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

FORM 10-K

(Mark One)

X **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31 , 2024

OR

o **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 001-38419

Arcus Biosciences, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**47-3898435**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

3928 Point Eden Way
Hayward , CA 94545
(Address of principal executive offices)

Registrant's telephone number, including area code: (510) 694-6200

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

Titles of Each Class	Trading Symbol(s)	Name of Each Exchange on which Registered
Common Stock, Par Value $0.0001 Per Share	RCUS	The New York Stock Exchange

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 x No o

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

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 x No o

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted 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 x No o

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

Large accelerated filer	x	Accelerated filer	o
Non-accelerated filer	o	Smaller reporting company	o
Emerging growth company	o		

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. o

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. x

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on The New York Stock Exchange on June 28, 2024 was $ 825,139,210 . This excludes 30,061,124 shares of the Registrant's Common Stock held by Gilead Sciences, Inc., and 7,129,056 shares held by executive officers, directors and stockholders affiliated with directors at that date. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by or under common control with the registrant.

The number of shares of Registrant's Common Stock outstanding as of February 19, 2025 was 105,841,422 .

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Definitive Proxy Statement relating to the 2024 Annual Meeting of Shareholders are incorporated by reference into Part III of this Report. The Definitive Proxy Statement will be filed within 120

days of the Registrant's fiscal year ended December 31, 2024.

Auditor Firm ID: 42	Auditor Name: Ernst & Young, LLP	Auditor Location: San Mateo, California , USA

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INFORMATION REGARDING FORWARD-LOOKING STATEMENTS AND OUR WEBSITE

This Annual Report on Form 10-K ("Annual Report") includes “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements relate to future events or to our future operating or financial performance and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. Forward-looking statements may include, but are not limited to, statements about:

- our expectations regarding our relationship with Gilead;
- our expectations regarding the timing and achievement of our investigational product development activities and ongoing and planned clinical trials, including initiation of new clinical trials, completion of enrollment and availability and timing for reporting of data from ongoing clinical trials;
- our ability to develop intra-portfolio combinations and highly-differentiated small-molecule investigational products, including our ability to create small-molecule investigational products with ideal pharmacological properties and desired clinical effects;
- our expectations regarding the efficiency and speed with which we can create and advance small-molecule investigational products and develop our investigational products and combination therapies;
- our reliance on third parties to conduct our ongoing and future clinical trials and third-party manufacturers to manufacture and supply our investigational products;
- our expectations regarding the nature of the immuno-oncology pathways we are targeting, the size of the potential patient population and the potential market size;
- our ability to obtain and maintain control of our combination investigational products and maximize the commercial potential of our investigational products;
- our ability to obtain and maintain regulatory approvals of our investigational products and the potential market opportunities for commercializing our investigational products;
- our ability to retain and recruit key personnel, estimates of our expenses, future revenue, capital requirements and our needs for additional financing;
- our ability to develop, acquire and advance investigational products into, and successfully complete, clinical trials;
- our initiation, scope, design, timing, progress and results of future research and development programs, preclinical studies and clinical trials;
- our ability to obtain and maintain intellectual property rights covering our investigational products;
- our expectations regarding the developments and projections relating to our competitors;
- our expectations regarding our industry; and
- our expectations as to the effect that geopolitical instability and public health outbreaks will have on our company.

The words “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “design,” “intend,” “expect,” “could,” “plan,” “potential,” “predict,” “seek,” “should,” “would” or the negative version of these words and similar expressions are intended to identify forward-looking statements. We have based these forward-looking statements on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, strategy, short- and long-term business operations and objectives and financial needs.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in the Risk Factor Summary below and in Item 1A of this Annual Report, “Risk Factors.” Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Annual Report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, advancements, discoveries, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, except as required by law, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Annual Report to conform these statements to actual results or to changes in our expectations.

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

We intend to use our website www.arcusbio.com as a means of disclosing material non-public information and for complying with our disclosure obligations under the Regulation FD. Such disclosures will be included on the company’s website under the heading “Investors & Media.” Accordingly, investors should monitor such portions of the company’s website, in addition to following the company’s press releases, SEC filings and public conference calls and webcasts (if any). The information contained on, or that may be accessed through our website is not part of, and is not incorporated into, this Annual Report on Form 10-K.

RISK FACTOR SUMMARY

The following is a summary of the key risks and uncertainties that make an investment in our securities speculative and risky. The below summary does not contain all of the information that may be important to you, and you should read this summary together with the more detailed description of the risks set forth under "Item 1A. Risk Factors" of this Annual Report.

Risks Related to our Limited Operating History, Financial Position and Capital Requirements

- We have a history of operating losses, have never generated any revenue from product sales and anticipate that we will continue to incur significant losses for the foreseeable future.
- We may need to obtain additional funding. If we do not receive or are unable to raise additional capital when needed, we may be forced to restrict our operations or delay, reduce or eliminate our product development programs.

Risks Related to the Discovery and Development of our Investigational Products

- If we are unable to obtain regulatory approval for our investigational products, or experience significant delays in doing so, our business will be materially harmed.
- Preliminary and interim data from our clinical studies that we announce or publish from time to time are subject to audit and verification procedures that could result in material changes in the final data and may change as more patient data become available.
- Enrollment and retention of subjects in clinical trials is expensive and time consuming and can be made more difficult or rendered impossible by competing treatments, clinical trials of competing investigational products, geopolitical instability and public health epidemics, each of which could result in significant delays and additional costs in our product development activities, or in the failure of such activities.
- Serious adverse events, undesirable side effects or other unexpected properties of our investigational products may be identified during development or after approval, which could lead to the discontinuation of our clinical development programs, refusal by regulatory authorities to approve our investigational products or limitations on the use of our investigational products or, if discovered following marketing approval, revocation of marketing authorizations or subsequent limitations on the use of our investigational products.
- A key element of our strategy is the development of intra-portfolio combinations. If we are not successful in discovering, developing and commercializing investigational products that take advantage of different mechanisms of action to achieve superior outcomes relative to the use of single agents or other combination therapies, our ability to achieve our strategic objectives would be impaired.
- Certain of our investigational products may require companion diagnostics in certain indications. Failure to successfully develop, validate and obtain regulatory clearance or approval for such tests could harm our product development strategy or prevent us from realizing the full commercial potential of our investigational products.

Risks Related to Reliance on Third Parties, Manufacturing and Commercialization

- We expect to depend on our collaboration with Gilead Sciences, Inc. ("Gilead") for the research, development, manufacture and commercialization of our investigational products. If this collaboration is not successful, our business could be adversely affected.
- We rely on third parties to conduct our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects.
- Even if we receive marketing approval, we may not be successful in commercializing our investigational products.

- Even if we receive marketing approval for one or more of our investigational products, our commercial success is dependent on obtaining coverage and reimbursement approval for a product from a government or other third-party payor, which coverage may be delayed or may not be sufficient to cover our costs.
- Obtaining and maintaining regulatory approval of investigational products in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. Even if our investigational products are approved by the FDA, they may never be approved or commercialized outside the United States ("U.S."), which would limit our ability to realize their full market potential.
- Any investigational products for which we intend to seek approval as biologic products may face competition sooner than anticipated.

Risks Related to our In-Licenses and Other Strategic Agreements

- We are currently party to several in-license agreements under which we acquired rights to use, develop, manufacture and/or commercialize certain of our investigational products. If we breach our obligations under these agreements, we may be required to pay damages, lose our rights to these investigational products or both, which would adversely affect our business and prospects.

Risks Related to Intellectual Property

- If we are unable to obtain and maintain sufficient intellectual property protection for our investigational products, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be adversely affected.
- We may become involved in lawsuits alleging that we have infringed the intellectual property rights of third parties or to protect or enforce our patents or other intellectual property, which litigation could be expensive, time consuming and adversely affect our ability to develop or commercialize our investigational products.
- Changes in patent law in the U.S. and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our investigational products.
- We may rely on trade secret and proprietary know-how which can be difficult to trace and enforce, and if we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

Risks Related to our Business Operations and Industry

- We expect to expand our business operations and, as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.
- We face substantial competition, which may result in others discovering, developing or commercializing products more quickly or marketing them more successfully than us. If their investigational products are shown to be safer or more effective than ours, then our commercial opportunity will be reduced or eliminated.
- Our internal information technology systems, and those of our third-party CROs and other third parties upon which we rely, are subject to failure, security breaches and other disruptions, which could result in a material disruption of our investigational products' development programs, jeopardize sensitive information, prevent us from accessing critical information or result in a loss of our assets, and potentially expose us to notification obligations, loss, liability or reputational damage and otherwise adversely affect our business.
- Failure to comply with privacy and data protection laws, regulations or other obligations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.
- Changes in healthcare law and implementing regulations, as well as changes in healthcare policy, may impact our business in ways that we cannot currently predict, and may have a significant adverse effect on our business and results of operations.

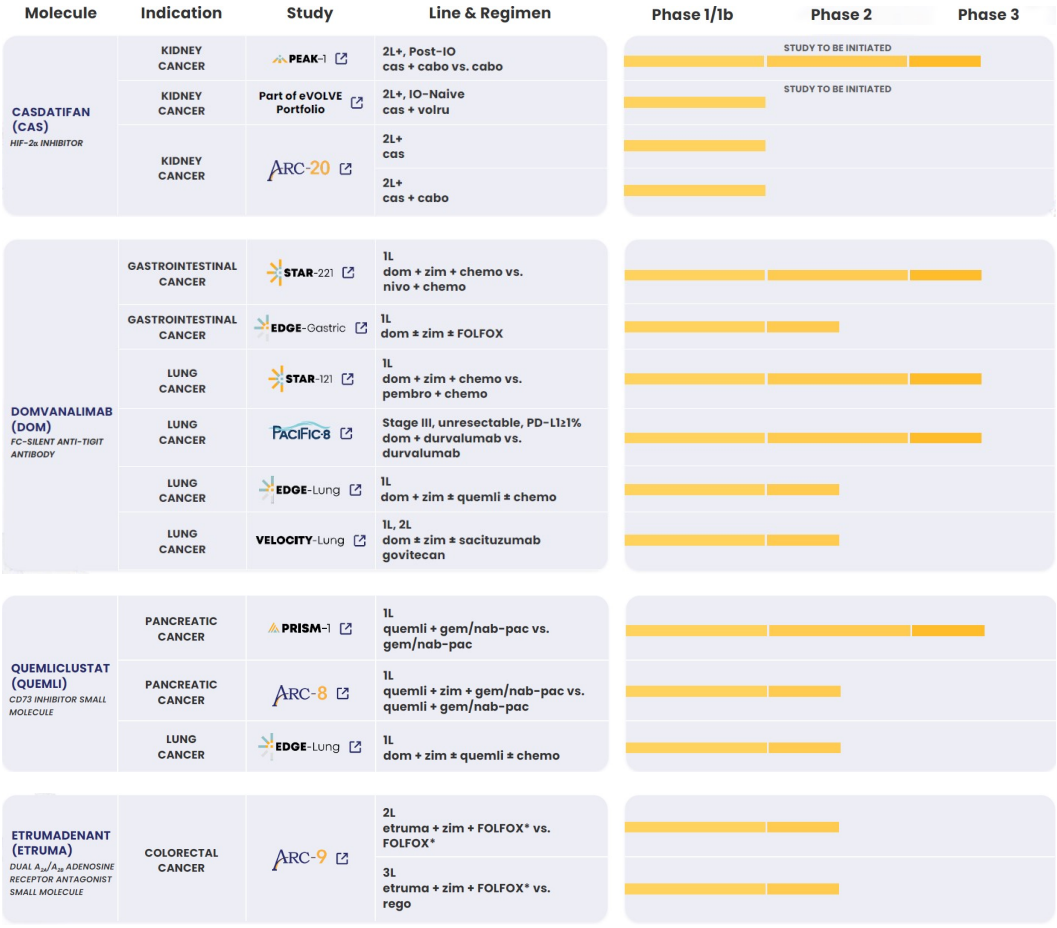
PART I

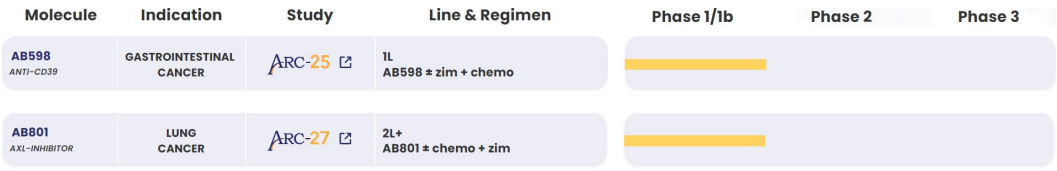
Item 1. Business

Company Overview

We are a clinical-stage biopharmaceutical company focused on creating best-in-class therapies. Using our robust and highly efficient drug discovery capability, we have created a significant portfolio of investigational products which are in clinical development, with our most advanced molecule, an anti-TIGIT antibody, now in multiple Phase 3 registrational studies targeting lung and gastrointestinal ("GI") cancers. Our deep portfolio of novel small molecules and enabling antibodies allows us to create highly differentiated therapies, which we are developing to treat multiple large indications. We expect our clinical-stage portfolio to continue to expand and to include molecules targeting immuno-oncology, cancer cell-intrinsic and immunological pathways. Our vision is to create, develop and commercialize highly differentiated therapies that have a meaningful impact on patients.

The below summarizes our current clinical-stage portfolio:





cabo: cabozantinib; cas: casdatifan; chemo: chemotherapy; dom: domvanalimab; etruma: etrumadenant; gem/nab-pac: gemcitabine/nab-paclitaxel; IO: immuno-oncology; nivo: nivolumab; pembro: pembrolizumab; quemli: quemliclustat; RCC: renal cell carcinoma; rego: regorafenib; zanza: zanzalintinib; zim: zimberelimab

*+/- biologic, e.g. bevacizumab or biosimilar, will be included for all patients in whom it is not contraindicated.

Our Clinical Product Portfolio

We currently have seven clinical programs focused on unique targets including HIF-2α, TIGIT, PD-1, adenosine A2a and A2b receptors, CD73, CD39, and AXL. In 2020, we entered into an Option, License and Collaboration Agreement (as amended, the "Gilead Collaboration Agreement") with Gilead to strategically advance our portfolio through a collaborative relationship. The Gilead Collaboration Agreement provides Gilead with an exclusive license to our anti-PD-1 program (including zimberelimab) and time-limited exclusive option rights to our clinical programs, which they have exercised for our anti-TIGIT program (including domvanalimab), adenosine receptor antagonist program (including etrumadenant) and CD73 program (including quemliclustat). Our HIF-2α program (including casdatifan) is no longer subject to Gilead's option under the Gilead Collaboration Agreement and Gilead has no further rights to the program. The Gilead Collaboration Agreement and our strategic partnership with Gilead is discussed in more detail below under "License and Collaborations—Gilead Collaboration".

HIF-2α Program

Casdatifan is our oral, small-molecule inhibitor of HIF-2α and is our first investigational product against a cancer cell-intrinsic target to enter clinical development. HIF-2α is a protein that is involved in sensing oxygen availability in multiple organs. In certain tumors, HIF-2α activity is highly dysregulated as a result of genetic abnormalities. This creates a situation of pseudohypoxia and the abnormal increase in HIF-2α-mediated expression of a wide array of proteins involved in cancer cell proliferation, survival, treatment resistance and angiogenesis.

Our focus for casdatifan is to maximize the opportunity in clear cell renal cell carcinoma ("ccRCC") across a variety of settings using a multi-pronged clinical development plan. The initial registrational pathways that we plan to pursue will focus on combination approaches that build on top of standard of care therapies, while also exploring opportunities for casdatifan to become a foundational standard of care. Our development program for casdatifan currently includes the following:

- **PEAK-1** is a planned Phase 3 clinical trial to evaluate casdatifan and cabozantinib in ccRCC patients that have received prior immunotherapy, which we expect to initiate in the second quarter of 2025.
- A planned Phase 1b clinical trial that is part of AstraZeneca's eVOLVE portfolio, where we expect to evaluate casdatifan and volrustomig (AstraZeneca's anti-PD-1 / anti-CTLA-4 bispecific antibody) in patients with advanced ccRCC who have not received prior immunotherapy (IO-naive setting). Ipilimumab, an anti-CTLA-4 antibody, plus nivolumab, an anti-PD-1 antibody, is approved as a standard of care therapy in first-line ccRCC. We expect the Phase 1b portion to be initiated by the middle of 2025.
- **ARC-20** is a Phase 1 clinical trial evaluating casdatifan in multiple cohorts, including cohorts evaluating: (1) casdatifan monotherapy (50 mg, 100 mg and 150 mg) in late-line ccRCC; (2) casdatifan and cabozantinib in second-line ccRCC; (3) casdatifan plus zimberelimab in first-line ccRCC; (4) casdatifan monotherapy in first-line ccRCC patients with IMDC score of "favorable risk"; and (5) casdatifan monotherapy in ccRCC patients that have received prior immuno-oncology therapy.

We recently shared interim data from three cohorts of our ARC-20 study, each evaluating casdatifan monotherapy in ccRCC patients at different doses. At the time of data cut-off (January 3, 2025), the analysis showed that most patients in each cohort (81-87%) experienced disease control with either a partial response or stable disease and were still on treatment. Key highlights from the analysis include an observed 33% response rate in the cohort administering 100mg of casdatifan once daily and the cohort administering 50mg of casdatifan twice a day showing a median progression-free survival ("mPFS") of 9.7 months (the mPFS for the other cohorts had not been reached at the time of the data cut-off).

Anti-TIGIT Program

TIGIT is believed to play an important role in suppressing the immune response to cancer. The primary ligand for TIGIT (T cell immunoreceptor with Ig and ITIM domains) is CD155, a protein that plays both inhibitory and stimulatory roles in regulating the activity of effector immune cells, such as T and natural killer ("NK") cells. TIGIT is an inhibitory receptor highly expressed on T cells displaying an exhausted phenotype, tumor-infiltrating Treg, and NK cells. During the past couple of years, expression of TIGIT, along with PD-1, on precursor exhausted T cells ("Tpex"), a key population that mediates some of the therapeutic effects of anti-PD-1 agents, has become well documented. The ligands for TIGIT, including CD155, are broadly expressed on multiple cell types in the tumor microenvironment, including cancer cells. CD155 binding to TIGIT results in inhibition of immune cells.

As T cells are important in the immune response, domvanalimab was engineered to lack Fc-receptor binding in order to minimize the risk of depleting such cells, which we believe may provide domvanalimab with an advantage over Fc-enabled anti-TIGIT antibodies.

We are pursuing a broad Phase 2 and Phase 3 development program for domvanalimab in combination with our anti-PD-1 antibody, zimberelimab, in multiple settings, including lung, GI and head and neck cancers. As described below, each of our Phase 3 studies are evaluating domvanalimab with a PD-(L)1 antibody versus the relevant global standard of care. We estimate that the total addressable market for the ongoing and planned Phase 3 trials of domvanalimab is over $10 billion annually, based on the size of the drug treatable U.S. patient populations.

We have the following ongoing Phase 3 studies for domvanalimab:

- **STAR-221** is a Phase 3 study evaluating domvanalimab in combination with zimberelimab and chemotherapy versus nivolumab and chemotherapy in first-line unresectable or metastatic GI cancers.
- **STAR-121** is a Phase 3 study evaluating domvanalimab in combination with zimberelimab and chemotherapy versus pembrolizumab and chemotherapy in first-line non-small cell lung cancer ("NSCLC").
- **PACIFIC-8** is a Phase 3 study evaluating domvanalimab in combination with durvalumab following chemoradiation in Stage 3 NSCLC, a setting in which durvalumab is already approved.

In addition, we are evaluating domvanalimab in the following Phase 2 studies:

- **EDGE-Gastric** is a Phase 2 study evaluating the combination of domvanalimab and zimberelimab with and without FOLFOX in GI cancers.
- **EDGE-Lung** is a Phase 2 study evaluating the combination of domvanalimab and zimberelimab with and without quemliclustat and chemotherapy in first- and second-line NSCLC.
- **VELOCITY-Lung** is a Phase 2 study evaluating domvanalimab with and without zimberelimab and sacituzumab govitecan-hziy ("Trodelvy®") in first- and second-line NSCLC.

Anti-PD-1 Program

We are currently evaluating zimberelimab with various intra-portfolio combination partners in many of our ongoing clinical studies. Zimberelimab has been approved in China for classical Hodgkin's Lymphoma, based on data generated independently by Guangzhou Gloria Biosciences, Co. ("Gloria Biosciences"), which owns the commercial rights to zimberelimab in China. To date, zimberelimab has been evaluated by us and Gloria Biosciences, either alone or in combination with other agents, in over 2,500 patients.

Adenosine Pathway Programs

Under conditions of cellular damage or cell death, such as in response to certain chemotherapies, large amounts of adenosine triphosphate ("ATP") are released into the extracellular environment, where it is converted into adenosine monophosphate by the enzyme CD39 and then into adenosine by the enzyme CD73. The generation of large amounts of extracellular adenosine results in an immunosuppressive response that counteracts some of the potentially beneficial effects of chemotherapy. Two receptors important in mediating the effect of adenosine are A2a, which is expressed on T and NK cells, and A2b, which is co-expressed with A2a on myeloid cells. We currently have three clinical programs targeting the adenosine pathway.

CD73 Program

Quemliclustat is a small molecule inhibitor that targets the CD73 enzyme in the ATP-adenosine pathway. The CD73 enzyme plays a critical role in the last step in the conversion of extracellular ATP into adenosine. We believe targeting CD73 could be a highly effective approach to inhibiting adenosine-mediated immune suppression by suppressing adenosine generation.

We believe quemliclustat was the first small-molecule CD73 inhibitor to enter clinical development. While there are several anti-CD73 antibodies in development, we believe that a small-molecule approach to CD73 inhibition could offer several advantages, including more complete inhibition of CD73 enzymatic activity, deeper tumor penetration, and potential for both intravenous and oral delivery.

In addition to the EDGE-Lung study described above, we are evaluating quemliclustat in the following studies:

- **PRISM-1** is a Phase 3 study in metastatic pancreatic cancer evaluating quemliclustat with gemcitabine and nab-paclitaxel (the standard-of-care chemotherapies used for advanced pancreatic cancer) against gemcitabine and nab-paclitaxel.
- **ARC-8** is a Phase 1b study in metastatic pancreatic cancer evaluating quemliclustat with gemcitabine and nab-paclitaxel (the standard-of-care chemotherapies used for advanced pancreatic cancer) with or without zimberelimab.

Adenosine Receptor Antagonist Program

Etrumadenant is an orally bioavailable small molecule. Unlike most other clinical-stage adenosine receptor antagonists, which only target one of the two receptors, etrumadenant is a highly potent and reversible antagonist of the adenosine A2a and A2b receptors. We believe that activation of the adenosine A2a receptors on T cells, NK cells and myeloid cells mediates a significant portion of the immunosuppressive effects of adenosine. Further, because binding of adenosine to A2b receptors on myeloid cells also contributes significantly to intra-tumoral immune suppression, we believe that activating these A2b receptors will further mitigate adenosine's immunosuppressive effects. Consequently, etrumadenant could prove to have more robust anti-tumor effects and activity in a broader range of tumor types than other adenosine A2a or A2b antagonists in clinical development.

Our studies evaluating etrumadenant are designed to support the potential of etrumadenant in multiple indications that represent substantial market opportunities with significant unmet need. We are evaluating etrumadenant in our ARC-9 study. ARC-9 is a Phase 2 study evaluating etrumadenant with zimberelimab and FOLFOX, and with and without bevacizumab vs. FOLFOX with and without bevacizumab or regorafenib in second- and third-line metastatic colorectal cancer.

CD39 Program

CD39 is a key enzyme in the adenosine pathway and facilitates the removal of ATP from the tumor microenvironment and its conversion into adenosine. AB598 is our anti-CD39 antibody. By targeting the CD39 enzyme, we hope to increase ATP in the tumor environment which could, in turn, lead to an enhanced adaptive (T cell) immune response against tumors. We are evaluating AB598 in our ARC-25 study. ARC-25 is a Phase 1/1b study evaluating AB598 with and without zimberelimab and chemotherapy in gastric cancers.

AXL Program

The AXL receptor tyrosine kinase ("AXL") is a transmembrane protein overexpressed in a variety of cancers and certain immune cells. AXL signaling has been implicated in creating an immunosuppressive tumor microenvironment, promoting resistance to chemotherapy and immunotherapy drugs, and is associated with poor prognosis in a variety of cancers. AB801 is our AXL inhibitor and is being evaluated in our ARC-27 study. ARC-27 is a Phase 1b study evaluating AB801 with and without chemotherapy in NSCLC.

Our Early-Stage Drug Discovery Programs

We have active early-stage discovery efforts focused on the creation of additional development candidates aimed at regulating various aspects of the anti-tumor immune response as well as other cancer-intrinsic pathways, which we believe play an important role in many human cancers. Casdatifan, quemliclustat, etrumadenant, AB801 and AB598 are all products of our internal discovery program. We are currently pursuing several new small molecules aimed at modulating key biological pathways in various types of cancer that are responsible for the abnormal growth and resistance to current therapies.

