipeline research, clinical trials management and manufacturing development activities to be eligible for the research and development tax relief programs for the year ended December 31, 2022. Qualifying expenditures largely comprise of employment costs for research staff, consumables, a proportion of relevant, permitted sub-contract costs and certain internal overhead costs incurred as part of research projects for which the Company does not receive commercial or other funding income. Credits related to the SME and RDEC Programs are recorded as other operating income in the consolidated statements of operations and other comprehensive (loss)/income. Under both schemes, the Company receives cash rebate payments of up to 33.3% of eligible research and development expenditures and these payments are not dependent on the Company's pre-tax net income levels. The Company has qualified under the more favorable SME regime for the year ended December 31, 2021 and expects to qualify under the SME regime for the year ending December 31, 2022.

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.

Business Combinations

Business combinations are accounted for under the acquisition method. Acquired assets and assumed liabilities are measured at their fair values at the acquisition date. The excess of the consideration transferred over the net fair value of assets acquired and liabilities assumed is recorded as goodwill. The accounting for an acquisition involves a considerable amount of judgement and estimation. Cost, income, market or a combination of approaches may be used to establish the fair value of consideration exchanged, assets acquired, and liabilities assumed, depending on the nature of those items. The valuation approach is determined in accordance with generally accepted valuation methods. Key areas of estimation and judgment may include the selection of valuation approaches, cost of capital, market characteristics, cost structure, impacts of synergies, and estimates of terminal value, among other factors.

While the Company uses estimates and assumptions as part of the purchase price allocation process to estimate the value of assets acquired and liabilities assumed, estimates are inherently uncertain and subject to refinement. During the measurement period, which maybe up to one year from the acquisition date, the Company may record adjustments to the assets acquired and liabilities assumed, with a corresponding offset to goodwill, to the extent that adjustments are identified to the preliminary purchase price allocation. Upon conclusion of the measurement period, or final determination of the value of the assets acquired and liabilities assumed, whichever comes first, any subsequent adjustments are recorded to results of operations. Results of operations related to business combinations are included prospectively beginning with the date of acquisition and transaction costs related to business combinations are recorded within general and administrative expenses.

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 products 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 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.

The Company performed its annual impairment assessment of goodwill in the fourth quarter of 2022 by performing a qualitative analysis for its single identified reporting unit for goodwill and determined that it is more likely than not that the fair value of the reporting unit exceeded its carrying amount.

(in thousands, except share and per share data)

Intangible Assets

Intangible assets are estimated by management based on the fair value of assets acquired. These include acquired technology, licenses, an option over non-financial assets and a research and development discovery platform ("Discuva Platform"). Intangible assets are amortized from one to 18 years on a straight-line basis which represents the estimated periods of benefit and the expected pattern of consumption.

Our intangible assets are recorded at fair value at the time of their acquisition, assigned an estimated useful life, and amortized primarily on a straight-line basis over their estimated useful lives or over the period of the relevant agreement for an option over non-financial assets. Intangible assets are stated in our consolidated balance sheets net of accumulated amortization and impairments, if applicable.

The Company evaluates the recoverability of its intangible and long-lived assets whenever events and changes in circumstances indicate that the carrying amount of an asset or asset group may not be fully recoverable. If events and circumstances indicate that the carrying amount may not fully be recoverable, the carrying values of the asset or asset group are evaluated in relation to their operating performance and future undiscounted cash flows of the underlying business. If the future undiscounted cash flows are less than their carrying value, impairment exists. The impairment is measured as the difference between the carrying value and the fair value of the underlying asset or asset group. Fair values are based on estimates of market prices and assumptions concerning the amount and timing of estimated future cash flows and assumed discount rates, reflecting varying degrees of perceived risk.

Amortization of intangible assets is included as part of the research and development expense line shown on the face of the consolidated statement of operations and comprehensive loss.

As of December 31, 2022 and 2021, intangible assets were $0 and $10,399, respectively. The carrying value of $10,399 as of December 31, 2021 related to the Discuva Platform has been impaired in full during the year end December 31, 2022.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Cost comprises the purchase price plus any incidental costs of acquisition and commissioning.

Depreciation is calculated based on cost, less residual value, in equal annual installments over the estimated useful lives of the assets. The residual value, if significant, is reassessed annually.

Leasehold improvements	Over the shorter of the asset's useful life or the remaining lease term
Laboratory equipment	2 - 10 years
Office and IT equipment	3 - 5 years

Depreciation is recognized as part of the general and administrative and research and development expense lines shown on the face of the consolidated statement of operations and comprehensive loss depending on the nature of the underlying assets.

Expenditures for repairs and maintenance are expensed as incurred. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in loss from operations.

Leases

The Company has operating leases for real estate. The Company does not have any finance leases. Under ASC 842, 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.

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 exceeds the estimated costs. When evaluating the adequacy of these balances, the Company analyzes progress of the studies, including 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 highly 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 estimates expected forfeitures at the time of grant instead of accounting for forfeitures as they occur. Stock option and restricted stock unit 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 in the same manner in which the award recipient's payroll costs are classified.

Income Taxes

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 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 uncertainty in income taxes 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. 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 used 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, 2022 and 2021, the Company had no uncertain tax positions.

Concentration of Credit Risk and of Significant Supplier

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

The credit risk with respect to customers and funding bodies is limited as the Company has only a small number of these arrangements.

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.

Cash and Cash Equivalents

We consider 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, and the related investment income is recognized in net loss. As of December 31, 2022, cash equivalents were comprised of a money market funds and U.S. treasury securities with maturities less than 90 days from the date of purchase. We did not have cash equivalents as of December 31, 2021.

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. On December 15, 2022, the Company transferred $300,000 into an escrow fund reserved for the Company's initial upfront payment to Akeso in connection with the License Agreement, as described further in Note 23. Following the Antitrust Clearance Date, on January 17, 2023, the License Agreement closed and Akeso was issued 10 million shares of Company common stock pursuant to the Common Stock Issuance Agreement and was paid $274,900 in cash as initial upfront payment. The remaining amounts in escrow were returned to the Company's operating cash accounts.

Assumed Contingent Liabilities

As part of the acquisition of Discuva Limited in December 2017, the Company assumed certain contingent liabilities as certain employees, former employees and former directors of Discuva Limited are eligible for payments from Discuva Limited based on specified development and clinical milestones related to proprietary product candidates developed under the Discuva Platform. The timing of these potential payments is uncertain. The fair value of the assumed contingent liability was estimated using the expected value of the payments. The assumed contingent liabilities are subsequently measured at amortized cost using discounted cash flow models which calculate the risk adjusted net present values of estimated potential future cash flows of the payments. The assumed contingent liabilities are remeasured when there is a specific significant event that provides evidence of a significant change in the probability of successful development and clinical milestones being achieved. The models will be updated for changes in the probability of successful development and clinical milestones being achieved and other associated assumptions with the discount factor remaining unchanged within the model. A discount factor of 13% has been used to discount the contingent liabilities back to net present value. This discount factor has been calculated using appropriate measures and rates which could have been obtained in the period that the contingent liabilities were assumed. Accretion of the discount factor and gains or losses upon remeasurement are recognized as part of operating expenses in the consolidated statements of operations and comprehensive loss.

Warrants

Warrants issued by the Company are recognized and classified as equity when, upon exercise, the Company would issue a fixed amount of its own equity instruments (common stock) in exchange for a fixed amount of cash or another financial asset.

Consideration received, net of incremental costs directly attributable to the issue of such new warrants, is shown in equity. Such warrants are not remeasured at fair value in subsequent reporting periods.

Warrants issued in which external services are received as consideration for equity instruments of the company should be measured at the fair value of the goods or services received. Only if the fair value of the services cannot be measured reliably would the fair value of the equity instruments granted be used. The fair value for the warrants is calculated using the Black-Scholes formula and recorded in the consolidated statement of operations and comprehensive loss on a straight-line basis over the period of the consulting services. If the services are terminated prior to the end of the consultancy agreement, the warrants cease vesting and any unvested portion of the warrants will lapse immediately.

The warrants in issue are classified within stockholders' equity as they are indexed to the Company's own shares of common stock and require settlement in its shares of common stocks with no provision for any cash settlement.

5. Recently Issued or Adopted Accounting Pronouncements

In November 2021, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2021-10, " Government Assistance (Topic 832)". This ASU increases the transparency of government assistance including the disclosure of (1) the types of assistance, (2) an entity's accounting for the assistance, and (3) the effect of the assistance on an entity's financial statements as diversity currently exists in the recognition, measurement, presentation and disclosure of government assistance received by business entities because of the lack of specific authoritative guidance in U.S. GAAP. This ASU is effective for annual periods, and interim periods within those fiscal years, beginning after December 15, 2021. Early application of this ASU is permitted. The Company applied the amendments of this ASU to its disclosures during the fourth quarter of 2021 and the application of this ASU did not have a material impact on its financial position, results of operations or cash flows.

In October 2021, the FASB issued ASU No. 2021-08, "Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers". This ASU improves the accounting for acquired revenue contracts with customers in a business combination by addressing diversity in practice and inconsistency relating to: 1) recognition of an acquired contract liability and 2) payment terms and their effect on subsequent revenue recognized by the acquirer. The amendments in this ASU require acquiring entities to apply Topic 606 to recognize and measure contract assets and contract liabilities in a business combination, whereas current U.S. GAAP requires that the acquirer measure such assets and liabilities at

(in thousands, except share and per share data)

fair value on the acquisition date. This ASU is effective for annual periods, and interim periods within those fiscal years, beginning after December 15, 2022. The Company will apply this ASU on a prospective basis for business combinations once this ASU is effective and at that time, will be able to determine the potential impact on its financial position, results of operations or cash flows.

In May 2021, the FASB issued AS No. 2021-04, "Earnings Per Share (Topic 260), Debt - Modifications and Extinguishments (Subtopic 470-50), Compensation - Stock Compensation (Topic 718), and Derivatives and Hedging Contracts in Entity's Own Equity (Subtopic 815-40) - Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options". This ASU provides clarification and reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (such as warrants) that remain equity classified after modification or exchange. This ASU is effective for annual periods, and interim periods within those fiscal years, beginning after December 15, 2021. The Company will apply this ASU on a prospective basis for any modifications or exchanges once this ASU is effective and at that time, will be able to determine the potential impact on its financial position, results of operations or cash flows.

In December 2019, the FASB issued ASU No. 2019-12, "Income Taxes (Topic 740)". This ASU simplifies the accounting for income taxes by removing certain exceptions to the general principles in Topic 740. The amendments also improve consistent application and simplify U.S. GAAP for other areas of Topic 740 by clarifying and amending existing guidance. This ASU is effective for annual periods, and interim periods within those fiscal years, beginning after December 15, 2020. The Company adopted this ASU during the first quarter of 2021 and the adoption of this ASU did not have a material impact on its financial position, results of operations or cash flows.

6. Segment Reporting

The Company's chief operating decision makers (the "CODM function"), which are the Company's Co-CEOs, Mr. Duggan and Dr. Zanganeh, utilize consolidated financial information 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 as a single reportable operating segment. The Company's single operating segment covers the Company's research and development activities, primarily comprising of oncology product research activities (including ivonescimab), antibiotic pipeline research activities, and CDI program activities. As the Company operates in one operating segment, all required financial segment information can be found in the consolidated financial statements.

The Company operates in two geographic regions: the U.K. and the U.S. The following table summarizes the Company's long-lived assets, which include the Company's property and equipment, net and right-of-use assets by geography:

	Year Ended December 31, 2022	Year Ended December 31, 2021
United Kingdom	$ 2,517	$ 2,762
United States[(1)]	2,564	722
	$ 5,081	$ 3,484

[(1)] The increase of long-lived assets in the United States is primarily attributed to additional right-of-use assets recorded related to the Company's first and second amendments to its sublease agreement during the period for its Menlo Park, California, U.S. location.

For details of revenue from external customers by geography refer to Note 7.

(in thousands, except share and per share data)

7. Revenue

The following table summarizes revenue by category:

	Year Ended December 31, 2022	Year Ended December 31, 2021
Licensing agreements	$ 705	$ 1,809

Revenue recognized consists of amounts received from the Company's license and commercialization agreement with Eurofarma Laboratórios S.A.

The following table summarizes revenue by geography:

	Year Ended December 31, 2022	Year Ended December 31, 2021
Latin America	$ 705	$ 1,809

The analysis of revenue by geography has been identified on the basis of the geographical location of each collaboration partner.

The following table summarizes the deferred revenue relating to Eurofarma Laboratórios S.A. and deferred other income relating to BARDA (as defined in Note 8):

	2022	2021
Beginning deferred revenue and other income, January 1 [(1)]	$ 7,939	$ 8,939
Additions	1,397	5,443
Amount of deferred revenue and other income recognized in the statement of operations	(8,790)	(6,438)
Foreign currency adjustment	(546)	(5)
Ending deferred revenue and other income, December 31 [(2)]	$ —	$ 7,939

[(1)] Beginning deferred revenue and other income as of January 1, 2022 and 2021 included $7,939 of current and $0 of long-term deferred revenue and other income, and $8,370 of current and $569 of long-term deferred revenue and other income, respectively.
[(2)] Ending deferred revenue and other income as of December 31, 2022 and 2021 included $0 of current and $0 of long-term deferred revenue and other income, and $7,939 of current and $0 of long-term deferred revenue and other income, respectively.

As of January 1, 2022, deferred revenue and other income is compromised of $756 and $7,183 relating to Eurofarma and BARDA, respectively. As of December 31, 2022, deferred revenue was $0.

Refer to Note 8 below for further details regarding other income recognized under the BARDA contract.

Eurofarma Laboratórios S.A.

On December 21, 2017, Summit announced it had entered into an exclusive license and commercialization agreement with Eurofarma Laboratórios S.A. ("Eurofarma"), pursuant to which the Company granted Eurofarma the exclusive right to commercialize ridinilazole in specified countries in South America, Central America and the Caribbean. The Company has retained commercialization rights in the rest of the world.

(in thousands, except share and per share data)

Under the terms of the license and commercialization agreement with Eurofarma, the Company received an upfront payment of $2,500 in December 2017. In February 2020, the Company reached the first enrollment milestone and earned $1,000. In September 2021, the Company reached the second enrollment milestone and earned $1,250. The terms of the contract have been assessed under ASC 606 and currently only the upfront payment and the first two enrollment milestone payments are included in the transaction price. These payments were initially reported as deferred revenue in the balance sheet and were recognized as revenue ratably over the performance period.

Revenue recognized during the years ended December 31, 2022 and 2021 related to the upfront payment and the first two enrollment milestones earned in accordance with the Company's revenue recognition policy. The revenue was recognized ratably over the determined performance period to reflect the transfer of control to the customer occurring over the time period that the research and development services were provided by the Company. This output method is, in management's judgment, the best measure of progress towards satisfying the performance obligation. As of December 31, 2022 and 2021, the current contract liability relating to the Eurofarma contract was $0 and $756, respectively, and was recorded in current deferred revenue in the consolidated balance sheet. As of December 31, 2022, the Company has recognized $4,678 of cumulative income since inception.

8. Other Operating Income

The following table sets forth the components of other operating income by category:

	Year Ended December 31, 2022	Year Ended December 31, 2021
Other operating income by category:		
Funding income from BARDA (as defined below)	$ 8,085	$ 4,604
Research and development tax credits	4,523	15,206
Grant income from CARB-X (as defined below)	1,808	1,158
	$ 14,416	$ 20,968

BARDA (as defined below)

In September 2017, the Company was awarded a funding contract from the Biomedical Advanced Research and Development Authority ("BARDA"), part of the Office of the Assistant Secretary for Preparedness and Response at the United States Department of Health and Human Services, in support of the Company's Ri-CoDIFy clinical trials and clinical development of of ridinilazole. The awarded contract was originally worth up to $62,000. In June 2019 and again in January 2020, BARDA increased the value of the contract such that it is now worth up to $72,500 and brought the total amount of committed funding to $62,400.

The remaining federal government funding is dependent on BARDA in its sole discretion exercising the final independent option work segment, upon the achievement by the Company of certain agreed-upon milestones for ridinilazole. This option work segment was never exercised by BARDA. The contract ran through April 2022 and was extended through December 2022 as a no cost contract, solely to close out open activities. As of December 31, 2022, based on translation of historical foreign currency amounts in the period of recognition, the Company has recognized $59,203 of cumulative income since contract inception. As a result of the Company's decision, on September 28, 2022, to not pursue further internal clinical development of ridinilazole and seek partners or a divestiture related to ridinilazole as a path forward for the clinical development of the asset, the Company recorded expenses for the remaining clinical trial costs associated with the close out activities of ridinilazole and recognized the remainder of the deferred income that had been received from BARDA prior to the expenses being recognized during the third quarter of 2022.

Research and development credits

Income from tax credits, consist of R&D tax credits received in the U.K. The Company benefits from two U.K. research and development tax credit cash rebate regimes: Small and Medium Enterprise Program ("SME, Program") and the Research and

(in thousands, except share and per share data)

Development Expenditure Credit Program ("RDEC Program"). Qualifying expenditures largely comprise of employment costs for research staff, consumables, a proportion of relevant, permitted sub-contract costs and certain internal overhead costs incurred as part of research projects for which the Company does not receive income. Tax credits related to the SME Program and RDEC Program are recorded as other operating income in the consolidated statements of operations and other comprehensive loss. Under both schemes, the Company receives cash payments that are not dependent on the Company's pre-tax net income levels.

Based on criteria established by His Majesty's Revenue and Customs ("HMRC"), a portion of expenditures being carried out in relation to the Company's pipeline research and development, clinical trials management and third-party manufacturing development activities are eligible for the SME regime and the Company expects such elements of research and development expenditure incurred in its UK entities will also continue to be eligible for the SME regime for future periods.

As of December 31, 2022 and 2021, the current research and development tax credit receivable was $5,766 and $15,695, respectively.