We also have several active early-stage discovery efforts focused on the discovery of molecules that regulate excessive immune activity in the context of various types of inflammation and auto-immune diseases.

Commercialization Plans

Subject to timely exercise of Gilead's and Taiho Pharmaceutical Co., Ltd.'s ("Taiho") respective option rights discussed below, the Gilead Collaboration Agreement provides us with a potential commercialization partner for the U.S. and the rest of the world, excluding Japan and certain other Asian countries, and the Option and License Agreement that we entered into with Taiho (the "Taiho Agreement") provides us with a potential commercialization partner for Japan and certain other Asian countries. For those investigational products being developed in a program that Gilead does not exercise its option to (such as casdatifan), we expect to have the infrastructure or additional third-party collaborations in place to commercialize such projects with an experienced sales, marketing and distribution organization. In the U.S., we have an option to co-promote with Gilead, which we have elected for domvanalimab and zimberelimab. As we approach commercialization, we intend to begin building the necessary infrastructure and sales, marketing and commercial capabilities to co-promote our products, if approved, for the U.S.

Licenses and Collaborations

Gilead Collaboration

Clinical Programs

Under the Gilead Collaboration Agreement, Gilead obtained an exclusive license to develop and commercialize our anti-PD-1 program (including zimberelimab) in certain markets and time-limited exclusive options to develop and commercialize (i) any of our clinical programs existing at the time of entering into the Gilead Collaboration Agreement and (ii) any programs that enter clinical development during the 10-year collaboration term. Gilead's continued option rights are contingent upon Gilead making $100 million continuation payments on each anniversary of the agreement in 2026 and 2028.

Gilead's options expire, on a program-by-program basis, after a prescribed period, following the achievement of a clinical development milestone in such program and our delivery to Gilead of the requisite data package. To date, Gilead has exercised its option to our anti-TIGIT program (including domvanalimab), adenosine receptor antagonist program (including etrumadenant) and CD73 program (including quemliclustat). Gilead's option rights to our HIF-2α program (including casdatifan) have expired. Gilead may exercise its option to additional programs at any time prior to the expiration of the option and upon payment of an option fee of $150 million per program.

For each program that Gilead has exercised its option, both companies will co-develop and equally share global development costs, subject to certain opt-out rights that we have, caps on our spending and related subsequent adjustments, and certain other exceptions.

For each optioned program, provided we have not exercised our opt-out rights (if applicable), we have an option to co-promote in the U.S. with equal sharing of related profits and losses. Gilead has the right to exclusively commercialize any optioned programs outside of the U.S., subject to the rights of our existing partners to any territories, and Gilead will pay to us tiered royalties as a percentage of revenues ranging from the high teens to the low twenties. Further, with respect to domvanalimab, we remain eligible to receive up to $500 million in milestone payments.

Preclinical Programs

Under the Gilead Collaboration Agreement, Gilead has also received options to two oncology research programs (the "Oncology Research Programs") and up to four jointly selected research programs that target inflammatory diseases (the "Inflammation Research Programs"). We will lead discovery and early development activities for all Oncology Research Programs and Inflammation Research Programs.

With respect to the Oncology Research Programs, Gilead has the right to exercise its option, on a program-by-program basis, upon our completion of certain IND-enabling activities for an option payment of $60 million. If the option is exercised by Gilead at this stage, the collaboration terms for optioned programs will be applicable to each research program except, with respect to commercialization outside of the U.S., Gilead would pay us tiered royalties as a percentage of revenues ranging from high single digits to low double digits. If Gilead declines to exercise its option at this stage, Gilead maintains an option, on a program-by-program basis, which must be exercised prior to the expiration of a prescribed period following the achievement of a clinical development milestone in such program and our delivery to Gilead of the requisite data package. If the option is exercised by Gilead at this later clinical stage for an option payment of $150 million, the collaboration terms for optioned programs will be applicable to the joint development program including that, with respect to commercialization outside of the U.S., Gilead would pay us tiered royalties as a percentage of revenues ranging from the high-teens to the low twenties.

With respect to the Inflammation Research Programs, we have received an aggregate of $35 million for the two Inflammation Research Programs that have been jointly selected and will receive an upfront payment of $17.5 million for any additional Inflammation Research Program selected prior to May 12, 2025. For Inflammation Research Programs, Gilead will have an option to license each program at two separate, prespecified time points. For the first two Inflammation Research Programs, Gilead has the right, on a program-by-program basis, to either (i) exercise its option upon our completion of certain IND-enabling activities for an option payment of $45 million or (ii) extend its option and exercise it following the achievement of a clinical development milestone for an option payment of $150 million. If Gilead exercises its option at the earlier time point for the first two programs, we would be eligible to receive up to $375 million in regulatory and commercial milestone payments as well as tiered royalties for each optioned program. For any other Inflammation Research Program option exercised by Gilead, the parties would have rights to co-develop and share global development costs and to co-commercialize and share profits in the U.S. for that program.

Common Stock Purchase Agreement and Investor Rights Agreement

In connection with our entry into the Gilead Collaboration Agreement, we and Gilead entered into a Common Stock Purchase Agreement (as amended, the "Stock Purchase Agreement") and Investor Rights Agreement (as amended, the "Investor Rights Agreement"). We refer to the Gilead Collaboration Agreement, Stock Purchase Agreement and Investor Rights Agreement as the "Gilead Agreements". Under the Stock Purchase Agreement, Gilead has the right, at its option, to purchase additional shares from us, up to a maximum ownership of 35% of our then-outstanding voting common stock, from time to time until July 2025, at a purchase price per share equal to the greater of a 20% premium to market (based on a trailing five-day average closing price) at the time Gilead exercises such option, and the $33.54 initial purchase price per share. The Investor Rights Agreement provides Gilead with registration rights, pro rata participation rights in certain future financings and the right to designate three individuals, which they have exercised, to be appointed to our board of directors.

Taiho License

In 2017, we entered into the Taiho Agreement pursuant to which Taiho obtained an exclusive option to in-license development and commercialization rights to programs during a five-year term for which IND-enabling studies had begun. These rights are geographically limited to Japan and certain other Asian countries (excluding China) (the "Taiho Territory"). To date, Taiho has exercised its option to (i) etrumadenant (the adenosine receptor antagonist program); (ii) zimberelimab (the anti PD-1 program); (iii) domvanalimab and AB308 (the anti-TIGIT program); and (iv) quemliclustat (the CD73 program). While the five-year term expired in September 2022, Taiho retains option rights to our HIF-2α program (including casdatifan) and CD39 program (including AB598). Taiho's options to these programs expire, on a program-by-program basis, after a prescribed period following the achievement of a clinical development milestone in such program and our delivery to Taiho of the requisite data package.

For each Taiho optioned program, Taiho is obligated to pay to us (i) an option exercise payment for each program that is between $3 million to $15 million, (ii) clinical, regulatory and commercialization milestones of up to $275 million and (iii) royalties on net sales in Taiho's territories ranging from high single digits to mid-teens. Royalties will be payable on a licensed product-by-licensed product and country-by-country basis during the period of time commencing on the first commercial sale of a licensed product in a country and ending upon the later of: (a) ten (10) years from the date of first commercial sale of such licensed product in such country; and (b) expiration of the last-to-expire valid claim of our patents covering the manufacture, use or sale or exploitation of such licensed product in such country. Taiho is also responsible for the development and commercialization of licensed products in the Taiho Territory.

WuXi Biologics License - anti-PD-1

Our PD-1 license agreement (the "WuXi PD-1 Agreement") with WuXi Biologics Ireland Limited ("WuXi Biologics"), which we entered into in 2017 as subsequently amended, provides us with an exclusive license to (i) develop, use and manufacture products that include an anti-PD-1 antibody, including zimberelimab, throughout the world and (ii) commercialize any such products, throughout the world except in Greater China. Pursuant to the terms of the WuXi PD-1 Agreement, we may incur future clinical and regulatory milestone payments, commercialization milestone payments up to $375 million, and royalty payments that range from high single-digits to low teens of net sales beginning on the first commercial sale and ending on the later of (i) ten (10) years following such first commercial sale and (ii) the expiry of all patents that may subsequently be issued or granted that cover the product in such country, hereafter referred to as the royalty term.

Under the WuXi PD-1 Agreement, we are obligated to appoint WuXi Biologics as our exclusive manufacturer of the drug substance for such licensed products for a specified period of time subject to certain exceptions. Our sublicensees, however, may manufacture, at any time, certain portions of their requirements for such product subject to certain conditions. We made certain covenants not to commercialize any anti-PD-1 antibody licensed or obtained by us after the date of the license agreement with WuXi Biologics other than anti-PD-1 antibodies licensed from WuXi Biologics, subject to certain exceptions as set forth in the WuXi Agreement. This agreement terminates, on a licensed product-by-licensed product and country-by-country basis, on expiration of the royalty term for such licensed product for the applicable country.

Abmuno License

In 2016, we entered into a license agreement (the "Abmuno Agreement") with Abmuno Therapeutics LLC ("Abmuno") for a worldwide exclusive license to develop, use, manufacture, and commercialize products that include an anti-TIGIT antibody, including domvanalimab. Under the agreement, we may be required to make additional clinical, regulatory and commercialization milestone payments of up to $88 million.

The Abmuno Agreement terminates on the latest of (i) the expiry of the last-to-expire Abmuno licensed patent that covers a product that contains an anti-TIGIT antibody, (ii) the date on which there is no longer an Abmuno licensed patent application that is still pending and has been pending for a certain period of time that covers a product that contains an anti-TIGIT antibody and (iii) 10 years from the date of first commercial sale.

Our Strategy

Our overarching vision is to create a broad portfolio of best-in-class therapies and develop combinations that bring transformative clinical benefits over current treatment options. Our clinical development approach aims to generate meaningful data in the most efficient manner possible in order to rapidly advance our investigational products through clinical trials. Some of the key elements of our strategy include:

- **Building a differentiated portfolio by focusing on intra-portfolio combinations.** We are building a diverse portfolio of small-molecule investigational products, such as casdatifan, that target different immune mechanisms, as well as cell-intrinsic pathways important for cancer growth and metastasis. In addition to small molecules, we are also developing antibody investigational products that target what we believe are some of the most important immune checkpoint receptors, including PD-1 and TIGIT, that we expect to be critical components of our intra-portfolio combinations. By combining these antibody candidates with our internally discovered small-molecule investigational products, we believe we can create highly differentiated combination products.
- **Designing our clinical trials to advance our compounds as quickly and efficiently as possible** . Our goal is to identify the best combinations and settings and to rapidly generate randomized proof-of-concept data for our investigational products early in their development. We leverage platform trial designs, such as our ARC-20 and EDGE-Lung studies, which allow us to evaluate multiple dosages, combinations and settings for a single tumor type in one clinical trial and compare those combinations against combinations that include the standard-of-care.

- **Pursuing combinations and indications based on strong biological rationales** . In selecting indications to pursue, we are focusing on those that are most dependent on the pathways targeted by our agents. We are also focusing on patient populations and settings where we believe there is still considerable unmet need. As an example, several oncology indications, such as pancreatic cancer and colorectal cancer, have a high percentage of cases that are driven by certain oncogenic mutations (e.g., KRAS mutations) which are associated with poor responses to current available therapies and poor overall survival, and are associated with high expression levels of CD73.
- **Maximizing the value of our portfolio through strategic collaborations and research and development arrangements.** We seek to establish collaborative relationships that will provide us with access to capital, opportunities and/or expertise. For example, as of December 31, 2024, our collaboration with Gilead has provided us with nearly $1.7 billion in funding, through both non-dilutive payments and equity investments. For each program that Gilead exercises its option to, we have received, or will receive, a substantial option payment and, subject to certain exceptions, Gilead will share 50% of the global costs for our activities within our joint development plan for that program, while preserving for us the option to co-promote our investigational products in the U.S., should they be approved. See “—Licenses and Collaborations—Gilead Collaboration” above for more information about Gilead’s cost sharing obligations. Similarly, the Taiho Agreement provides us with a development and, if approved, commercialization partner for the Taiho Territory. We intend to continue to establish strategic collaborations so that we can bring our investigational products to the broadest patient population possible.

Manufacturing and Supply

We do not own or operate, and currently have no plans to establish, any manufacturing or storage facilities. We rely, and expect to continue to rely, on third parties for the manufacture of our investigational products for preclinical and clinical testing. If any of our optioned investigational products obtain marketing approval, we expect to continue to use third-party manufacturers along with Gilead’s internal manufacturing infrastructure, as appropriate, to deliver commercial supply. We also rely, and expect to continue to rely, on third parties to package, label, store and distribute our investigational products, as well as for our commercial products if marketing approval is obtained. We believe that this strategy allows us to maintain a more efficient infrastructure by eliminating the need for us to invest in our own manufacturing facilities, equipment and personnel while also enabling us to focus our expertise and resources on the development of our investigational products.

To date, we have obtained active pharmaceutical ingredients ("API") and drug product for our investigational products from single-source third-party contract manufacturers. We are in the process of developing our supply chain for each of our investigational products and intend to put in place framework agreements under which third-party contract manufacturers will generally provide us with necessary quantities of API and drug product on a project-by-project basis based on our development needs. With respect to zimberelimab, we agreed, as part of the WuXi PD-1 Agreement, that WuXi Biologics would be our exclusive manufacturer of zimberelimab drug substance with respect to clinical and commercial supplies until a certain number of years after marketing approval for zimberelimab, subject to certain exceptions.

As we advance our investigational products through development, we will consider our lack of redundant supply for the API and drug product for each of our investigational products to protect against any potential supply disruptions. We generally expect to rely on third parties for the manufacture of any companion diagnostics we may develop.

Competition

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, development experience and scientific knowledge provide us with competitive advantages, we face potential competition from many different sources, including large pharmaceutical and biotechnology companies, academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for the research, development, manufacturing and commercialization of cancer immunotherapies. Any investigational products that we successfully develop and commercialize will compete with new immunotherapies that may become available in the future.

We will compete in the segments of the pharmaceutical, biotechnology and other related markets that develop immuno-oncology treatments. There are many other companies that have commercialized and/or are developing immuno-oncology treatments for cancer including large pharmaceutical and biotechnology companies, such as AstraZeneca plc ("AstraZeneca"), BeiGene, Ltd. ("BeiGene"), The Bristol-Myer Squibb Company ("Bristol-Myers Squibb"), GlaxoSmithKline plc ("GSK"), Merck & Co., Inc. ("Merck"), Novartis Inc. ("Novartis"), Pfizer Inc. ("Pfizer"), Regeneron Pharmaceuticals, Inc. ("Regeneron") in partnership with Sanofi Pasteur, Inc. ("Sanofi"), and Roche Holdings AG through its subsidiary Genentech ("Roche/Genentech").

For our anti-TIGIT antibody, domvanalimab, we are aware of several pharmaceutical companies developing antibodies against this target, including AstraZeneca, BeiGene, iTeos Therapeutics, Inc. ("iTeos") in partnership with GSK, Merck and Roche/Genentech. To our knowledge, there are no approved anti-TIGIT antibodies, and the most advanced agents are in Phase 3 development.

For our dual adenosine receptor antagonist, etrumadenant, we are aware that Merck (through Merck KGaA) has initiated clinical development of dual adenosine receptor antagonists. We are aware of clinical-stage selective adenosine A2a receptor antagonists being developed by other companies, including AstraZeneca, iTeos, and Portage Biotech Inc. ("Portage"). Clinical-stage selective adenosine A2b receptor antagonists are also being developed by companies such as Palobiofarma S.L. and Portage. To our knowledge, there are no adenosine receptor antagonists approved for the treatment of cancer, and the most advanced is in Phase 2 development.

For our small molecule CD73 inhibitor, quemliclustat, we are aware of several pharmaceutical companies developing antibodies against this target, including AstraZeneca, Bristol-Myers Squibb, I-MAB Biopharma (Shanghai) Co., Ltd., Incyte Corporation, Innate Pharma S.A., Innovent Biologics, Inc. and Novartis, all of which have advanced their CD73 antibodies into clinical development. Other pharmaceutical companies have small-molecule programs against this target, of which we believe only Antengene Corporation Limited and ORIC Pharmaceuticals Inc. are in clinical development. To our knowledge, there are no approved CD73 molecules, and the most advanced is in Phase 3 development.

For our anti-PD-1 antibody, zimberelimab, multiple large pharmaceutical companies have already received regulatory approvals for their anti-PD-1/PD-L1 antibodies, including AstraZeneca, BeiGene/Novartis, Bristol-Myers Squibb, Merck, Pfizer in partnership with Merck KGaA, Regeneron in partnership with Sanofi Genzyme and Roche/Genentech, and there are also many other anti-PD-1 and anti-PD-L1 antibodies in clinical development.

For our HIF-2α inhibitor, casdatifan, Merck received approval for belzutifan in Von Hippel-Lindau disease in 2021, advanced renal cell carcinoma in 2023 and has a number of clinical studies assessing its activity in cancer settings. Other pharmaceutical companies, including Novartis and NiKang Therapeutics, Inc., have small-molecule HIF-2α inhibitors in development. Arrowhead Pharmaceuticals Inc. has an RNA-based anti-HIF-2α agent in Phase 2 development.

Many of the companies which we may compete with have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These potential competitors also compete with us in recruiting and retaining qualified scientific and management personnel and in establishing clinical trial sites and enrolling subjects for our clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

We could see a reduction or elimination of our commercial opportunity 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 or our collaborators may develop. Our competitors also may obtain U.S. Food and Drug Administration (the "FDA") or foreign regulatory 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 or our collaborators are able to enter the market. The key competitive factors affecting the success of all of our investigational products, if approved, are likely to be their efficacy, safety, convenience, price, the effectiveness of companion diagnostics (if required), the level of biosimilar or generic competition and the availability of reimbursement from government and other third-party payors.

Intellectual Property

Our commercial success depends in large part on our ability to obtain and maintain patent protection in the U.S. and other countries for our investigational products, to operate without infringing valid and enforceable patents and proprietary rights of others, and to prevent others from infringing on our proprietary or intellectual property rights. We seek to protect our proprietary position by filing, in the U.S. and other foreign jurisdictions, patent applications intended to cover the composition of matter of our investigational products, their methods of use, and related discoveries, technologies, inventions and improvements that may be commercially important to our business. We may also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. We also intend to take advantage of regulatory protection afforded through data exclusivity, market exclusivity and patent term extensions where available.

As of February 1, 2025, our patent estate includes over 800 pending or issued patents worldwide, including 32 issued U.S. patents directed to compositions of matter, pharmaceutical compositions and methods of use for our investigational products and research programs. The term of any patents that issue will vary in accordance with the laws of each jurisdiction, but is typically 20 years from the earliest effective filing date. Our issued patents and any patents that may issue in the future from our company-owned or licensed pending applications are projected to expire between 2036 and 2044, absent any patent term adjustments or extensions.

The patent positions for biotechnology and pharmaceutical companies like us are generally uncertain and can involve complex legal, scientific and factual issues. Changes in either the patent laws or their interpretation in the U.S. and other countries may diminish our ability to protect our investigational products and enforce the patent rights that we own or license, and could affect the value of such intellectual property. With respect to both company-owned and licensed intellectual property, we cannot guarantee that the patent applications we are currently pursuing or may file in the future will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Our competitors may independently develop similar investigational products or technologies that are outside the scope of the rights granted under any issued patents that we own or exclusively in-license. We cannot be sure that any patents granted to us will be commercially useful in protecting our products or their methods of use or manufacture. Moreover, even issued patents do not guarantee us the right to commercialize our products. For example, third parties may have blocking patents that could be used to prevent us from commercializing or manufacturing our investigational products.

Because of the extensive time required for development, testing and regulatory review of an investigational product, it is possible that, before a product can be commercialized, any patent protection for such product may expire or remain in force for only a short period following commercialization, thereby reducing the commercial advantage the patent provides. In the U.S., the term of a patent covering an FDA approved product may, in certain cases, be eligible for a patent term extension under the Hatch-Waxman Act as compensation for the loss of patent term during the FDA regulatory review process. The period of extension may be up to five years, but cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent among those eligible for an extension and only those claims covering the approved product, a method for using it or a method for manufacturing it may be extended. Similar provisions are available in Europe and in certain other jurisdictions to extend the term of a patent that covers an approved product. While we intend to seek patent term extensions in any jurisdictions where they are available, there is no guarantee that the applicable authorities, including the FDA, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions.

Government Regulation

Government Regulation and Product Approval

Government authorities in the U.S., at the federal, state and local level, and in other countries and jurisdictions, including the European Union (the "EU"), extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of therapeutic products, such as those we are developing. The processes for obtaining regulatory approvals in the U.S. and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

FDA Approval Process

In the U.S., the FDA regulates under the Federal Food, Drug, and Cosmetic Act (the "FDCA"), and biologics under the FDCA and the Public Health Service Act (the "PHSA"), and their respective implementing regulations. These laws and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of drug and biological products. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as clinical hold, FDA refusal to approve pending regulatory applications, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

The process required by the FDA before a drug or biological product may be marketed in the U.S. generally includes the following:

- Completion of certain preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices ("GLP") or other applicable regulations;
- Submission to the FDA of an Investigational New Drug application ("IND"), which must become effective before human clinical trials may begin in the U.S.;
- Performance of adequate and well-controlled human clinical trials according to Good Clinical Practices ("GCP"), to establish the safety and efficacy of the investigational product for its intended use;
- Submissions to the FDA of a New Drug Application ("NDA") or Biologic License Application ("BLA") for a new product.
- Satisfactory completion of an FDA inspection of the facility or facilities where the investigational product is manufactured to assess compliance with the FDA's current Good Manufacturing Practices ("cGMP"), to assure that the facilities, methods and controls are adequate to preserve the investigational product's identity, strength, quality, purity, and potency;
- Potential FDA audit of the preclinical and clinical trial sites that generated the data in support of the NDA/BLA; and
- FDA review and approval of the NDA/BLA.

Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the investigational product or disease. A clinical hold may occur at any time during the life of an IND and may affect one or more specific trials or all trials conducted under the IND.

Preclinical tests include laboratory evaluation of an investigational product's chemistry, formulation, and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the investigational product. The conduct of the preclinical tests must comply with federal regulations and requirements, including GLP requirements for certain studies. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about an investigational product's chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during clinical trials due to safety concerns about on-going or proposed clinical trials or non-compliance with specific FDA requirements, and the trials may not begin or continue until the FDA notifies the sponsor that the hold has been lifted.

Clinical trials involve the administration of the investigational product to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted, among other things: (i) in compliance with federal regulations; (ii) in compliance with GCPs, which is comprised of standards and regulations meant to protect the rights and health of subjects and to define the roles of clinical trial sponsors, administrators, and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. subjects and subsequent protocol amendments must be submitted to the FDA as part of the IND. While the IND is active, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or in vitro testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time, or impose other sanctions if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial subjects. The trial protocol and informed consent information for subjects in clinical trials must also be submitted to an institutional review board ("IRB") for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions. The study sponsor may also suspend a clinical trial at any time on various grounds, including a determination that the subjects are being exposed to an unacceptable health risk. In addition, some studies also include oversight by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial. There are also requirements governing the reporting of ongoing clinical studies and clinical trial results to public registries, including clinicaltrials.gov.

Clinical trials to support NDAs/BLAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the investigational product into human subjects, including healthy volunteers, or in some cases patients with the target disease or condition, the investigational product is tested to assess safety, tolerability, pharmacokinetics, and pharmacological actions associated with increasing doses, and, if possible, early evidence on effectiveness. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the investigational product for a particular indication, dosage tolerance, and optimal dosage, and to identify common adverse effects and safety risks. Phase 3 trials are undertaken to obtain additional information about clinical efficacy and safety in a larger number of subjects, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit risk relationship of the investigational product and to provide adequate information for the labeling of the investigational product. In most cases, the FDA requires two adequate and well-controlled clinical trials to demonstrate the efficacy of the investigational product. A single Phase 3 trial may be sufficient in certain circumstances.

In some cases, the FDA may require, or sponsors may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These clinical trials, sometimes referred to as “Phase 4 studies,” may be used to gain additional experience from the treatment of patients in the approved therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

Concurrent with clinical trials, sponsors usually complete additional animal safety studies and also develop additional information about the chemistry and physical characteristics of the investigational product and finalize a process for manufacturing commercial quantities of the investigational product in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the investigational product and, among other things, the manufacturer must develop methods for testing the quality, purity and potency of the investigational product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the investigational product does not undergo unacceptable deterioration over its proposed shelf-life.

After completion of the required clinical testing, an NDA, for an investigational drug product, or a BLA, for an investigational biological product, is prepared and submitted to the FDA. FDA approval of the NDA or BLA is required before marketing of the product may begin in the U.S. The NDA or BLA must include the results of all preclinical, clinical, and other testing and a compilation of data relating to the investigational product's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA or BLA is substantial. The submission of most NDAs and BLAs is additionally subject to a substantial application user fee, and the applicant under an approved NDA or BLA is also subject to program user fees.

The FDA has 60 days from its receipt of an NDA or BLA to determine whether the application will be accepted for filing based on the FDA's threshold determination that the application is sufficiently complete to permit substantive review. The FDA may refuse to file any NDA or BLA that it deems incomplete or not properly reviewable at the time of submission, and may request additional information rather than accept an application for filing. In this event, the NDA or BLA must be resubmitted with the additional information and the resubmitted application also is subject to review before the FDA accepts it for filing.

Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs and BLAs. Most applications considered for standard review are reviewed within ten months of the date the FDA files the NDA or BLA; most applications designated for priority review are reviewed within six months of the date the FDA files the NDA or BLA. Priority review can be applied to an NDA or BLA for an investigational product that the FDA determines has the potential to treat a serious or life-threatening condition and, if approved, would be a significant improvement in safety or effectiveness compared to available therapies. The review process for both standard and priority review may be extended by the FDA for three additional months to respond to new information deemed a "major amendment" to the application.

Among other things, the FDA reviews an NDA or BLA to determine whether the product is safe and effective for its intended use, a BLA to determine whether the product is safe, pure, and potent, and in each case, whether the investigational product is being manufactured in accordance with cGMP. The FDA may also refer applications for novel investigational products, or investigational products that present difficult questions of safety or efficacy, to an advisory committee—typically a panel that includes clinicians and other experts—for review, evaluation, and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs. Additionally, the FDA will typically inspect the facility or the facilities at which the investigational product is manufactured. The FDA will not approve the investigational product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. To assure GCP and cGMP compliance, an applicant must incur significant expenditures of time, money and effort in the areas of training, record keeping, production and quality control.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the NDA or BLA does not satisfy the criteria for approval and deny approval. Data obtained from clinical trials are not always conclusive. The FDA may disagree with our trial design or interpret data from preclinical studies and clinical trials differently than we interpret the same data. If the FDA decides not to approve the NDA or BLA in its present form, the FDA will issue a complete response letter that will generally describe all of the specific deficiencies in the application identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. If a complete response letter is issued, the applicant may either resubmit the NDA or BLA, addressing the deficiencies identified in the letter, or withdraw the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA or BLA, the FDA will issue an approval letter. An approval letter authorizes commercial marketing of the drug or biological product in the U.S. with specific prescribing information for specific indications.

Even if an investigational product receives regulatory approval, such approval will be granted for specific indications and dosages and the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk evaluation and mitigation strategy ("REMS"), or otherwise limit the scope of any approval. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use ("ETASU"). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the product. In addition, the FDA may require post marketing clinical trials, including "Phase 4" clinical trials, designed to further assess a product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Foreign Clinical Trials to Support an IND, NDA, or BLA

The FDA will accept as support for an IND, NDA, or BLA a well-designed, well-conducted, non-IND foreign clinical trial if it was conducted in accordance with GCPs and the FDA is able to validate the data from the trial through an on-site inspection, if necessary.

Regulatory applications based solely on foreign clinical data meeting these criteria may be approved if the foreign data are applicable to the U.S. population and U.S. medical practice, the trials have been performed by clinical investigators of recognized competence, and the data may be considered valid without the need for an on-site inspection by FDA or, if FDA considers such an inspection to be necessary, FDA is able to validate the data through an on-site inspection or other appropriate means. Failure of an application to meet any of these criteria may result in the application not being approvable based on the foreign data alone.

Expedited Development and Review Programs

The FDA has various programs, including Fast Track, priority review, accelerated approval and Breakthrough Therapy, which are intended to expedite or simplify the process for reviewing investigational products designed to address serious or life threatening conditions, or provide for the approval of a such investigational products on the basis of an effect on a surrogate or intermediate endpoint. Even if an investigational product qualifies for one or more of these programs, the FDA may later decide that the investigational product no longer meets the conditions for qualification or that the time period for FDA review or approval will not be shortened. For example, Fast Track is a process designed to facilitate the development and expedite the review of investigational products designed to treat serious or life-threatening diseases or conditions, demonstrate the potential to address unmet medical needs for the disease or condition. The sponsor of a Fast Track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA or BLA is submitted, the application may be eligible for priority review. With regard to a Fast Track product candidate, the FDA may consider for review sections of the NDA or BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA or BLA, the FDA agrees to accept sections of the NDA or BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA or BLA.

In addition the FDA also provides Breakthrough Therapy designation. A sponsor may seek FDA designation of an investigational product as a “breakthrough therapy” if the investigational product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the investigational 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. Breakthrough Therapy designation provides all the features of Fast Track designation in addition to intensive guidance on an efficient product development program beginning as early as Phase 1, and FDA organizational commitment to expedited development, including involvement of senior managers and experienced review staff in a cross-disciplinary review, where appropriate.

An NDA or BLA is also eligible for priority review if the investigational product is designed to treat a serious condition, and if approved, would provide a significant improvement in safety or efficacy compared to available therapies. The FDA will attempt to direct additional resources to the evaluation of an NDA or BLA designated for priority review in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for review of new molecular entity NDAs and original BLAs under its current PDUFA review goals.

Accelerated approval provides for an earlier approval for an investigational product that meets the following criteria: is intended to treat a serious or life-threatening disease or condition, generally provides a meaningful advantage over available therapies and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality ("IMM") that is reasonably likely to predict an effect on IMM or other clinical benefit. A surrogate endpoint is a laboratory measurement or physical sign used as an indirect or substitute measurement representing a clinically meaningful outcome. As a condition of approval, the FDA generally requires that a sponsor of a product receiving accelerated approval perform confirmatory post-marketing clinical trials to verify and describe the predicted effect on IMM or other clinical endpoint, and the product may be subject to accelerated withdrawal procedures if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product or the sponsor fails to conduct such confirmatory trials in a timely manner. In addition, for products being considered for Accelerated Approval, the FDA requires pre-approval of promotional materials within certain timeframes, which could adversely impact the timing of the commercial launch of the product.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biological product intended to treat a rare disease or condition—generally a disease or condition that affects fewer than 200,000 individuals in the U.S., or if it affects more than 200,000 individuals in the U.S., there is no reasonable expectation that the cost of developing and making a product available in the U.S. for such disease or condition will be recovered from sales of the product.

Orphan drug designation must be requested before submitting a marketing application for the therapeutic for that particular disease or condition. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan Drug Designation entitles a party to financial incentives such as opportunities for grant funding toward clinical trial costs, tax advantages and user-fee waivers. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The FDA may revoke orphan drug designation, and if it does, it will publicize the drug is no longer designated as an orphan drug.

If an investigational product with orphan drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the investigational product is generally entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same investigational product for the same disease or condition, except in very limited circumstances, for seven years. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Orphan drug exclusivity, however, could also block the approval of an investigational product for seven years if a competitor obtains approval of the same investigational product, as defined by the FDA, or if such investigational product is determined to be contained within the competitor's investigational product for the same condition or disease.

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

Patent Term Restoration

After approval, owners of relevant drug or biological product patents may apply for up to a five-year patent extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act. The allowable patent term extension is calculated as half of the product's testing phase—the time between IND and NDA or BLA submission—and all of the review phase—the time between NDA or BLA submission and approval, up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years.

For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the U.S. Patent and Trademark Office (the "USPTO") must determine that approval of the investigational product covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for an investigational product for which an NDA or BLA has not been submitted.

Hatch-Waxman Exclusivity

Non-patent exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent data exclusivity within the U.S. to the first applicant to gain approval of an NDA for a new chemical entity. An investigational product is a new chemical entity if the FDA has not previously approved any other new investigational product containing the same active moiety, which is the molecule or ion responsible for the action of the investigational product substance. During the exclusivity period, the FDA may not accept for review an Abbreviated New Drug Application ("ANDA") or a 505(b)(2) NDA submitted by another company for another version of such investigational product where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement.

The FDCA also provides three years of non-patent data exclusivity for an NDA, 505(b)(2) NDA or supplement to an approved NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing investigational product. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for investigational products containing the original active agent. Unlike five-year new chemical entity exclusivity, an award of three-year exclusivity does not block the FDA from accepting ANDA or 505(b)(2) applications; it only prevents FDA from approving such applications. Five-year and three-year exclusivity also will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Biosimilars

The Biologics Price Competition and Innovation Act of 2009 (the "BPCIA") created an abbreviated approval pathway for biological investigational products shown to be highly similar to or interchangeable with an FDA licensed reference biological product. Biosimilarity sufficient to reference a prior FDA-approved product requires that there be no differences in conditions of use, route of administration, dosage form, and strength, and no clinically meaningful differences between the biological investigational product and the reference product in terms of safety, purity, and potency. Biosimilarity must be shown through analytical trials, animal trials, and a clinical trial or trials, unless the Secretary of Health and Human Services waives a required element. A biosimilar investigational product may be deemed interchangeable with a prior approved product if it meets the higher hurdle of demonstrating that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

A reference biologic is granted 12 years of exclusivity from the time of first licensure of the reference product, and no application for a biosimilar can be submitted for four years from the date of licensure of the reference product. During this 12-year period of exclusivity, another sponsor may still obtain approval of a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own data. The first biologic investigational product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against a finding of interchangeability for other biologics for the same condition of use for the lesser of (i) one year after first commercial marketing of the first interchangeable biosimilar, (ii) 18 months after the first interchangeable biosimilar is approved if there is no patent challenge, (iii) 18 months after resolution of a lawsuit over the patents of the reference biologic in favor of the first interchangeable biosimilar applicant, or (iv) 42 months after the first interchangeable biosimilar's application has been approved if a patent lawsuit is ongoing within the 42-month period. Substitution at the pharmacy level of biosimilar products deemed to be interchangeable is governed by state pharmacy law.

Post-approval Requirements

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. In addition, the FDA may under some circumstances require testing and surveillance programs to monitor the effect of approved products that have been commercialized, and the FDA under some circumstances has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs. There also are continuing, annual program fees for any marketed products. Any product manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things:

- record-keeping requirements;
- reporting of adverse experiences associated with the product;
- providing the FDA with updated safety and efficacy information;
- therapeutic sampling and distribution requirements;
- notifying the FDA and gaining its approval of certain manufacturing or labeling changes;
- registration and listing requirements; and

- complying with FDA promotion and advertising requirements, which include, among other things, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved labeling, limitations on industry-sponsored scientific and educational activities and requirements for promotional activities involving the internet.

The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label may be subject to significant liability. However, physicians may, in their independent medical judgment, prescribe legally available products for off-label uses. The FDA does not regulate the behavior of physicians in their choice of treatments but the FDA does restrict manufacturer's communications on the subject of off-label use of their products.

Manufacturers, their subcontractors, and other entities involved in the manufacture and distribution of approved drug and biological products are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and some state agencies for compliance with cGMP, including data integrity requirements, and other laws. The FDA periodically inspects manufacturing facilities to assess compliance with ongoing regulatory requirements, including cGMP, which impose extensive procedural, substantive and record-keeping requirements upon us and third-party manufacturers engaged by us if our products are approved. In addition, changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require FDA approval before being implemented. FDA regulations would also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and our third-party manufacturers. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance. Failure to comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory actions, such as:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters, or untitled letters;
- clinical holds on ongoing or planned clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

In addition, therapeutic manufacturers in the U.S. must comply with applicable provisions of the Drug Supply Chain Security Act and provide and receive product tracing information, maintain appropriate licenses, ensure they only work with other properly licensed entities, and have procedures in place to identify and properly handle suspect and illegitimate product.

Disclosure of Clinical Trial Information

Sponsors of clinical drug trials (other than certain Phase 1 trials) are required to register and disclose certain clinical trial information. Information related to the investigational product, comparator(s), patient population, phase of investigation, trial sites and investigators and other aspects of the clinical trial is made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of certain trials may be delayed until the new product or new indication being studied has been approved. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Additional Controls for Biological Products

To help reduce the increased risk of the introduction of adventitious agents, the PHSA emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases in the U.S. and between states.

After a BLA is approved, the biological product may also be subject to official lot release as a condition of approval. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer.

FDA Regulation of Companion Diagnostics

If use of an in vitro diagnostic is essential to safe and effective use of a drug or biologic product, then the FDA generally will require approval or clearance of the diagnostic, known as a companion diagnostic and regulated by FDA as a medical device, at the same time that the FDA approves the investigational product. The review of an in vitro companion diagnostic in conjunction with the review of an investigational product involves coordination of review between internal organizations within FDA. In the U.S., the FDCA and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Unless an exemption applies, each medical device commercially distributed in the U.S. generally requires either FDA clearance of a 510(k) premarket notification, or approval of a premarket approval ("PMA") application prior to commercial distribution. Most companion diagnostics require approval of a PMA.

If used to make critical treatment decisions, such as patient selection, the diagnostic device may be considered a significant risk device under the FDA's Investigational Device Exemption ("IDE") regulations, in which case, the sponsor of the diagnostic device will be required to submit and obtain approval of an IDE application and subsequently comply with the IDE regulations for the use of the diagnostic device in clinical studies. However, according to FDA guidance, if a diagnostic device and a drug are to be studied together to support their respective approvals, both products can be studied in the same investigational study, if the study meets both the requirements of applicable IDE regulations and the IND regulations.

The FDA has generally required companion diagnostics designed to select the patients who may respond to cancer treatment to obtain approval of a PMA for that diagnostic simultaneously with approval of the oncology therapeutic. The PMA process, including the gathering of clinical and preclinical data and the submission to and review by the FDA, can take several years or longer. It involves a rigorous premarket review during which the applicant must prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing and labeling.

PMAs are subject to a substantial application fee. In addition, PMAs for certain devices must generally include the results from extensive preclinical and adequate and well-controlled clinical trials to establish the safety and effectiveness of the device for each indication for which FDA approval is sought. In particular, for a diagnostic, the applicant must generally demonstrate that the diagnostic produces reproducible results when the same sample is tested multiple times by multiple users at multiple laboratories. As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with the Quality System Regulation (the "QSR") which currently imposes elaborate testing, control, documentation and other quality assurance requirements.

PMA approval is not guaranteed, and the FDA may ultimately respond to a PMA submission by denying approval, or by responding with a not approvable letter citing deficiencies in the application. To respond to such deficiencies, FDA may require the PMA sponsor to collect additional clinical trial or other data that may be expensive and time-consuming to generate and that can substantially delay approval. If the FDA's evaluation of the PMA application is favorable, the FDA may issue an approval order, or issue an approvable letter requiring the applicant's agreement to specific conditions, such as changes in labeling, or specific additional information, such as submission of final labeling, in order to secure final approval of the PMA. If the FDA concludes that the applicable criteria have been met, the FDA will issue an approval order for the approved indications, which can be more limited than those originally sought by the applicant. The PMA can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution.

After a device is placed on the market following appropriate approval or clearance from the FDA, it remains subject to significant regulatory requirements. Medical devices may be marketed only for the uses and indications for which they are cleared or approved. Device manufacturers must also establish registration and device listings with the FDA. A medical device manufacturer's manufacturing processes and those of its suppliers are required to comply with the applicable portions of the QSR, which currently cover the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging and shipping of medical devices. Domestic facility records and manufacturing processes are subject to periodic unscheduled inspections by the FDA. The FDA also may inspect foreign facilities that export products to the U.S.

Other U.S. Healthcare Laws and Compliance Requirements

In the U.S, our activities are subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare & Medicaid Services (the "CMS") other divisions of the U.S. Department of Health and Human Services ("HHS"), such as the Office of Inspector General, the U.S. Department of Justice (the "DOJ") and individual U.S. Attorney offices within the DOJ, and state and local governments. These laws include, without limitation, the anti-fraud and abuse provisions of the Social Security Act and the false claims laws, each as amended, as applicable.

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

The federal false claims, including the federal False Claims Act (the "FCA"), impose significant penalties and can be enforced by private citizens through civil qui tam actions, and civil monetary penalty laws prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal healthcare programs, including Medicare and Medicaid, or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. For instance, historically, pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, off-label, and thus generally non-reimbursable, uses. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA.

The federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (collectively, “HIPAA”), created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the Anti-Kickback Statute, the ACA amended the intent standard for certain healthcare fraud statutes under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Also, many states have similar, and typically more prohibitive, fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Additionally, to the extent that our product is sold in a foreign country, we may be subject to similar foreign laws.

Certain of our products, once approved, may be administered by a physician. Under currently applicable U.S. law, certain products not usually self-administered (including injectable drugs) may be eligible for coverage under Medicare through Medicare Part B. Medicare Part B is part of original Medicare, the federal health care program that provides health care benefits to the aged and disabled, and covers outpatient services and supplies, including certain pharmaceutical products, that are medically necessary to treat a beneficiary’s health condition. As a condition of receiving Medicare Part B reimbursement for a manufacturer’s eligible drugs or biologicals, the manufacturer is required to participate in other government healthcare programs, including the Medicaid Drug Rebate Program and the 340B Drug Pricing Program. The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of HHS as a condition for states to receive federal matching funds for the manufacturer’s outpatient drugs furnished to Medicaid patients. Under the 340B Drug Pricing Program, the manufacturer must extend discounts to entities that participate in the program.

In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as Average Sales Price ("ASP") and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these 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 U.S. It is difficult to predict how Medicare coverage and reimbursement policies will be applied to our products for which we obtain marketing authorization, and coverage and reimbursement under different federal healthcare programs are not always consistent. Medicare reimbursement rates may also reflect budgetary constraints placed on the Medicare program.

Additionally, the federal Physician Payments Sunshine Act (the "Sunshine Act") and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) report annually to CMS information related to certain payments or other transfers of value made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members. Failure to report accurately could result in penalties. In addition, many states also govern the reporting of payments or other transfers of value, many of which differ from each other in significant ways, are often not pre-empted, and may have a more prohibitive effect than the Sunshine Act, thus further complicating compliance efforts.

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

Ensuring business arrangements with third parties comply with applicable healthcare laws and regulations is a costly endeavor. Violation of any of the federal and state healthcare laws described above or any other current or future governmental regulations that apply to drug manufacturers may result in significant penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, additional reporting obligations and oversight if the manufacturer becomes subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of operations.

Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any investigational products for which we may obtain regulatory approval. In the U.S. and in foreign markets, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage and establish adequate reimbursement levels for such products. In the U.S., third-party payors include federal and state healthcare programs, private managed care providers, health insurers and other organizations. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid in the U.S., and commercial payors are critical to new product acceptance.

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which therapeutics they will pay for and establish reimbursement levels. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a therapeutic is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

We cannot be sure that reimbursement will be available for any product that we commercialize and, if coverage and reimbursement are available, what the level of reimbursement will be. Coverage may also be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Reimbursement may impact the demand for, or the price of, any product for which we obtain regulatory approval. Additionally, our collaborators will be required to obtain coverage and reimbursement for any companion diagnostic tests they develop separate and apart from the coverage and reimbursement we seek for our investigational products, once approved.

Third-party payors are increasingly challenging the price, examining the medical necessity, and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with branded drugs and drugs administered under the supervision of a physician. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA approvals. Our investigational products may not be considered medically necessary or cost-effective. Obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our product on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. 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 for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any investigational product that we successfully develop.

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

The marketability of any investigational products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care, the increasing influence of health maintenance organizations, and additional legislative changes in the U.S. has increased, and we expect will continue to increase, the pressure on healthcare pricing. The downward pressure on the rise in healthcare costs in general, particularly prescription medicines, medical devices and surgical procedures and other treatments, has become very intense. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare Reform

In the U.S. and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of investigational products, restrict or regulate post-approval activities, and affect the ability to profitably sell investigational products for which marketing approval is obtained. Among policy makers and payors in the U.S. and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the U.S., the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, the ACA has substantially changed healthcare financing and delivery by both governmental and private insurers. Among the ACA provisions of importance to the pharmaceutical and biotechnology industries, in addition to those otherwise described above, are the following: (i) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations; (ii) established an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs; (iii) expanded the availability of lower pricing under the 340B drug pricing program by adding new entities to the program; (iv) increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price ("AMP"); (v) expanded the eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals, thereby potentially increasing manufacturers' Medicaid rebate liability; (vi) created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and (vii) established a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

There have been legal and political challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form. Further, there have been a number of health reform measures by the former Biden administration that have impacted the ACA. For example, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 ("IRA"), into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and by creating a new manufacturer discount program.

Further legislation or regulation could be passed that could harm our business, financial condition and results of operations. Other legislative changes have been proposed and adopted since the ACA was enacted. For example, in August 2011, the Budget Control Act of 2011, was signed into law which, among other things, included aggregate reductions to Medicare payments to providers that went into effect beginning on April 1, 2013 and, due to subsequent legislation, will stay in effect until 2032 unless additional Congressional action is taken. Additionally, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory Medicaid drug rebate cap, which was previously set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024.

Additionally, there has been increasing legislative and enforcement interest in the U.S. with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. In August 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (which began in 2025). CMS has published the negotiated prices for the initial ten drugs, which will first be effective in 2026, and has published the list of the subsequent 15 drugs that will be subject to negotiation. The IRA permits the Secretary of the Department of Health and Human Services, or HHS, to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented, although the Medicare drug price negotiation program is currently subject to legal challenges. For that and other reasons, it is currently unclear how the IRA will be effectuated, or the impact of the IRA on our business.

On December 7, 2023, the former Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

Individual states in the U.S. have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and other transparency measures. Some states have enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states.

We anticipate that current and future healthcare reform measures could result in additional downward pressure on coverage and the price that we receive for any approved product, and could seriously harm our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability from product sales, or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from investigational products that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop investigational products.

The Foreign Corrupt Practices Act

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

Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

Other Regulations

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

Rest of World Government Regulation

In addition to regulations in the U.S., we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. Whether or not we obtain FDA approval to conduct clinical trials or market a product, we must obtain the requisite approvals from regulatory authorities in foreign jurisdictions prior to the commencement of clinical trials or marketing of the product in those countries. The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

Europe and United Kingdom

Similar to the U.S. and Australia, the conduct of clinical trials in the EU are subject to regulatory controls. The current EU Clinical Trials Regulation 536/2014 (the "Regulation") aims to simplify and streamline the approval of clinical trials in the EU. For example, the sponsor shall submit a single application for approval of a clinical trial via the EU portal. As part of the application process, the sponsor shall propose a reporting member state, who will coordinate the validation and evaluation of the application. The reporting member state shall consult and coordinate with the other concerned member states. If an application is rejected, it can be amended and resubmitted through the EU portal. If an approval is issued, the sponsor can start the clinical trial in all concerned member states. However, a concerned member state can in limited circumstances declare an “opt-out” from an approval. In such a case, the clinical trial cannot be conducted in that member state. The Regulation also aims to streamline and simplify the rules on safety reporting, and introduces enhanced transparency requirements such as mandatory submission of a summary of the clinical trial results to the EU database.

Commercialization of our investigational products may only occur in the EU following approval of a marketing application, which can be obtained through either a centralized or a decentralized procedure:

- Under the centralized procedure, a marketing application is submitted to the European Medicines Agency (the "EMA"), where it will be evaluated by the Committee for Medicinal Products for Human Use. If this committee delivers a favorable opinion, this typically results in the grant by the European Commission of a single marketing authorization that is valid for all EU member states. The centralized procedure is mandatory for certain types of drugs, such as biotechnology medicinal drugs, orphan medicinal drugs, and medicinal drugs containing a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, autoimmune and viral diseases. The centralized procedure is optional for drugs containing a new active substance not yet authorized in the European Economic Area (the "EEA"), or for drugs that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.
- Under the decentralized procedure, an identical dossier is submitted to the competent authorities of each of the member states in which a marketing authorization is sought, one of which is selected by the applicant as the Reference Member State (the "RMS"). The competent authority of the RMS prepares a draft assessment report, a draft summary of the drug characteristics ("SPC") and a draft of the labeling and package leaflet, which are sent to the other member states (the "Member States Concerned") for their approval. If the Member States Concerned raise no objections, based on a potential serious risk to public health, to the assessment, SPC, labeling, or packaging proposed by the RMS, the drug is subsequently granted a national marketing authorization in all the member states (*i.e.*, in the RMS and the Member States Concerned).

We will be subject to additional regulations with respect to any activities we conduct in the EU and the UK. For example, the EU General Data Protection Regulation (the "EU GDPR") and the United Kingdom's General Data Protection Regulation (the "UK GDPR" and, together with the EU GDPR, the "GDPR") applies to health-related and other personal data of individuals in the EU and UK, respectively. The GPDR imposes more stringent operational requirements on processors and controllers of personal data, including, for example, expanded disclosures about how personal data is collected, used and shared, limitations on retention of personal data, more stringent requirements pertaining to genetic, biometric and health data, mandatory data breach notification requirements, and higher standards for controllers to demonstrate valid consent for certain data processing activities. The GDPR further provides that EU member states may implement their own additional laws and regulations in relation to the processing of genetic, biometric or health data, which could result in differences in the GDPR's implementation among member states. The GDPR increases our responsibility and liability in relation to personal data that we process, and we must put in place additional mechanisms to ensure compliance with GDPR.