CARB-X (as defined below)

In May 2021, the Company announced the selection of a new preclinical candidate, SMT-738, from the DDS-04 series for development in the fight against multi-drug resistant infections, specifically Carbapenem-resistant Enterobacteriaceae ("CRE") infections. Simultaneously, the Company announced it had received an award from the Trustees of Boston University under the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator program ("CARB-X") to progress this candidate through preclinical development and Phase Ia clinical trials. The award commits initial funding of up to $4,100, with the possibility of up to another $3,700 based on the achievement of future milestones. As of December 31, 2022, based on translation of historical foreign currency amounts in the period that the amounts were recognized, the Company has recognized $2,875 of cumulative income since contract inception. During the quarter ended September 30, 2022, CARB-X announced changes to its funding arrangements and terms and conditions. As a result, the current arrangement concluded as of June 30, 2022, however the Company has the ability to recognize reimbursements for any milestone payments related to work incurred subsequent to this date in accordance with this agreement.

9. Other Expense, net

The following table sets forth the components of other (expense) income:

	Year Ended December 31, 2022	Year Ended December 31, 2021
Foreign currency loss	$ (4,109)	$ (2,135)
Interest expense on promissory notes payable to related parties	(4,401)	(242)
Investment income	1,513	—
Other income (expense), net	304	(39)
Other Expense, net	$ (6,693)	$ (2,416)

For the year ended December 31, 2022, other expense, net primarily consisted of unfavorable changes in foreign currency, loan interest expense incurred related to the $520,000 and $25,000 promissory notes, as described in Note 17, partially offset by investment income related to our money market funds and investments in highly liquid U.S. treasury securities, which are classified as cash equivalents as of December 31, 2022.

For the year ended December 31, 2021, other expense, net primarily consisted of unfavorable changes in foreign currency and loan interest expense incurred related to the $55,000 promissory note, as described in Note 22.

(in thousands, except share and per share data)

10. Income Tax

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

	Year Ended December 31, 2022	Year Ended December 31, 2021
United Kingdom	$ (46,868)	$ (72,244)
United States	(31,914)	(16,358)
Loss before income taxes	$ (78,782)	$ (88,602)

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, 2022 or December 31, 2021.

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, 2022	Year Ended December 31, 2021
Deferred tax assets:		
Net operating loss carryforward	$ 52,948	$ 49,422
Research and development credit carryforward	1,723	941
Stock-based compensation	3,879	2,560
Section 174 Research and Development Capitalization	3,553	—
Other	2,139	1,477
Total deferred tax assets	64,242	54,400
Deferred tax liabilities:		
Intangible asset	—	(2,600)
Other	(226)	(54)
Total deferred tax liabilities	(226)	(2,654)
Net deferred tax assets before valuation allowance	64,016	51,746
Valuation allowance	(64,016)	(51,746)
Deferred tax, net	$ —	$ —

For the year ended December 31, 2022 and 2021, the Company recorded a deferred tax asset of $64,242 and $54,400 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 and excess tax benefits related to stock-based compensation. Management has considered the Company’s history of cumulative net losses in the United States ("U.S.") and the United Kingdom ("U.K."), 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 benefits of its U.S. federal and state deferred tax assets and U.K. deferred tax assets. Accordingly, a full valuation allowance has been established against these net deferred tax assets as of December 31, 2022 and 2021, respectively. The Company reevaluates the positive and negative evidence at each

reporting period. The Company's valuation allowance increased during 2021 by $12,270 primarily due to the generation of net operating loss and stock-based compensation.

As of December 31, 2022 and 2021, the Company had U.S. Federal gross operating loss carryforwards of approximately $11,620 and $4,921, 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 will generally limit 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 $7,278 in U.S. State gross loss carryforwards which expire through various dates through 2036 and as of December 31, 2022, the Company had an estimated U.S. federal research and development tax credit carryforwards of $1,723 which may be available to offset future tax liabilities, and each begin to expire in 2041. The Company also had approximately $199,091 in U.K. gross loss carryforwards available to use against future taxable profits on a year-by-year basis (a potential deferred tax asset of $49,773). 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 UK 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.

The 2017 Tax Cuts and Jobs Act ("TCJA") created a requirement that US corporations include in income earnings of certain controlled foreign corporations ("CFC") 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.

IRC Section 174 generally permitted taxpayers that incurred research expenses to deduct them in the current year. For tax years beginning before January 1, 2022, taxpayers were able to make an election with respect to research and experimental ("R&E") expenditures incurred in connection with a trade or business to either currently deduct or defer and amortize such expenditures. The TCJA amended this provision to require that R&E expenditures be capitalized and amortized, but delayed the effective date of this amendment, which applies to tax years beginning January 1, 2022 or later. As such, the changes to IRC Section 174

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pursuant to the TCJA are currently applicable to the Company for the 2022 tax year. R&E expenditures attributable to U.S. based research must be amortized over a period of five years and R&E expenditures attributable to research conducted outside of the U.S. must be amortized over a period of 15 years. As such, the Company is capitalizing $14,830 R&E expenditures with a net adjustment of $13,347 to account for the capitalization and amortization of R&D expenses incurred in the U.S.

On March 27, 2020, the United States enacted the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"). The Cares Act includes provisions relating to refundable payroll tax credits, deferment of the employer portion of certain payroll taxes, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations, and technical corrections to tax depreciation methods for qualified improvement property. The CARES Act also established a Paycheck Protection Program whereby certain small businesses are eligible for a loan to fund payroll expenses, rent, and related costs.

The Company considered the provisions under the CARES Act and elected not to take advantage of the provisions of the CARES Act as the effect of such provisions was not expected to have a material impact on the Company's results of operations, cash flows, and consolidated financial statements.

During 2021, the U.K. Government announced that from April 1, 2023, the corporation tax rate would increase to 25%. This new law was enacted on June 10, 2021. The overall effect of the change was an increase in net deferred tax assets by $9,311 and an increase in valuation allowance by an equal amount for the year ended December 31, 2021. No changes to this rate have been made during 2022.

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

	Year Ended December 31, 2022	Year Ended December 31, 2021
U.S. federal income tax statutory rate	21.0 %	21.0 %
Change in valuation allowance	(16.8)	(10.5)
Non-deductible expenses	—	(0.4)
Refundable research and development tax credit	(3.6)	(8.3)
Effect of foreign operations taxed at various rates	2.1	0.5
Stock-based compensation	(2.2)	(1.6)
Other	(0.5)	(0.7)
	— %	— %

In the U.K., the Company is entitled to a research and development tax relief for small and medium-sized enterprises which allows the Company an enhanced deduction rate of 230% on qualifying research and development expenditure (the tax relief). If the Company incurs tax losses, it is entitled to surrender the lesser of unrelieved tax loss sustained and the tax relief. As the realization of the tax relief does not depend on generation of future taxable income or the Company's ongoing tax status or tax position, the Company does not consider the tax relief as an element of income tax accounting under ASC 740. For the year ended December 31, 2022 and 2021, the Company recognized research and development tax relief of $4,523 and $15,206 respectively, which is included in other operating income in the consolidated statements of operations and other comprehensive loss.

It is the intention of the Company to reinvest the earnings of its non-U.S. subsidiaries in those operations and not to repatriate the earnings to the U.S. Accordingly, the Company does not provide for deferred taxes on differences between financial reporting and tax basis in its investments in foreign subsidiaries as they are considered permanent in duration or are not expected to reverse in the foreseeable future.

(in thousands, except share and per share data)

The Company does not have any uncertain tax positions as of December 31, 2022. In the U.K., tax returns for the year ended December 31, 2021 remains subject to examination by HMRC.

In the U.S., the Company files income tax returns in various states. In the U.S., tax years from 2019 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 2019 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. The Company's policy is to recognize interest and penalties related to uncertain tax positions as part of its income tax provision. As of December 31, 2022, and 2021, the Company has recorded no liability for unrecognized tax benefits, interest, or penalties related to federal, state or foreign income tax matters.

11. Loss per Share

The following table sets forth the computation of basic and diluted net loss per share:

	Year Ended December 31, 2022	Year Ended December 31, 2021
Net loss	$ (78,782)	$ (88,602)
Basic weighted average number of shares of common stock outstanding	193,336,063	131,714,225
Diluted weighted average number of shares of common stock outstanding	193,336,063	131,714,225
Basic net loss per share	$ (0.41)	$ (0.67)
Diluted net loss per share	$ (0.41)	$ (0.67)

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 anti-dilutive. Because the Rights Offering exercise price of $1.05 per share was less than the closing price of $1.82 per share on March 1, 2023, the expiration of the Rights Offering (further detailed in Note 23), the Company has retroactively adjusted earnings per share and weighted average number of shares outstanding for the bonus element for all periods presented.

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:

	2022	2021
Options to purchase common stock	19,476,359	13,797,556
Warrants	5,821,137	5,821,137
Shares expected to be purchased under employee stock purchase plan	229,475	202,045
	25,526,971	19,820,738

(in thousands, except share and per share data)

12. Goodwill and Intangible Assets

Goodwill

The Company's annual evaluation for impairment of goodwill consists of one reporting unit. In accordance with the Company's policy, the Company completed its annual evaluation for impairment in the fourth quarter of 2022 using the qualitative assessment. No impairment charge was recognized for the year ended December 31, 2022 and there have been no cumulative goodwill impairment charges recognized to date.

As of December 31, 2022 and 2021, goodwill was $1,798 and $2,009, respectively. Changes year over year are the result of foreign currency movements.

Intangible Assets

Components of the Company's acquired intangible assets are comprised of the following:

	December 31, 2022		
	Gross	Accumulated amortization and impairment charges	Net
Utrophin program acquired	$ 4,015	$ (4,015)	$ —
Discuva platform acquired	12,900	(12,900)	—
Option over non-financial asset	816	(816)	—
Other intangibles	133	(133)	—
	$ 17,864	$ (17,864)	$ —

	December 31, 2021		
	Gross	Accumulated amortization and impairment charges	Net
Utrophin program acquired	$ 4,487	$ (4,487)	$ —
Discuva platform acquired	14,416	(4,017)	10,399
Option over non-financial asset	912	(912)	—
Other intangibles	148	(148)	—
	$ 19,963	$ (9,564)	$ 10,399

In December 2017, we expanded our activities in the field of infectious diseases with the acquisition of Discuva Limited, a privately held United Kingdom-based company. Through this acquisition, we obtained a bacterial genetics platform and a suite of software-based technologies (collectively termed our "Discuva Platform"), which facilitates the discovery and development of new mechanism antibiotics. In conjunction with the significant change in the Company's strategy and shift in focus to the therapeutic area of oncology, the Company determined that it will cease further investment in the Discuva Platform and evaluate further options for the use of the Discuva Platform. Management have concluded that this indicated the carrying amount of the acquired Discuva Platform intangible asset may not be recoverable and hence performed an assessment using a probability-weighted approach to determine the undiscounted cash flows of the asset, which indicated that an impairment exists. Based on the assessment to compare the fair value of the asset to its carrying amount, an impairment charge of $8.5 million was recognized during the year ended December 31, 2022, representing the aggregate carrying value of the intangible asset. This impairment charge is presented as impairment of intangible assets in the consolidated statements of operations and comprehensive loss.

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Changes year over year in the gross amount of intangible assets are the result of foreign currency movements only. Amortization expense was $914 and $1,017 for the years ended December 31, 2022 and 2021, respectively. Changes year over year in the accumulated amount of amortization and impairment also include the effect of foreign currency movements.

13. Cash Equivalents and Fair Value Measurements

The following tables set forth the fair value of the Company's financial assets measured at fair value on a recurring basis and indicates the level within the fair value hierarchy utilized to determine such values:

	Fair Value Measurements as of December 31, 2022 using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 60,783	$ —	$ —	$ 60,783
U.S. Government treasury bills	$ —	$ 225,730	$ —	$ 225,730
Total financial assets	$ 60,783	$ 225,730	$ —	$ 286,513

The table above does not include cash at December 31, 2022 of $62,094. There were no cash equivalents held by the Company as of December 31, 2021. Cash at December 31, 2021 was $71,791.

The Company's financial instruments include cash and cash equivalents and restricted cash. Cash consists of non-interest-bearing deposits denominated in the U.S. dollar, British pound and Euro, while cash equivalents consists of interest-bearing money market fund deposits denominated in the U.S. dollar and U.S. treasury bills, and restricted cash consists of interest-bearing deposits denominated in the U.S. dollar.

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. The carrying value of the Company’s promissory notes approximates its fair value due to the recent issuance of the notes in December 2022 when compared to market interest rates (which represents a Level 2 measurement).

14. Property and Equipment

Property and equipment consisted of the following:

	December 31, 2022	December 31, 2021
Laboratory equipment	$ 505	$ 546
Furniture and fixtures, office equipment and software	889	819
Leasehold improvements	809	365
Property and equipment, gross	2,203	1,730
Less: accumulated depreciation	1,297	1,036
Property and equipment, net	$ 906	$ 694

Depreciation expense for the years ended December 31, 2022 and 2021 was $349 and $330, respectively.

15. Research and Development Prepaid Expenses and Accrued Liabilities

Included within prepaid expenses at December 31, 2022 and 2021 is $442 and $6,138, respectively, of prepayments relating to research and development expenditures. Included within accrued liabilities at December 31, 2022 and 2021 is $8,911 and $5,226, respectively, relating to research and development expenditures.

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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. However, prepaid expenses decrease and accrued liabilities increase as the activities progress, and if actual costs incurred exceed the prepaid expense, an accrual will be recorded for the liability. 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.

16. Leases

The Company has operating leases for real estate. The Company does not have any finance leases.

During the year ended December 31, 2022, the Company recorded $2,860 of additional right-of-use assets of which $2,755 related to the first and second amendments to its sublease agreement during the period for its Menlo Park, California, United States location and $105 which related to a remeasurement of the right of use asset and lease liability following a contractual rent review resulting in an increase in rent payments during the period for its Oxfordshire, United Kingdom location.

The carrying value of the right-of-use assets as of December 31, 2022 and 2021 is $4,175 and $2,790 , respectively.
The elements of lease expense were as follows:

Lease Cost:	Year Ended December 31, 2022	Year Ended December 31, 2021
Fixed lease costs	$ 1,384	$ 785
Variable lease costs	137	164
Short-term lease[1]	31	278
Total lease cost	$ 1,552	$ 1,227

[1] Short-term lease costs relate to the Company's Cambridge, Massachusetts, United States office lease which the Company exited during fiscal year 2022.

The weighted average discount rate and the weighted average remaining lease term were 5.7% and 3.4 years, respectively, as of December 31, 2022. The weighted average discount rate and the weighted average remaining lease term were 2.5% and 3.9 years, respectively, as of December 31, 2021. The Company made cash payments related to lease liabilities of $1,092 and $1,041 for the years ending December 31, 2022 and 2021 respectively.

Future lease payments under non-cancelable leases as of December 31, 2022 are detailed as follows:

Year Ending December 31,	
2023	$ 1,474
2024	1,502
2025	1,533
2026	381
Total lease payments	4,890
Less: imputed interest	437
Total operating lease liabilities	$ 4,453
Total operating lease liabilities balance sheet presentation:	
Current lease liabilities	$ 1,690
Non-current lease liabilities	2,763
	$ 4,453

(in thousands, except share and per share data)

17. Promissory Notes Payable to Related Parties

Non-current and current debt consisted of the following:

	Current notes		Non-current notes	
	December 31, 2022	December 31, 2021	December 31, 2022	December 31, 2021
Principal amounts	$ 20,000	$ —	$ 500,000	—
Debt discount	(230)	—	(5,460)	$ —
Total promissory notes payable to related parties	$ 19,770	$ —	$ 494,540	$ —

March 2022 Promissory Note

On March 10, 2022, Mr. Duggan, entered into a Note Purchase Agreement (the “March 2022 Note”), pursuant to which he loaned the Company $25,000 in exchange for the issuance by the Company of an unsecured promissory note in the amount of $25,000. The March 2022 Note accrued interest at a rate per annum equal to the prime rate as reported in the *Wall Street Journal*. The March 2022 Note, including all accrued interest, became due upon the earlier of (i) the consummation of a registered public offering with net proceeds of no less than $25,000 or (ii) 18 months from the date of issuance of the March 2022 Note. Debt issuance costs associated with the March 2022 Note were immaterial and expensed as incurred. The March 2022 Note of $25,000, plus accrued interest of $434 has been repaid to Mr. Duggan on August 10, 2022 in connection with the completion of the rights offering with aggregate gross proceeds of $100,000.

The Company incurred interest expense of $1,296 for the year ended December 31, 2022, which included amortized imputed interest of $861 for the year ended December 31, 2022.

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 would mature and become 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 will mature and become due on September 15, 2023. The maturity dates of the December 2022 Notes could be 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 shall consummate 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 shall 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 (the “Rights Offering”), 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 (i) the net proceeds of such capital raise or (ii) 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").

(in thousands, except share and per share data)

The Notes accrue interest at an initial rate of 7.5%. All interest on the Notes shall be paid on the date of signing for the period through February 15, 2023. Such prepaid interest shall be paid in a number of shares of the Company's 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 the Company entered into the Note Purchase Agreement, plus $0.01), which was 9,720,291 shares. For all applicable periods following the February 15, 2023, interest shall accrue 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.

Debt issuance costs associated with the Notes were $44 and we capitalized as part of the carrying value of the promissory notes payable to related parties. The Company incurred interest expense of $3,105 for the year ended December 31, 2022, which included amortized imputed interest of $395.

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. The effective interest rate of the Duggan February Note and Zanganeh Note was 8.7% and the effective interest rate of the Duggan September Note was 8.8%.

The Company incurred interest expense of $244 for the year ended December 31, 2021, which included amortized imputed interest $159 for the year ended December 31, 2021, respectively, related to the March 24, 2021 Note Purchase Agreement with Mr. Duggan, for $55,000 which was subsequently rescinded and replaced by a second note on April 20, 2021, of the same amount, and paid in full in May 2021, as described further in Note 22.

As of December 31, 2022, and reflecting the Company's election to extend the term of the Duggan February Note and the Duggan September Note, the estimated future principal payments due were as follows:

Year Ending December 31,		
2023	$	20,000
2024		500,000
	$	520,000

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, the $400,000 Duggan Promissory Note matured and became due, and the Company repaid all principal and accrued interest thereunder using a portion of the proceeds from this rights offering.

18. Other Non-Current Liabilities

Included within other non-current liabilities at December 31, 2022 and 2021 is $1,209 and $2,531, respectively, relating to assumed contingent liabilities. As part of the acquisition of Discuva Limited in December 2017, the Company assumed certain contingent liabilities as certain employees, former employees and former directors of Discuva Limited are eligible for payments from Discuva Limited based on specified development and clinical milestones related to proprietary product candidates developed under the Discuva Platform. The timing of these potential payments is uncertain.

In conjunction with the significant change in the Company's strategy and shift in focus to the therapeutic area of oncology, the Company determined that it will cease further investment in the Discuva platform and evaluate further options for the use of the Discuva Platform. As a result, management has revised the estimated presented value of these payments and remeasured the contingent liabilities. This resulted in recording a gain on remeasurement of liabilities of $1,265 during the year ended December 31, 2022, which is included net as part of the research and development expenses in the consolidated statement of operations and comprehensive loss.

There were no remeasurement losses or gains recognized during the year ended December 31, 2021.

19. Stockholders' Equity

Common Stock

In August 2022, the Company announced the closing of its 2022 rights offering ("2022 Rights Offering). The rights offering commenced on July 18, 2022, and the associated subscription rights expired on August 8, 2022. The 2022 Rights Offering received aggregate gross proceeds of $100,000 from the sale of 103,092,783 shares of common stock. Mr. Duggan and Dr. Zanganeh fully subscribed to their respective basic subscription rights and oversubscribed, at a price per share of $0.97. Offering costs of $111 were incurred.

On May 12, 2021, the Company closed its rights offering ("2021 Rights Offering"), which was fully subscribed and received aggregate gross proceeds of $75,000 from the sale of 14,312,976 shares of common stock to existing investors at a price per share of $5.24. Offering costs of $159 were incurred.

Warrants

As part of the private placement on December 24, 2019, the participating investors were granted warrants with the right to subscribe for 5,261,350 shares of common stock at an exercise price of $1.58, exercisable any time in the period commencing on the date falling six months following December 24, 2019 and ending on the tenth anniversary of admission. Each warrant entitles the warrant holder to subscribe in cash for one share. Shares of common stock allotted pursuant to the exercise of the warrant will rank in full for all dividends and other distributions with a record date after the exercise date with the shares of common stock in issue at that date. The Company has the option to require the warrant holder to exercise some or all of the outstanding warrants after the third anniversary date if the ten-day volume weighted average price of the shares of common stock as reported on Nasdaq represents a premium of at least 50 percent to the exercise price. The warrants are classified within stockholders' equity as they are indexed to the Company's shares of common stock and require settlement in its shares of common stock with no provision for any cash settlement.

Also, as part of the private placement on December 24, 2019, certain consultants were granted warrants with the right to subscribe for 3,358,732 shares of common stock in exchange for certain services. The warrants have an exercise price of $1.44 and vest quarterly over three years. If the consulting agreement terminated prior to three years after the date of the grant, all unvested warrants will be deemed cancelled. On June 30, 2020, the consulting agreement was terminated and 2,798,945 warrants cancelled immediately. The remaining 559,787 of outstanding warrants are held by Dr. Zanganeh and Dr. Elaine Stracker.

Warrants granted over shares of common stock to consultants in exchange of certain services are similar to stock-based compensation (see Note 20). The Company had 5,821,137 total warrants outstanding as of December 31, 2022 and 2021, respectively, and an intrinsic value of $15,640 as of December 31, 2022 and $6,559 as of December 31, 2021.

Dividends

The Company has never declared or paid cash dividends on its shares of common stock or on Summit Therapeutics plc's ordinary shares. The Company currently intends to retain all of its future earnings to fund the development and expansion of its business.

20. Stock-Based Compensation

2016 Long Term Incentive Plan

Upon the effectiveness of the 2020 Stock Incentive 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 (the "2020 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.

On July 27, 2022, the Company held a Special Meeting of Stockholders (the "Special Meeting") whereby the following matters were submitted to a vote of the Company's stockholders at the Special Meeting and the Board of Directors resolved the following: (i) an amendment to the Company's Restated Certificate of Incorporation, dated September 18, 2020, to increase the number of authorized shares of common stock by 100,000,000 (from 250,000,000 to 350,000,000); and (ii) an amendment to the Summit Therapeutics Inc. 2020 Stock Incentive Plan (the "Plan") to increase the number of shares of the Company's common stock issuable under the Plan by 8,000,000 shares.

As of December 31, 2022, there are 5,879,768 shares available to be issued under the 2020 Plan.

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, 2022, there were 2,628,893 shares available to be issued under the 2020 ESPP.

The first offering period of the 2020 ESPP plan consisted of seven months, commencing on August 2, 2021 and completed on February 28, 2022. The second offering period commenced on March 1, 2022 and was completed on August 31, 2022. Offering periods thereafter will be six months in duration and will commence immediately proceeding 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.

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, 2022, 176,857 shares were issued under the 2020 ESPP. As the first offering period of the 2020 ESPP plan completed during the fiscal year ended December 31, 2022, no shares were issued under the 2020 ESPP during the fiscal year ended December 31, 2021.

(in thousands, except share and per share data)

Stock Option Valuation

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, 2022	Year Ended December 31, 2021
Risk-free interest rate	3.11 %	1.05 %
Expected term (in years)	5.9	5.7
Expected volatility	91.2 %	74.5 %
Expected annual dividends per share	— %	— %

The following table summarizes the Company's stock option activity for the year ended December 31, 2022:

	Number of share options	Weighted average exercise price	Weighted average remaining contractual term	Aggregate intrinsic value
Outstanding as of December 31, 2021	13,797,556	$ 5.55	8.6 years	$ 712
Granted	9,837,797	1.31		
Forfeited	(4,097,040)	4.89		
Exercised	(61,954)	2.04		
Outstanding as of December 31, 2022	19,476,359	$ 3.55	8.8 years	$ 29,657
Outstanding as of December 31, 2022 - vested and expected to vest	13,110,654	4.49	8.5 years	$ 11,799
Exercisable at December 31, 2022	3,895,109	$ 4.91	8.0 years	$ 1,652

During the year ended December 31, 2022, the Compensation Committee of the Company's Board of Directors and management approved 6,984,000 option grants to its executives and certain employees of the Company which will vest based upon certain market-based and revenue performance conditions.

The weighted-average grant-date fair value of stock options granted during the years ended December 31, 2022 and 2021 was $0.87 and $3.50, per share, respectively. The aggregate intrinsic value of stock options exercised during the years ended December 31, 2022 and December 31, 2021 was $142 and $3,744, 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, 2022, total unrecognized compensation cost related to unvested stock option grants was approximately $12,274. This amount is expected to be recognized over a weighted average period of approximately 1.8 years. This excludes unvested market-based and performance stock options outstanding that were deemed not probable of vesting as of December 31, 2022, constituting 6,764,000 shares with unrecognized stock-based compensation expense of $4,655, for which the timing of recognition will be determined once the conditions for achievement become probable.

(in thousands, except share and per share data)

In September 2021, the Compensation Committee of the Board of Directors approved a modification to the Company's outstanding performance-based stock option awards for active employees which removed the performance-based vesting criteria from these awards. Following this modification, the option awards are subject only to previously existing time-based vesting conditions. The Company accounted for this change as a modification in accordance with the requirements of Accounting Standards Codification Topic 718. As a result, 9,250,000 options, related to twenty-five employees, that were previously authorized that had not achieved a grant date became granted on September 24, 2021 relating to the modification. The Company is recognizing the newly assessed measurement date fair value of the awards as compensation expense over the remaining vesting period.

Warrants

The fair value of warrants is estimated on the date of grant using the Black-Scholes valuation methodology. Expected volatilities are based on historical share price performance, weighted to exclude periods of unusually high volatility. The Company assumed the warrants to be exercised immediately on vesting. The risk-free rate is equal to the prevailing U.K. Gilts rate at grant date that most closely matches the expected term of the grant, as the warrants were issued when the Company was domiciled in the U.K.. Expected dividend yield is zero, and consistent with the Board of Directors' view that the Company's business model is to generate value through capital growth rather than the payment of dividends.

Each warrant entitles the warrant holder to subscribe in cash for one share. Shares of common stock allotted pursuant to the exercise of the warrant will rank in full for all dividends and other distributions with a record date after the exercise date with the shares of common stock in issue at that date.

As of December 31, 2022, 5,821,137 warrants were granted, of which 559,787 warrants were granted to consultants and 5,261,350 warrants were granted to investors. All warrants are considered vested at December 31, 2022, have a weighted-average exercise price of $1.56, an aggregate intrinsic value of $15,640, and a weighted average remaining contractual life of 3.5 years.

At December 31, 2022, there was no unrecognized compensation expense related to warrants.

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, 2022	Year Ended December 31, 2021
Research and development	$ 4,303	$ 5,909
General and administrative	7,645	6,895
Total stock-based compensation	$ 11,948	$ 12,804

21. Commitments and Contingencies

Fixed asset purchase commitments

At December 31, 2022 and 2021, the Company had no capital commitments.

Lease commitments

Refer to Note 16 for a discussion of the Company's lease commitments.

Debt commitments

Refer to Note 17 for discussion of promissory notes payable to related parties.

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. As of December 31, 2022, total contractual commitments, excluding leases commitments and debt commitments, are estimated to be approximately $11,510 and the majority of these commitments are due within one year.

The Company has certain commitments under its agreements with the Akeso, Wellcome Trust, the University College London and certain employees, former employees and former directors of Discuva, pursuant to which it will be required to pay royalties or make milestone payments. The License Agreement with Akeso also contains certain manufacturing and purchase commitments. As of December 31, 2022, 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.

Indemnifications

The Company's certificate of incorporation provides that it will indemnify the directors and officers to the fullest extent permitted by Delaware law. In addition, the Company has entered into indemnification agreements with all of the directors and executive officers. These indemnification agreements may require the Company, among other things, to indemnify each such director or executive officer for some expenses, including attorneys' fees, judgments, fines, and settlement amounts incurred by him or her in any action or proceeding arising out of his or her service as one of the Company's directors or executive officers. The Company believes the fair value for these indemnification obligations is minimal. Accordingly, the Company has not recognized any liabilities relating to these obligations as of December 31, 2022.

Legal Proceedings

The Company is not currently subject to any material legal proceedings.

22. Related Party Transactions

March 24, 2021 Note Purchase Agreement

On March 24, 2021, Mr. Duggan, the Company's Executive Chairman and Chief Executive Officer and primary stockholder, entered into a Note Purchase Agreement (the "Initial Purchase Agreement") pursuant to which he loaned the Company $55,000 in exchange for the issuance by the Company of an unsecured promissory note (the "Initial Note") in the amount of $55,000. The Initial Note was to accrue interest at a rate per annum equal to 150% of the applicable 10 Year United States Treasury rate, as adjusted monthly. The rate was initially estimated to be approximately 2.4%. The terms of the Initial Note were that it would mature and become due upon the earlier of (i) the consummation of a registered public offering with net proceeds of no less than $55,000, or (ii) 13 months from the date of issuance of the Initial Note. On April 20, 2021, the Company determined, with Mr. Duggan's agreement, to rescind both the Initial Purchase Agreement and the Initial Note issued thereunder, and repaid the principal amount of the Initial Note in full, without interest or penalty.

April 20, 2021 Note Purchase Agreement

On April 20, 2021, subsequent to the repayment of the Initial Note, Mr. Duggan entered into a second Note Purchase Agreement (the "Second Purchase Agreement") pursuant to which he loaned the Company $55,000 in exchange for the issuance by the Company of an unsecured promissory note (the "Second Note") in the amount of $55,000. The Second Note accrued interest at a rate per annum equal to 150% of the applicable 10 Year United States Treasury rate, as adjusted monthly (initially estimated to be approximately 2.4%). The Company was permitted to prepay any portion of the Second Note at its option without penalty.

May 12, 2021 Rights Offering ("2021 Rights Offering")

On May 12, 2021, the Company closed its 2021 Rights Offering, which was fully subscribed. Aggregate gross proceeds from the 2021 Rights Offering were $75,000 from the sale of 14,312,976 shares of the Company's common stock, of which 11,365,921 shares were purchased by Mr. Duggan and 389,977 shares were purchased by Dr. Zanganeh, at price of $5.24 per share. In connection with the closing of the 2021 Rights Offering, the Second Note, issued by the Company to Mr. Duggan, matured and became due and was repaid using a portion of the proceeds from the 2021 Rights Offering.

March 26, 2021 Sublease Agreement with Maky Zanganeh and Associates, Inc.

On March 26, 2021, the Company entered into a sublease with Maky Zanganeh and Associates, Inc. ("MZA") consisting of 4,500 square feet of office space at 2882 Sand Hill Road, Menlo Park, California (the "Sublease"). Dr. Zanganeh, the Company's Co-Chief Executive Officer and President, is the sole owner of MZA. The sublease ran until September 2022. The rent payable under the terms of the sublease was equivalent to the proportionate share of the rent 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, 2022 and 2021, payments of $544 and $556, were made pursuant to the sublease.

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 MZA, described above. 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.

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, dated August 1, 2022, 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 (the "Expansion Premises") 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 year ended December 31, 2022 payments of $54, were made pursuant to the secondment amendment to the sublease.

March 10, 2022 Note Purchase Agreement

On March 10, 2022, the Company entered into a Note Purchase Agreement (the "March 2022 Note"), with Mr. Duggan, pursuant to which Mr. Duggan loaned the Company $25,000 in exchange for the issuance by the Company of an unsecured promissory note in the amount of $25,000. The March 2022 Note accrued interest at a rate per annum equal to the prime rate as reported in the *Wall Street Journal*, which was 3.25% as of the effective date and 4.75% as of June 30, 2022. The March 2022 Note, including accrued interest, became due upon the earlier of (i) the consummation of a registered public offering with net proceeds of no less than $25,000 or (ii) 18 months from the date of issuance of the March 2022 Note, and was repaid on August 10, 2022.

2022 Rights Offering ("2022 Rights Offering")

In August 2022, the Company announced the closing and final results of its previously announced rights offering. The 2022 Rights Offering commenced on July 18, 2022, and the associated subscription rights expired on August 8, 2022. Aggregate gross proceeds received from the rights offering were $100,000 from the sale of 103,092,783 shares of common stock. Mr. Duggan and Dr. Zanganeh fully subscribed to their respective basic subscription rights and oversubscribed, at a price of $0.97 per share. Issuance costs were $111. In connection with the closing of the 2022 Rights Offering, the March 2022 Note matured and became due, and the Company repaid all principal and accrued interest thereunder using a portion of the proceeds from the 2022 Rights Offering on August 10, 2022.

December 6, 2022 Note Purchase Agreement

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 would mature and become 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 will mature and become due on September 15, 2023. The maturity dates of the December 2022 Notes could be 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 shall consummate 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 shall 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 (the "Rights Offering"), 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 (i) the net proceeds of such capital raise or (ii) 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 accrue interest at an initial rate of 7.5%. All interest on the Notes shall be paid on the date of signing for the period through February 15, 2023. Such prepaid interest shall be paid in a number of shares of the Company's 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 the Company entered into the Note Purchase Agreement, plus $0.01), which was 9,720,291 shares. For all applicable periods following the February 15, 2023, interest shall accrue on the outstanding principal balance of the Notes at the United States 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 United States prime rate plus 300 basis points, as adjusted monthly.

23. Subsequent Events

Akeso Collaboration and License Agreement

On December 5, 2022, the Company entered into the License Agreement with Akeso, which is detailed further in Note 1. The License Agreement closed on January 17, 2023, and both Akeso and Summit entered into the Common Stock Issuance Agreement ("Issuance Agreement"). Pursuant to the License Agreement and Issuance Agreement, Akeso elected to receive 10 million shares of Company common stock in lieu of cash and was paid $274,900 in cash as the initial upfront payment. The remaining $200,000 of the upfront payment was paid on March 6, 2023. As regulatory approval for ivonescimab has not yet been granted, the Company will record in-process research and development expenses in the first quarter of 2023 for the cash payments of $474,900 and for the fair market value of the 10 million shares issued to Akeso.

Maturity date extension and rectification of promissory notes issued pursuant to the Note Purchase Agreement

As disclosed in Notes 17 and 22, 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, see Notes 17 and 22 for further details.

2023 Rights Offering ("Rights Offering")

On December 6, 2022, the Company announced a rights offering for its existing shareholders to participate in the purchase of additional shares of its common stock. The Rights Offering commenced on February 7, 2023 and the associated subscription rights expired on March 1, 2023. Aggregate gross proceeds from the Rights Offering were $500,000 from the sale of 476,190,471 shares of the Company's common stock at a price of $1.05 per share. Issuance costs were approximately $500.

Repayment of promissory 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, the $400,000 Duggan Promissory Note, which is defined in Note 17, matured and became due, and the Company repaid all principal and accrued interest thereunder using a portion of the proceeds from the Rights Offering.

SUMMIT THERAPEUTICS INC.
2020 STOCK INCENTIVE PLAN

As Amended and Restated on July 27, 2022

1. Purpose

The purpose of this 2020 Stock Incentive Plan (the "*Plan*") of Summit Therapeutics Inc., a Delaware corporation (the "*Company*"), is to advance the interests of the Company's stockholders by enhancing the Company's ability to attract, retain and motivate persons who are expected to make important contributions to the Company and by providing such persons with equity ownership opportunities and performance-based incentives that are intended to better align the interests of such persons with those of the Company's stockholders. Except where the context otherwise requires, the term "*Company*" shall include any of the Company's present or future parent or subsidiary corporations as defined in Sections 424(e) or (f) of the Internal Revenue Code of 1986, as amended, and any regulations thereunder (the "*Code*") and any other business venture (including, without limitation, joint venture or limited liability company) in which the Company has a controlling interest, as determined by the Board of Directors of the Company (the "*Board*").

2. Eligibility

All of the Company's employees, officers and directors, as well as consultants and advisors to the Company (as such terms consultants and advisors are defined and interpreted for purposes of Form S-8 under the Securities Act of 1933, as amended (the "*Securities Act*"), or any successor form) are eligible to be granted Awards (as defined below) under the Plan. Each person who is granted an Award under the Plan is deemed a "*Participant*." "*Award*" means Options (as defined in Section 5), SARs (as defined in Section 6), Restricted Stock (as defined in Section 7), Restricted Stock Units (as defined in Section 7) and Other Stock-Based Awards (as defined in Section 8).