Data Privacy and Security

Numerous state, federal and foreign laws, regulations and standards govern the collection, use, access to, confidentiality and security of health-related and other personal information, and could apply now or in the future to our operations or the operations of our partners. In the U.S., numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws and consumer protection laws and regulations govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, certain foreign laws govern the privacy and security of personal data, including health-related data. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Human Capital Resources

Our culture and values can be defined by one overarching concept: We do the right things for the right reasons. We take pride in hard work and approach our mission—to create, develop and commercialize highly differentiated combination therapies that have the potential to cure—with a great sense of urgency. We recognize that our employees are a critical component to our success and we strive to attract the best talent from a range of sources, including an internship program through which we have developed strong relationships with multiple universities to foster talent and attract skilled graduates.

As of December 31, 2024, our company turnover rate is lower than the industry average. While the competition for talent remains strong as the number of biotechnology and pharmaceutical companies headquartered in the San Francisco Bay Area remains high, we believe we can attract and retain the talent we need to be successful. As of December 31, 2024, we had 627 full-time employees, approximately 34% of whom hold Ph.D., M.D., R.N., or similar degrees and certifications. Of our employees, approximately 81% were engaged in research and development activities. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

We are an equal opportunity employer. As of December 31, 2024, among our employees, 56% were female and, among our leadership (which we define as employees at the vice president level and above), approximately 38% were female. As of December 31, 2024, 57% of our employees and 48% of our leadership identify as being from diverse racial and ethnic groups. On our board of directors, four of our eleven directors self-identify as female, and two self-identify as being from a diverse racial or ethnic group.

We recognize that attracting skilled talent is only one part of the equation. We endeavor to retain and motivate our employees by empowering them to make the decisions they are most qualified and best positioned to decide and by providing opportunities for growth and development, such as through our education reimbursement program. We focus on wellness through our company-funded lunch program, a stipend to assist with wellness and commuter expenses, and our coverage of 95% of the costs for healthcare benefits. Further, we conduct periodic talent reviews to identify high-performing and high-potential talent within the organization. This data is used to inform specific development opportunities for current and future leaders, create custom leadership training, drive meaningful development conversations and enable succession planning for key roles. We conduct an employee survey to measure employee engagement and to inform future talent initiatives.

Corporate Information

We were incorporated under the laws of the State of Delaware in April 2015. Our principal executive offices are located at 3928 Point Eden Way, Hayward, CA 94545, and our telephone number is (510) 694-6200. Our website address is www.arcusbio.com. The information on, or that can be accessed through, our website is not incorporated by reference into this Annual Report.

We operate and manage our business as one reportable and operating segment. See Note 1, Organization, liquidity and capital resources, in Part II, Item 8 for additional information.

We file Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other information with the Securities and Exchange Commission ("SEC"). Our filings with the SEC are available free of charge on the SEC's website at www.sec.gov and on our website under the "Investors" tab as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

Item 1A. Risk Factors.

You should consider carefully the following risk factors, together with all the other information in this report, including our Consolidated Financial Statements and notes thereto, and in our other public filings with the SEC. The occurrence of any of the following risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. You should consider all of the risk factors described when evaluating our business.

Risks Related to our Limited Operating History, Financial Position and Capital Requirements

We have a history of operating losses, have never generated any revenue from product sales and anticipate that we will continue to incur significant losses for the foreseeable future.

We are a clinical-stage biopharmaceutical company with a limited operating history that may make it difficult to evaluate the success of our business to date and to assess our future viability. All of our investigational products are in development, and none have been approved for commercial sale, nor have we ever generated any revenue from product sales. Our revenues to date have been primarily from upfront and milestone payments, R&D support and clinical materials reimbursement from our strategic partners. For the years ended December 31, 2024 and 2023, we had net losses of $283 million and $307 million, respectively. As of December 31, 2024, we had an accumulated deficit of $1.1 billion. While we may receive income from year to year under the Gilead Agreement and the Taiho Agreement, we generally expect to incur substantial and increasing levels of operating losses over the next several years and for the foreseeable future as we advance our investigational products. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

To become and remain profitable on a sustained basis, we must develop and eventually commercialize a product with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our investigational products, obtaining marketing approval for these investigational products, manufacturing, marketing and selling those products for which we may obtain marketing approval and satisfying any post-marketing requirements. We may never succeed in these activities, and even if we succeed in commercializing one or more of our investigational products, we may never generate revenues that are significant or large enough to achieve sustained profitability. In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges. If we do achieve profitability from product sales, we may not be able to sustain or increase profitability on a quarterly or annual basis, and we will continue to incur substantial R&D and other expenditures to develop and market additional investigational products. Our failure to become and remain profitable on a sustained basis would decrease the value of the company and could impair our ability to raise capital, maintain our R&D efforts, expand our business or continue our operations. A decline in the value of our company could also cause our stockholders to lose all or part of their investment.

We may need to obtain additional funding. If we do not receive, or are unable to raise additional capital when needed, we may be forced to restrict our operations or delay, reduce or eliminate our product development programs.

The development of biopharmaceutical investigational products is capital intensive. Since our inception, we have used substantial amounts of cash to fund our operations and expect our expenses to increase substantially during the next few years as our investigational products advance through large late-stage or registrational clinical trials. If we obtain marketing approval for any of our investigational products, we expect to incur significant commercialization expenses related to marketing, sales, manufacturing and distribution.

As of December 31, 2024, we had $992 million of cash, cash equivalents and marketable securities, which we believe will be sufficient to fund our planned level of operations for the foreseeable future and provide funding to our initial pivotal read-outs for domvanalimab, quemliclustat and casdatifan including STAR-221, PRISM-1 and PEAK-1. We cannot guarantee that we will be able to obtain additional capital in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate some or all of our R&D programs or future commercialization efforts. In addition, if we are able to raise additional capital, raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our intellectual property or investigational products. Our future capital requirements will depend on many factors related to the cost and timing of developing our investigational products, including:

- the number, scope, rate of progress and costs of clinical programs and investigational products, as well as drug discovery, preclinical development activities, and laboratory testing;
- the scope of any cost sharing arrangements with our strategic partners;

- the timing and amount of milestone payments and option fees we receive under the Gilead Collaboration Agreement and the Taiho Agreement;
- the cost, timing and outcome of regulatory review of our investigational products; and
- the cost associated with commercializing our investigational products, if they receive marketing approval.

Risks Related to the Discovery and Development of our Investigational Products

If we are unable to obtain regulatory approval for our investigational products, or experience significant delays in doing so, our business will be materially harmed.

We have no products approved for sale and our investigational products must be approved by the FDA in the U.S. and similar regulatory authorities outside the U.S., such as the EMA, prior to commercialization. The process of obtaining marketing approvals, both in the U.S. and abroad, is expensive and takes many years, if approval is obtained at all, and can vary substantially based upon a variety of factors. 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 investigational product's safety and efficacy, or with respect to biological investigational products, safety, purity and potency. Securing marketing approval also requires, among other things, the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities, among other requirements. Our investigational products may not be effective, may be only moderately effective, may not have an acceptable durability of response, may not have an acceptable risk-benefit profile or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude us from obtaining marketing approval or limit their commercial use. Our investigational products may not be approved even if they achieve their primary endpoints in any Phase 3 clinical trials or other registrational trials we or our collaborators conduct.

The FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and in determining when or whether marketing approval will be obtained for any of our investigational products. Regulatory authorities 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 an investigational product. 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 also cause delays in or prevent the approval of an application. For example, since a key element of our strategy is the development of intra-portfolio combinations, regulatory authorities may disagree that we have sufficiently demonstrated the contribution of each investigational product or other agent in our combination trials to any observed therapeutic effects and require further studies to further characterize the activity of each component within the combination.

The FDA or comparable regulatory authorities can delay, limit or deny approval of an investigational product for many reasons, including:

- such authorities may disagree with the design or execution of our clinical trials;
- negative or ambiguous results from our clinical trials or results may not meet the level of statistical significance or persuasiveness required by the FDA or comparable foreign regulatory authorities for approval;
- serious and unexpected drug-related side effects may be experienced by participants in our clinical trials or by individuals using drugs similar to our investigational products;
- the population studied in our clinical trials may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- such authorities may not accept clinical data from trials that are conducted at clinical facilities or in countries where the standard of care is potentially different from that of their own country;
- we may be unable to demonstrate that an investigational product's clinical and other benefits outweigh its safety risks;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- such authorities may not agree that the data collected from clinical trials of our investigational products are acceptable or sufficient to support the submission of a BLA, NDA or other submission or to obtain regulatory approval in the U.S. or elsewhere;

- such authorities may disagree with us regarding the formulation, labeling and/or the product specifications of our investigational products;
- such authorities may find deficiencies in the manufacturing processes or facilities of the third-party manufacturers with which we contract for clinical and commercial supplies; or
- such authorities may not accept a submission due to, among other reasons, the content or formatting of the submission.

We may be unable to establish any long-term supply agreements with third-party manufacturers or to do so on acceptable terms, which increases the risk of failing to timely obtain sufficient quantities of our investigational products or such quantities at an acceptable cost.

Even if we are able to obtain marketing approvals for any of our investigational products, those approvals may be for indications that are not as broad as desired or may contain other limitations that would adversely affect our ability to generate revenue from sales of those products. Moreover, if we are not able to differentiate our product against other approved products within the same class of drugs our business would be materially harmed and our ability to generate revenue from that class of drugs would be severely impaired. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of that investigational product and would materially adversely impact our business and prospects.

If we experience delays in obtaining approval or if we fail to obtain approval of our investigational products, the commercial prospects for our investigational products may be harmed and our ability to generate revenues will be materially impaired.

Clinical drug development is a lengthy, expensive and uncertain process. If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of our investigational products, if approved, may be delayed and the credibility of our management team may be adversely affected and, as a result, our stock price may decline.

The R&D of drugs and biological products is an extremely risky industry. Only a small percentage of investigational products that enter the development process ever receive marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of any investigational product, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety, purity, potency and/or efficacy of our investigational products in humans. Clinical testing is expensive, can take many years to complete and its outcome is uncertain.

Further, from time to time, we may provide guidance regarding the expected timing or costs of various scientific, clinical, regulatory and other product development goals; including goals regarding the commencement or completion of, or the availability of data from, scientific studies and clinical trials and the submission of regulatory filings. Any such guidance will be based on a variety of assumptions, such as the rate of events in a trial. The actual timing or cost of these goals can vary dramatically compared to our guidance, in some cases for reasons beyond our control. If we do not meet such guidance the commercialization of our products may be delayed and the credibility of our management team may be adversely affected and, as a result, our stock price may decline.

The results of preclinical studies and early clinical trials are not always predictive of future results.

The results of preclinical and early clinical trials of our investigational products and other products with the same mechanism of action may not be predictive of the results of later-stage clinical trials. For example, we have presented data from multiple Phase 2 studies (such as ARC-8 and EDGE-Gastric) that are evaluating the same or similar regimen in the same setting as one of our current or potentially future Phase 3 studies. Data from these Phase 2 studies may not be predictive of the results of any of our Phase 3 studies even if evaluating the same regimen and setting. Clinical trial failure may result from a multitude of factors including flaws in study design, dose selection, placebo effect, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits. As such, failure in clinical trials can occur at any stage of testing. A number of companies in the biopharmaceutical industry have suffered setbacks in the advancement of clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from clinical trials are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may further delay, limit or prevent marketing approval. In particular, results from uncontrolled trials, meaning trials in which there is no control group such as a placebo group, are inherently difficult to interpret. This difficulty is compounded in clinical trials such as ours, in which two or more investigational products that have not yet been approved are being evaluated. Accordingly, the data generated during preclinical or early clinical trials evaluating our investigational products may not be predictive of future clinical trial results

for these or other investigational products when studied in a randomized environment or larger patient populations or with different study designs.

Any difficulties or delays in the commencement or completion, or the termination or suspension, of our current or planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue or adversely affect our commercial prospects.

Before obtaining approval from regulatory authorities for the commercialization of any of our investigational products, we must conduct extensive clinical trials to demonstrate the safety purity, potency, or efficacy of the investigational candidate in humans. Before we can initiate clinical trials for any investigational products in the U.S. or in other jurisdictions, we must submit the results of preclinical studies to the FDA or comparable regulatory authorities along with other information, including information about the investigational product's chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an IND or similar regulatory submission. The FDA or comparable foreign regulatory authorities may require us to conduct additional preclinical studies for any investigational product before it allows us to initiate clinical trials under any IND or similar regulatory submission, which may lead to delays and increase the costs of our preclinical development programs. Moreover, even if we commence clinical trials, issues may arise that could cause regulatory authorities to suspend or terminate such clinical trials. Any such delays in the commencement or completion of our ongoing and planned clinical trials for our investigational products could significantly affect our product development timelines and product development costs and harm our financial position.

We do not know whether our planned clinical trials will begin on time or be completed on schedule, if at all. The timing for commencement, data readouts and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials;
- obtaining allowance or approval from regulatory authorities to commence a trial or reaching a consensus with regulatory authorities on trial design;
- the FDA or comparable foreign regulatory authorities disagreeing as to the implementation of our clinical trials;
- any failure or delay in reaching an agreement with Contract Research Organizations ("CROs") and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in identifying, recruiting and training suitable clinical investigators;
- obtaining approval from one or more institutional review boards, or ethics committees at clinical trial sites;
- IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- changes or amendments to the clinical trial protocol;
- clinical sites deviating from the trial protocol or dropping out of a trial;
- failure by our CROs to perform in accordance with GCP requirements or applicable regulatory rules and guidelines in other countries;
- manufacturing sufficient quantities of our investigational products, or obtaining sufficient quantities of combination therapies for use in clinical trials;
- subjects failing to enroll or remain in our trials at the rate we expect, or failing to return for post-treatment follow-up, including subjects failing to remain in our trials;
- patients choosing an alternative product for the indications for which we are developing our investigational products or participating in competing clinical trials;
- lack of adequate funding to continue a clinical trial or costs being greater than we anticipate;
- subjects experiencing severe or serious unexpected drug-related adverse effects;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies that could be considered similar to our investigational products;

- selection of clinical endpoints that require prolonged periods of clinical observation or extended analysis of the resulting data;
- or failure of our CMOs to produce clinical trial materials in sufficient quantities in accordance with current Good Manufacturing Practice ("cGMP"), regulations or other applicable requirements; and
- third parties being unwilling or unable to satisfy their contractual obligations to us in a timely manner.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or applicable clinical trial protocols, adverse findings from inspections of clinical trial sites by the FDA or comparable foreign regulatory authorities, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using an investigational product, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to regulators or to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Further, conducting clinical trials in foreign countries, as we continue to do for our investigational products, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled subjects in foreign countries to adhere to clinical protocols as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, and political and economic risks, including war, relevant to such foreign countries. In addition, many of the factors that cause, or lead to, the termination suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of an investigational product. Any resulting delays to our clinical trials could shorten any period during which we may have the exclusive right to commercialize our investigational products. In such cases, our competitors may be able to bring products to market before we do, and the commercial viability of our investigational products could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects.

Preliminary, topline, and interim data from our clinical studies that we announce or publish from time to time are subject to audit and verification procedures that could result in material changes in the final data and may change as more patient data become available.

From time to time, we publish preliminary, topline or interim data from our clinical studies. Such publications are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. For example, topline and preliminary data remain subject to audit confirmation and verification procedures that may result in the final data being materially different from the topline or preliminary data we previously published. Interim data are also subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. As a result, interim, topline and preliminary results that we report may differ from future results of the same studies and should be viewed with caution until the final data are available. As such material changes between previously reported topline, preliminary and interim results and final data could significantly harm our business prospects and our stock price may decline.

Most of our clinical trials are open-label studies and may be susceptible to bias.

Most of our clinical trials, including our Phase 3 trials, are open-label studies in which both the patient and investigator know whether the patient is receiving the investigational products or either an existing approved drug or placebo. Open-label clinical trials are susceptible to bias that may exaggerate any therapeutic effect or overestimate the risk associated with the investigational product. Patients may perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. Investigators may interpret the information of the treated group more favorably given their awareness of the treatment regimen or may attribute safety risks to the investigational product. If regulatory agencies feel that we have not implemented sufficient controls to prevent such biases or that the controls we have implemented were ineffective, we may experience delays or negative outcomes in our applications for drug approval. In addition, the FDA and other regulatory authorities may disfavor the use of open-studies, or otherwise not agree that the results from open-label studies, regardless of outcome, will support submission of an application for marketing approval in the indications we are targeting, and we may be required to conduct randomized trials evaluating our investigational products before we are able to able to obtain marketing approval of our investigational products, if ever.

Enrollment and retention of subjects in clinical trials is expensive and time consuming and can be made more difficult or rendered impossible by competing treatments, clinical trials of competing investigational products, geopolitical instability and public health epidemics, each of which could result in significant delays and additional costs in our product development activities, or in the failure of such activities.

We may encounter delays in enrolling, or be unable to enroll and maintain, a sufficient number of subjects to complete any of our clinical trials. Patient enrollment and retention in clinical trials is a significant factor in the timing and cost of clinical trials and depends on many factors, including among other things, the size of the patient population required for analysis of the trial's primary endpoints, the nature of the trial protocol, our ability to recruit clinical trial investigators with the appropriate competencies and experience, the existing body of safety and efficacy data with respect to the investigational product (including data that we report in our other clinical trials using the same investigational products) or with respect to other investigational products with the same mechanism of action as our investigational products, the number and nature of competing products or investigational products and ongoing clinical trials of competing investigational products for the same indication, the proximity of subjects to clinical trial sites, the eligibility criteria for the clinical trial and our ability to obtain and maintain subject consents. See "Item 1. Business—Competition" for additional information regarding competing programs.

Geopolitical instability and public health outbreaks may also have an adverse impact on our clinical trial operations. Delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our investigational products. In addition, we expect to rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we intend to enter into agreements governing their services, we will have limited influence over their actual performance. Failures in planned subject enrollment or retention may result in increased costs or program delays and could render further development impossible.

Serious adverse events, undesirable side effects or other unexpected properties of our investigational products may be identified during development or after approval, which could lead to the discontinuation of our clinical development programs, refusal by regulatory authorities to approve our investigational products or limitations on the use of our investigational products or, if discovered following marketing approval, revocation of marketing authorizations or subsequent limitations on the use of our investigational products.

As we continue to develop our investigational products and initiate clinical trials of additional investigational products, serious adverse events, undesirable side effects or unexpected characteristics may emerge causing us to abandon these investigational products or limit their development to more narrow uses or subpopulations in which the serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Even if our investigational products initially show promise in early clinical trials, the side effects of drugs are frequently only detectable after they are tested in larger, Phase 3 clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval. Sometimes, it can be difficult to determine if the serious adverse or unexpected side effects were caused by the investigational product or another factor, especially in oncology subjects who may suffer from other medical conditions and be taking other medications.

Additionally, adverse developments in clinical trials of investigational products conducted by others or adverse events associated with commercial products offered by others may cause the FDA or other regulatory oversight bodies to suspend or terminate our clinical trials or change the requirements for approval of any of our investigational products, or otherwise adversely affect the clinical and commercial development of our investigational products.

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

Other potentially significant negative consequences associated with adverse events include:

- institutional review boards, ethics committees, or safety monitoring committees may recommend that enrollment or dosing be placed on hold or that additional safety measures be implemented for ongoing clinical trials;

- we may be required to suspend marketing of a product, or we may decide to remove such product from the marketplace;
- regulatory authorities may withdraw or change their approvals of a product;
- regulatory authorities may require additional warnings or contraindications on the label or limit access of a product to selective specialized centers with additional safety reporting and with requirements that patients be geographically close to these centers for all or part of their treatment;
- we may be required to create a medication guide outlining the risks of a product for patients, or to conduct post-marketing studies;
- we may be required to change the way a product is dosed, distributed, or administered, or conduct additional clinical trials;
- we may be subject to limitations on how we may promote the product;
- we could be subject to fines, injunctions, or the imposition of criminal or civil penalties, or be sued and held liable for harm caused to subjects or patients; and
- a product may become less competitive, and our reputation may suffer.

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

Adverse findings from clinical trials conducted by third parties investigating the same investigational products as us in different territories or different investigational products directed to the same target as one of our programs could adversely affect our development program.

Lack of efficacy, adverse events, undesirable side effects, or other adverse findings may emerge in clinical trials conducted by third parties investigating the same investigational products as us in different territories or different investigational products directed to the same target as one of our programs. For example, we and Gloria Biosciences each licensed our rights to the same anti-PD-1 antibody (which we refer to as zimberelimab) from WuXi Biologics. Gloria Biosciences refers to this antibody as GLS-010 and is conducting clinical trials with GLS-010 in China. We have no control over their clinical trials or development program, and adverse findings from the results or their conduct of clinical trials could adversely affect our development of zimberelimab or even the viability of zimberelimab as an investigational product. We may be required to report Gloria Biosciences' adverse events or unexpected side effects to the FDA or comparable foreign regulatory authorities, which could, among other things, order us to cease further development of zimberelimab. We may face similar risks from any independent development conducted with our investigational products by Gilead and Taiho, following any exercise of their respective options to our programs.

Further, we have no control over the clinical trials or development programs of third parties developing investigational products directed to the same target as one of our programs. Adverse findings or clinical trial results from such trials could adversely affect the commercial prospects of our investigational products and cause our stock price to fluctuate or decline.

A key element of our strategy is the development of intra-portfolio combinations. If we are not successful in discovering, developing and commercializing investigational products that take advantage of different mechanisms of action to achieve superior outcomes relative to the use of single agents or other combination therapies, our ability to achieve our strategic objectives would be impaired.

A key element of our strategy is to build a broad portfolio of investigational products that will allow for the development of intra-portfolio combinations. We believe that by developing or licensing these investigational products, we can control the combinations we pursue and, if and when approved, maximize the commercial potential of these combinations. However, these combinations have not been tested before and may fail to demonstrate synergistic activity against immunological targets, may fail to achieve superior outcomes relative to the use of single agents or other combination therapies, may exacerbate adverse events associated with one of the investigational products when used as monotherapy, or may fail to demonstrate sufficient safety or efficacy traits in clinical trials to enable us to complete those clinical trials or obtain marketing approval for the combination therapy. Any of these events could delay our programs. In addition, our early clinical trials may test more than one investigational product in uncontrolled studies, and it may be difficult to interpret the results of those uncontrolled trials or evaluate the contribution of each investigational agent in such combination.

Even if we are successful in developing combination therapies, competition from other investigational products in the same class which are either already approved or further along in development than ours may prevent us from realizing the commercial potential of our combination therapies and prevent us from achieving our strategic objectives.

Development of combination therapies may present more or different challenges than development of single agent therapies.

Many of our investigational products are being pursued in combination with one or more additional products or investigational products. The development of combination therapies may be more complex than the development of single agent therapies and generally requires that sponsors demonstrate the contribution of each investigational product to the claimed effect and the safety and efficacy of the combination as a whole. This requirement may make the design and conduct of clinical trials more complex, requiring more clinical trial subjects. We also may not be able to meet the FDA's current or future approval standards required for combination therapies or combination products, if we decided to administer or package a combination therapy as a single drug product. For example, under the "combination rule", the FDA may not file or approve a fixed-dose combination product unless each component of a proposed drug product is shown to make a contribution to the claimed effects and the dosage of each component (amount, frequency, duration) is safe and effective for the intended population. To satisfy these requirements, the FDA may recommend we conduct a clinical factorial study, designed to assess the effects attributable to each drug in the combination product. Moreover, the applicable requirements for approval of a combination therapy may differ from country to country.

In the event that one of our investigational products were to fail to demonstrate sufficient safety and efficacy or establish its contribution to the claimed effects of a combination therapies, we would need to identify alternatives. For example, we expect that our anti-PD-1 antibody, zimberelimab, will form the backbone of many of the investigational combination therapies we are pursuing. If we are unable to demonstrate the contribution of zimberelimab to the claimed effects of an investigational combination therapy, we would need to identify an anti-PD-1 antibody for use in such combination therapy. In the event we are unable to do so or are unable to do so on commercially reasonable terms, our business and prospects would be materially harmed.

Certain of our investigational products may require companion diagnostics in certain indications. Failure to successfully develop, validate and obtain regulatory clearance or approval for such tests could harm our product development strategy or prevent us from realizing the full commercial potential of our investigational products.

Companion diagnostics are subject to regulation by the FDA and comparable foreign regulatory authorities as a medical device and may require separate regulatory authorization prior to commercialization of either the companion diagnostic or the relevant investigational product. According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared for that indication. Depending on the data from our clinical trials, we may utilize diagnostic tests, during our clinical trial enrollment process to help identify patients with characteristics that we believe will be most likely to respond to our investigational products. For example, certain clinical trials that we are conducting, such as our STAR-221 trial, use a diagnostic test to measure PD-L1 levels in tumor samples provided by enrolled patients. Our future trials may also use a diagnostic test to help identify eligible patients. In addition, we have significant efforts directed to identifying changes in various cells and proteins to understand their relationship, if any, to the clinical activity observed in our clinical trials and to assess if such cells and/or proteins could be used as predictive biomarkers to select for patients more likely to respond to our investigational products. However, we cannot be certain that we will be able to identify any such biomarkers, that such biomarkers will result in us identifying the appropriate patients for our investigational products or that we or any third-party collaborators will be able to validate any diagnostic tests incorporating any predictive biomarkers we may identify.