3. Administration and Delegation

(a) Administration by Board of Directors. The Plan will be administered by the Board. The Board shall have authority to grant Awards and to adopt, amend and repeal such administrative rules, guidelines and practices relating to the Plan as it shall deem advisable. The Board may construe and interpret the terms of the Plan and any Award agreements entered into under the Plan. The Board may correct any defect, supply any omission or reconcile any inconsistency in the Plan or any Award in the manner and to the extent it shall deem expedient and it shall be the sole and final judge of such expediency. All decisions by the Board shall be made in the Board's sole discretion and shall be final and binding on all persons having or claiming any interest in the Plan or in any Award.

(b) Appointment of Committees. To the extent permitted by applicable law, the Board may delegate any or all of its powers under the Plan to one or more committees or subcommittees of the Board (a "*Committee*"). All references in the Plan to the "*Board*" shall mean the Board or a Committee of the Board or the officers referred to in Section 3(c) to the extent that the Board's powers or authority under the Plan have been delegated to such Committee or officers.

(c) Delegation to Officers. Subject to any requirements of applicable law (including as applicable Sections 152 and 157(c) of the General Corporation Law of the State of Delaware), the Board may delegate to one or more officers of the Company the power to grant Awards (subject to any limitations under the Plan) to employees or officers of the Company and to exercise such other powers under the Plan as the Board may determine, provided that the Board shall fix the terms of Awards to be granted by such officers, the maximum number of shares subject to Awards that the officers may grant, and the time period in which such Awards may be granted; and provided further, that no officer shall be authorized to grant Awards to any "executive officer" of the Company (as defined by Rule 3b-7 under the Securities Exchange Act of 1934, as amended (the "*Exchange Act*")) or to any "officer" of the Company (as defined by Rule 16a-1(f) under the Exchange Act).

4. Stock Available for Awards

(a) Number of Shares; Share Counting.

(1) Authorized Number of Shares. Subject to adjustment under Section 9, Awards may be made under the Plan for up to such number of shares of common stock, $0.01 par value per share, of the Company (the "*Common Stock*") as is equal to the sum of:

(A) 16,000,000 shares of Common Stock; plus

(B) such additional number of shares of Common Stock (up to 5,000,000 shares) as is equal to the number of shares of Common Stock subject to awards granted by the Summit Therapeutics plc (the "*Predecessor Company*") prior to the Redomiciliation Date (as defined in Section 11(c)) pursuant to the Predecessor Company's 2016 Long Term Incentive Plan, the Predecessor Company's 2005 EMI Scheme Rules or outside of any equity incentive plan and assumed by the Company on the Redomiciliation Date which awards expire, terminate or are otherwise surrendered, canceled, forfeited or repurchased by the Company at their original issuance price pursuant to a contractual repurchase right (subject, however, in the case of Incentive Stock Options to any limitations of the Code); plus

(C) an annual increase to be added on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2021 and continuing for each fiscal year until, and including, the fiscal year ending December 31, 2030, equal to the least of (i) 6,400,000 shares of Common Stock, (ii) 4% of the outstanding shares on such date and (iii) an amount determined by the Board.

Any or all of the shares of Common Stock available for issuance under the Plan may be issued as Incentive Stock Options (as defined in Section 5(b)) under the Plan. Shares issued under the Plan may consist in whole or in part of authorized but unissued shares or treasury shares.

(2) Share Counting. For purposes of counting the number of shares available for the grant of Awards under the Plan under this Section 4(a):

(A) all shares of Common Stock covered by SARs shall be counted against the number of shares available for the grant of Awards under the Plan; *provided, however*, that (i) SARs that may be settled only in cash shall not be so counted and (ii) if the Company grants an SAR in tandem with an Option for the same number of shares of Common Stock and provides that only one such Award may be exercised (a "*Tandem SAR*"), only the shares covered by the Option, and not the shares covered by the Tandem SAR, shall be so counted, and the expiration of one in connection with the other's exercise will not restore shares to the Plan;

(B) to the extent a Restricted Stock Unit award may be settled only in cash, no shares shall be counted against the shares available for the grant of Awards under the Plan;

(C) if any Award (i) expires or is terminated, surrendered or canceled without having been fully exercised or is forfeited in whole or in part (including as the result of shares of Common Stock subject to such Award being repurchased by the Company at the original issuance price pursuant to a contractual repurchase right) or (ii) results in any Common Stock not being issued (including as a result of an SAR that was settleable either in cash or in stock actually being settled in cash), the unused Common Stock covered by such Award shall again be available for the grant of Awards; *provided, however*, that (1) in the case of Incentive Stock Options, the foregoing shall be subject to any limitations under the Code, (2) in the case of the exercise of an SAR, the number of shares counted against the shares available under the Plan shall be the full number of shares subject to the SAR multiplied by the percentage of the SAR actually exercised, regardless of the number of shares actually used to settle such SAR upon exercise and (3) the shares covered by a Tandem SAR shall not again become available for grant upon the expiration or termination of such Tandem SAR; and

(D) shares of Common Stock delivered (by actual delivery, attestation, or net exercise) to the Company by a Participant to (i) purchase shares of Common Stock upon the exercise of an Award or (ii) satisfy tax withholding obligations with respect to Awards (including shares retained from the Award creating the tax obligation) shall be added back to the number of shares available for the future grant of Awards.

(b) Substitute Awards. In connection with a merger or consolidation of an entity with the Company or the acquisition by the Company of property or stock of an entity, the Board may grant Awards in substitution for any options or other stock or stock-based awards granted by such entity or an affiliate thereof. Substitute Awards may be granted on such terms as the Board deems appropriate in the circumstances, notwithstanding any limitations on Awards contained in the Plan. Substitute Awards shall not count against the overall share limit set forth in Section 4(a)(1) or any sublimit contained in the Plan, except as may be required by reason of Section 422 and related provisions of the Code.

5. Stock Options

(a) General. The Board may grant options to purchase Common Stock (each, an "*Option*") and determine the number of shares of Common Stock to be covered by each Option, the exercise price of each Option and the conditions and limitations applicable to the exercise of each Option, including conditions relating to applicable federal or state securities laws, as it considers necessary or advisable.

(b) Incentive Stock Options. An Option that the Board intends to be an "incentive stock option" as defined in Section 422 of the Code (an "*Incentive Stock Option*") shall only be granted to employees of Summit Therapeutics Inc., any of Summit Therapeutics Inc.'s present or future parent or subsidiary corporations as defined in Sections 424(e) or (f) of the Code, and any other entities the employees of which are eligible to receive Incentive Stock Options under the Code, and shall be subject to and shall be construed consistently with the requirements of Section 422 of the Code. An Option that is not intended to be an Incentive Stock Option shall be designated a "*Nonstatutory Stock Option*." The Company shall have no liability to a Participant, or any other party, if an Option (or any part thereof) that is intended to be an Incentive Stock Option is not an Incentive Stock Option or if the Company converts an Incentive Stock Option to a Nonstatutory Stock Option.

(c) Exercise Price. The Board shall establish the exercise price of each Option or the formula by which such exercise price will be determined. The exercise price shall be specified in the applicable Option agreement. The exercise price shall be not less than 100% of the Grant Date Fair Market Value (as defined below) of the Common Stock on the date the Option is granted; *provided* that if the Board approves the grant of an Option with an exercise price to be determined on a future date, the exercise price shall be not less than 100% of the Grant Date Fair Market Value on such future date. "*Grant Date Fair Market Value*" of a share of Common Stock for purposes of the Plan will be determined as follows:

(1) if the Common Stock trades on a national securities exchange, the closing sale price (for the primary trading session) on the date of grant; or

(2) if the Common Stock does not trade on any such exchange, the average of the closing bid and asked prices on the date of grant as reported by an over-the-counter marketplace designated by the Board; or

(3) if the Common Stock is not publicly traded, the Board will determine the Grant Date Fair Market Value for purposes of the Plan using any measure of value it determines to be appropriate (including, as it considers appropriate, relying on appraisals) in a manner consistent with the valuation principles under Code Section 409A, except as the Board may expressly determine otherwise.

For any date that is not a trading day, the Grant Date Fair Market Value of a share of Common Stock for such date will be determined by using the closing sale price or average of the bid and asked prices, as appropriate, for the immediately preceding trading day and with the timing in the formulas above adjusted accordingly. The Board can substitute a particular time of day or other measure of "closing sale price" or "bid and asked prices" if appropriate because of exchange or market procedures or can, in its sole discretion, use weighted averages either on a daily basis or such longer period as complies with Code Section 409A.

The Board has sole discretion to determine the Grant Date Fair Market Value for purposes of the Plan, and all Awards are conditioned on the Participants' agreement that the Board's determination is conclusive and binding even though others might make a different determination.

(d) Duration of Options. Each Option shall be exercisable at such times and subject to such terms and conditions as the Board may specify in the applicable option agreement; *provided, however*, that no Option will be granted with a term in excess of 10 years.

(e) Exercise of Options. Options may be exercised by delivery to the Company of a notice of exercise in a form (which may be electronic, and which may be provided to a third party equity plan administrator) approved by the Company, together with payment in full (in the manner specified in Section 5(f)) of the exercise price for the number of shares for which the Option is exercised. Shares of Common Stock subject to the Option will be delivered by the Company as soon as practicable following exercise.

(f) Payment Upon Exercise. Common Stock purchased upon the exercise of an Option granted under the Plan shall be paid for as follows:

(1) in cash or by check, payable to the order of the Company;

(2) except as may otherwise be provided in the applicable Option agreement or approved by the Board, by (i) delivery of an irrevocable and unconditional undertaking by a creditworthy broker to deliver promptly to the Company sufficient funds to pay the exercise price and any required tax withholding or (ii) delivery by the Participant to the Company of a copy of irrevocable and unconditional instructions to a creditworthy broker to deliver promptly to the Company cash or a check sufficient to pay the exercise price and any required tax withholding;

(3) to the extent provided for in the applicable Option agreement or approved by the Board, by delivery (either by actual delivery or attestation) of shares of Common Stock owned by the Participant valued at their fair market value (valued in the manner determined by (or in a manner approved by) the Board), provided (i) such method of payment is then permitted under applicable law, (ii) such Common Stock, if acquired directly from the Company, was owned by the Participant for such minimum period of time, if any, as may be established by the Board and (iii) such Common Stock is not subject to any repurchase, forfeiture, unfulfilled vesting or other similar requirements;

(4) to the extent provided for in the applicable Nonstatutory Stock Option agreement or approved by the Board, by delivery of a notice of "net exercise" to the Company, as a result of which the Participant would receive (i) the number of shares underlying the portion of the Option being exercised, less (ii) such number of shares as is equal to (A) the aggregate exercise price for the portion of the Option being exercised divided by (B) the fair market value of the Common Stock (valued in the manner determined by (or in a manner approved by) the Board) on the date of exercise;

(5) to the extent permitted by applicable law and provided for in the applicable Option agreement or approved by the Board by payment of such other lawful consideration as the Board may determine; or

(6) by any combination of the above permitted forms of payment, to the extent approved by the Board.

(g) Limitation on Repricing. Unless such action is approved by the Company's stockholders, the Company may not (except as provided for under Section 9): (1) amend any outstanding Option granted under the Plan to provide an exercise price per share that is lower than the then-current exercise price per share of such outstanding Option, (2) cancel any outstanding option (whether or not granted under the Plan) and grant in substitution therefor new Awards under the Plan (other than Awards granted pursuant to Section 4(b)) covering the same or a different number of shares of Common Stock and having an exercise or measurement price per share lower than the then-current exercise price per share of the canceled option, (3) cancel in exchange for a cash payment any outstanding Option with an exercise price per share above the then-current fair market value of the Common Stock (valued in the manner determined by (or in the manner approved by) the Board) or (4) take any other action under the Plan that constitutes a "repricing" within the meaning of the rules of the Nasdaq Stock Market or any other exchange or marketplace on which the Company stock is listed or traded (the "Exchange").

6. Stock Appreciation Rights

(a) General. The Board may grant Awards consisting of stock appreciation rights ("*SARs*") entitling the holder, upon exercise, to receive an amount of Common Stock or cash or a combination thereof (such form to be determined by the Board) determined by reference to appreciation, from and after the date of grant, in the fair market value of a share of Common Stock (valued in the manner determined by (or in the manner approved by) the Board) over the measurement price established pursuant to Section 6(b). The date as of which such appreciation is determined shall be the exercise date.

(b) Measurement Price. The Board shall establish the measurement price of each SAR and specify it in the applicable SAR agreement. The measurement price shall not be less than 100% of the Grant Date Fair Market Value of the Common Stock on the date the SAR is granted; *provided* that if the Board approves the grant of an SAR effective as of a future date, the measurement price shall be not less than 100% of the Grant Date Fair Market Value on such future date.

(c) Duration of SARs. Each SAR shall be exercisable at such times and subject to such terms and conditions as the Board may specify in the applicable SAR agreement; *provided, however*, that no SAR will be granted with a term in excess of 10 years.

(d) Exercise of SARs. SARs may be exercised by delivery to the Company of a notice of exercise in a form (which may be electronic) approved by the Company, together with any other documents required by the Board.

(e) Limitation on Repricing. Unless such action is approved by the Company's stockholders, the Company may not (except as provided for under Section 9): (1) amend any outstanding SAR granted under the Plan to provide a measurement price per share that is lower than the then-current measurement price per share of such outstanding SAR, (2) cancel any outstanding SAR (whether or not granted under the Plan) and grant in substitution therefor new Awards under the Plan (other than Awards granted pursuant to Section 4(b)) covering the same or a different number of shares of Common Stock and having an exercise or measurement price per share lower than the then-current measurement price per share of the canceled SAR, (3) cancel in exchange for a cash payment any outstanding SAR with a measurement price per share above the then-current fair market value of the Common Stock (valued in the manner determined by (or in a manner approved by) the Board) or (4) take any other action under the Plan that constitutes a "repricing" within the meaning of the rules of the Exchange.

7. Restricted Stock; Restricted Stock Units

(a) General. The Board may grant Awards entitling recipients to acquire shares of Common Stock ("*Restricted Stock*"), subject to the right of the Company to repurchase all or part of such shares at their issue price or other stated or formula price (or to require forfeiture of such shares if issued at no cost) from the recipient in the event that conditions specified by the Board in the applicable Award are not satisfied prior to the end of the applicable restriction period or periods established by the Board for such Award. The Board may also grant Awards entitling the recipient to receive shares of Common Stock or cash to be delivered as soon as practicable after the time such Award vests or is settled ("*Restricted Stock Units*") (Restricted Stock and Restricted Stock Units are each referred to herein as a "*Restricted Stock Award*").

(b) Terms and Conditions for All Restricted Stock Awards. The Board shall determine the terms and conditions of a Restricted Stock Award, including the conditions for vesting and repurchase (or forfeiture) and the issue price, if any.

(c) Additional Provisions Relating to Restricted Stock.

(1) Dividends. Unless otherwise provided in the applicable Award agreement, any dividends (whether paid in cash, stock or property) declared and paid by the Company with respect to shares of Restricted Stock ("*Accrued Dividends*") shall be paid to the Participant only if and when such shares become free from the restrictions on transferability and forfeitability that apply to such shares. Each payment of Accrued Dividends will be made no later than the end of the calendar year in which the dividends are paid to stockholders of that class of stock or, if later, the 15th day of the third month following the lapsing of the restrictions on transferability and the forfeitability provisions applicable to the underlying shares of Restricted Stock.

(2) Stock Certificates. The Company may require that any stock certificates issued in respect of shares of Restricted Stock, as well as dividends or distributions paid on such Restricted Stock, shall be deposited in escrow by the Participant, together with a stock power endorsed in blank, with the Company (or its designee). At the expiration of the applicable restriction periods, the Company (or such designee) shall deliver the certificates no longer subject to such restrictions to the Participant or if the Participant has died, to his or her Designated Beneficiary. "*Designated Beneficiary*" means (i) the beneficiary designated, in a manner determined by the Board, by a Participant to receive amounts due or exercise rights of the Participant in the event of the Participant's death or (ii) in the absence of an effective designation by a Participant, the Participant's estate.

(d) Additional Provisions Relating to Restricted Stock Units.

(1) Settlement. As soon as practicable after the vesting of and/or lapsing of any other restrictions (i.e., settlement) with respect to each Restricted Stock Unit, the Participant shall be entitled to receive from the Company such number of shares of Common Stock and/or (if so provided in the applicable Award agreement) an amount of cash equal to the fair market value (valued in the manner determined by (or in a manner approved by) the Board) of such number of shares of Common Stock as are set forth in the applicable Restricted Stock Unit agreement. The Board may provide that settlement of Restricted Stock Units shall be deferred, on a mandatory basis or at the election of the Participant in a manner that complies with Section 409A of the Code.

(2) Voting Rights. A Participant shall have no voting rights with respect to any Restricted Stock Units.

(3) Dividend Equivalents. The Award agreement for Restricted Stock Units may provide Participants with the right to receive an amount equal to any dividends or other distributions declared and paid on an equal number of outstanding shares of Common Stock ("*Dividend Equivalents*"). Dividend Equivalents may be settled in cash and/or shares of Common Stock, as provided in the Award agreement, and shall be subject to the same restrictions on transfer and forfeitability as the Restricted Stock Units with respect to which paid.

8. Other Stock-Based Awards

(a) General. The Board may grant other Awards of shares of Common Stock, and other Awards that are valued in whole or in part by reference to, or are otherwise based on, shares of Common Stock or other property ("*Other Stock-Based Awards*"). Such Other Stock-Based Awards shall also be available as a form of payment in the settlement of other Awards granted under the Plan or as payment in lieu of compensation to which a Participant is otherwise entitled. Other Stock-Based Awards may be paid in shares of Common Stock or cash, as the Board shall determine.

(b) Terms and Conditions. Subject to the provisions of the Plan, the Board shall determine the terms and conditions of each Other Stock-Based Award, including any purchase price applicable thereto.