We currently do not have any plans to develop diagnostic tests internally. We are therefore dependent on the sustained cooperation and effort of third-party collaborators in developing and, if our investigational products are approved for use only with an approved companion diagnostic test, obtaining approval and commercializing these tests. If these parties are unable to successfully develop and obtain marketing authorization for companion diagnostics for use with any of our investigational products, or experience delays in doing so, the development of our investigational products may be adversely affected and we may not be able to obtain marketing authorization for these investigational products. Furthermore, our ability to market and sell, as well as the commercial success, of any of our investigational products that require a companion diagnostic will be tied to, and dependent upon, the receipt of required regulatory authorization and the continued ability of such third parties to make the companion diagnostic commercially available on reasonable terms in the relevant geographies. Any failure to develop, validate, obtain and maintain marketing authorization and supply for a companion diagnostic we need will harm our business prospects.

The design or our execution of our ongoing and future clinical trials may not support marketing approval.

The design or execution of a clinical trial can determine whether its results will support marketing approval, and flaws in the design or execution of a clinical trial may not become apparent until the clinical trial is well advanced. In some instances, there can be significant variability in safety or efficacy results between different trials with the same investigational product due to numerous factors, including differences in trial protocols, size and type of the patient populations, variable adherence to the dosing regimen or other protocol requirements and the rate of dropout among clinical trial participants. The FDA or comparable foreign regulatory authorities may disagree with our trial designs and our interpretation of data from preclinical studies or clinical trials. Even if we adhere to guidance or advice given by the FDA or comparable foreign regulatory authorities, such adherence does not guarantee that the FDA will agree with our trial designs or data interpretations or prevent the FDA from changing the requirements for the approval of any investigational product.

We have conducted, and continue to conduct, portions of our clinical trials outside the U.S., and the FDA may not accept data from trials conducted in foreign locations.

We have conducted, and we expect to continue to conduct, portions of our clinical trials outside the U.S. Although the FDA may accept data from clinical trials conducted outside the U.S., acceptance of these data is subject to certain conditions imposed by the FDA. For example, in cases where data from foreign clinical trials are intended to serve as the sole basis for regulatory approval in the U.S., the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, if the study was not otherwise subject to an IND, the FDA will not accept the data as support for an application for regulatory approval unless the study is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar requirements for clinical data gathered outside of their respective jurisdictions. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. We cannot assure you that the FDA will accept data from trials conducted outside the U.S. If the FDA does not accept the data from such clinical trials, we would likely need to conduct additional trials, which would be costly and time-consuming and delay or permanently halt our development of our investigational products.

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

The ability of the FDA and foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's or foreign regulatory authorities' ability to perform routine functions. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies, may also slow the time necessary for new drugs, and biologics or modifications to approved drugs and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections at domestic and foreign manufacturing facilities from March 2020 until July 2021. If a prolonged government shutdown occurs, or if new global health concerns otherwise hinder or prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Risks Related to Reliance on Third Parties, Manufacturing and Commercialization

We expect to depend on our collaboration with Gilead for the research, development, manufacture and commercialization of our investigational products. If this collaboration is not successful, our business could be adversely affected.

Our strategy for fully developing and commercializing our investigational products is dependent upon maintaining our current arrangements with Gilead and our other strategic partners. Our ability to leverage these arrangements to produce commercial success will depend, among other things, on our collaborators' cooperation and ability to successfully meet their responsibilities with regards to a clinical program. We cannot predict the success of any collaboration that we enter into. Our partnership with Gilead poses a number of risks that could materially impact our operations and financial condition including, but not limited to, the following:

- conflicts may arise between us and Gilead, such as conflicts regarding the combinations or indications to pursue or concerning the interpretation of clinical data, the commercial potential of any optioned investigational products, the interpretation of financial provisions or the ownership of intellectual property developed during the collaboration;
- if our joint development program does not result in the successful development and commercialization of products or if Gilead terminates the collaboration agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration;
- we will be heavily dependent on Gilead for its further development and commercialization of the investigational products from the programs that it opts in to;
- we may not be successful in this collaboration due to various other factors, including our ability to demonstrate proof of concept in one or more clinical studies so that Gilead will exercise its option to these programs;
- we have appointed three individuals that were designated by Gilead to our board of directors pursuant to the terms of the Investor Rights Agreement, and Gilead owns approximately 32.6% of our outstanding common stock as of December 31, 2024. Gilead acquired an additional 1.4 million shares of our common stock in the February 2025 underwritten offering and subsequently held approximately 29.7% of our common stock as of February 19, 2025. They have the right (but not the obligation) to acquire additional shares from us up to an amount resulting in Gilead owning a total of 35% of our outstanding common stock and, as a result, may be able to exert significant influence over our company;
- Gilead could independently develop, or develop with third parties, products that compete directly or indirectly with our investigational products if Gilead believes that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours; and
- it will be difficult for us to enter into new collaborations for any programs to which Gilead retains its option rights.

Given the breadth of the collaboration with Gilead, our ability to form new collaborations in the future will be limited. If Gilead declines to exercise its option to a program, we may need to enter into new collaborations for such programs with companies that have more resources and experience than us. We may not be successful in these efforts because third parties may not view our investigational products as having the requisite potential to demonstrate safety and efficacy. If and when we collaborate with a third-party for development and commercialization of an investigational product, we can expect to relinquish some or all of the control over the future success of that investigational product to the third-party. Our ability to 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.

We rely on third parties to conduct our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects.

We are and expect to remain dependent on third parties, such as CROs, clinical investigators and consultants, to conduct our ongoing clinical trials and any future clinical trials of our investigational products. The timing of the initiation

and completion of these trials will therefore be partially controlled by such third parties and may result in delays to our development programs.

There is no guarantee that any CROs, investigators or other third parties that help conduct or participate in our clinical trials will devote adequate time and resources to such trials or perform as contractually required. While we have and will have agreements governing the activities of our CROs, investigators and other consultants, we have limited influence over their actual performance. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards and requirements, and our reliance on our CROs and other third parties does not relieve us of our regulatory responsibilities.

If any of these third parties fails to meet expected deadlines, fails to adhere to our clinical protocols, fails to meet regulatory requirements or guidelines (including any GCPs or comparable requirements enforced by the FDA or comparable foreign regulatory authorities), or otherwise performs in a substandard manner, our ability to use data generated from our clinical trials may be jeopardized the timelines for our clinical trials may be extended or delayed, or our development activities may be suspended or terminated. If any of our clinical trial sites terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in our ongoing clinical trials unless we are able to transfer those subjects to another qualified clinical trial site. In addition, our CROs have the right to terminate their agreements with us in the event of an uncured material breach and under other specified circumstances, and if so terminated, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms or at all. Switching or adding additional CROs, investigators and other third parties involves additional cost and requires our management's time and focus.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the utility of certain data from the clinical trial may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any NDA or BLA we submit to the FDA, or equivalent marketing application to other regulatory authorities outside the U.S. Any such delay or rejection could prevent us from commercializing our investigational products, which would have material adverse impact on our business, financial condition and prospects.

Supply by third parties of the investigational products, standard-of-care drugs or comparator agents used in our clinical trials may become limited or interrupted which could delay, prevent or impair our development efforts.

Manufacturing biologics, especially in large quantities, is often complex and may require the use of innovative technologies to handle living cells. We rely, and expect to continue to rely, on third parties for the manufacture and supply of our investigational products for preclinical and clinical testing, as well as for commercial manufacture if any of our investigational products are approved. If any of these third-parties fail to perform these activities for us, nonclinical or clinical development of our investigational products could be delayed, which could have an adverse effect on our business, financial condition, results of operations, and/or growth prospects. Further, we currently have limited manufacturing arrangements for our investigational products and expect that each of our investigational products will only be covered by single source suppliers for the foreseeable future. Our reliance on limited manufacturing arrangements increases the risk that we will not have and may not be able to obtain sufficient quantities of our investigational products for use in our clinical trials and, if approved, commercial activities. For example, WuXi Biologics, located in China, is currently our sole manufacturer of zimberelimab and domvanalimab. We regularly assess our supply needs against our manufactured quantities, however, if WuXi Biologics, or any other manufacturer that we rely on, is unable or unwilling to provide the quantity of material we require, there is no guarantee that any reserves we have of our investigational products will be sufficient for our future clinical development plans. If any reserves we have are depleted and we are unable to establish a reliable source of supply, our development efforts, and if approved, commercial activities, could be delayed or impaired. See the risk factor titled "Unfavorable global economic, political and trade conditions could adversely affect our business, financial condition or results of operations and may exacerbate the effects of the risks described herein."

Any supply chain challenges may affect our ability to supply clinical sites with our investigational products and any standard-of-care drugs and comparator agents that we use in our clinical trials. These supply chain challenges can include longer lead times for the manufacturers of our investigational products to obtain raw materials, longer timeframes to procure or lack of supply for standard-of-care drugs or comparator agents used in our clinical trials, and transit delays at each point in the manufacturing, supply or distribution chain. For example, we use various standard-of-care chemotherapies, including 5-flourouracil and oxaliplatin in our STAR-221 clinical trial, and carboplatin in certain of our clinical trials. However, certain of the countries where we conduct these clinical trials are experiencing a shortage in the supply of these chemotherapies. These supply chain challenges may prevent us from enrolling subjects into our clinical trials, may result in increased costs for our clinical trials, and may otherwise delay, prevent or impair our development efforts.

Our manufacturing partners are subject to extensive regulation. In the event any of our manufacturers fail to comply with such regulations or perform its obligations, our business may be adversely affected and we may need to delay or halt the development of our investigational products.

We do not control the manufacturing process of our contract manufacturing partners and are completely dependent on them for compliance with cGMP requirements for manufacture of our investigational products, including assuring that their processes have adequate quality control, quality assurance and qualified personnel. In the event that any of our manufacturers fail to comply with regulatory requirements, such as the requirement to implement and operate quality systems to control and assure the quality of investigational products and products approved for sale and other requirements imposed by cGMP regulations, or if any of our manufacturers fail to perform its obligations to us in relation to quality, timing or otherwise, we may be forced to suspend or terminate our development activities.

In particular, we currently do not have the capabilities or resources to manufacture our investigational products ourselves and any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements. In some cases, the technical skills or technology required to manufacture our investigational products may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third-party and a feasible alternative may not exist. If we are required to change manufacturers for any reason, including as a result of geopolitical tensions, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines, and we may be required to conduct additional clinical trials or perform additional development activities to demonstrate comparability of lots of our investigational products to those produced by prior manufacturers.

Our or a third-party's failure to execute on our manufacturing requirements on commercially reasonable terms and in compliance with cGMP or other regulatory requirements could adversely affect our business in a number of ways, including:

- an inability to initiate or complete clinical trials of our investigational products in a timely manner;
- delays in submitting regulatory applications, or receiving regulatory approvals, for our investigational products;
- subjecting third-party manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease development or to recall batches of our investigational products; and
- in the event of approval to market and commercialize an investigational products, an inability to meet commercial demands.

Our employees, clinical trial investigators, CROs, consultants, vendors, collaboration partners and any potential commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, clinical trial investigators, CROs, consultants, vendors, collaboration partners and any potential commercial partners. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (i) FDA laws and regulations or those of comparable foreign regulatory authorities, including those laws that require the reporting of true, complete and accurate information, (ii) manufacturing standards, (iii) federal and state health and data privacy, security, fraud and abuse, government price reporting, transparency reporting requirements, and other healthcare laws and regulations in the U.S. and abroad, or (iv) laws that require the true, complete and accurate reporting of financial information or data. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, as well as a disclosure program and other applicable policies and procedures, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Even if we receive regulatory approval for any investigational product, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense.

Following potential approval of any our investigational products, the FDA may impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly and time-consuming post-approval studies, post-market surveillance or clinical trials to monitor the safety and efficacy of the product. The FDA may also require a REMS as a condition of approval of our investigational products, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our investigational products, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our products will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCP requirements for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with our products, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

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

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

In addition, if any of our investigational products are approved, our product labeling, advertising and promotion will be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about drug and biological products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for an investigational product, physicians may nevertheless, in their independent medical judgment, prescribe it to their patients in a manner that is inconsistent with the approved label. The FDA does not regulate the behavior of physicians in their choice of treatments but the FDA does restrict manufacturer's communications on the subject of off-label use of their products. If we are found to have promoted such off-label uses, we may become subject to liability. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our investigational products. In addition, the FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our investigational products. We also cannot predict the likelihood, nature or extent of government If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

Even if we receive marketing approval, we may not be successful in commercializing our investigational products.

We have no sales, marketing or distribution capabilities or experience. If any of our investigational products ultimately obtains regulatory approval, we, whether alone or in collaboration with Gilead for programs that we commercialize together, may not be able to effectively or successfully market the product due to a number of factors, including:

- the imposition by regulatory authorities of significant restrictions on a product's indicated uses, marketing or distribution;

- the imposition by regulatory authorities of costly and time-consuming post-approval studies, post-market surveillance or additional clinical trials;
- our failure to establish sales and marketing capabilities;
- the failure of our products to achieve the degree of market acceptance by physicians, patients, hospitals, cancer treatment centers, healthcare payors and others in the medical community necessary for commercial success;
- unfavorable pricing regulations or third-party coverage and reimbursement policies; and
- inaccuracies in our estimates of the addressable patient population resulting in a smaller market opportunity than we believed.

Even if we receive marketing approval for one or more of our investigational products, our commercial success is dependent on obtaining coverage and reimbursement approval for a product from a government or other third-party payor, which coverage may be delayed or may not be sufficient to cover our costs.

Our commercial success is dependent on obtaining coverage and reimbursement approval for a product from a government or other third-party payor, which is a time-consuming and costly process that could require us and any collaborators to provide supporting scientific, clinical and cost effectiveness data for the use of our products to the payor. There may be significant delays in obtaining such coverage and reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a product 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 products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with branded therapeutics and therapeutics administered under the supervision of a physician. Additionally, our collaborators will be required to obtain coverage and reimbursement for any related companion diagnostics tests they develop separate and apart from the coverage and reimbursement we seek for our investigational products, once approved.

Reimbursement may also impact the demand for, and the price of, any product for which we obtain marketing approval. Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with those medications. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate reimbursement is critical to new product acceptance and we expect to experience pricing pressures in connection with the sale of any of our investigational products due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes.

Our ability to obtain coverage and reimbursement approval for any of our investigational products, if approved, could have a material adverse effect on the demand for that investigational product, and on our business and our overall financial condition.

Obtaining and maintaining regulatory approval of investigational products in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. Even if our investigational products are approved by the FDA, they may never be approved or commercialized outside the U.S., which would limit our ability to realize their full market potential.

In order to market any products within a country, we or our collaborators must establish and comply with numerous and varying regulatory requirements of such country regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us or our collaborators and may require additional preclinical studies or clinical trials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. However, obtaining and maintaining regulatory approval of investigational products in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, the approval of zimberelimab for the treatment of recurrent or refractory classical Hodgkin's Lymphoma in China by Gloria Biosciences does not improve the chances of FDA approval for any BLA that we may submit for zimberelimab

in the U.S. in any indication. In addition, our or our collaborators' failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any investigational products approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we or our collaborators fail to comply with regulatory requirements in international markets or fail to obtain and maintain required approvals, our ability to realize the full market potential of our products will be harmed.

Any investigational products for which we intend to seek approval as biologic products may face competition sooner than anticipated.

The BPCIA created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until twelve years from the date on which the reference product was first licensed. During this twelve-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The law is complex and is still being interpreted and implemented by the FDA. As a result, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

Zimberelimab and domvanalimab are biological products and we may develop additional biological products in the future. We believe that any of our current and future investigational products approved as a biological product under a BLA should qualify for the twelve-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to Congressional action or otherwise, or that the FDA will not consider our investigational products to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, could be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products will depend on a number of marketplace and regulatory factors.

Risks Related to our In-Licenses and Other Strategic Agreements

We are currently party to several in-license agreements under which we acquired rights to use, develop, manufacture and/or commercialize certain of our investigational products. If we breach our obligations under these agreements, we may be required to pay damages, lose our rights to these investigational products or both, which would adversely affect our business and prospects.

We rely, in part, on license and other strategic agreements, which subject us to various obligations, including diligence obligations with respect to development and commercialization activities, reporting and notification obligations, payment obligations for achievement of certain milestones and royalties on product sales, negative covenants and other material obligations. We may need to devote substantial time and attention to ensuring that we are compliant with our obligations under these agreements. If we fail to comply with the obligations under our license agreements or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and our licensors may have the right to terminate the license. If our license agreements are terminated, we may not be able to develop, manufacture, market or sell the products covered by our agreements and those being tested or approved in combination with such products. Such an occurrence could materially adversely affect the value of the investigational product being developed under any such agreement and any other investigational products being developed or tested in combination. Domvanalimab, which we in-licensed from Abmuno, and zimberelimab, which we in-licensed from WuXi Biologics, are being evaluated in combination in our two most advanced Phase 3 studies, STAR-121 and STAR-221. In the event we breach any of our license agreements with Abmuno and/or WuXi Biologics, and our license agreements are terminated, we would have to cease these development activities, or we would have to negotiate a new or reinstated agreement, which may not be available to us on equally favorable terms, or at all.

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

ability to maintain our collaborations or other strategic partnerships on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected investigational products.

We may not realize the benefits of any acquisitions, in-license or other collaborations or strategic alliances that we enter into.

We have entered into in-license agreements with multiple licensors and option agreements to enable the development and commercialization of our investigational products worldwide. In the future, we may seek to enter into acquisitions or additional licensing arrangements with third parties to expand our pipeline or that we believe will complement or augment our development and commercialization efforts with respect to our investigational products and any future investigational products that we may develop. These transactions can entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, investigational products or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business. As a result, if we enter into in-license, acquisition or collaboration agreements, or strategic partnerships, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business.

Risks Related to Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for our investigational products, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the U.S. and other countries with respect to our investigational products and research programs. We seek to protect our proprietary position by filing patent applications in the U.S. and abroad related to our novel discoveries and technologies that are important to our business, however, we cannot predict:

- if and when patents may issue based on our patent applications;
- the scope of protection of any patent issuing based on our patent applications;
- whether the claims of any patent issuing based on our patent applications will protect our investigational products and their intended uses or prevent others from commercializing competitive technologies or products;
- whether or not third parties will find ways to invalidate or circumvent our patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; and/or
- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose.

Obtaining and enforcing patents 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. Even if we successfully file and prosecute a patent application, we may not be able to maintain and/or enforce the issued patent. We may determine that filing or maintaining such a patent or any action to enforce a patent may be too high or not in the best interest of our company or our stockholders. It is also possible that we will fail to identify patentable aspects of our R&D results before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our R&D output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

We also cannot be certain that the claims in our pending patent applications directed to our investigational products and/or technologies will be considered patentable by the USPTO or by patent offices in foreign countries. One

aspect of the determination of patentability of our inventions depends on the scope and content of the "prior art," information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim. Even if the patents do issue based on our patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our investigational products is threatened, it could dissuade companies from collaborating with us to develop and threaten our ability to commercialize our investigational products. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our issued patents will be considered valid by courts in the U.S. or foreign countries.

We may become involved in lawsuits alleging that we have infringed the intellectual property rights of third parties or to protect or enforce our patents or other intellectual property, which litigation could be expensive, time consuming and adversely affect our ability to develop or commercialize our investigational products.

The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our products candidates. Third parties may assert infringement claims against us based on existing or future intellectual property rights. If we were sued for patent infringement, we would need to demonstrate that our investigational products, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity may be difficult. For example, in the U.S., proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. If we are found to infringe a third-party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing investigational product or product. Alternatively, we may be required to obtain a license from such third-party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing investigational product. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our investigational products or force us to cease some of our business operations, which could materially harm our business.

In addition, we may find that competitors are infringing our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against which we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Moreover, we cannot assure you that we will have sufficient financial or other resources to defend or pursue such litigation, which typically last for years before they are concluded. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific

personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on our business and operations. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of former employers or competitors. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may become subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor.

While we may litigate to defend ourselves against these claims, even if we are successful, litigation could result in substantial costs and could be a distraction to management. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our investigational products, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition.

We may not be able to protect our intellectual property rights outside of the U.S.

Patents are of national or regional effect, and filing, prosecuting and defending patents on all of our investigational products throughout the world would be prohibitively expensive. As such, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Further, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals or biologics, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. In addition, certain developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. Further, we file patent applications in Russia and the Eurasian patent office, which is headquartered in Moscow. Sanctions against Russia may make it difficult to file and maintain patents in these countries, and Russia has taken actions against "unfriendly" countries, including the U.S., which may adversely affect the scope of and/or our ability to enforce our intellectual property rights. In any of these countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third-party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. However, the patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation, resulting in court decisions, including Supreme Court decisions, which have increased uncertainties as to the ability to obtain and enforce patent rights in the future. Changes in either the patent laws or interpretation of the patent laws in the U.S. and other countries could increase the uncertainties and costs. For example, in September 2011 the Leahy-Smith America Invents Act (the "America Invents Act") was signed into law and included a number of significant changes to U.S. patent law as then existed. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. After March 2013, under the America Invents Act, the U.S. transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third-party was the first to invent the claimed invention. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications

and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

In addition, in 2012, the European Patent Package, or EU Patent Package, regulations were passed with the goal of providing a single pan-European Unitary Patent and a new European Unified Patent Court, or UPC, for litigation involving European patents. Implementation of the EU Patent Package occurred on June 1, 2023. Under the UPC, all European patents, including those issued prior to ratification of the European Patent Package, will by default automatically fall under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents, and allow for the possibility of a competitor to obtain pan-European injunctions. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and product candidates and, resultantly, on our business, financial condition, prospects and results of operations. It will be several years before we will understand the scope of patent rights that will be recognized and the strength of patent remedies that will be provided by the UPC. Under the EU Patent Package as currently proposed, we will have the right to opt our patents out of the UPC over the first seven years of the court's existence, but doing so may preclude us from realizing the benefits of the new unified court. Moreover, if we do not meet all of the formalities and requirements for opt-out under the UPC, our future European patents could remain under the jurisdiction of the UPC.

We may rely on trade secret and proprietary know-how which can be difficult to trace and enforce and, 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 investigational products, we may also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Elements of our investigational product, including processes for their preparation and manufacture, may involve proprietary know-how, information, or technology that is not covered by patents, and thus for these aspects we may consider trade secrets and know-how to be our primary intellectual property. Any disclosure, either intentional or unintentional, by our employees, third parties with which we share our facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

Trade secrets and know-how can be difficult to protect. We require our employees to enter into written employment agreements containing provisions of confidentiality and obligations to assign to us any inventions generated in the course of their employment. We and any third parties with which we share facilities enter into written agreements that include confidentiality and intellectual property obligations to protect each party's property, potential trade secrets, proprietary know-how, and information. We further seek to protect our potential trade secrets, proprietary know-how, and information in part, by entering into non-disclosure and confidentiality agreements with parties who are given access to them, such as our corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. With our consultants, contractors, and outside scientific collaborators, these agreements typically include invention assignment obligations. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the U.S. are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third-party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third-party, our competitive position would be harmed.

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

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties

involved in developing our investigational products or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Patent terms may be inadequate to protect our competitive position on our investigational products for an adequate amount of time.

Patent rights are of limited duration. Given the amount of time required for the development, testing and regulatory review of new investigational products, patents protecting such candidates might expire before or shortly after such investigational products are commercialized. Even if patents covering our investigational products are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic products. A patent term extension based on regulatory delay may be available in the U.S. However, only a single patent can be extended for each marketing approval, and any patent can be extended only once, for a single product. Moreover, the scope of protection during the period of the patent term extension does not extend to the full scope of the claim, but instead only to the scope of the product as approved. Laws governing analogous patent term extensions in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Additionally, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

Risks Related to our Business Operations and Industry

We expect to expand our business operations, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to grow our business operations, including adding employees in sales and marketing, if any of our investigational products receives marketing approval. To manage our anticipated future growth, we must:

- identify, recruit, integrate, maintain and motivate additional qualified personnel;
- manage our development efforts effectively, including the initiation and conduct of clinical trials for our investigational products; and
- improve our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to develop, manufacture and commercialize our investigational products will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert financial and other resources, as well as a disproportionate amount of its attention, away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our investigational products and, accordingly, may not achieve our research, development and commercialization goals.

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

Our ability to compete in the highly competitive biopharmaceuticals industry depends upon our ability to attract, retain and motivate highly skilled and experienced personnel with scientific, medical, regulatory, manufacturing and management skills and experience. We conduct our operations in the San Francisco Bay Area, a region that is home to many other biopharmaceutical companies as well as many academic and research institutions, resulting in fierce competition for qualified personnel and rapidly increasing wages. Our industry also has experienced a high rate of turnover in recent years. While we have expanded a number of our in-office roles to permit remote work arrangements, allowing us to seek talent from outside the San Francisco Bay Area, we still may not be able to attract or retain qualified personnel in the future due to the intense competition for a limited number of qualified personnel among biopharmaceutical companies.

Many of the other biopharmaceutical companies we compete with have greater financial and other resources, different risk profiles and a longer history in the industry than we do. Our competitors may provide higher compensation, more diverse opportunities and/or better opportunities for career advancement. Any or all of these competing factors may limit our ability to continue to attract and retain high quality personnel, which could negatively affect our ability to successfully develop and commercialize our investigational products and to grow our business and operations as currently contemplated.

We are highly dependent on the services of our founders, Terry Rosen, Ph.D., who serves as our Chief Executive Officer, and Juan Jaen, Ph.D., who serves as our President.

We are highly dependent on the services of our founders, Terry Rosen, Ph.D., who serves as our Chief Executive Officer, and Juan Jaen, Ph.D., who serves as our President. Although we have entered into employment agreements with them, they are not for a specific term, and each of them may terminate their employment with us at any time, though we are not aware of any present intention of either of these individuals to leave us.

Drs. Rosen and Jaen have significant experience identifying and developing biopharmaceuticals. We believe that their drug discovery and development experience, and overall biopharmaceutical company management experience, would be difficult to replace. However, the historical results, past performance and/or acquisitions of companies with which they were affiliated do not necessarily predict or guarantee similar results for our company. Further, Drs. Rosen and Jaen have certain other business and personal commitments outside of serving as the Chief Executive Officer and President of Arcus, including serving on the boards of other companies and foundations, which may result in diversion of their focus and attention on our company.

We face substantial competition, which may result in others discovering, developing or commercializing products more quickly or marketing them more successfully than us. If their investigational products are shown to be safer or more effective than ours, then our commercial opportunity will be reduced or eliminated.

We compete in the segments of the pharmaceutical, biotechnology and other related markets that develop immunotherapies for the treatment of cancer, which is highly competitive with rapidly changing standards of care. As such, 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 or that would render any products that we may develop obsolete or non-competitive. Our competitors also may 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 are aware of several pharmaceutical companies developing products in the same class as our investigational products, some of which are further along in development than our corresponding assets. See “Item 1. Business—Competition” for additional information regarding our competitors.

As more investigational products within a particular class of drugs proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change. Consequently, the results of our clinical trials for investigational products in that class will likely need to show a risk benefit profile that is competitive with or more favorable than those products and investigational products in order to obtain marketing approval or, if approved, a product label that is favorable for commercialization. If the risk benefit profile is not competitive with those products or investigational products, or if the approval of other agents for an indication or patient population significantly alters the standard of care with which we tested our investigational products, we may have developed a product that is not commercially viable, that we are not able to sell profitably or that is unable to achieve favorable pricing or reimbursement. In such circumstances, our future product revenue and financial condition would be materially and adversely affected.

Our internal information technology systems, and those of our third-party CROs and other third parties upon which we rely, are subject to failure, security breaches and other disruptions, which could result in a material disruption of our investigational products’ development programs, jeopardize sensitive information, prevent us from accessing critical information or result in a loss of our assets, and potentially expose us to notification obligations, loss, liability or reputational damage and otherwise adversely affect our business.

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information, including but not limited to intellectual property, proprietary business information and personal information (collectively, "Sensitive Information").

We also have outsourced elements of our operations to third parties, and as a result we manage a number of third-party contractors and other parties who have access to our sensitive information. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If the third parties we rely on experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if these third parties fail to satisfy their privacy- or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such an award. In addition, supply chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

Despite the implementation of security measures, given the size and complexity and the increasing amounts of sensitive information that they maintain, our internal information technology systems and those of our third-party CROs and other third parties upon which we rely are vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners, and/or other third parties, or from cyberattacks by malicious third parties (including the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information and other assets), which may compromise our system infrastructure, lead to data leakage, impair key business processes or other critical business operations, delay our development programs, or result in the loss of assets or other liability. Our reliance on internet technology and the number of our employees who are working remotely has increased the opportunities for cybercriminals to exploit vulnerabilities. There can be no assurance that our cybersecurity risk management program and processes, including our policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems and information. Further, we cannot assure you that our data protection efforts and our investment in information technology will prevent breakdowns, data leakages, breaches in our systems or other cyber incidents that could have a material adverse effect upon our reputation, business, operations or financial condition.

Furthermore, as the cyber threat landscape evolves, these attacks are growing in frequency, sophistication and intensity, and becoming increasingly difficult to detect. There can be no assurance that we and our third-party CROs and other third parties upon which we rely will be successful in detecting, preventing or fully recovering systems or data from all breakdowns, service interruptions, attacks or breaches of systems that could adversely affect our business and operations and/or result in the loss or disclosure of critical or sensitive data or other assets, which could result in financial, legal, business or reputational harm to us. Ransomware attacks have risen dramatically and we may be forced to pay to unlock our data and information, re-access our systems and resume our ability to conduct business operations. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. The loss of clinical trial data for our investigational products could significantly increase our costs to recover or reproduce the data and result in delays in our development programs, impair our ability to obtain marketing approval and reduce the commercial opportunity for our investigational products.

We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of any third parties we rely), but we may not be able to detect and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Moreover, significant disruptions of our internal information technology systems or security breaches could result in the loss, misappropriation, and/or unauthorized access, use, or disclosure of, or the prevention of access to, Sensitive Information, which could result in financial, legal, business, and reputational harm to us. In particular, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our clinical trial subjects or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

Although we maintain insurance coverage to insure against losses suffered as a result of malicious intrusions and cyberattacks, such coverage may be insufficient to fully compensate us for the loss or there may be disputes with our insurers about the availability of insurance coverage for our claims. Cyber insurance may become increasingly difficult to maintain and we may not be able to maintain coverage at a reasonable cost or in an amount adequate to compensate for any loss or satisfy any liability that may arise. Our contracts may not contain limitations of liability, and even where they do,

there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations.

Our sensitive information could be leaked, disclosed, or revealed as a result of or in connection with the use of generative artificial intelligence ("AI") technologies by our employees, personnel, or the third parties upon whom we rely. Any sensitive information (including confidential, competitive, proprietary, or personal data) that is inputted into a third-party generative AI platform could be leaked or disclosed to others, including if sensitive information is used to train the third parties' AI model.

Unfavorable global economic, political and trade conditions could adversely affect our business, financial condition or results of operations and may exacerbate the effects of the risks described herein.

Current global economic conditions are highly volatile due to a number of reasons, including geopolitical instability, such as the military conflicts between Russia and Ukraine, the conflicts between Israel and Hamas, recent inflation that increased our operating expenses and disruptions in the capital and credit markets that may reduce our ability to raise additional capital when needed on acceptable terms, if at all.

Emerging international trade relations, new legislation and tariffs may also adversely impact our operations and/or financial condition by limiting or preventing the activities of third parties that we engage, increasing import costs or increasing the cost of our operations. New or increased tariffs, export controls or other trade barriers could result in higher prices for the materials we use and the investigational products we are developing and could materially impact our supply chain and manufacturing costs. Recent congressional legislative actions, proposed executive orders, sanctions, tariffs and other measures discourage contracting with Chinese companies on the development or manufacturing of pharmaceutical products and may restrict trade with China. WuXi Biologics, located in China, is currently our sole manufacturer of zimberelimab and domvanalimab. If WuXi Biologics becomes subject to trade restrictions, sanctions, increased tariffs or other regulatory requirements by the U.S. government, or if the U.S. or Chinese government take retaliatory actions due to recent or increased tensions between the U.S. and mainland China, it could materially impact our ability to obtain additional supply of zimberelimab and domvanalimab or significantly increase our manufacturing costs. Finding a replacement manufacturer could require significant effort and/or be prohibitively expensive, and we may not be able to do so in a timely manner which could have an adverse impact on our operations, operating results and financial condition.

Furthermore, the recent inflationary environment related to increased aggregate demand and supply chain constraints has increased our operating expenses and may continue to affect our operating expenses. Economic conditions may also strain our suppliers, possibly resulting in supply disruptions that impact our ongoing clinical trials and other operations. A significant worsening of global economic conditions could materially increase these risks we face.

Any new or prolonged downturn of global economic conditions could harm our business operations, and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

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

Our future profitability may depend, in part, on our ability to commercialize our investigational products in foreign markets for which we may rely on collaboration with third parties. We are not permitted to market or promote any of our investigational products before we receive marketing approval from the applicable regulatory authority in that foreign market, and we may never receive such marketing approval for any of our investigational products. To obtain marketing approval in many foreign countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our investigational products, and we cannot predict success in these jurisdictions. If we obtain approval of our investigational products and ultimately commercialize our investigational products in foreign markets, we would be subject to additional risks and uncertainties, including:

- our customers' ability to obtain reimbursement for our investigational products in foreign markets;
- our inability to directly control commercial activities because we are relying on third parties;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;

- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries;
- the existence of additional potentially relevant third-party intellectual property rights;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of our investigational products could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs.

We or the third parties upon which we depend may be adversely affected by earthquakes, fires or other natural disasters.

Our headquarters and main research facility are located in the San Francisco Bay Area, which in the past has experienced severe earthquakes and fires. In addition, fires and other natural disasters may increase in frequency and severity over time due to climate change. If these earthquakes, fires, other natural disasters, terrorism and similar unforeseen events beyond our control were to prevent us from using all or a significant portion of our headquarters or research facility, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. We do not have a disaster recovery or business continuity plan in place and may incur substantial expenses as a result of the absence or limited nature of our internal or third-party service provider disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business. Furthermore, integral parties in our supply chain are operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our ability to conduct our clinical trials, our development plans and business.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred substantial losses during our history and our ability to generate profits in the future is uncertain. Unused net operating loss ("NOL") carryforwards the tax year ended December 31, 2017 and prior tax years will carry forward to offset future taxable income, if any, until such unused NOLs expire. Unused NOLs generated after December 31, 2017, under current tax law, will not expire. Our NOLs may be carried forward indefinitely. In addition, the future deductibility of such NOLs will be limited to 80% of current year taxable income in any given year.

Both our current and our future unused losses (and tax credit carryforwards) may be subject to further limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "IRC"), 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 three-year period. We performed an analysis under IRC Section 382 and 383 through October 31, 2020 with respect to our NOL and credit carryforwards. We concluded that an ownership change, as defined under IRC Section 382, occurred in previous years, but that such ownership change did not result in the expiration of our NOL or credit carryforwards prior to utilization. We may incur additional ownership changes in the future in connection with any equity issuance, including any additional issuances to Gilead. If we experience any such ownership change, we may be limited in our ability to use our NOL and credit carryforwards and be required to make material cash tax payments.

Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited. For example, California recently enacted a franchise tax law limiting the usability of California state NOLs to offset taxable income for tax years beginning on or after January 1, 2024 and January 1, 2027. Similar laws in the future could accelerate or permanently increase state taxes owed. Therefore, even if we attain sustained profitability, we may be unable to use all or a material portion of our NOLs and other tax attributes, which could adversely affect our future cash flows.

Changes in tax laws and regulations or exposure to additional tax liabilities could adversely affect our financial results.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. We actively monitor legislative and regulatory developments that may affect our tax liability in order to identify and evaluate if such proposals would have a material impact, whether detrimental or beneficial, on our financial results. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. For example, beginning in 2022, the Tax Cuts and Jobs Act of 2017 eliminates the option to currently deduct R&D expenditures and requires taxpayers to capitalize and amortize U.S. based and non-U.S. based R&D expenditures over five and fifteen years, respectively, pursuant to IRC Section 174. We cannot predict whether, when, in what form, or with what effective dates, tax laws, regulations and rulings may be enacted, promulgated or issued, which could result in an increase in our or our stockholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law.

Risks Related to Our Industry

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

We face an inherent risk of product liability exposure related to the testing of our investigational products 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 investigational products or products caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- delay or termination of clinical trials;
- decreased demand for any investigational products or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial subjects;
- initiation of investigations by regulators;
- significant costs to defend the related litigation and diversion of management's time and our resources;
- substantial monetary awards to study subjects or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

Although we maintain product liability insurance coverage, it may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage as our investigational products advance through clinical trials and if we successfully commercialize any products. 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.

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

We and third parties upon whom we rely may be subject to federal, state, and foreign data protection, privacy, and information security laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations. In the U.S., numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the FTC Act), that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. While we do not believe that we are currently acting as a covered entity or business associate under HIPAA and thus are not directly regulated under HIPAA, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or

conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information.

The legislative and regulatory landscape for privacy and data security continues to evolve, and we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data security in the U.S., the EU, the United Kingdom (the "UK") and other jurisdictions. This increased focus on privacy and data security issues may negatively affect our operating results and our business. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 (collectively, "CCPA") applies to personal information of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future.

Foreign data protection laws also apply to health-related and other personal data obtained outside the U.S. The EU General Data Protection Regulation (the "EU GDPR"), the UK General Data Protection Regulation (the "UK GDPR" and, together with the EU GDPR, the "GDPR") and Canada's Personal Information Protection and Electronic Documents Act ("PIPEDA"), or the applicable provincial alternatives, impose strict requirements, including the obligation to appoint data protection officers in certain circumstances, rights for individuals to be "forgotten" and to data portability, and the obligation to make public notification of significant data breaches. Under the GDPR, data protection authorities can impose temporary or definitive bans on data processing and other corrective actions or fines of up to 4% of our total worldwide turnover or up to €20 million under the EU GDPR/£17.5 million pounds sterling under the UK GDPR (in either case, whichever is higher), or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. In Canada, PIPEDA and various related provincial laws, as well as Canada's Anti-Spam Legislation ("CASL"), may apply to our operations. We also target customers in Asia and may be subject to new and emerging data privacy regimes, including China's Personal Information Protection Law ("PIPL").

We may also be subject to new laws governing the privacy of consumer health data. For example, Washington's My Health My Data Act ("MHMD") broadly defines consumer health data, places restrictions on processing such data (including imposing stringent requirements for consent), provides consumers certain rights with respect to their health data, and creates a private right of action to allow individuals to sue for violations of the law. Other states are considering and may adopt similar laws.

In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the U.S. or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the EEA and the UK have significantly restricted the transfer of personal data to the U.S. and other to countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the U.S. in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant organizations based in the U.S. who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the U.S. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the U.S., or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the U.S., are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

We are also bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. We publish privacy policies, notices and other statements regarding data privacy and security. If these policies, notices or statements are found to be deficient, lacking in transparency, deceptive, unfair, or

misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

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

Our failure (or that of the third parties upon whom we rely) to comply with U.S. and foreign data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Claims that we or the third parties upon whom we rely have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis; if viable, these claims carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, as relevant, 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 defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

Our business operations expose us to broadly applicable fraud and abuse, transparency, government price reporting, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Our operations are subject to various U.S. federal and state health care laws, including fraud and abuse, transparency and other healthcare laws and regulations, and similar laws in other jurisdictions in which we conduct our business. These laws may impact, among other things, our research and proposed sales, marketing and education programs and constrain the business of financial arrangements and relationships with healthcare providers, physicians and other parties through which we market, sell and distribute our products for which we obtain marketing approval. The laws that may affect our ability to operate include, but are not limited to the federal Anti-Kickback Statute; federal civil and criminal false claims laws, such as the False Claims Act; HIPAA; federal and state consumer protection and unfair competition laws; the federal transparency requirements under the Sunshine Act; state and foreign law equivalents of each of these federal laws; and state and foreign laws that require pharmaceutical companies to implement compliance programs. Many of these laws are discussed in detail above under "Item 1. Business—Government Regulation—Other U.S. Healthcare Laws and Compliance Requirements".

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have continued their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time-and resource-consuming and can divert management's attention from the business. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. We have entered into consulting and advisory board arrangements with physicians and other healthcare providers, including some who could influence the use of our investigational products, if approved. Because of the complex and far-reaching nature of these laws, regulatory agencies may view these transactions as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to other significant civil, criminal and administrative penalties such as fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could substantially disrupt our operations. If any of the physicians or other healthcare providers or entities with which we expect to do business is 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.

Changes in healthcare law and implementing regulations, as well as changes in healthcare policy, may impact our business in ways that we cannot currently predict, and may have a significant adverse effect on our business and results of operations.

In the U.S. and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of investigational products, restrict or regulate post-approval activities, and affect the ability to profitably sell investigational products for which marketing approval is obtained. Among policy makers and payors in the U.S. and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the U.S., the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. Many of these initiatives are discussed in detail above under “Item 1. Business—Government Regulation—Healthcare Reform."

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.

U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations (collectively, "Trade Laws") prohibit, among other things, companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving (directly or indirectly) corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We also expect our non-U.S. activities to increase over time. We expect to rely on third parties for research, preclinical studies, and clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other marketing approvals. We can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

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, and the third parties with which we share our facilities, 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. Each of our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Each of our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. We could be held liable for any resulting damages in the event of contamination or injury resulting from the use of hazardous materials by us or the third parties with which we share our facilities, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

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. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

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 R&D. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Risks Related to Owning our Common Stock

The stock price of our common stock has been and may continue to be volatile or may decline regardless of our operating performance.

The market price of our common stock has fluctuated and may fluctuate significantly in response to numerous factors, many of which are beyond our control, including:

- overall performance of the equity markets;
- our operating performance and the performance of other similar companies;

- results from our ongoing clinical trials and future clinical trials with our current and future investigational products or of our competitors;
- changes in our projected operating results that we provide to the public, our failure to meet these projections or changes in recommendations by securities analysts that elect to follow our common stock;
- regulatory, trade or legal developments in the U.S. and other countries, including changes in tariffs or other trade restrictions and the changes in the structure of healthcare payment systems;
- the level of expenses related to future investigational products or clinical development programs;
- our failure to achieve product development goals in the timeframe we announce;
- announcements of acquisitions, strategic alliances or significant agreements by us or by our competitors;
- recruitment or departure of key personnel;
- the economy as a whole and market conditions in our industry;
- trading activity by a limited number of stockholders who together beneficially own a majority of our outstanding common stock;
- the size of our market float; and
- any other factors discussed in this report.

In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many immuno-oncology companies. Stock prices of many immuno-oncology companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. In the past, stockholders have filed securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs, divert resources and the attention of management from our business and adversely affect our business.

The amount of our future losses is uncertain and our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

Our quarterly and annual operating results may fluctuate significantly in the future due to a variety of factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and success or failure of clinical trials for our investigational products or competing investigational products, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- our progress towards the achievement of any product development goals or milestones we announce, including any delays or failures which lead to the suspension or termination of any clinical trial or development program;
- the timing and cost of, and level of investment in, research and development ("R&D") activities relating to our investigational products, which may change from time to time;
- option fees received by us in connection with option exercises by Gilead and/or Taiho pursuant to their respective option agreements and/or payments received by us from Gilead or Taiho in connection with the achievement of certain development and/or regulatory milestones;
- amounts payable by us in connection with the achievement of development, regulatory and commercial milestones under our in-license and other strategic agreements;
- our ability to attract, hire and retain qualified personnel;
- expenditures that we will or may incur to develop additional investigational products;
- our ability to obtain marketing approval for our investigational products, and the timing and scope of any such approvals we may receive;
- the changing and volatile U.S. and global economic environments , including the impact of tariffs, inflation and rising interest rates, and domestic or international political instability; and
- future accounting pronouncements or changes in our accounting policies.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide.

The concentration of our stock ownership will likely limit our stockholders' ability to influence corporate matters, including the ability to influence the outcome of director elections and other matters requiring stockholder approval.

Based upon shares outstanding as of December 31, 2024, our executive officers, directors and the holders of more than 5% of our outstanding common stock, in the aggregate, beneficially owned approximately 54.4% of our common stock. In particular, as of December 31, 2024, Gilead owns approximately 32.6% of our outstanding common stock, Gilead acquired an additional 1.4 million shares of our common stock in the February 2025 underwritten offering and subsequently held approximately 29.7% of our common stock as of February 19, 2025 (and has the right to acquire additional shares of our common stock from us to enable it to own up to 35% of our outstanding common stock), and we have appointed its three designees to our board of directors pursuant to the terms of the Investor Rights Agreement. As a result, these stockholders, acting together, will have significant influence over all matters that require approval by our stockholders, including the election of directors and approval of significant corporate transactions. Corporate actions might be taken even if other stockholders oppose them. This concentration of ownership might also have the effect of delaying or preventing a change of control of our company that other stockholders may view as beneficial.

Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock.

Our status as a Delaware corporation and the anti-takeover provisions of the Delaware General Corporation Law may discourage, delay or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change of control would be beneficial to our existing stockholders. In addition, our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that may make the acquisition of our company more difficult, including the following:

- a classified board of directors with three-year staggered terms, which could delay the ability of stockholders to change the membership of a majority of our board of directors;
- the ability of our board of directors to issue shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of our board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by a majority vote of our entire board of directors, the chairman of our board of directors or our chief executive officer, which could delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;
- the requirement for the affirmative vote of holders of at least 66 ⅔% of the voting power of all of the then-outstanding shares of the voting stock, voting together as a single class, to amend the provisions of our amended and restated certificate of incorporation relating to the management of our business or our amended and restated bylaws, which may inhibit the ability of an acquirer to effect such amendments to facilitate an unsolicited takeover attempt; and
- advance notice procedures with which stockholders must comply to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

In addition, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time. A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision.

These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delay or impede a merger, tender offer or proxy contest involving our company. The existence of these provisions could negatively affect the price of our common stock and limit opportunities for our stockholders to realize value in a corporate transaction.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation and our bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our certificate of incorporation or our bylaws or any action asserting a claim against us that is governed by the internal affairs doctrine. In addition, to prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our bylaws provide that the federal district courts of the U.S. will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees and may discourage these types of lawsuits. While the Delaware courts have determined that these types 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 these provisions, which 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.

General Risk Factors

Sales of substantial amounts of our shares may cause the price of our common stock to decline.

The price of our common stock could decline if there are substantial sales of our common stock, including any sales by us, our directors, executive officers, significant stockholders or the sales agents under the equity distribution agreement, or if there is a large number of shares of our common stock available for sale and the market perceives that sales will occur. We have also registered shares of common stock that we have issued and may issue under our employee equity incentive plans. These shares can be sold freely in the public market upon issuance, subject to vesting conditions and, in the case of our affiliates, volume limitations under Rule 144 under the Securities Act.

If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could result in sanctions or other penalties that would harm our business.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of the New York Stock Exchange. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal controls over financial reporting.

Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"). Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. Accordingly, we cannot assure you that we will not in the future identify one or more material weaknesses in our internal control over financial reporting, which may have a negative impact on our ability to timely and accurately produce financial statements, may result in a material misstatement of our Consolidated Financial Statements or may negatively impact the confidence level of our stockholders and other market participants with respect to our reported financial information.

Ensuring that we have adequate internal controls over financial reporting is a costly and time-consuming effort that needs to be re-evaluated frequently. Further, remote work arrangements have led to changes in work patterns that can make it more difficult to properly perform our controls and may create risks that result in deficiencies in the design of our controls. To the extent necessary, implementing any changes to our internal controls may distract our officers and employees, entail substantial costs to modify our existing processes and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and harm our business.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Risk management and strategy

We have implemented and maintain a cybersecurity program that includes various processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third-party hosted services, communications systems, hardware and software (collectively, "Information Systems"), and our critical data, including clinical trial and candidate data, intellectual property, and confidential information that is proprietary, strategic or competitive in nature (collectively with Information Systems, "Information Systems and Data").

Our program is designed and assessed using the National Institute of Standards and Technology Cybersecurity Framework ("NIST CSF"), which guides our approach to identifying, assessing, and managing material cybersecurity risks relevant to our business. While we use this framework to inform our cybersecurity practices, this does not imply compliance with any particular technical standards, specifications, or requirements.

Under this framework, our information security function, led by our Chief Information Officer, helps to identify, assess and manage the Company's cybersecurity threats and risks. This function helps to identify and assess risks from cybersecurity threats by monitoring and evaluating our threat environment using various methods including, for example deploying automated tools in certain environments, subscribing to and analyzing reports and services that identify certain cybersecurity threats, conducting scans of certain aspects of the Company's threat environment, evaluating certain threats that are reported to us, conducting internal and external audits and internal threat assessment of certain environments, engaging third parties to conduct threat assessments, and conducting vulnerability assessments.

We have engaged third-party providers to periodically assess certain of our internal controls and procedures for information security. We have also taken certain measures to mitigate cybersecurity risks, including, for example, cybersecurity awareness training for employees and management, periodic testing through simulated "phishing" campaigns (and require remedial training based on results) and the adoption of an incident response plan, vulnerability management policy and business recovery plan.