9. Adjustments for Changes in Common Stock and Certain Other Events

(a) Changes in Capitalization. In the event of any stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event, or any dividend or distribution to holders of Common Stock other than an ordinary cash dividend, (i) the number and class of securities available under the Plan, (ii) the share counting rules set forth in Section 4(a), (iii) the number and class of securities and exercise price per share of each outstanding Option, (iv) the share and per-share provisions and the measurement price of each outstanding SAR, (v) the number of shares subject to and the repurchase price per share subject to each outstanding award of Restricted Stock and (vi) the share and per-share-related provisions and the purchase price, if any, of each outstanding Restricted Stock Unit award and each outstanding Other Stock-Based Award, shall be equitably adjusted by the Company (or substituted Awards may be made, if applicable) in the manner determined by the Board. Without limiting the generality of the foregoing, in the event the Company effects a split of the Common Stock by means of a stock dividend and the exercise price of and the number of shares subject to an outstanding Option are adjusted as of the date of the distribution of the dividend (rather than as of the record date for such dividend), then an optionee who exercises an Option between the record date and the distribution date for such stock dividend shall be entitled to receive, on the distribution date, the stock dividend with respect to the shares of Common Stock acquired upon such Option exercise, notwithstanding the fact that such shares were not outstanding as of the close of business on the record date for such stock dividend.

(b) Reorganization Events.

(1) Definition. A "*Reorganization Event*" shall mean: (a) any merger or consolidation of the Company with or into another entity as a result of which all of the Common Stock of the Company is converted into or exchanged for the right to receive cash, securities or other property or is canceled, (b) any transfer or disposition of all of the Common Stock of the Company for cash, securities or other property pursuant to a share exchange or other transaction or (c) any liquidation or dissolution of the Company.

(2) Consequences of a Reorganization Event on Awards Other than Restricted Stock.

(A) In connection with a Reorganization Event, the Board may take any one or more of the following actions as to all or any (or any portion of) outstanding Awards other than Restricted Stock on such terms as the Board determines (except to the extent specifically provided otherwise in an applicable Award agreement or another agreement between the Company and the Participant): (i) provide that such Awards shall be assumed, or substantially equivalent Awards shall be substituted, by the acquiring or succeeding corporation (or an affiliate thereof), (ii) upon written notice to a Participant, provide that all of the Participant's unvested Awards will be forfeited immediately prior to the consummation of such Reorganization Event and/or that all of the Participant's unexercised Awards will terminate immediately prior to the consummation of such Reorganization Event unless exercised by the Participant (to the extent then exercisable) within a specified period following the date of such notice, (iii) provide that outstanding Awards shall become exercisable, realizable or deliverable, or restrictions applicable to an Award shall lapse, in whole or in part prior to or upon such Reorganization Event, (iv) in the event of a Reorganization Event

under the terms of which holders of Common Stock will receive upon consummation thereof a cash payment for each share surrendered in the Reorganization Event (the "*Acquisition Price*"), make or provide for a cash payment to Participants with respect to each Award held by a Participant equal to (A) the number of shares of Common Stock subject to the vested portion of the Award (after giving effect to any acceleration of vesting that occurs upon or immediately prior to such Reorganization Event) multiplied by (B) the excess, if any, of (I) the Acquisition Price over (II) the exercise, measurement or purchase price of such Award and any applicable tax withholdings, in exchange for the termination of such Award, (v) provide that, in connection with a liquidation or dissolution of the Company, Awards shall convert into the right to receive liquidation proceeds (if applicable, net of the exercise, measurement or purchase price thereof and any applicable tax withholdings) and (vi) any combination of the foregoing. In taking any of the actions permitted under this Section 9(b)(2), the Board shall not be obligated by the Plan to treat all Awards, all Awards held by a Participant, or all Awards of the same type, identically.

(B) Notwithstanding the terms of Section 9(b)(2)(A), in the case of outstanding Restricted Stock Units that are subject to Section 409A of the Code: (i) if the applicable Restricted Stock Unit agreement provides that the Restricted Stock Units shall be settled upon a "change in control event" within the meaning of Treasury Regulation Section 1.409A-3(i)(5)(i), and the Reorganization Event constitutes such a "change in control event", then no assumption or substitution shall be permitted pursuant to Section 9(b)(2)(A)(i) and the Restricted Stock Units shall instead be settled in accordance with the terms of the applicable Restricted Stock Unit agreement; and (ii) the Board may only undertake the actions set forth in clauses (iii), (iv) or (v) of Section 9(b)(2)(A) if the Reorganization Event constitutes a "change in control event" as defined under Treasury Regulation Section 1.409A-3(i)(5)(i) and such action is permitted or required by Section 409A of the Code; if the Reorganization Event is not a "change in control event" as so defined or such action is not permitted or required by Section 409A of the Code, and the acquiring or succeeding corporation does not assume or substitute the Restricted Stock Units pursuant to clause (i) of Section 9(b)(2)(A), then the unvested Restricted Stock Units shall terminate immediately prior to the consummation of the Reorganization Event without any payment in exchange therefor.

(C) For purposes of Section 9(b)(2)(A)(i), an Award (other than Restricted Stock) shall be considered assumed if, following consummation of the Reorganization Event, such Award confers the right to purchase or receive pursuant to the terms of such Award, for each share of Common Stock subject to the Award immediately prior to the consummation of the Reorganization Event, the consideration (whether cash, securities or other property) received as a result of the Reorganization Event by holders of Common Stock for each share of Common Stock held immediately prior to the consummation of the Reorganization Event (and if holders were offered a choice of consideration, the type of consideration chosen by the holders of a majority of the outstanding shares of Common Stock); *provided, however*, that if the consideration received as a result of the Reorganization Event is not solely common stock of the acquiring or succeeding corporation (or an affiliate thereof), the Company may, with the consent of the acquiring or succeeding corporation, provide for the consideration to be received upon the exercise or settlement of the Award to consist solely of such number of shares of common stock of the acquiring or succeeding corporation (or an affiliate thereof) that the Board determines to be equivalent in value (as of the date of such determination or another date specified by the Board) to the per share consideration received by holders of outstanding shares of Common Stock as a result of the Reorganization Event.

(3) Consequences of a Reorganization Event on Restricted Stock. Upon the occurrence of a Reorganization Event other than a liquidation or dissolution of the Company, the repurchase and other rights of the Company with respect to outstanding Restricted Stock shall inure to the benefit of the Company's successor and shall, unless the Board determines otherwise, apply to the cash, securities or other property which the Common Stock was converted into or exchanged for pursuant to such Reorganization Event in the same manner and to the same extent as they applied to such Restricted Stock; *provided, however*, that the Board may provide for termination or deemed satisfaction of such repurchase or other rights under the instrument evidencing any Restricted Stock or any other agreement between a Participant and the Company, either initially or by amendment. Upon the occurrence of a Reorganization Event involving the liquidation or dissolution of the Company, except to the extent specifically provided to the contrary in the instrument evidencing any Restricted Stock or any other agreement between a Participant and the Company, all restrictions and conditions on all Restricted Stock then outstanding shall automatically be deemed terminated or satisfied.

10. General Provisions Applicable to Awards

(a) Transferability of Awards. Awards shall not be sold, assigned, transferred, pledged or otherwise encumbered by the Participant, either voluntarily or by operation of law, except by will or the laws of descent and distribution or, other than in the case of an Incentive Stock Option, pursuant to a qualified domestic relations order, and, during the

life of the Participant, shall be exercisable only by the Participant; *provided, however*, that, except with respect to Awards subject to Section 409A of the Code, the Board may permit or provide in an Award for the gratuitous transfer of the Award by the Participant to or for the benefit of any immediate family member, family trust or other entity established for the benefit of the Participant and/or an immediate family member thereof if the Company would be eligible to use a Form S-8 under the Securities Act for the registration of the sale of the Common Stock subject to such Award to such proposed transferee; *provided further*, that the Company shall not be required to recognize any such permitted transfer until such time as such permitted transferee shall, as a condition to such transfer, deliver to the Company a written instrument in form and substance satisfactory to the Company confirming that such transferee shall be bound by all of the terms and conditions of the Award. References to a Participant, to the extent relevant in the context, shall include references to authorized transferees. For the avoidance of doubt, nothing contained in this Section 10(a) shall be deemed to restrict a transfer to the Company.

(b) Documentation. Each Award shall be evidenced in such form (written, electronic or otherwise) as the Board shall determine. Each Award may contain terms and conditions in addition to those set forth in the Plan.

(c) Board Discretion. Except as otherwise provided by the Plan, each Award may be made alone or in addition or in relation to any other Award. The terms of each Award need not be identical, and the Board need not treat Participants uniformly.

(d) Termination of Status. The Board shall determine the effect on an Award of the disability, death, termination or other cessation of employment, authorized leave of absence or other change in the employment or other status of a Participant and the extent to which, and the period during which, the Participant, or the Participant's legal representative, conservator, guardian or Designated Beneficiary, may exercise rights or receive any benefits under the Award.

(e) Withholding. The Participant must satisfy all applicable federal, state, and local or other income and employment tax withholding obligations before the Company will deliver stock certificates or otherwise recognize ownership of Common Stock under an Award. The Company may elect to satisfy the withholding obligations through additional withholding on salary or wages. If the Company elects not to or cannot withhold from other compensation, the Participant must pay the Company the full amount, if any, required for withholding or have a broker tender to the Company cash equal to the withholding obligations. Payment of withholding obligations is due before the Company will issue any shares on exercise, vesting or release from forfeiture of an Award or at the same time as payment of the exercise or purchase price, unless the Company determines otherwise. If provided for in an Award or approved by the Board, a Participant may satisfy the tax obligations in whole or in part by delivery (either by actual delivery or attestation) of shares of Common Stock, including shares retained from the Award creating the tax obligation, valued at their fair market value (valued in the manner determined by (or in a manner approved by) the Company); *provided*, *however*, except as otherwise provided by the Board, that the total tax withholding where stock is being used to satisfy such tax obligations cannot exceed the Company's minimum statutory withholding obligations (based on minimum statutory withholding rates for federal, state and local tax purposes, including payroll taxes, that are applicable to such supplemental taxable income), except that, to the extent that the Company is able to retain shares of Common Stock having a fair market value (determined by, or in a manner approved by, the Company) that exceeds the statutory minimum applicable withholding tax without financial accounting implications or the Company is withholding in a jurisdiction that does not have a statutory minimum withholding tax, the Company may retain such number of shares of Common Stock (up to the number of shares having a fair market value equal to the maximum individual statutory rate of tax (determined by, or in a manner approved by, the Company)) as the Company shall determine in its sole discretion to satisfy the tax liability associated with any Award. Shares used to satisfy tax withholding requirements cannot be subject to any repurchase, forfeiture, unfulfilled vesting or other similar requirements.

(f) Amendment of Award. Except as otherwise provided in Sections 5(g) and 6(e) with respect to repricings and Section 11(d) with respect to actions requiring stockholder approval, the Board may amend, modify or terminate any outstanding Award, including but not limited to, substituting therefor another Award of the same or a different type, changing the date of exercise or realization, and converting an Incentive Stock Option to a Nonstatutory Stock Option. The Participant's consent to such action shall be required unless (i) the Board determines that the action, taking into account any related action, does not materially and adversely affect the Participant's rights under the Plan or (ii) the change is permitted under Section 9.

(g) Conditions on Delivery of Stock. The Company will not be obligated to deliver any shares of Common Stock pursuant to the Plan or to remove restrictions from shares previously issued or delivered under the Plan until (i) all conditions of the Award have been met or removed to the satisfaction of the Company, (ii) in the opinion of the Company's counsel, all other legal matters in connection with the issuance and delivery of such shares have been satisfied, including any applicable securities laws and regulations and any applicable stock exchange or stock market rules and regulations and (iii) the Participant has executed and delivered to the Company such representations or agreements as the Company may consider appropriate to satisfy the requirements of any applicable laws, rules or regulations.

(h) Acceleration. The Board may at any time provide that any Award shall become immediately exercisable in whole or in part, free from some or all restrictions or conditions, or otherwise realizable in whole or in part, as the case may be.

11. Miscellaneous

(a) No Right To Employment or Other Status. No person shall have any claim or right to be granted an Award by virtue of the adoption of the Plan, and the grant of an Award shall not be construed as giving a Participant the right to continued employment or any other relationship with the Company. The Company expressly reserves the right at any time to dismiss or otherwise terminate its relationship with a Participant free from any liability or claim under the Plan, except as expressly provided in the applicable Award.

(b) No Rights As Stockholder; Clawback Policy. Subject to the provisions of the applicable Award, no Participant or Designated Beneficiary shall have any rights as a stockholder with respect to any shares of Common Stock to be issued with respect to an Award until becoming the record holder of such shares. In accepting an Award under the Plan, a Participant agrees to be bound by any clawback policy the Company has in effect or may adopt in the future.

(c) Effective Date and Term of Plan. The Plan shall become effective on the later of the date on which the Predecessor Company becomes a wholly-owned subsidiary of the Company pursuant to a scheme of arrangement under the laws of England and Wales (the "*Redomiciliation Date*") and the date on which the Plan is approved by the Company's stockholders; provided however that Company stockholder approval prior to the Redomiciliation Date shall only be effective if approval of the Plan by the Predecessor Company's shareholders has also been obtained on or prior to the Redomiciliation Date (the date on which the Plan becomes effective, the "*Effective Date*"). No Awards shall be granted under the Plan after the expiration of 10 years from the Effective Date, but Awards previously granted may extend beyond that date.

(d) Amendment of Plan. The Board may amend, suspend or terminate the Plan or any portion thereof at any time provided that no amendment that would require stockholder approval under the rules of the Exchange may be made effective unless and until the Company's stockholders approve such amendment. In addition, if at any time the approval of the Company's stockholders is required as to any other modification or amendment under Section 422 of the Code or any successor provision with respect to Incentive Stock Options, the Board may not effect such modification or amendment without such approval. Unless otherwise specified in the amendment, any amendment to the Plan adopted in accordance with this Section 11(d) shall apply to, and be binding on the holders of, all Awards outstanding under the Plan at the time the amendment is adopted, provided the Board determines that such amendment, taking into account any related action, does not materially and adversely affect the rights of Participants under the Plan. No Award shall be made that is conditioned upon stockholder approval of any amendment to the Plan unless the Award provides that (i) it will terminate or be forfeited if stockholder approval of such amendment is not obtained within no more than 12 months from the date of grant and (ii) it may not be exercised or settled (or otherwise result in the issuance of Common Stock) prior to such stockholder approval.

(e) Authorization of Sub-Plans (including for Grants to non-U.S. Employees). The Board may from time to time establish one or more sub-plans under the Plan for purposes of satisfying applicable securities, tax or other laws of various jurisdictions. The Board shall establish such sub-plans by adopting supplements to the Plan containing (i) such limitations on the Board's discretion under the Plan as the Board deems necessary or desirable or (ii) such additional terms and conditions not otherwise inconsistent with the Plan as the Board shall deem necessary or desirable. All supplements adopted by the Board shall be deemed to be part of the Plan, but each supplement shall apply only to Participants within the affected jurisdiction and the Company shall not be required to provide copies of any supplement to Participants in any jurisdiction which is not the subject of such supplement.

(f) Compliance with Section 409A of the Code. If and to the extent (i) any portion of any payment, compensation or other benefit provided to a Participant pursuant to the Plan in connection with his or her employment termination constitutes "nonqualified deferred compensation" within the meaning of Section 409A of the Code and (ii) the Participant is a specified employee as defined in Section 409A(a)(2)(B)(i) of the Code, in each case as determined by the Company in accordance with its procedures, by which determinations the Participant (through accepting the Award) agrees that he or she is bound, such portion of the payment, compensation or other benefit shall not be paid before the day that is six months plus one day after the date of "separation from service" (as determined under Section 409A of the Code) (the "*New Payment Date*"), except as Section 409A of the Code may then permit. The aggregate of any payments that otherwise would have been paid to the Participant during the period between the date of separation from service and the New Payment Date shall be paid to the Participant in a lump sum on such New Payment Date, and any remaining payments will be paid on their original schedule.

The Company makes no representations or warranty and shall have no liability to the Participant or any other person if any provisions of or payments, compensation or other benefits under the Plan are determined to constitute nonqualified deferred compensation subject to Section 409A of the Code but do not to satisfy the conditions of that section.

(g) Limitations on Liability. Notwithstanding any other provisions of the Plan, no individual acting as a director, officer, employee or agent of the Company will be liable to any Participant, former Participant, spouse, beneficiary, or any other person for any claim, loss, liability, or expense incurred in connection with the Plan, nor will such individual be personally liable with respect to the Plan because of any contract or other instrument he or she executes in his or her capacity as a director, officer, employee or agent of the Company. The Company will indemnify and hold harmless each director, officer, employee or agent of the Company to whom any duty or power relating to the administration or interpretation of the Plan has been or will be delegated, against any cost or expense (including attorneys' fees) or liability (including any sum paid in settlement of a claim with the Board's approval) arising out of any act or omission to act concerning the Plan unless arising out of such person's own fraud or bad faith.

(h) Governing Law. The provisions of the Plan and all Awards made hereunder shall be governed by and interpreted in accordance with the laws of the State of Delaware, excluding choice-of-law principles of the law of such state that would require the application of the laws of a jurisdiction other than the State of Delaware.

Certain confidential information contained in this document, marked by [**], has been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K because it is both (i) not material and (ii) the type of information that the registrant treats as private or confidential.

FIRST AMENDMENT SUBLEASE

This FIRST AMENDMENT TO SUBLEASE (this **"First Amendment")** is made and entered into as of the 19th day of July, 2022, by and between MAKY ZANGANEH & ASSIOCIATES INC., a California corporation **(**hereinafter called **"Sublandlord"),** and SUMMIT THERAPEUTICS SUB, INC., a Delaware corporation **(hereinafter called "Subtenant").**

RECITALS:

A. Whereas Sublandlord and Subtenant entered into that certain Sublease dated 1st March 2021 (the **"Sublease"),** whereby Sublandlord leased to Subtenant and Subtenant leased from Sublandlord a certain portion of the 4,960 feet of the space (the **"Premises")** commonly known as Suite 106, which is leased to Sublandlord, more specifically approximately 4,500 square feet of the Premises (hereinafter call the "Sublease Premises") located on the first (1st) floor of that certain office building located at 2882 Sand Hill Road, Menlo Park, California (the **"Building").**

B. Sublandlord and Subtenant desire to extend the Term of the Sublease, and to make other modifications to the Sublease, and in connection therewith, Sublandlord and Subtenant desire to amend the Sublease as hereinafter provided.

AGREEMENT:

NOW, THEREFORE, in consideration of the foregoing recitals and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto hereby agree as follows:

1. **Capitalized Terms.** All capitalized terms when used herein shall have the same meaning as is given such terms in the Sublease unless expressly superseded by the terms of this First Amendment.

2. **Sublease Term.** Sublandlord and Subtenant acknowledge that the Term of the Sublease is currently scheduled to expire on September 30, 2022. Sublandlord and Subtenant hereby agree to extend the Term of the Lease for a period of thirty-nine (39) months, from October 1, 2022 through December 31, 2025. The period of time commencing on October 1, 2022 and terminating on December 31, 2025, shall be referred to herein as the **"Extended Term."**

3. **Rent.** Prior to October **1,** 2022, Subtenant shall continue to pay Rent for the Premises in accordance with the terms of the Sublease. Commencing on October 1, 2022, and continuing throughout the Extended Term, Subtenant shall pay to Sublandlord monthly installments of Base Rent for the Premises as follows:

Period	Monthly Base Rent	Monthly Base Rent Per Rentable Square Foot
October 1, 2022 - September 30, 2023	[**]	[**]
October 1, 2023 - September 30, 2024	[**]	[**]
October 1, 2024 - September 30, 2025	[**]	[**]
October 1, 2025-December 31, 2025	[**]	[**]

Sublandlord will invoice Subtenant monthly, via email, at least 14 days prior to the due date of sublease payment, with instructions to pay the Landlord, Sand Hill Commons REIT, Inc. directly, including relevant bank instructions for wiring funds. Subtenant agrees to pay rent directly to the Landlord, Sand Hill Commons REIT, Inc. no later than the 1st of each month.

4. **Abated Base Rent.** Provided that Subtenant is not then in default of the Sublease (as amended), Subtenant shall not be obligated to pay the Base Rent otherwise attributable to the Premises (the **"Rent Abatement")** during the calendar months of October 2022, November 2022 and December 2022 (the **"Rent Abatement Period").** Sublandlord and Subtenant acknowledge that the aggregate amount of the Rent Abatement equals [**] (i.e., [* *] per month). Subtenant acknowledges and agrees that the foregoing Rent Abatement has been granted to Subtenant as additional consideration for entering into this First Amendment, and for agreeing to pay the Rent and performing the terms and conditions otherwise required under the Sublease (as amended). If Subtenant shall be in default under the Sublease (as amended) and shall fail to cure such default within the notice and cure period, if any, permitted for cure pursuant to the Sublease (as amended), then Sublandlord may at its option, by notice to Subtenant, elect, in addition to any other remedies Sublandlord may have under the Sublease (as amended), one or both of the following remedies: (i) that Subtenant shall immediately become obligated to pay to Sublandlord all Base Rent abated hereunder during the Rent Abatement Period, with interest as provided pursuant to the Sublease (as amended) from the date such Base Rent would have otherwise been due but for the abatement provided herein, or (ii) that the dollar amount of the unapplied portion of the Rent Abatement as of such default shall be converted to a credit to be applied to the Base Rent applicable at the end of the Extended Term and Subtenant shall immediately be obligated to begin paying Base Rent for the Premises in full.

5. **Subtenant's Share of Building Direct Expenses.** Subtenant shall continue to be obligated to pay Subtenant's Proportionate Share (which is [**]) of Sublandlord's Proportionate Share of Operating Costs ("Additional Rent") allocable to the Building in connection with the Premises, which arise or accrue prior to October 1, 2022, in accordance with the terms of the Sublease. Effective as of October 1, 2022, and continuing throughout the Extended Term, the Base Year with respect Operating Costs arising or accruing thereafter shall be the calendar year 2022. Subtentant shall pay the prorata share (which is [**]) of Sublandlord's Additional Rent within ten (10) days of receipt of such accounting of costs.

6. **Other Expenses.** In addition, to the Base Rent and Additional Rent, Subtenant shall promptly pay to Sublandlord (i) any amounts due as a result of Subtenant's request, including , but not limited to costs incurred for after hours HVAC use pursuant to the terms of the Master Lease (ii) a proportionate amount of Sublandlord's cable, internet and phone costs and office supplies (if Subtenants uses Sublandlord's services); and (any amount due to compensate Sublandlord for damages resulting from the negligent or willful misconduct of Subtenant ("Additional Costs").

7. **Improvements.** Except as specifically set forth in the Work Letter attached hereto as **Exhibit A,** there are no obligations of the Landlord to provide or pay for any improvement work or services related to the improvement of the Premises as to the Tenant, and Subtenant shall continue to accept the Lease Premises in its presently existing, "as-is" condition. For purposes of clarity, the Landlord has no obligations to Subtenant whatsoever as to improvements to the Sublease Premises.

8. **No Brokers.** Sublandlord and Subtenant hereby warrant to each other that they have had no dealings with any real estate broker or agent in connection with the negotiation of this First

Amendment, and that they know of no real estate broker or agent who is entitled to a commission in connection with this First Amendment. Each party agrees to indemnify and defend the other party against and hold the other party harmless from and against any and all claims, demands, losses, liabilities, lawsuits, judgments, and costs and expenses (including, without limitation, reasonable attorneys' fees) with respect to any leasing commission or equivalent compensation alleged to be owing on account of the indemnifying party's dealings with any real estate broker or agent occurring by, through, or under the indemnifying party. The terms of this Section 7 shall survive the expiration or earlier termination of the term of the Sublease, as hereby amended.

9. Counterparts. This First Amendment may be executed in multiple counterparts, each of which is to be deemed original for all purposes, but all of which together shall constitute one and the same instrument. Delivery by facsimile, or e-mail of a PDF copy, or by using electronic signature technology (e.g., via DocuSign or similar electronic signature technology), of a counterpart of this First Amendment executed by Sublandlord or Subtenant shall constitute delivery by such party of such party's executed counterpart of this First Amendment.

10. Effectiveness of Agreement. In no event shall any draft of this First Amendment create any rights, obligations or liabilities, it being intended that only a fully executed and delivered copy of this First Amendment will bind the parties hereto.

11. No Further Modification. Except as set forth in this First Amendment, all of the terms and provisions of the Sublease shall remain unmodified and in full force and effect. In the event of a conflict between the terms of the Sublease and the terms of this First Amendment, the terms of this First Amendment shall control. The provisions of the Sublease, as amended and supplemented by this First Amendment, are hereby ratified and confirmed by Subtenant and Sublandlord in all respects.

[continued on the following page

IN WITNESS WHEREOF, this First Amendment has been executed as of the day and year first above written.

"SUBLANDLORD"

Maky Zanganeh & Associates
a California corporation

By: /s/ Maky Zanganeh Dated 7/25/2022

Name: Maky Zanganeh

Title: _____

"SUBTENANT"

SUMMIT THERAPEUTICS SUB, INC
a Delaware corporation

By: /s/Ankur Dhingra Dated 7/25/2022

Name: Ankur Dhingra

Title: CFO

EXHIBIT A

TENANT WORK LETTER

Except as specifically set forth herein, Sublandlord shall not be obligated to provide or pay for any improvement work or services related to the improvement of the Premises, and Subtenant shall accept the Premises in its presently existing, "as-is" condition. Notwithstanding the foregoing, Landlord has agreed with Tenant, at Landlord's sole cost and expense, to (i) install new carpet throughout the Premises, (ii) repaint the interior walls of the Premises, and (iii) other minor cosmetic improvements as may be mutually agreed upon by Landlord and Tenant (the **"Tenant Improvements")** if Tenant so elects; provided, however, in no event shall the cost to construct such Tenant Improvements exceed, in the aggregate, an amount equal to [* *] *(i.e., [* *]* for each of the [**] rentable square feet of the Premises) (the **"Tenant Improvement Allowance")** and the work is completed prior to December 31, 2022**.** In the event that Tenant elects to proceed with the Tenant Improvements and the Landlord reasonably determines the total cost to construct the Tenant Improvements exceeds the Tenant Improvement Allowance, Tenant shall pay the amount of such excess to Landlord within [**] days following written demand by Landlord. Subtenant agrees, in the event, the total cost to construct the Tenant Improvements shall exceed the Tenant Improvement Allowance, to pay its pro-rata share of such cost to the Tenant for the Tenant Improvements, i.e., [**] of such costs within [**] days following written demand by Sublandlord. For purposes of this paragraph, "cost" shall be the actual cost to Landlord of performing Tenant Improvements including, without limitation, design, permitting, construction of the Tenant Improvements, plus a construction management fee determined in accordance with the terms in Section 7.6 of the Master Lease .If, however, the cost of the Tenant Improvements is less than the Tenant Improvement Allowance, and there is no then existing Event of Default by Subtenant under the Sublease (as amended), then Subtenant may elect, by written notice to Sublandlord for Sublandlord to provide Subtenant with a pro-rata credit (the **"Pro-rata Base Rent Credit")** against the payment(s) of Base Rent next due and owing for the Premises in an amount equal to the pro-rata difference between the Tenant Improvement Allowance and the cost. Any pro-rata portion of the Tenant Improvement Allowance remaining after December 31, 2022 shall remain with Landlord and/or if applicable to the Sublandlord and Subtenant shall have no right or claim to the same against the Landlord or Sublandlord.

Since Subtenant is currently occupying the Sublease Premises, during the Tenant Improvements, and therefore receives the benefits of such Tenant Improvements, Subtenant hereby agrees that the construction of the Tenant Improvements shall in no way constitute a constructive eviction of Subtenant nor entitle Subtenant to any abatement of rent. Neither the Landlord nor the Sublandlord shall have any responsibility or for any reason be liable to Subtenant for any direct or indirect injury to or interference with Subtenant's business arising from the Tenant Improvements, nor shall Subtenant be entitled to any compensation or damages from Sublandlord for loss of the use of the whole or any part of the Sublease Premises or of Subtenant's personal property or improvements resulting from the Tenant Improvements.

Certain confidential information contained in this document, marked by [**], has been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K because it is both (i) not material and (ii) the type of information that the registrant treats as private or confidential.

SECOND AMENDMENT TO SUBLEASE

This SECOND AMENDMENT TO SUBLEASE (this **"Second Amendment")** has an Effective Date of the 1st day of August, 2022, by and between MAKY ZANGANEH & ASSIOCIATES INC., a California corporation **(**hereinafter called **"Sublandlord"),** and SUMMIT THERAPEUTICS SUB, INC., a Delaware corporation **(hereinafter called "Subtenant").**

RECITALS:

A. Whereas Sublandlord and Subtenant entered into that certain Sublease dated 1st March 2021 (the **"Original Sublease"),** as amended by that certain First Amendment to the Sublease dated as of July 19, 2022 (the "**First Amendment**", and together with the Original Sublease, the "**Sublease**") whereby Sublandlord leased to Subtenant and Subtenant leased from Sublandlord a certain portion of the 4,960 feet of the space (the **"Premises")** commonly known as Suite 106, which is leased to Sublandlord, more specifically approximately 4,500 square feet of the Premises (hereinafter call the "**Existing Premises")** located on the first (1st) floor of that certain office building located at 2882 Sand Hill Road, Menlo Park, California (the **"Building").**

B. Whereas Subtenant desires to expand the Sublease Premises to include that certain space consisting of approximately 1,277 rentable square feet of space commonly known as Suite 104 and located on the first (1st) floor of the Building (the **"Expansion Premises"),** as delineated on **Exhibit A** attached hereto and made a part hereof, and to make other modifications to the Sublease, and in connection therewith, Sublandlord and Subtenant desire to amend the Sublease as hereinafter provided.

AGREEMENT:

NOW, THEREFORE, in consideration of the foregoing recitals and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto hereby agree as follows:

1. **Capitalized Terms.** All capitalized terms when used herein shall have the same meaning as is given such terms in the Sublease unless expressly superseded by the terms of this Second Amendment.

2. **Modification of Sublease Premises**. Effective as of August 1, 2022 (the "Expansion Commencement Date"), Subtenant shall lease from Sublandlord and Sublandlord shall lease to Subtenant the Expansion Premises. Consequently, effective upon the Expansion Commencement Date, the Sublease Premises shall be increased to include the Expansion Premises. Sublandlord and Subtenant hereby acknowledge that such addition of the Expansion Premises to the Existing Premises shall, effective as of the Expansion Commencement Date, increase the size of the Sublease Premises to approximately 5,777 rentable square feet, and that the Sublease Premises and the Expansion Premises may hereinafter collectively be referred to as the "Sublease Premises".

3. **Lease Term.** The term of Subtenant's lease of the Expansion Premises shall commence on the Expansion Commencement Date and shall expire conterminously with

Subtenant's Lease of the Sublease Premises on December 31, 2025, unless sooner terminated as provided in the Sublease, as hereby amended.

4. Base Rent.

4.1 **Existing Premises.** Subtenant shall continue to pay Base Rent for the Existing Premises in accordance with the terms of the Sublease.

4.2 **Expansion Premises.** Commencing on July 1, 2022. Subtenant shall pay to Sublandlord monthly installments of Base Rent for the Expansion Premises as follows:

	Monthly Base Rent	Monthly Base Rent Per Rentable Square Foot
Aug 1, 2022-June 30, 2023	[**]	[**]
July1, 2023-June 30, 2024	[**]	[**]
July 1, 2024-June 30, 2025	[**]	[**]
July 1, 2025-December 31 2025	[**]	[**]

Sublandlord will invoice Subtenant [**], via email, at least [**] days prior to the due date of sublease payment, with instructions to pay the Landlord, Sand Hill Commons REIT, Inc. directly, including relevant bank instructions for wiring funds. Subtenant agrees to pay rent directly to the Landlord, Sand Hill Commons REIT, Inc. no later than the 1st of each month.

5. **Expansion Premises Abated Base Rent.** Provided that Subtenant is not then in default of the Sublease (as amended), Subtenant shall not be obligated to pay the Base Rent otherwise attributable to the Expansion Premises (the "Rent Abatement") during the calendar months of August 2022 and September 2022 (the "Rent Abatement Period"). Sublandlord and Subtenant acknowledge that the aggregate amount of the Rent Abatement equals [**] (i.e., [**] per month). Subtenant acknowledges and agrees that the foregoing Rent Abatement has been granted to Subtenant as additional consideration for entering into this Second Amendment, and for agreeing to pay the Rent and performing the terms and conditions otherwise required under the Sublease (as amended). If Subtenant shall be in default under the Sublease (as amended) and shall fail to cure such default within the notice and cure period, if any, permitted for cure pursuant to the Sublease (as amended), then Sublandlord may at its option, by notice to Subtenant, elect, in addition to any other remedies Sublandlord may have under the Sublease (as amended), one or both of the following remedies:(i) that Subtenant shall immediately become obligated to pay to Sublandlord all Base Rent abated hereunder during the Rent Abatement Period, with interest as provided pursuant to the Sublease (as amended) from the date such Base Rent would have otherwise been due but for the abatement provided herein, or (ii) that the dollar amount of the unapplied portion of the Rent Abatement as of such default shall be converted to a credit to be applied to the Base Rent applicable at the end of the Term and Subtenant shall immediately be obligated to begin paying Base Rent for the Expansion Premises in full.

6. Subtenant's Share of Building Direct Expenses.

6.1 **Subtenant's Proportionate Share.** Effective as of July 1, 2022, Subtenant's Proportionate Share shall equal [**]%.

6.2 **Existing Premises.** Subtenant shall continue to be obligated to pay Subtenant's Proportionate Share of Operating Costs in connection with the Existing Premises in accordance with the terms set forth in the Sublease (including, without limitation, Section 5 of the First Amendment).

6.3 **Expansion Premises.** Effective as of July 1, 2022, Subtenant be obligated to pay Subtenant's Proportionate Share of Operating Costs Share (which is [**]%) of Sublandlord's Proportionate Share of Operating Costs ("Additional Rent") in connection with the Expansion Premises in accordance with the terms of the Sublease based on a Base Year of calendar year 2022.

6.4 **Other Expenses.** In addition, to the Base Rent and Additional Rent, for the Existing Premises and Expansion Premises, Subtenant shall promptly pay to Sublandlord (i) any amounts due as a result of Subtenant's requests, including , but not limited to costs incurred for after hours HVAC use for the Existing Premises and Expansion Premises pursuant to the terms of the Master Lease (ii) a proportionate amount of Sublandlord's cable, internet and phone costs and office supplies Existing Premises and Expansion Premises (if Subtenants uses Sublandlord's services); and (any amount due to compensate Sublandlord for damages resulting from the negligent or willful misconduct of Subtenant ("Additional Costs").

7. **Improvements**. Except as specifically set forth in the Work Letter attached hereto as Exhibit B, there are no obligations of the Landlord to provide or pay for any improvement work or services related to the improvement of the Premises as to the Tenant and Subtenant shall continue to accept the Sublease Premises in its presently existing, "as-is" condition. For purposes of clarity, the Landlord has no obligations to Subtenant whatsoever as to improvements to the Sublease Premises.

8. **No Brokers**. Sublandlord and Subtenant hereby warrant to each other that they have had no dealings with any real estate broker or agent in connection with the negotiation of this Second Amendment, and that they know of no real estate broker or agent who is entitled to a commission in connection with this Second Amendment. Each party agrees to indemnify and defend the other party against and hold the other party harmless from and against any and all claims, demands, losses, liabilities, lawsuits, judgments, and costs and expenses (including, without limitation, reasonable attorneys' fees) with respect to any leasing commission or equivalent compensation alleged to be owing on account of the indemnifying party's dealings with any real estate broker or agent occurring by, through, or under the indemnifying party. The terms of this Section 8 shall survive the expiration or earlier termination of the term of the Lease, as hereby amended.