Furthermore, our information security function works with a security committee (the "Security Committee") to prioritize our risk management processes, mitigate cybersecurity threats that are more likely to lead to a material impact to our business and evaluate material risks from cybersecurity threats against our overall business objectives. We use third-party service providers to perform a variety of functions throughout our business, such as CROs and contract manufacturing organizations ("CMOs"). Under our information security function, we perform risk and security assessments for certain of our vendors that involves a review of the vendor's written security program. Depending on the nature of the services provided, and the sensitivity of the Information Systems and Data at issue, and the identity or experience of the provider, our vendor management process may involve different levels of assessment designed to help identify cybersecurity risks associated with a provider and we may impose contractual obligations related to cybersecurity on the vendor.

We have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected us, including our operations, business strategy, results of operations, or financial condition. We face risks from cybersecurity threats that, if realized, are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition. For a description of the risks from cybersecurity threats that may materially affect the Company and how they may do so, please see "Risk Factors - Our internal information technology systems, and those of our third-party CROs and other third parties upon which we rely, are subject to failure, security breaches and other disruptions, which could result in a material disruption of our investigational products' development programs, jeopardize sensitive information, prevent us from accessing critical information or result

in a loss of our assets, and potentially expose us to notification obligations, loss, liability or reputational damage and otherwise adversely affect our business.” in Part I, Item 1A herein.

Governance

Our board of directors considers cybersecurity risk management as part of its general oversight function. The board of directors’ audit committee is responsible for overseeing our cybersecurity risk management processes, including oversight and mitigation of risks from cybersecurity threats.

Our Security Committee is comprised of key management stakeholders and experts and is chaired by our Chief Information Officer , who has over 20 years of strategic and operational IT/cybersecurity leadership experience and multiple cybersecurity certifications, from leading security organizations such as (ISC)2, Cloud Security Alliance, Cisco Security, Microsoft Security. The Security Committee is responsible for helping to integrate cybersecurity risk considerations into our overall risk management strategy and communicating key priorities to relevant personnel, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

The audit committee receives periodic reports from our Chief Information Officer concerning significant cybersecurity threats and risk and the processes we have implemented to address them. Under our incident response plan, certain incidents would also be reported to the board.

Our management team takes steps to stay informed about and monitor efforts to prevent, detect, mitigate, and remediate cybersecurity risks and incidents through various means, which may include: briefings from internal personnel; threat intelligence and other information obtained from public or private sources, including external consultants engaged by us; and alerts and reports produced by security tools deployed in our IT environment.

Item 2. Properties

As of December 31, 2024, our corporate headquarters, which includes executive offices and research and development and business operations, consist of approximately 151,000 square feet of leased office and laboratory space in an office park in Hayward, California. We also lease approximately 109,000 square feet of office space in Brisbane, California. The lease terms for both facilities expire in 2031, subject to options for us to extend the lease term. We have subleased approximately 31,000 square feet of our Brisbane office to a third-party, which commenced in October 2023 and extends through 2028. We have also subleased approximately 19,000 square feet of our Brisbane office to a third-party, which commenced in December 2024 and extends through 2031.

Item 3. Legal Proceedings

We are not currently a party to any material legal proceedings. From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

Item 4. Mine Safety Disclosures

None.

PART II

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

Market Information and Stockholders

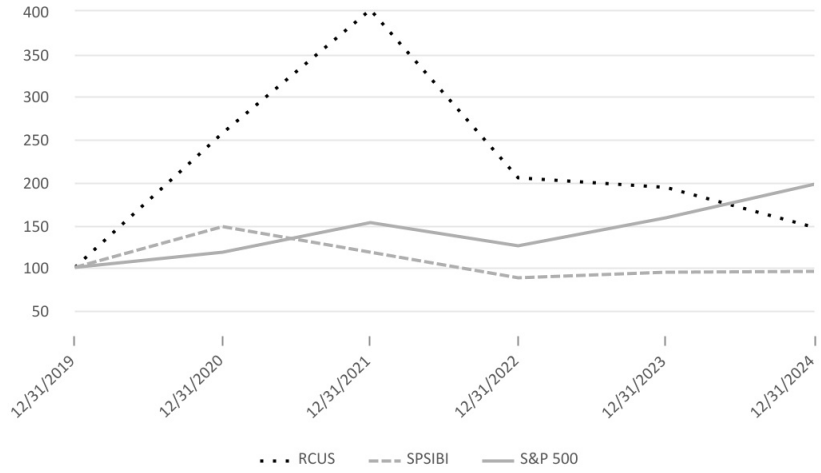
Our common stock trades on the New York Stock Exchange under the symbol "RCUS." As of February 7, 2025, we had 34 stockholders of record as reported by our transfer agent. This does not include beneficial owners whose shares are held in street name.

Dividend Policy

We have never declared or paid cash dividends on our stock. We intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors.

Performance Graph

The following graph compares the cumulative stockholders returns for the past five years through December 31, 2024 for (i) our common stock, (ii) the Standard & Poor ("S&P") Biotechnology Index and (iii) S&P 500 Index, assuming $100 invested on December 31, 2019, and reinvestment of dividends if paid. The stockholder return shown on the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns. This graph shall not be deemed "soliciting material" or be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any of our filings under the Securities Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.



$100 investment in stock or index	Ticker	12/31/2019	12/31/2020	12/31/2021	12/31/2022	12/31/2023	12/31/2024
Arcus Biosciences, Inc.	RCUS	$ 100	$ 257	$ 401	$ 205	$ 194	$ 147
S&P Biotechnology Index	SPSIBI	$ 100	$ 148	$ 118	$ 88	$ 94	$ 95
S&P 500 Index	S&P 500	$ 100	$ 118	$ 152	$ 125	$ 158	$ 197

Issuer Purchases of Equity Securities

None.

Item 6. 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 financial statements and related notes included in this Annual Report. This discussion and other parts of this Annual Report contain forward-looking statements that involve risk and uncertainties, such as statements of our plans, objectives, expectations, and intentions. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section of this Annual Report titled "Risk Factors."

Overview

We are a clinical-stage biopharmaceutical company focused on creating best-in-class therapies. Using our robust and highly efficient drug discovery capability, we have created a significant portfolio of investigational products which are in clinical development, with our most advanced molecule, an anti-TIGIT antibody, now in multiple Phase 3 registrational studies targeting lung and GI cancers. Our deep portfolio of novel small molecules and enabling antibodies allows us to create highly differentiated therapies, which we are developing to treat multiple large indications. We expect our clinical-stage portfolio to continue to expand and to include molecules targeting immuno-oncology, cancer cell-intrinsic and immunological pathways. Our vision is to create, develop and commercialize highly differentiated therapies that have a meaningful impact on patients.

Significant Developments

The following is a summary of significant developments affecting our business since the filing of our Annual Report on Form 10-K for the year ended December 31, 2023:

Corporate Developments

- In February 2025, we announced that Gilead's time-limited exclusive option rights to our HIF-2α program (including casdatifan) have expired. As a result, Gilead has no future rights to casdatifan and we retain full global development and commercial rights, subject to Taiho's option right for the Taiho Territory.
- In February 2025, we issued through an underwritten offering, 13.6 million shares of our common stock at a price of $11.00 per share, for total gross proceeds of approximately $150 million, before deducting underwriting discounts, commissions and offering expenses.
- In October 2024, we entered into a clinical collaboration with AstraZeneca to evaluate casdatifan, our investigational HIF-2α inhibitor, in combination with volrustomig, AstraZeneca's investigational PD-1/CTLA-4 bispecific antibody, in IO-naive patients with ccRCC. AstraZeneca will operationalize the study.
- In July 2024, Taiho exercised its option for quemliclustat, our investigational small molecule CD73 inhibitor, for the Taiho Territory, and in October 2024, opted to participate in the global Phase 3 trial of quemliclustat, PRISM-1, and became obligated to reimburse us for their portion of the global study costs. As a result, Taiho will operationalize the Japanese sites for the global Phase 3 PRISM-1 study evaluating quemliclustat in pancreatic cancer. In February 2025, Taiho dosed their first patient in Japan for PRISM-1.
- In January 2024, we amended the Stock Purchase Agreement with Gilead, pursuant to which Gilead made an equity investment of $320 million through the purchase of our common stock at $21.00 per share.

HIF-2α Program

- In February 2025, we presented clinical data from three monotherapy expansion cohorts of ARC-20 in a rapid oral session at the 2025 American Society of Clinical Oncology ("ASCO") Genitourinary Symposium. At the time of data cut-off (January 3, 2025), observations from the expansion cohorts included:
    - A 9.7-month mPFS was reached for the 50mg twice-a-day (BID) casdatifan monotherapy cohort; mPFS was not yet reached for other cohorts.
    - Confirmed objective response rate ("ORR") ranged from 25% to 33%, with 2 of the cohorts exceeding 30% (including one partial response that confirmed after the data cut-off).
    - Rates of primary progressive disease (progression at or before their first disease assessment) ranged from 14% to 19%.

  Most patients (81-87%) experienced disease control with either a partial response or stable disease and were still on treatment.

Anti-TIGIT Program

- In November 2024, we presented results at the Society for Immunotherapy of Cancer ("SITC") annual meeting from Part 1 of ARC-10, a randomized study evaluating domvanalimab plus zimberelimab in PD-L1-high NSCLC, which showed:
  - A 36% reduction in risk of death (hazard ratio=0.64) was observed for domvanalimab plus zimberelimab compared to that of zimberelimab alone.
  - Zimberelimab reached a median overall survival of two years, and the median overall survival for domvanalimab plus zimberelimab was not reached.
  - Treatment-related adverse events leading to treatment discontinuation were low (10.5%) for the combination of domvanalimab and zimberelimab.
- In June 2024, we presented updated data at the ASCO Annual Meeting from Arm A1 of the Phase 2 EDGE-Gastric study which showed 12.9 months mPFS for domvanalimab plus zimberelimab and chemotherapy in first-line upper GI adenocarcinomas, which exceeded historical benchmarks for anti-PD-1 plus chemotherapy.

Adenosine-Pathway Programs

- In October 2024, we initiated PRISM-1, a Phase 3 trial of quemliclustat combined with gemcitabine/nab-paclitaxel versus gemcitabine/nab-paclitaxel in pancreatic cancer.
- In June 2024, we presented data at the ASCO Annual Meeting from ARC-9, a randomized Phase 1b/2 study evaluating etrumadenant plus zimberelimab, FOLFOX chemotherapy and bevacizumab ("EZFB") versus regorafenib in third-line metastatic colorectal cancer ("mCRC").
  - Results showed 19.7 months median overall survival for the EZFB arm and EZFB significantly reduced the risk of death by 63% and risk of disease progression by 73% compared to regorafenib. This is the longest median overall survival reported in third-line mCRC to date in a randomized trial.

Strategic Partnerships

Gilead Sciences, Inc.

In 2020, we and Gilead entered into the Gilead Collaboration Agreement. Under the Gilead Collaboration Agreement, Gilead obtained an exclusive license to zimberelimab and time-limited exclusive options to all of our then-current and future programs during the 10-year collaboration term. The agreement was amended in 2021 (the "First Gilead Collaboration Agreement Amendment"), under which Gilead obtained rights to an additional four of our investigational products: domvanalimab, etrumadenant, quemliclustat and AB308. Gilead's time-limited exclusive option rights to our HIF-2α program (including casdatifan) have expired. For each program to which Gilead exercised or exercises its option, the parties will co-develop globally and co-commercialize the program in the U.S., subject to certain exceptions, and Gilead will have the right to commercialize the program outside of the U.S., subject to the rights of our existing partners in certain territories. Furthermore, we and Gilead agreed to collaborate on two oncology research programs, for which we will lead discovery and early development activities.

In 2023, we amended the Gilead Collaboration Agreement (the "Second Gilead Collaboration Agreement Amendment") to further expand the collaboration to include up to four jointly selected research-stage programs that target inflammatory diseases for which we will lead discovery and early development activities.

In the first quarter of 2024, we further amended the Gilead Collaboration Agreement (the "Third Gilead Collaboration Agreement Amendment") to provide that (i) Gilead is required to pay the $100 million option continuation payment due on the fourth anniversary of the Gilead Collaboration Agreement, which was received in the third quarter 2024 and (ii) we would fund certain activities, including the Phase 3 PRISM-1 study evaluating quemliclustat in pancreatic cancer.

Concurrent with the Gilead Collaboration Agreement in 2020, we also entered into the Stock Purchase Agreement and Investor Rights Agreement.

The Stock Purchase Agreement was amended in 2021 (the "First Stock Purchase Agreement Amendment"), in 2023 (the "Second Stock Purchase Agreement Amendment"), and was amended and restated in the first quarter 2024 (the "Third Stock Purchase Agreement Amendment"). Under the Stock Purchase Agreement, Gilead has the right, at its option until July 2025, to purchase up to a maximum ownership of 35% of our then-outstanding voting common stock.

The Investor Rights Agreement was amended in 2022 (the "First Investor Rights Agreement Amendment") and was amended and restated in the first quarter 2024 (the "Second Investor Rights Agreement Amendment"). Under the Investor Rights Agreement, as amended, Gilead has the right to designate three individuals to be appointed to our board of directors.

As of December 31, 2024, Gilead held approximately 32.6% of our outstanding common stock. Gilead acquired an additional 1.4 million shares of our common stock in the February 2025 underwritten offering and subsequently held approximately 29.7% of our common stock as of February 19, 2025.

Taiho Pharmaceutical Co., LTD.

In 2017, we entered into the Taiho Agreement pursuant to which Taiho was granted time-limited options to exclusively license for the Taiho Territory the development and commercialization rights to each of our programs that arose over a five-year period ending in September 2022. As of December 31, 2024, Taiho has licenses for the Taiho Territory to (i) etrumadenant (the adenosine receptor antagonist program); (ii) zimberelimab (the anti-PD-1 program); (iii) domvanalimab and AB308 (collectively, the anti-TIGIT program); and (iv) quemliclustat (the CD73 program).

Other Licenses, Collaborations, and Research and Development Arrangements

We have in-licensed rights to anti-PD-1 and CD39 antibodies from WuXi Biologics, and to domvanalimab from Abmuno. We also have clinical collaboration agreements with AstraZeneca for the Phase 3 PACIFIC-8 trial evaluating domvanalimab and durvalumab in Stage 3 NSCLC and for a Phase 1/1b study evaluating casdatifan and volrustomig in IO-naive patients with ccRCC. We are also party to an agreement with BVF Partners L.P. ("BVF") to support the discovery and development of compounds for the treatment of inflammatory diseases.

Financial Overview

Since commencing operations in 2015, we have devoted substantially all of our efforts and financial resources to building our research and development capabilities, advancing our investigational product pipeline, and establishing our corporate infrastructure. To date, we have financed our operations primarily from the sale of our equity securities; upfront or milestone payments received from our research, collaboration and license agreements with our strategic partners, including Gilead; and debt financing. We expect to incur substantial expenditures in the foreseeable future for the development and potential commercialization of our investigational products and ongoing internal research and development programs. At this time, we cannot reasonably estimate the nature, timing or aggregate amount of costs for our development, potential commercialization, and internal research and development programs.

As of December 31, 2024, we had $992 million of cash, cash equivalents and marketable securities, which together with the proceeds from our equity financing in February 2025, we believe will be sufficient to fund our planned level of operations for the foreseeable future and provide funding to our initial pivotal read-outs for domvanalimab, quemliclustat and casdatifan, including STAR-221, PRISM-1 and PEAK-1.

Components of Operating Results

Revenues

We have not generated any revenue from product sales and do not expect to generate any revenue from product sales for the foreseeable future. All revenue recognized to date has been through research, collaboration and license arrangements with strategic partners.

License and Development Services Revenue

Our license and development services revenue consists of amounts recognized from the portions of the nonrefundable upfront payments received from Gilead and Taiho and allocated to performance obligations for licenses or R&D activities performed by us as we develop our investigational products under the terms of our collaboration agreements. License and development services revenues are recognized based upon the timing of the delivery of a license or service if delivery is complete, or based on estimates of each performance obligation's percentage of completion at the period end if it is still in process. We calculate percentage of completion as a ratio of effort incurred to date on each performance obligation to the total estimated effort to be incurred to satisfy that performance obligation.

Other Collaboration Revenue

Other collaboration revenue consists primarily of amounts recognized from the portions of the nonrefundable upfront payments received from Gilead and Taiho and allocated to performance obligations relating to their access to our investigational pipeline or our obligation to perform certain discovery and early development activities. Revenue related to

access rights is recognized over the period of access, and revenue related to discovery and early development activities is recognized as the performance obligation is satisfied.

Operating Expenses

Research and Development Expenses

Our R&D expenses consist of costs incurred in connection with the R&D of our pipeline programs. These expenses include preclinical and clinical expenses, payroll and personnel expenses, including stock-based compensation for our employees in R&D, laboratory supplies, product licenses, consulting costs, contract research, and depreciation. Shared facility expenses are allocated to functional groups proportionally based on usage. Under certain collaboration agreements we agree to share R&D expenses with our partners. Such cost sharing arrangements may result in receiving reimbursement from our partners or require that we reimburse our partners for qualified expenses. We expense both internal and external R&D costs as they are incurred. We record advance payments for services that will be used or rendered for future R&D activities as prepaid expenses and recognize them as an expense as the related services are performed. We recognize reimbursement for shared costs incurred by us and reimbursed by our partners as a reduction in R&D expense as the underlying costs are incurred.

We do not allocate all our costs by investigational product, as a significant amount of R&D expenses include internal costs, such as payroll and other personnel expenses, and certain external costs that are not recorded at the investigational product level. In particular, with respect to internal costs, several of our departments support multiple R&D programs, and we do not allocate those costs by investigational product.

The level of our future R&D investment will depend on a number of factors and uncertainties, including the breadth of the joint development program agreed to with Gilead for the optioned programs, the outcome of our efforts, and the amount of cost reimbursements or milestone payments we receive from our collaborators. We expect our R&D expenses to increase substantially during the next few years as we pursue joint development programs with Gilead and advance these programs towards regulatory approval. We also expect to advance new programs into the clinic. All of this will require significant growth in our development capabilities and infrastructure. In addition, our joint development programs with Gilead for the optioned molecules are anticipated to include a significant number of later-stage clinical trials, which typically include a larger number of subjects, are of a longer duration and include more geographic regions. As we advance our clinical-stage programs and prepare to seek regulatory approval, we will also need to increase our late-stage manufacturing activities. As a result, we expect our preclinical, clinical, and contract manufacturing expenses to increase significantly relative to what we have incurred to date.

In addition, under our arrangements with WuXi Biologics, Abmuno, AstraZeneca and BVF, we may incur additional clinical and regulatory milestone payments based on the development progress of our investigational products. We may also be required to pay royalties in the event of a successful product launch and our receipt of commercial revenues. Therefore, we are unable to predict the timing or the final cost to complete our clinical programs or validation of our manufacturing and supply processes and delays may occur due to numerous factors. Factors that could cause or contribute to delays or additional costs include, but are not limited to, those discussed in “Item 1A. Risk Factors.”

General and Administrative Expenses

General and Administrative ("G&A") expenses consist principally of personnel-related costs including payroll and stock-based compensation for personnel in executive, finance, human resources, information technology, business and corporate development, and other administrative functions. Shared facility expenses are allocated to functional groups proportionally based on usage. Our G&A expenses also include professional fees for legal, consulting, and accounting services, rent and other facilities costs, fixed asset depreciation, and other general operating expenses not otherwise classified as R&D expenses. We do not receive significant reimbursements of these costs through our collaboration with Gilead.

We anticipate that our G&A expenses will increase during the next few years as we support our growing R&D activities, including due to staff expansion, and other costs associated with increased infrastructure needs.

Impairment of Long-Lived Assets

Impairment charges consist of impairment of right-of-use assets resulting from updated plans in the first quarter 2024 for a portion of our office space.

Non-Operating Income, net

Non-operating income, net consists primarily of interest earned on our investments in fixed-income marketable securities, interest expense on our loan financing with Hercules, and non-cash interest expense incurred under the effective interest method on our liability for sale of future royalties to BVF.

Results of Operations

The following table summarizes our results of operations (in millions):

	Year Ended December 31, 2024	Change	Year Ended December 31, 2023	Change	Year Ended December 31, 2022
Revenues:					
License and development service revenue	$ 222	178 %	$ 80	8 %	$ 74
Other collaboration revenue	36	(3) %	37	(3) %	38
Total revenues	258	121 %	117	4 %	112
Operating expenses:					
Research and development	448	32 %	340	18 %	288
General and administrative	120	3 %	117	13 %	104
Impairment of long-lived assets	20	*	—	*	—
Total operating expenses	588	29 %	457	17 %	392
Loss from operations	(330)	(3) %	(340)	21 %	(280)
Non-operating income, net	48	23 %	39	179 %	14
Loss before income taxes	(282)	(6) %	(301)	13 %	(266)
Income tax expense	(1)	(83) %	(6)	*	(1)
Net loss	$ (283)	(8) %	$ (307)	15 %	$ (267)

* Not meaningful

Total Revenues

The increase in Total revenues for 2024 as compared to 2023 was primarily driven by increased revenues from license and development services due to a cumulative catch-up to revenue in the first quarter 2024 of $107 million as a result of the Third Gilead Collaboration Agreement Amendment based on the updated transaction price and measure of progress for the partially satisfied performance obligations; and Taiho's exercise of its option for the license of quemliclustat for the Taiho Territory of $15 million, which was recognized as revenue upon the delivery of the license in the third quarter of 2024.

The increase in Total revenues for 2023 as compared to 2022 was primarily driven by increased revenues from license and development services due to the progress in the research and development activities under our Taiho collaboration R&D services and our inflammation programs which commenced in 2023, partially offset by a decrease in revenue recognized for Taiho access rights which expired in 2022.

See Note 5, Revenues, in Part II, Item 8 for further discussion of the amount and timing of revenues recognized from our license and collaboration agreements.

Research and Development Expenses

We group all of our R&D activities and the related expenditures into categories as described below:

		Included as of December 31, 2024	
Category	Description	Program-Level Expenses	Key Clinical Trials
Late-stage development programs	R&D expenses incurred related to a Phase 3 clinical program intended to result in registration of a new product. This includes all unallocated program-level expense not directly attributable to a specific clinical trial once a molecule enters into one or more Phase 3 clinical trials.	domvanalimab zimberelimab quemliclustat**	PACIFIC-8 STAR-121 STAR-221 PRISM-1 ARC-10*
Early-stage R&D and preclinical programs	R&D expenses incurred for activities ranging from early-stage R&D and preclinical to Phase 2 clinical trials. This includes all unallocated program-level expense not directly attributable to a specific clinical trial unless the related program has entered into one or more Phase 3 clinical trials.	quemliclustat** etrumadenant casdatifan AB598 AB801	ARC-7 ARC-8 ARC-9 ARC-20 ARC-25 ARC-26* ARC-27 EDGE-Lung EDGE-Gastric STELLAR-009* VELOCITY-Lung VELOCITY-HNSCC
Compensation and personnel costs	Internal costs, such as salaries, non-cash stock-based compensation, and other personnel expenses for our R&D employees.	—	—
Other costs	Facilities, depreciation, and other external costs that are not recorded at the investigational product level.	—	—
Partnership reimbursements	Reimbursements from our collaboration partners for shared costs incurred by us and recognized as a reduction in R&D expense.	—	—

* Study discontinued or completed

** Quemliclustat moved from early-stage development and preclinical program to a late-stage development program in the third quarter 2024

The following table summarizes our R&D expenses by category (in millions):

Category	Year Ended December 31, 2024	Change	Year Ended December 31, 2023	Change	Year Ended December 31, 2022
Late-stage development programs	$ 252	50 %	$ 168	35 %	$ 124
Early-stage R&D and preclinical programs	132	3 %	128	(12) %	145
Compensation and personnel costs	178	16 %	154	18 %	130
Other costs	51	(2) %	52	4 %	50
Partnership reimbursements	(165)	2 %	(162)	1 %	(161)
Total research and development	$ 448	32 %	$ 340	18 %	$ 288

The increase in R&D expenses for 2024 as compared to 2023 was primarily driven by higher costs to support our expanding late-stage development program activities, driven by higher enrollment in our Phase 3 studies for domvanalimab and the initiation of the quemliclustat Phase 3 trial PRISM-1, and the timing of our manufacturing activities. Our growing headcount drove an increase in compensation and personnel costs, including a $3 million increase in non-cash stock-based compensation. Our partnership reimbursements were flat compared to the prior year despite the increases in gross costs, due to increases in Gilead-led activities and programs fully funded by us.

The increase in R&D expenses for 2023 as compared to 2022 was primarily driven by higher costs to support our expanding late-stage development program activities, including standard-of-care therapeutic purchases, partially offset by lower clinical manufacturing costs due to the timing of activities. Our growing headcount drove an increase in compensation and personnel costs, including a $2 million increase in non-cash stock-based compensation. The overall increase was partially offset by reduced spend in our early-stage R&D and preclinical program activities due to fewer Phase 2 studies and higher clinical manufacturing costs in 2022 to support expanding study activities.