9. **CASp Disclosures**. For purposes of Section 1938(a) of the California Civil Code, Sublandlord hereby discloses to Subtenant, and Subtenant hereby acknowledges, that neither the Existing Premises nor the Expansion Premises have undergone inspection by a Certified Access Specialist (CASp). As required by Section J938(e) of the California Civil Code, Landlord hereby states as follows: "A Certified Access Specialist (CASp) can inspect the subject premises and determine whether the subject premises comply with all of the applicable construction-related accessibility standards under state law. Although state law does not require a CASp inspection of the subject premises, the commercial

property owner or lessor may not prohibit the lessee or tenant from obtaining a CASp inspection of the subject premises for the occupancy or potential occupancy of the lessee or tenant, if requested by the lessee or tenant. The parties shall mutually agree on the arrangements for the time and manner of the CASp inspection, the payment of the fee for the CASp inspection, and the cost of making any repairs necessary to correct violations of construction-related accessibility standards within the premises." In furtherance of the foregoing, Sublandlord and Subtenant hereby agree as follows that Sublandlord shall request such inspection on behalf of Subtenant and that: (a) any such CASp inspection requested by Sublandlord shall be conducted, at Subtenant's sole cost and expense, by a CASp designated by the Landlord's under the Landlord's reasonable rules and requirements; (b) Subtenant, at its sole cost and expense, shall be responsible for making any improvements or repairs within the Existing Premises and the Expansion Premises to correct violations of construction-related accessibility standards; and (c) if anything done by or for Subtenant in its use or occupancy of the Existing Premises or the Expansion Premises shall require any improvements or repairs to the Building or Project (outside the Existing Premises or the Expansion Premises) to correct violations of construction-related accessibility standards, then Subtenant shall reimburse Sublandlord directly, upon demand, for any costs charged to the Sublandlord by Landlord for performing such improvements or repairs.

10. **Counterparts**. This Second Amendment may be executed in multiple counterparts, each of which is to be deemed original for all purposes, but all of which together shall constitute one and the same instrument. Delivery by facsimile, or e-mail of a PDF copy, or by using electronic signature technology (e.g., via DocuSign or similar electronic signature technology), of a counterpart of this Second Amendment executed by Sublandlord or Subtenant shall constitute delivery by such party of such party's executed counterpart of this Second Amendment.

11. **Effectiveness of Agreement**. In no event shall any draft of this Second Amendment create any rights, obligations or liabilities, it being intended that only a fully executed and delivered copy of this Second Amendment will bind the parties hereto.

12. **No Further Modification**. Except as set forth in this Second Amendment. all of the terms and provisions of the Sublease shall remain unmodified and in full force and effect. In the event of a conflict between the terms of the Sublease and the terms of this Second Amendment, the terms of this Second Amendment shall control. The provisions of the Sublease, as amended and supplemented by this Second Amendment, are hereby ratified and confirmed by Subtenant and Sublandlord in all respects.

[continued on the following page]

IN WITNESS WHEREOF. this Second Amendment has been executed as of the day and year first above written.

"SUBLANDLORD" MAKY ZANGANEH & ASSOCIATES
a California corporation

By: /s/ Maky Zanganeh Dated 7/29/2022

Name: Maky Zanganeh

Title: Coo

"SUBTENANT" SUMMIT THERAPEUTICS SUB, INC
a Delaware corporation

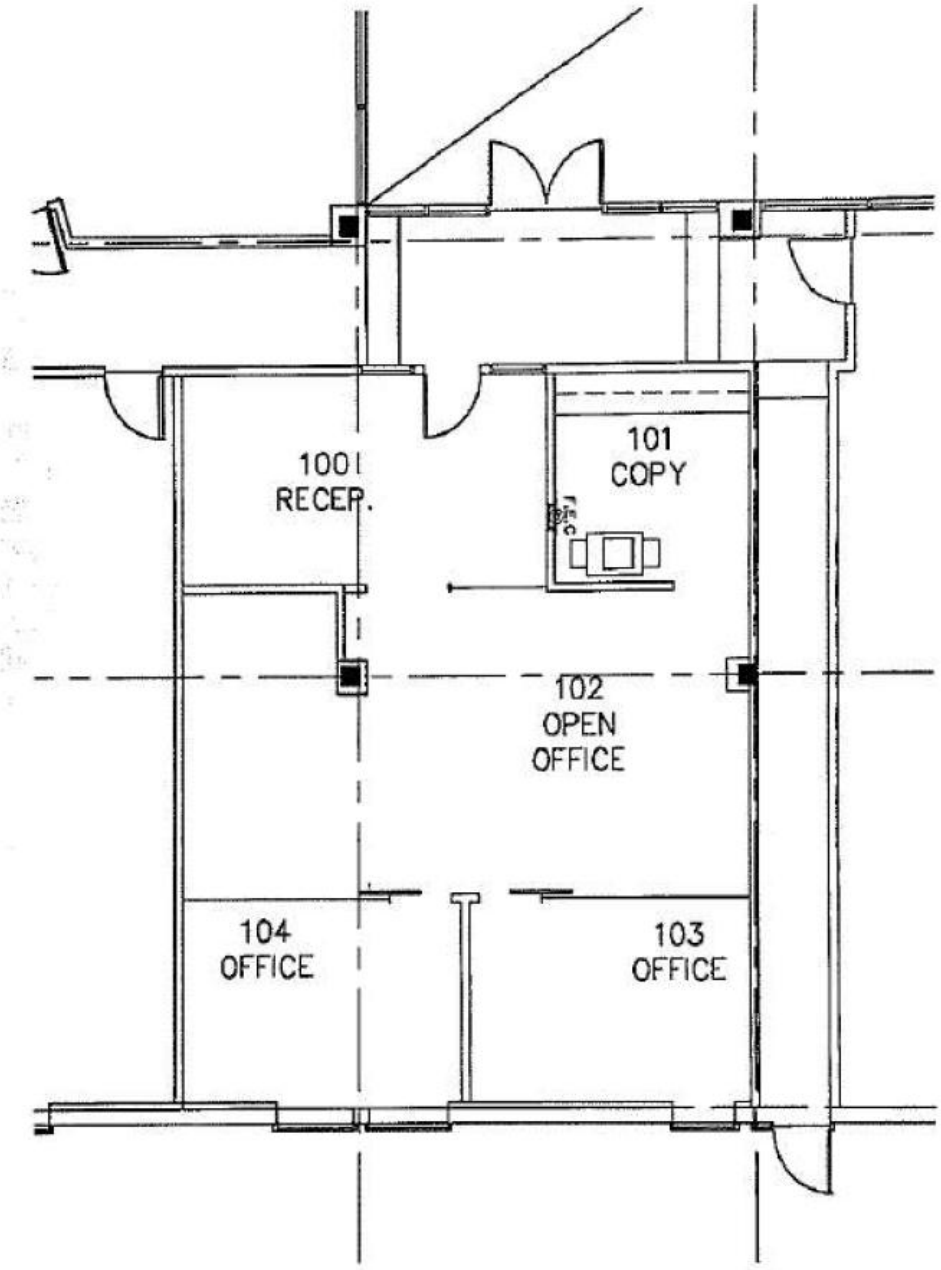
By: /s/ Ankur Dhingra Dated 7/24/2022

Name: Ankur Dhingra

Title: CFO

EXHIBIT A

EXPANSION PREMISES



SUITE 104 • FLOOR PLAN

EXHIBIT B

TENANT WORK LETTER

Except as specifically set forth herein, Sublandlord shall not be obligated to provide or pay for any improvement work or services related to the improvement of the Expansion Premises, and Subtenant shall accept the Expansion Premises in its presently existing, "as-is" condition. Notwithstanding the foregoing, Landlord has agreed with Tenant, at Landlord's sole cost and expense, to (i) install new carpet throughout the Expansion Premises, and (ii) repaint the interior walls of the Expansion Premises (the "**Tenant Improvements"**). All such Tenant Improvements shall be completed to Landlord's "Building standard" condition, using Building standard methods, materials, and procedures, in Building standard color or colors (if applicable) to be designated by Tenant, subject to availability, which designation shall be made by Tenant within five (5) days following Landlord's request.

The Landlord estimates that the total cost to perform the Tenant Improvements, plus a construction management fee determined in accordance with the terms in Section 7.6 of the Master Lease (the "**Total Cost**"), is likely to exceed [**] (i.e., an amount equal to [**] per rentable square foot of the Expansion Premises) (the "**Allowance Amount**"). If, however, the Total Cost is less than the Allowance Amount, and there is no then existing Event of Default by Tenant under the Lease (as amended), then Tenant may elect, by written notice to Landlord for Landlord to (i) provide Tenant with a credit (the "**Base Rent Credit**") against the payment(s) of Base Rent next due and owing for the Expansion Premises in an amount equal to the difference between the Allowance Amount and the Total Cost, or (ii) as an allowance towards Alterations to be performed by Tenant in the Premises in accordance with the terms set forth in Section 7.3 of the Original Lease (and which allowance shall be subject to disbursement by Landlord in accordance with Landlord's standard disbursement procedures). The Allowance Amount must be used as payment for the Tenant Improvements, or as Base Rent Credit, or as an allowance, each as provided hereinabove no later than December 31, 2022, and any portion of the Allowance Amount remaining after such date shall remain with Landlord and Tenant shall have no right or claim to the same.

Subtenant and Sublandlord agree that if the cost of the Tenant Improvements is less than the Tenant Allowance Amount, and there is no then existing Event of Default by Subtenant under the Sublease (as amended), then Subtenant may elect, by written notice to Sublandlord for the Sublandlord to provide Subtenant with a credit (the **" Base Rent Credit")** against the payment(s) of Base Rent next due and owing for the Expansion Premise in an amount equal to the difference between the Tenant Allowance Amount and the cost for the Tenant Improvements. Any portion of the Tenant Allowance Amount remaining after December 31, 2022 shall remain with Landlord and/ or if applicable with the Sublandlord and Subtenant shall have no right or claim to the same.

15 April 2022

Ankur Dhingra

Email: [**]

Re: Offer of Employment

Dear Ankur,

We are delighted to offer you the position of CFO at Summit Therapeutics, Inc. ("the Company"). Your start date will be May [31], 2022. We trust that your knowledge, skills and experience will be among our most valuable assets. This offer letter, together with the appendices attached hereto, sets forth the details of your employment and we would ask you to read through each of the sections and sign where indicated to accept this offer. An overview of the initial terms of your employment and compensation is set out below and in Appendix 1, Appendix 2, and Appendix 3.

Title: CFO. This position is classified as an exempt position under the Fair Labor Standards Act ("FLSA") and state law where applicable.

Location/Reporting Relationship: You are being offered the position of CFO reporting to Maky Zanganeh and Bob Duggan based in the California office. As you progress with the Company, your position and location are, of course, subject to change.

Job Duties: You will be expected to perform those duties and responsibilities commonly associated with your position as CFO as well as other duties commensurate with your position as may be requested by the Company from time to time.

Base Salary: Your initial salary will be $37,500 per monthly pay period, which amounts to an annual base salary of $450,000 subject to deductions for taxes and other withholdings, and payable in accordance with the Company's normal payroll schedule. Such base salary may be adjusted from time to time in accordance with normal business practice and in the sole discretion of the Company.

Eligibility for Bonuses and Bonus Potential: Please refer to the terms set out in Appendix 2.

Benefits: Please refer to the details in Appendix 2. Employee contributions for benefits will be determined annually and may be subject to change from time to time.

Expense Reimbursements: Please refer to the details in Appendix 2.

Vacation and Sick Time: Please refer to the details in Appendix 2.

Confidentiality and Inventions Agreement: A condition precedent of your employment is execution of the Confidentiality and Inventions Agreement (see Appendix 3), which must be signed prior to your first day of work. You may not participate in any outside consulting activities during your employment with the Company without approval and you must at all times abide by your fiduciary obligations to the Company and your obligations relating to confidentiality.

In addition, as a Company employee, you will be expected to abide by the Company's policies and procedures at all times. Further, the Company's premises, including all workspaces, furniture, documents, and other tangible materials, and all information technology resources of the Company (including computers, tablets, mobile phones, phone system, email system, internet, electronic data, and other electronic files) are subject to oversight and inspection by the Company at any time without notice. Even messages and files sent or received that employees believe have been deleted are subject to the Company's review. Company employees should have no expectation of privacy with regard to any Company premises, materials, resources, information, email, voicemail, computer system or other electronic resources.

Based on the representations that you have made, the Company understands that you are under no restrictions, including any contractual restrictions, prohibiting you from entering into an employment relationship with the Company and performing all of the duties of your position as CFO. As an employee, you will comply with any confidentiality, non-competition and non-solicitation agreements you may have signed with previous employers and you represent that any such agreements will not affect your abilities to perform your responsibilities on behalf of the Company. You agree to indemnify and hold the Company harmless for any liability the Company may incur as the result of the existence of any such covenants, obligations or commitments and alleged violations of the same made by any former employer.

This written offer supersedes any oral or written representations made to you during the interview process by any representative of the Company. This letter shall not be construed as an agreement, either express or implied, to employ you for any stated term, and in no way shall alter the Company's policy of employment at will.

We look forward to working with you as an employee and sincerely believe this position offers an excellent opportunity for you to make a significant contribution to our organization as well as to enhance your own career.

To accept this offer, please sign below and return a copy to the undersigned no later than 19th April 2022.

Sincerely,

/s/ Campbell Hair
Campbell Hair, Head of HR

ACCEPTANCE

I, Ankur Dhingra, accept the terms and conditions of the above offer of employment.

Accepted by: Ankur Dhingra

Signature: /s/ Ankur Dhingra April 15, 2022

Signature / Date

Appendix 1

Details of Employment Offer

These terms are incorporated into and made a part of the employment offer from the Company to Ankur Dhingra.

You understand and agree that you owe a fiduciary duty of loyalty, fidelity and allegiance to act at all times in the best interests of the Company and you will not knowingly become involved in a conflict of interest with the Company. In addition, you will comply with all of the Company's current rules and new rules that may be issued from time to time.

The Company is an at-will employer. This means that your employment with the Company is voluntarily entered into and you are free to resign at any time, with or without notice. Similarly, the Company is free to conclude the employment relationship at any time, for any lawful reason or no reason and with or without notice. Accordingly, there is no promise that your employment will continue for a set period of time or that your employment will be terminated only under particular circumstances. No supervisor or manager of the Company is authorized to make any oral or written representations that alter this "at-will" relationship. Any exception to this "at-will" relationship must be approved by the President of the Company.

Your employment is contingent upon satisfactory proof that you are legally authorized to work in the United States. All individuals who are offered employment are required to submit proof of their identity and employment authorization. The Company may obtain background check reports both pre-employment and from time to time during your employment with the Company, as necessary and as permitted by law.

Other than the Confidentiality and Inventions Agreement, this offer letter is the entire agreement between you and the Company and no other verbal or written agreements, promises or representations that are not specifically stated in this offer are or will be binding upon the Company and were not detrimentally relied upon by you in deciding whether to accept this offer. Any changes to the terms and conditions in this offer letter are effective only if signed by the President of the Company.

Appendix 2
Summary of Initial Compensation and Benefits

1. Salary:	Annual gross base salary of $450,000 payable by direct deposit in accordance with the Company's normal monthly payroll schedule.
2. Bonus:	Each calendar year of your employment, you shall be eligible to receive a discretionary bonus in an amount to be solely determined by the Company of up to 50% of your annual base salary, payable in accordance with the Company's normal payroll practices. Because retention is an important reason for the Company's implementation of an annual bonus system, you must be employed by the Company on the date of the bonus payout to be eligible to receive a bonus. If you are not an employee of the Company on the date of the bonus payout, for whatever reason, you are not entitled to the bonus.
3. Vacation, Sick, & Holidays:	You shall receive paid vacation, sick, and holidays according to the Company's policies for similarly situated executives and as required by state and local law. Notwithstanding the above, you shall be entitled to at least 4 weeks of vacation per year (accruing 1.66 vacation days per month) and may, according to Company Policy and applicable law, carry over some days of accrued but unused vacation day benefits earned in one year into the next year. Upon termination of your employment for any reason, you will be paid for any accrued but unused vacation day benefits, but not sick time.
4. Insurance and Retirement Plans:	You shall be entitled to participate in the Company's group insurance plans for its employees ("Group Insurance") for which you are eligible, which includes Healthcare, Dental, Life and Disability Plans for which Company and employee contributions will be determined annually. You shall also be entitled to participate in a 401k 'Safe Harbor' retirement plan. Details of these benefit plans and eligibility requirements will be provided.
5.. Stock Option:	You have received options to purchase up to 600,000 shares of the Company's Common Stock. The vesting will be four equal annual installments, with the initial vesting period commencing on the date approved by the Compensation Committee, and then on the next three anniversary's of such date. The Company shall provide you with additional details and documentation regarding the options, including the terms and conditions governing eligibility, entitlement

	to and receipt of title. All stock option awards are subject to the approval of the Board in their absolute discretion.
7. Expense & Mileage Reimbursement:	You shall be reimbursed in accordance with state law.

This Appendix 2 provides an overview of employee benefits. Certain information has been summarized from more detailed sources and is not intended to take the place of the more detailed group benefit plan descriptions. If there is a conflict between what this Appendix 2 states and the plan documents, the plan documents will override the information in this Appendix 2. The offer letter and Appendix 2 do not guarantee any specific level of benefits or the continuation of specific benefits. Summit reserves the right to revise, rescind, change, or terminate any benefit at any time, in its sole discretion. Plan details and Summary Plan Descriptions will be provided to you. In addition, details are available from Human Resources.

Appendix 3

CONFIDENTIALITY AND INVENTIONS AGREEMENT

I, Ankur Dhingra, have been advised that the success and growth of Summit Corporation and its parent, subsidiaries or affiliates, if any (jointly the "Company"), depends, to a significant degree, on the development, ownership, use and protection of commercially valuable technical and non-technical information. It is important to the Company that all such information which heretofore has been developed or may be developed in the future by the Company, by me or other Company employees, be protected. Accordingly, as a condition to, and in connection with, my employment or continued employment by the Company, my access to proprietary business information, the compensation now and hereafter paid to me, the benefits, training opportunities and other terms and conditions of my employment, I acknowledge and agree to the following:

1. CONFIDENTIALITY AND NON-DISCLOSURE

1.1 Access to Confidential information

As a valued employee of the Company, I understand that I will receive, observe, have access to, or be involved in the conception, discovery or development of, information, products or processes which the Company considers to be a Trade Secret, or confidential, proprietary information, including, but not limited to, ideas, functions, Inventions (as subsequently defined), analysis, protocols, benchmarks, modeling, projects, specifications, devices, new product formulations, improvements on existing products, software, codes, formulas, logarithms, distribution methods, know-how, systems, techniques, research and development, schematics or technical documentation, marketing strategies, customer and supplier lists, anticipated customer requirements, pricing, unpublished financial or accounting or tax information, information about potential acquisitions, divestitures and investments, business trends or projections, employee personal information and/or any other information relating to the Company its affiliates and their domestic or international business (hereinafter, individually or collectively, referred to as "Confidential Information").

The term "Trade Secrets" shall be given its broadest possible interpretation under the Defend Trade Secrets Act of 2016, and shall include (without limitation) all forms and types of financial, business, scientific, technical, economic, or engineering information, including patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, whether tangible or intangible, and whether or how stored, that is compiled, or memorialized physically, electronically, graphically, photographically, or in writing by the Company.

1.2 Nondisclosure/Non-Use of Confidential Information

I agree that, during the period of my employment by the Company and after the termination of my employment for any reason, I will not, without the express prior written consent of the Company, disclose to any person, firm, corporation or other entity, or seek to use for my own benefit or for the benefit of any third party, such Confidential Information.

However, this restriction shall not apply and I will be released from the same with respect to that information, but only that specific information: which

(a) which has already become public by publication or otherwise, through no fault or conduct of mine, or others acting on my behalf or in concert with me; or

(b) to the extent expressly permitted by Section 5 herein or as otherwise to the extent expressly permitted by applicable law.

1.3 Nondisclosure/Non-Use of Third-Party Confidential Information

I understand that the Company has received and in the future will receive from third parties confidential or proprietary information ("Third Party Information") subject to a duty on the Company's part to maintain the confidentiality of such information and to use it only for certain limited purposes. During the term of my employment and thereafter, I will hold Third Party Information in the strictest confidence and will not disclose (except as required to be disclosed in connection with my work for the Company) Third Party Information unless expressly authorized by an officer of the Company in writing. I will not make any permitted disclosures unless such disclosure is in strict compliance with the Company's publication and presentation clearance policy.

1.4 Competitive Intelligence

I recognize that the Company has a legitimate business goal to be the leading competitor in the marketplace. I understand that any information that I obtain about the Company's competitors must be obtained lawfully. I understand that the Company will not seek or accept any confidential or competitive information obtained through misrepresentation, coercion, illegal or improper means. Further, I understand that if I obtain information in this manner, the Company will terminate my employment.

1.5 Return of Company Property

I agree that all Company information and any tangible property (whether or not constituting Confidential Information) to which I am given access to, or which is developed by me, during the period of my employment shall be and shall remain the exclusive property of the Company and shall, upon the termination of my employment or immediately on demand by the Company, be surrendered to the Company, together with all copies, abstracts or excerpts, including any computer files or other materials which embody or which may disclose such information, etc. I further agree that I shall return to the Company any originals or duplicates of any tangible or intangible Company property and not retain any copies thereof.

2. <u>INVENTIONS</u>

2.1 I agree that the Company shall be the exclusive owner of any improvement, development, idea, design, modification, formulation, know-how, Trade Secret, research, discovery or invention (hereinafter collectively called "Inventions"), whether patentable or not, (and the same shall be considered a "work made for hire" for the Company by me), which I

conceive, make, develop, or improve, during my employment, either solely or jointly with others, whether during or outside of normal working hours, and relating to any project, method, functions, analysis, protocols, benchmarks, modeling, specifications, devices, new product formulations, re-formulations, improvements on existing products, software, codes, source codes, formulas, logarithms, distribution methods, systems, techniques, research and development, schematics or technical documentation that is used, sold or is under development or consideration by the Company (hereinafter called the "Company Products") now or at any time during the course of my employment, or which are now used in, or in the future might be particularly adapted to, the production, use, sale or development of any of the Company's Products, and I will immediately disclose the same in writing to the President of the Company or other person duly designated by the Company.

I further agree that I will promptly disclose such Inventions to the Company and will assign to the Company all of my rights, title and interests in and to such Inventions and will perform all acts and execute all assignments and other documents necessary to establish the Company's exclusive title and rights to such Inventions, as well as all patent, trademark or copyright applications and assignments of the same as may be required by the Company in connection therewith without additional compensation. In the event that my employment is terminated, for any reason whatsoever, I agree to assist the Company in pursuing and obtaining appropriate patents, copyrights, and trademarks filings provided that, with respect to my post-termination cooperation, the Company will pay reasonable compensation and expense for my time.

In the event Company is unable for any reason, after reasonable effort, to secure my signature on any document needed in connection with the actions specified in this section, I hereby irrevocably designate and appoint Company and its duly authorized officers and agents as my agent and attorney in fact, which appointment is coupled with an interest, to act for and on my behalf to execute, verify and file any such documents and to do all other lawfully permitted acts to further the purposes of the preceding paragraph with the same legal force and effect as if executed by me.

2.2 Exceptions and Presumptions

To the extent I have, or claim, any prior right to, or interest in, any Trade Secrets, confidential information or inventions that I do not wish to be covered by my obligations under this Agreement, including my agreement to disclose and assign to the Company all rights, title and interests thereto, I have fully listed all such Trade Secrets, confidential information and inventions in the attached ***Schedule A***. I agree that, in the absence of a particular matter or item being listed on such ***Schedule A***, I am not claiming, and will not claim, any rights with respect to such matter or item. Further, to the extent any such Trade Secret, confidential information or invention claimed, and is listed by me, on such ***Schedule A***, my reserved rights will apply only to those specified matters, and will not extend to any improvements or derivations which may, during the course of my employment (and for six months thereafter) be made to, or be based upon, such scheduled matters.

Further, I understand that, **in accordance with Section 2872 of the California Labor Code**, I am not required to assign Inventions to the Company for which no equipment, supplies, facilities or Trade Secret or Confidential Information of the Company was used, and which was developed entirely on my own time, unless: (a) the Invention relates to the business of Company or to the Company's actual or demonstrably anticipated research or development; or (b) the Invention results from any work performed by me for the Company. I have reviewed the notification on ***Schedule B*** (Limited Exclusion Notification) and agree that my signature acknowledges receipt of the notification.

The foregoing limited exclusion does not apply to any patent or invention covered by a contract between the Company and the United States or any of its agencies requiring full title to such patent or invention to be in the United States.

I further acknowledge that it is reasonable, and so agree, that any Trade Secret, confidential information or invention conceived, developed or claimed by me within six months after the termination of my employment with the Company, for any reasons whatsoever, shall be deemed to have been conceived or developed during the course of my employment by the Company, and shall be subject to this Agreement.

During the period of my employment and for six months after termination of my employment, I will promptly disclose all Inventions to the Company fully and in writing and will hold such Inventions in trust for the sole right and benefit of the Company. In addition, after termination of my employment, I will disclose all patent applications filed by me within a year after termination of employment which relate to any Invention or to any work performed by me while I was employed by Company. At the time of each such disclosure, I will advise Company in writing of any Inventions that I believe fully qualify for protection under the provisions of any applicable Specific Inventions Law; and I will at that time provide to Company in writing all evidence necessary to substantiate that belief. Company will keep in confidence and will not use for any purpose or disclose to third parties without my consent any confidential information disclosed in writing to Company pursuant to this Agreement relating to Inventions that qualify fully for protection under a Specific Inventions Law. I will preserve the confidentiality of any Invention that does not fully qualify for protection under a Specific Inventions Law.

2.3 Binding Upon My Estate

I understand that my obligations and the Company's rights under this Agreement shall continue notwithstanding any termination or cessation of my employment with the Company, and that these obligations shall be binding upon my heirs, executors, assigns, or other legal representatives, and shall inure to the benefit of the Company, its parent/affiliates, and its successors and assignees.

3. REMEDIES OF COMPANY

3.1 In the event of my breach of this Agreement, including, but not limited to, any circumstance under which I have already disclosed or used (or it appears likely or imminent that I will disclose or use) any Confidential Information, I agree that the Company would be

irreparably damaged by reason of my breach, disclosure or use and, therefore, in addition to any other statutory, legal or equitable remedies to which the Company may be entitled, the Company shall have the right to obtain preliminary and/or permanent injunctive relief against me with respect to such breach, disclosure or use, and any such injunction may be without bond by the Company, any such bond requirement being hereby waived by me. I agree that any claim or cause of action that I may have against the Company arising out of my employment with the Company will not constitute a defense to the Company's enforcement of this Agreement. I agree that if the Company is successful in whole or in part in any legal or equitable action against me under this Agreement, the Company will be entitled to payment of all costs, including reasonable attorney's fees, from me.

Additionally, I acknowledge and agree that the non-disclosure obligations herein are essential to the protection of the Company's legitimate business interests and protection of its Trade Secrets and Confidential Information.

3.2 I understand and acknowledge that my disclosure or use of Confidential Information by me may expose me to civil and criminal liability under applicable laws, including, but not limited to, any applicable federal or state trade secret acts.

4. SCOPE OF DISCLOSURE RESTRICTIONS

4.1 Nothing in this Agreement prohibits me from communicating with government agencies about possible violations of federal, state, or local laws or otherwise providing information to government agencies, filing a complaint with government agencies, or participating in government agency investigations or proceedings. I understand that I am not required to notify the Company of any such communications; provided, however, that nothing herein authorizes the disclosure of information I obtained through a communication that was subject to the attorney-client privilege. Further, notwithstanding my confidentiality and nondisclosure obligations, I acknowledge that the Company is hereby advising me as follows pursuant to the Defend Trade Secrets Act: "An individual shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that (A) is made (i) in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. An individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the attorney of the individual and use the trade secret information in the court proceeding, if the individual (A) files any document containing the trade secret under seal; and (B) does not disclose the trade secret, except pursuant to court order."

5. MISCELLANEOUS

5.1 Severability

In the event a court of competent jurisdiction determines that any provision of this Agreement is unreasonable, invalid or unenforceable, the court has the power to alter the provisions to make them reasonable, valid and enforceable. Any such provision shall be

independent and separate from all other provisions and the invalidity of any one or more such provisions shall not affect the enforceability of the other provisions in this Agreement. Additionally, although the Company and I believe that the limitations as to time, geographical area and scope of activity contained herein are reasonable and do not impose a greater restraint than necessary to protect the goodwill or other business interests of the Company, if it is judicially determined otherwise, the limitations shall be reformed to the extent necessary to make them reasonable and not to impose a restraint that is greater than necessary to protect the goodwill or other legitimate business interests of the Company; provided, however, that in the event that such reformation is judicially determined to be impermissible, the parties authorize the Court to strike any language necessary to make the limitations reasonable and not impose a restraint that is greater than necessary to protect the goodwill or other legitimate business interests of the Company. The Company and I agree that the remaining provisions of such applicable section shall be valid and binding as though any invalid or unenforceable provision had not been included.

5.2 Non-Disparagement

I agree that I will not directly or indirectly say or do anything that would disparage, reflect negatively on, or call into question the Company's business operations, products, reputation, business relationships, or the reputation of any past or present directors, officers, employees, agents or affiliates, parents or subsidiaries of the Company. I understand that this non-disparagement provision does not limit my rights under Section 7 of the National Labor Relations Act or otherwise restrict my right to discuss the terms and conditions of my employment.

5.3 Governing Law/Jurisdiction

This Agreement, the construction of its terms, and the interpretation of my rights, duties and obligations shall be governed by and construed in accordance with the substantive laws of the State of California, without regard to choice of law principles.

5.4 Entire Agreement/Amendments/Waivers

This Agreement is the final, complete and exclusive agreement of the parties with respect to the subject matter hereof and supersedes and merges all prior discussions. No amendment, modification or waiver of this Agreement, or any of its provisions, shall be effective, binding, or enforceable, unless in writing and signed by both parties to this Agreement. I acknowledge and agree that I have the right to consult with counsel prior to signing this Agreement.

5.5 Assignment

My obligations under this Agreement are personal and shall not be assigned by me. This Agreement shall, however, be binding upon and inure to the benefit of the Company and its successors and assigns, including any corporation or entity with which or into which the Company may be merged or that may succeed to all or substantially all of its assets or business. I expressly consent to be bound by the provisions of this Agreement for the benefit of any successor or assign of the Company without the necessity that this

Agreement be re-signed, in which event "Company" shall be interpreted to include any successor or assign of the Company. The Company has the right to assign without notice to or consent from me.

5.6 Survival

The provisions of this Agreement will survive the termination of my employment and the assignment of this Agreement by the Company to any successor in interest or other assignee. The Company is not obligated to notify me of any such assignment.

5.7 Change in Title/Job Duties

Any change or changes in my title, position, status, role, duties, salary, compensation or benefits or other terms and conditions of employment or service will not affect the validity or scope of this Agreement.

5.8 Waiver

No waiver by the Company of any breach of this Agreement will be a waiver of any preceding or succeeding breach. No waiver by the Company of any right under this Agreement will be construed as a waiver of any other right. The Company will not be required to give notice to enforce strict adherence to all terms of this Agreement.

5.9 Headings and Captions/Counterpart

The headings and captions of the various subdivisions of this Agreement are for convenience of reference only and will in no way modify or affect the meaning or construction of any of the terms or provisions hereof. This Agreement may be executed in two or more counterparts, and by different parties hereto on separate counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

I understand that this Agreement affects my rights to inventions I make during my employment, and restricts my right to disclose or use the Company's confidential information during or subsequent to my employment. I hereby acknowledge that I have had adequate opportunity to review these terms and conditions and to reflect upon and consider the terms and conditions of this Agreement, and that I have had the opportunity to consult with counsel of my own choosing regarding such terms. I further acknowledge that I fully understand the terms of this Agreement and have voluntarily executed this Agreement. I have also completely filled out ***Schedule A*** *to this agreement and read and acknowledged* ***Schedule B*** *to this agreement.*

Acknowledged and agreed:

Ankur Dhingra

By: /s/ Ankur Dhingra

Name: Ankur Dhingra

Title:

Date: April 15, 2022

Countersigned:

SUMMIT THERAPEUTICS, INC.

By: /s/ Campbell Hair

Name: Campbell Hair

Title: Head of HR

Date: April 15, 2022

SCHEDULE A

CONFIDENTIALITY AND INVENTIONS AGREEMENT

In accordance with Section 2 (INVENTIONS) of the above referenced Agreement, I claim prior rights to the following:

_____

_____

_____

_____

(If none, initial here_____)

Ankur Dhingra

By: _____

Name: _____

Title: _____

Date: _____

SCHEDULE B

LIMITED EXCLUSION NOTIFICATION

This Is To Notify you in accordance with Section 2872 of the California Labor Code that the foregoing Agreement between you and the Company does not require you to assign or offer to assign to the Company any invention that you developed entirely on your own time without using the Company's equipment, supplies, facilities or Trade Secrets except for those inventions that either:

(1) Relate at the time of conception or reduction to practice of the invention to the Company's business, or actual or demonstrably anticipated research or development of the Company;

(2) Result from any work performed by you for the Company.

To the extent a provision in the foregoing Agreement purports to require you to assign an invention otherwise excluded from the preceding paragraph, the provision is against the public policy of the State of California and is unenforceable.

This limited exclusion does not apply to any patent or invention covered by a contract between the Company and the United States or any of its agencies requiring full title to such patent or invention to be in the United States.

I Acknowledge Receipt of a copy of this notification.

By: /s/ Ankur Dhingra
Ankur Dhingra

Date: April 15, 2022

WITNESSED BY:

_____
Signature

_____
(Printed Name of Representative)

_____
Date

Exhibit 21.1

SUBSIDIARIES OF THE REGISTRANT

Name of Subsidiary	Jurisdiction of incorporation or organization
Summit (Oxford) Limited	England and Wales
Discuva Limited	England and Wales
Summit Therapeutics Sub Inc.	Delaware, USA
Summit Therapeutics Limited	England and Wales
Summit Corporation Limited	England and Wales
Summit (Wales) Limited	England and Wales
Summit (Cambridge) Limited	England and Wales
Summit Discovery 1 Limited	England and Wales
Summit Corporation Employee Benefit Trust Company Limited	England and Wales
MuOx Limited	England and Wales
Summit Infectious Diseases Limited	England and Wales

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (Nos. 333-249316 and 333-251958) and Form S-8 (Nos. 333-249313, 333-238582, and 333-264163) of Summit Therapeutics Inc. of our report dated March 9, 2023 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
March 9, 2023

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Robert W. Duggan, certify that:

1. I have reviewed this Annual Report on Form 10-K of Summit Therapeutics Inc.;

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

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

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 9, 2023

By: /s/ Robert W. Duggan

Name: Robert W. Duggan
Title: Chief Executive Officer and Executive Chairman; (Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF CO-CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Dr. Mahkam Zanganeh, certify that:

1. I have reviewed this Annual Report on Form 10-K of Summit Therapeutics Inc.;

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

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

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the Company's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 9, 2023

By: /s/ Maky Zanganeh

Name: Dr. Maky Zanganeh

Title: Executive Director, Co-Chief Executive Officer, President and member of the Board (Principal Executive Officer)

Exhibit 31.3

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Ankur Dhingra, certify that:

1. I have reviewed this Annual Report on Form 10-K of Summit Therapeutics Inc.;

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

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

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 9, 2023

By: /s/ Ankur Dhingra

Name: Ankur Dhingra
Title: Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF CO-CHIEF EXECUTIVE OFFICER(S) AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Summit Therapeutics Inc. (the "Company") for the year ended December 31, 2022, as filed with the U.S. Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company does hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his or her knowledge:

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

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

Dated: March 9, 2023

/s/ Robert W. Duggan

Name: Robert W. Duggan
Title: Chief Executive Officer and Executive Chairman
(Principal Executive Officer)

Dated: March 9, 2023

/s/ Maky Zanganeh

Name: Dr. Maky Zanganeh
Title: Executive Director, Co-Chief Executive Officer, President and member of the Board
(Principal Executive Officer)

Dated: March 9, 2023

/s/ Ankur Dhingra

Name: Ankur Dhingra
Title: Chief Financial Officer
(Principal Financial Officer)