General and Administrative Expenses

The increase in G&A expenses for 2024 as compared to 2023 was primarily driven by the increased complexity of supporting our expanding clinical pipeline and partnership obligations. Our growing headcount and our stock awards drove an increase in employee compensation costs. The overall increase in G&A expenses was partially offset by income from subleases of space in our Brisbane office.

The increase in G&A expenses for 2023 as compared to 2022 was primarily driven by the increased complexity of supporting our expanding clinical pipeline and partnership obligations. Our growing headcount and our 2023 stock awards drove an increase in employee compensation costs, including $6 million in increased non-cash stock-based compensation.

Impairment of Long-Lived Assets

The increase in impairment expense for 2024 was due to our sublease of a portion of our office space, resulting in an impairment charge of $20 million, compared to no similar impairment in the prior year.

Non-Operating Income, net

The increase in Non-operating income, net for 2024 as compared to 2023 was primarily due to higher interest income resulting from increased investment yields and higher average portfolio balances as compared to the prior year, driven by $320 million received from Gilead in the first quarter 2024 under the amended Stock Purchase Agreement.

The increase in Non-operating income, net for 2023 as compared to 2022 was primarily due to higher interest income resulting from increased investment yields as compared to the prior year.

Income Tax Expense

The decrease in Income tax expense for 2024 as compared to 2023 was primarily due to a decrease in taxable income compared to the prior year.

The increase in Income tax expense for 2023 as compared to 2022 was primarily due to an increase in taxable income compared to the prior year.

The Income tax expense for each of the years shown considers the impact of the capitalization of R&D expenses for income tax purposes due to changes in U.S. legislation. The capitalization of R&D expenses may materially impact income tax expense in future years.

Liquidity and Capital Resources

Our cash and investments are held in a variety of interest-bearing instruments, including money market funds, U.S. government treasury and agency obligations, investments in corporate securities and certificates of deposit. Based on our existing business plan, we believe that our cash, cash equivalents, and marketable securities as of December 31, 2024, which together with the proceeds from our equity financing in February 2025, we believe will be sufficient to fund our planned level of operations for the foreseeable future and provide funding to our initial pivotal read-outs for domvanalimab, quemliclustat and casdatifan including STAR-221, PRISM-1 and PEAK-1.

Sources of Liquidity

To date, we have financed our operations primarily from the sale of our equity securities, upfront or milestone payments from our research, collaboration and license agreements with our strategic partners including Gilead and debt financing. We will need substantial additional funding to support our continuing operations and pursue our development strategy. Until such time that we can generate significant revenue from sales of our investigational products, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, including existing or potential collaborations with other companies or other strategic transactions. See “Item 1A. Risk Factors” for a discussion of the factors that could impact our liquidity.

Under the Stock Purchase Agreement, Gilead has the right, at its option, to purchase additional shares from us, up to a maximum ownership of 35% of our then-outstanding voting common stock, from time to time until July 2025. In the first quarter 2024, we further amended and restated the Stock Purchase Agreement and sold 15.2 million shares of our common stock to Gilead at a purchase price of $21.00 per share for total gross proceeds of $320 million. Of the $320 million equity investment, $87 million was determined to be a premium on the purchase of common stock and allocated to the performance obligations created by the Third Gilead Collaboration Agreement Amendment. As of December 31, 2024, Gilead held approximately 32.6% of our outstanding common stock arising from purchases in our 2020 public offering and purchases under the Stock Purchase Agreement and the related amendments. Gilead acquired an additional 1.4 million shares of our common stock in the February 2025 underwritten offering and subsequently held approximately 29.7% of our common stock as of February 19, 2025.

In 2023, we entered into an equity distribution agreement pursuant to which we may, from time to time, sell shares of our common stock having an aggregate offering price of up to $200 million. We had no activity during the year ended December 31, 2024, and during the year ended December 31, 2023, we issued and sold under this agreement 0.2 million shares of our common stock for total net proceeds of $5 million. See Note 15, Stockholders' equity, in Part II, Item 8 for further discussion.

In the third quarter 2024, we obtained a $250 million term loan facility from Hercules Capital, Inc. ("Hercules"). Under the terms of the term loan facility, $50 million was drawn at closing and an additional $100 million is committed and fully available at Arcus's sole option in minimum increments of $25 million. A second tranche of $100 million will be available to support strategic initiatives, subject to future approval by Hercules. See Note 13, Long-term debt, in Part II, Item 8 for further discussion.

In February 2025, we issued through an underwritten offering, 13.6 million shares of our common stock at a price of $11.00 per share, for total gross proceeds of approximately $150 million, before deducting underwriting discounts, commissions and offering expense.

Material Cash Requirements

We expect to incur substantial expenditures in the foreseeable future as we expand our pipeline and advance our investigational products through clinical development, the regulatory approval process and, if approved, commercial launch activities. For example, in the near term we expect to incur substantial expenses relating to our ongoing and planned clinical trials, the development and validation of our manufacturing processes, and other preclinical, research and discovery development activities. These expenditures will be partially offset by reimbursements for shared expenses from our collaborations, primarily the Gilead collaboration, for certain expenses incurred on their optioned programs.

See "Contractual Obligations and Commitments" for more information regarding our cash requirements from known contractual commitments.

Cash Flows

The following table summarizes our cash flow activities (in millions):

	Year Ended December 31,		
Net cash provided by (used in):	**2024**	**2023**	**2022**
Operating activities	$ (170)	$ (306)	$ 438
Investing activities	(84)	194	(413)
Financing activities	277	33	33

Operating Activities

Net cash used in operating activities for 2024 was $170 million as compared to net cash used in operating activities of $306 million for the same period in the prior year. The change in operating cash flows is primarily due to the receipt of the $100 million option continuation payment from Gilead in the third quarter 2024, the $87 million under the Third Gilead Collaboration Agreement Amendment in the first quarter 2024, and the receipt of $45 million in total from Taiho for development milestones and its opt-in on quemliclustat, partially offset by higher R&D expenditures.

Net cash used in operating activities for 2023 was $306 million as compared to net cash provided by operating activities of $438 million for the prior year. The change in operating cash flows is primarily due to $725 million received from Gilead in 2022 under the Gilead Collaboration Agreement.

Investing Activities

Cash used in investing activities for 2024 was primarily due to net purchases of marketable securities of $78 million as we invested a portion of the cash received from Gilead in the first quarter 2024 under the Third Stock Purchase Agreement Amendment.

Cash provided by investing activities for 2023 was primarily due to net proceeds from marketable securities of $218 million, partially offset by purchases of property and equipment of $24 million.

Cash used in investing activities for 2022 was primarily due to net purchases of marketable securities of $404 million as we invested a portion of the $725 million received from Gilead in 2022 under the Gilead Collaboration Agreement.

Financing Activities

Cash used in financing activities for 2024 was due to net proceeds of $228 million from issuance of our common stock to Gilead under the Third Stock Purchase Agreement Amendment, net proceeds of $47 million from our borrowings under the Hercules Agreement, and net proceeds of $2 million for stock issued under our equity award plans.

Cash provided by financing activities for 2023 was due to net proceeds of $25 million from issuance of our common stock, primarily due to stock purchases by Gilead, and proceeds of $8 million for stock issued under our equity award plans.

Cash provided by financing activities for 2022 was primarily due to net proceeds of $23 million for stock issued under our equity award plans and $10 million received under the BVF agreement.

Contractual Obligations and Commitments

We have cash requirements to pay third parties under various contractual obligations as discussed below.

We are obligated to make principal loan payments, interest payments and an end of term charge under the loan and security agreement with Hercules. See Note 13, Long-term debt, in Part II, Item 8 for further discussion.

We are obligated to make payments for operating leases. See Note 14, Leases, in Part II, Item 8 for further discussion.

We are contractually obligated to pay additional amounts that in the aggregate are significant, upon the achievement of various development, regulatory and commercial milestones for agreements we have entered into with third parties. These payments are contingent upon the occurrence of various future events, substantially all of which have a high degree of uncertainty of occurring, and any resulting cash requirements are managed through our operational budgeting processes. See Note 4, License and collaborations, in Part II, Item 8 for further discussion.

We have a liability for sale of future royalties which consists of the current balance of estimated contingent milestone and royalty payments under the BVF agreement. See Note 16, Fair value measurements, in Part II, Item 8 for further discussion.

We enter into contracts in the normal course of business with third parties for clinical trial management and execution, non-clinical studies and testing, manufacturing, and other services and products for operating purposes. These contracts are generally cancellable on 30 days' notice, and therefore we believe that our non-cancelable obligations under these agreements are not material.

See Liquidity and Capital Resources — Material Cash Requirements above for further discussion of our cash requirements.

Critical Accounting Judgments and Estimates

Our Consolidated Financial Statements have been prepared in accordance with U.S. GAAP. The preparation of these Consolidated Financial Statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the Consolidated Financial Statements, as well as the reported revenue and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in the notes to our Consolidated Financial Statements, we believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's significant judgments and estimates.

Revenue Recognition

As part of the accounting for contracts with customers, we develop assumptions that require judgment to determine the standalone selling price of each performance obligation identified in the contract.

In the first quarter 2024, we entered into the Third Gilead Collaboration Agreement Amendment, which we determined was a change in scope and price of the original contract and we accounted for this contract modification as both a modification of the existing contract and the creation of a new contract. (See Note 5, Revenues, in Part II, Item 8 for further discussion). We determined the standalone selling price of certain performance obligations and allocated the total transaction price to each performance obligation on a relative standalone selling price basis. The estimation of the standalone selling price included estimates for forecasted costs, development timelines, discount rates, and probabilities of technical and regulatory success.

Under the applicable accounting rules for such contract modifications, we did not adjust the accounting for completed performance obligations that were distinct from the modified goods or services. However, we were required to adjust revenue previously recognized to reflect the effect of the contract modification due to the updated transaction price allocated to the partially satisfied performance obligations and the updated measure of progress as of the modification date. Accordingly, we recognized a cumulative catch-up to revenue of $107 million based on the updated transaction price and measure of progress for the partially satisfied performance obligations.

A hypothetical 10% change in the updated standalone selling prices or the updated measure of progress as of the modification date related to Third Gilead Collaboration Agreement Amendment would have changed the cumulative catch-up to revenue recognized during the current year to date period by as much as $3 million or $32 million, respectively.

Recent Accounting Pronouncements

See “Recent Accounting Pronouncements” in Note 2 to our Consolidated Financial Statements in Item 8 for a discussion of recently adopted accounting pronouncements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risks that may result from changes in interest rates and foreign currency exchange rates.

Interest Rate Risk

Investments in marketable securities

As of December 31, 2024 and 2023, we had cash, cash equivalents and marketable securities of $992 million, and $866 million, respectively. This consisted of interest-bearing money market accounts and investments in corporate notes and U.S. government securities, which create an exposure to interest rate risk. A hypothetical 100 basis point increase in interest rates as of December 31, 2024 and 2023 would not have resulted in a material effect on the fair market value of our cash, cash equivalents and marketable securities. In addition, a hypothetical 100 basis point decrease in interest rates as of December 31, 2024 and 2023 would not result in a material effect on income in the respective ensuing year.

Long-term debt

As of December 31, 2024, we had outstanding debt with a carrying value of $48 million bearing interest at a rate equal to the greater of (i) 10.45% or (ii) the prime rate plus 1.95%. A hypothetical 100 basis point increase in the prime rate compared to December 31, 2024 would not have resulted in a material effect on the fair market value of our debt. In addition, a hypothetical 100 basis point increase in the prime rate compared to December 31, 2024 would not result in material impact to our income in the respective ensuing year.

Foreign Currency Exchange Risk

We do not have any foreign currency forward or cross currency swap contracts. We are exposed to foreign currency exchange rate risk inherent in our contracts with research institutions, CROs, and contract manufacturing organizations as certain services are performed by them outside the U.S. and billed in other currencies. A hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates as of December 31, 2024 and 2023, respectively would not result in material impact to our financial position or income in the respective ensuing year.

Item 8. Financial Statements and Supplementary Data

ARCUS BIOSCIENCES, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Arcus Biosciences, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Arcus Biosciences, Inc. (the Company) as of December 31, 2024 and 2023, the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2024, and 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 at December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2024, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2024, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated February 25, 2025 expressed an unqualified opinion thereon.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter 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.

Accounting for agreements with Gilead Sciences, Inc.

Description of the Matter	As described in Notes 3 and 5 to the consolidated financial statements, the Company has ongoing Option, License and Collaboration Agreements with Gilead Sciences, Inc., a related party, referred to as the "Gilead Agreements", which resulted in the recognition of $243 million of revenue for the year ended December 31, 2024 and $319 million of deferred revenue at December 31, 2024. Of the revenue recognized under the Gilead Agreements in 2024, $215 million related to amounts recognized as revenue when services are performed, based on the level of effort expended in a given period in relation to the total effort expected to be incurred to satisfy the applicable performance obligation. Management periodically updates its estimates of the total effort expected to be incurred to satisfy such performance obligations, with any changes in estimate potentially changing the amount of revenue previously recognized and/or the amount to be recognized in future periods. Auditing the Company's process for estimating the total effort expected to be incurred to satisfy such performance obligations is complex due to the significant judgment applied by the Company in determining the total effort.
How We Addressed the Matter in Our Audit	We obtained an understanding, evaluated the design, and tested the operating effectiveness of controls addressing the risks of material misstatement relating to the Company's process for estimating the total effort expected to be incurred to satisfy the identified performance obligations pursuant to the Gilead Agreements. Our audit procedures included, among others, obtaining and reading applicable board and committee meeting minutes, inquiring of research and development personnel, including program managers, and testing the completeness and accuracy of the data used by management to estimate the total effort expected to be incurred to satisfy the identified performance obligations pursuant to the Gilead Agreements.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2016.

San Mateo, California
February 25, 2025

ARCUS BIOSCIENCES, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(In millions, except per share amounts)

	Year Ended December 31,		
	2024	2023	2022
Revenues:			
License and development service revenue (Includes $ 207 , $ 75 and $ 74 from a related party)	$ 222	$ 80	$ 74
Other collaboration revenue (Includes $ 36 , $ 37 and $ 33 from a related party)	36	37	38
Total revenues	258	117	112
Operating expenses:			
Research and development (Includes $ 39 , $ 110 and $ 132 of net recoveries from a related party)	448	340	288
General and administrative (Includes ($ 2), $ — and $ 1 of net recoveries from (payments to) a related party)	120	117	104
Impairment of long-lived assets (see Note 14, Leases)	20	—	—
Total operating expenses	588	457	392
Loss from operations	(330)	(340)	(280)
Non-operating income (expense):			
Interest and other income, net	52	41	16
Interest expense	(4)	(2)	(2)
Total non-operating income, net	48	39	14
Loss before income taxes	(282)	(301)	(266)
Income tax expense	(1)	(6)	(1)
Net loss	$ (283)	$ (307)	$ (267)
Net loss per share:			
Basic and diluted	$ (3.14)	$ (4.15)	$ (3.71)
Shares used to compute net loss per share:			
Basic and diluted	90.1	74.0	72.0

See accompanying notes.

ARCUS BIOSCIENCES, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In millions)

	Year Ended December 31,		
	2024	2023	2022
Net loss	$ (283)	$ (307)	$ (267)
Other comprehensive income (loss)	—	7	(6)
Comprehensive loss	$ (283)	$ (300)	$ (273)

See accompanying notes.

ARCUS BIOSCIENCES, INC.

CONSOLIDATED BALANCE SHEETS

December 31, 2024 and 2023

(In millions, except per share amounts)

	December 31,	
	2024	2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 150	$ 127
Marketable securities	828	632
Receivable from collaboration partners ($ 6 and $ 20 from a related party)	20	38
Prepaid expenses and other current assets	18	34
Total current assets	1,016	831
Long-term marketable securities	14	107
Property and equipment, net	47	51
Other noncurrent assets ($ — and $ 6 from a related party)	73	106
Total assets	$ 1,150	$ 1,095
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 18	$ 17
Deferred revenue ($ 85 and $ 84 to a related party)	85	91
Other current liabilities	123	76
Total current liabilities	226	184
Deferred revenue, noncurrent ($ 234 and $ 291 to a related party)	234	307
Long-term debt	48	—
Other noncurrent liabilities	157	142
Commitments (Note 17)		
Stockholders' equity:		
Common stock and additional paid-in capital: $ 0.0001 par value per share; 400.0 shares authorized; 92.2 shares in 2024 and 75.5 shares in 2023 issued and outstanding	1,617	1,311
Accumulated deficit	(1,132)	(849)
Total stockholders' equity	485	462
Total liabilities and stockholders' equity	$ 1,150	$ 1,095

See accompanying notes.

ARCUS BIOSCIENCES, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

Years ended December 31, 2024, 2023 and 2022

(In millions)

	Number of shares of common stock	Common stock and additional paid-in capital	Accumulated deficit	Accumulated other comprehensive income (loss)	Total stockholders' equity
Balance at December 31, 2021	70.8	$ 1,118	$ (275)	$ (1)	$ 842
Issuance of common stock in connection with our equity award programs	2.1	23	—	—	23
Stock-based compensation	—	65	—	—	65
Other comprehensive loss	—	—	—	(6)	(6)
Net loss	—	—	(267)	—	(267)
Balance at December 31, 2022	72.9	1,206	(542)	(7)	657
Issuance of common stock (see Note 3, Related party - Gilead Sciences, Inc. and Note 15, Stockholders' Equity)	1.2	25	—	—	25
Issuance of common stock in connection with our equity award programs	1.4	7	—	—	7
Stock-based compensation	—	73	—	—	73
Other comprehensive income	—	—	—	7	7
Net loss	—	—	(307)	—	(307)
Balance at December 31, 2023	75.5	1,311	(849)	—	462
Issuance of common stock (see Note 3, Related party - Gilead Sciences, Inc. and Note 15, Stockholders' Equity)	15.2	228	—	—	228
Issuance of common stock in connection with our equity award programs	1.5	2	—	—	2
Stock-based compensation	—	76	—	—	76
Net loss	—	—	(283)	—	(283)
Balance at December 31, 2024	92.2	$ 1,617	$ (1,132)	$ —	$ 485

See accompanying notes.

ARCUS BIOSCIENCES, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In millions)

	Year Ended December 31,		
	2024	**2023**	**2022**
Cash flow from operating activities			
Net loss	$ (283)	$ (307)	$ (267)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Stock-based compensation expense	76	73	65
Depreciation and amortization	10	8	6
Noncash lease expense	7	8	8
Impairment on right-of use assets	20	—	—
Amortization of discounts on marketable securities	(25)	(19)	—
Other items, net	3	2	3
Changes in operating assets and liabilities:			
Receivable from collaboration partners ($ 14 , $ 19 and $ 704 from a related party)	28	15	704
Other assets ($ 6 , ($ 4) and ($ 2) from a related party)	22	(14)	2
Accounts payable	3	(1)	8
Deferred revenue (($ 56), ($ 77) and ($ 107) to a related party)	(56)	(68)	(112)
Other liabilities	25	(3)	21
Net cash provided by (used in) operating activities	(170)	(306)	438
Cash flow from investing activities			
Purchases of marketable securities	(1,043)	(788)	(1,241)
Proceeds from maturities of marketable securities	929	982	694
Proceeds from sales of marketable securities	36	24	143
Purchases of property and equipment	(6)	(24)	(6)
Other items, net	—	—	(3)
Net cash provided by (used in) investing activities	(84)	194	(413)
Cash flow from financing activities			
Proceeds from issuance of common stock ($ 228 , $ 20 and $ — from a related party), net	228	25	—
Proceeds from debt issuances, net	47	—	—
Proceeds from issuance of common stock pursuant to equity award plans	9	8	23
Payments of employee taxes related to net settlement of equity awards	(7)	—	—
Proceeds from sale of future royalties	—	—	10
Net cash provided by financing activities	277	33	33
Net increase (decrease) in cash, cash equivalents and restricted cash	23	(79)	58
Cash, cash equivalents and restricted cash at beginning of period	130	209	151
Cash, cash equivalents and restricted cash at end of period	$ 153	$ 130	$ 209
Supplemental disclosure of cash flow information			
Income taxes paid	$ —	$ 5	$ 3
Interest paid	$ 1	$ —	$ —
Non-cash investing and financing activities:			
Unpaid portion of property and equipment purchases included in Accounts payable and Other current liabilities	$ —	$ 2	$ 3

See accompanying notes.

ARCUS BIOSCIENCES, INC.

Notes to Consolidated Financial Statements

Note 1. Organization, liquidity and capital resources

Organization

Arcus Biosciences, Inc. (referred to as “Arcus,” “we,” “our,” “us,” or the “Company”) is a clinical-stage biopharmaceutical company focused on creating best-in-class therapies. Using our robust and highly efficient drug discovery capability, we have created a significant portfolio of investigational products which are in clinical development, with our most advanced molecule, an anti-TIGIT antibody, now in multiple Phase 3 registrational studies targeting lung and gastrointestinal cancers. Our deep portfolio of novel small molecules and enabling antibodies allows us to create highly differentiated therapies, which we are developing to treat multiple large indications.

We operate and manage our business as one reportable and operating segment, which is the business of developing and commercializing highly differentiated therapies that have a meaningful impact on patients. See Note 18, Segments of business, for more information.

Liquidity and Capital Resources

As of December 31, 2024, we had cash, cash equivalents and marketable securities of $ 992 million, which we believe will be sufficient to fund our planned operations for a period of at least twelve months following the date of filing of this Annual Report. See Note 19, Subsequent events, for additional information on stock issuances that occurred in February 2025.

Note 2. Summary of significant accounting policies

Basis of Presentation

The Consolidated Financial Statements, which include the accounts of Arcus as well as its wholly owned subsidiaries, have been prepared in accordance with U.S. GAAP and include all adjustments necessary for the fair presentation of the Company’s financial position for the periods presented. All intercompany transactions and balances have been eliminated in consolidation.

We assess whether we are the primary beneficiary of a Variable Interest Entity ("VIE") at the inception of the arrangement and at each reporting date. This assessment is based on our power to direct the activities of the VIE that most significantly impact the VIE’s economic performance and our obligation to absorb losses or the right to receive benefits from the VIE that could potentially be significant to the VIE. We do not have any significant interests in any variable interest entities of which we are the primary beneficiary.

Use of Estimates

The preparation of the Consolidated Financial Statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosures. We base our estimates on historical experience and on various market-specific and other relevant assumptions 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. Estimates are assessed and updated each period to reflect current information. Actual results may differ materially from those estimates.

Collaborative Arrangements

We assess whether our licensing and other agreements are collaborative arrangements based on whether they involve joint operating activities and whether both parties have active participation in the arrangement and are exposed to significant risks and rewards. For arrangements that we determine are collaborations, we identify each distinct performance obligation, and then determine whether a customer relationship exists for that distinct performance obligation. If we determine a performance obligation within the collaborative arrangement to be with a customer, we apply our revenue accounting policy. If a portion of a distinct bundle of goods or services within the collaborative arrangement is not with a customer, we apply recognition and measurement based on an analogy to authoritative accounting literature or, if there is no appropriate analogy, a reasonable, rational, and consistently applied accounting policy election. See Note 4, License and collaborations, for more information.

Revenues

We recognize revenue when a customer obtains control of promised goods or services in a contract for an amount that reflects the consideration we expect to receive in exchange for those goods or services. For contracts with customers, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy each performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. As part of the accounting for contracts with customers, we develop assumptions that require judgment to determine the standalone selling price of each performance obligation identified in the contract. In addition, variable consideration such as milestone payments are evaluated to determine if they are constrained and, therefore, excluded from the transaction price. We then allocate the total transaction price proportionally to each performance obligation based on their estimated standalone selling prices. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

We currently do not have product sales and our revenues are derived from research, collaboration and license arrangements with strategic partners. Such arrangements may require us to deliver various rights, services and/or goods, including intellectual property rights/licenses, R&D services, manufacturing services and/or commercialization services. The underlying terms of these arrangements may generally include consideration to Arcus in the form of one or more of the following: (i) nonrefundable, up-front license fees; (ii) milestone payments related to the achievement of developmental, regulatory, or commercial goals; (iii) royalties on net sales of licensed products; (iv) fees attributable to options to intellectual property; and (v) profit sharing.

In arrangements involving more than one performance obligation, each performance obligation is evaluated to determine whether it qualifies as distinct based on whether (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available and (ii) the good or service is separately identifiable from other promises in the contract. The consideration under the arrangement is then allocated to each separate distinct performance obligation based on its respective relative stand-alone selling price. The estimated selling price of each deliverable reflects our best estimate of what the selling price would be if the deliverable was regularly sold by us on a stand-alone basis or by using an adjusted market assessment approach if selling price on a stand-alone basis is not available. The consideration allocated to each distinct performance obligation is recognized as revenue when control of the related goods is transferred or services are performed. We evaluate each performance obligation to determine if it can be satisfied at a point in time or over time as services are performed. For performance obligations that are determined to be satisfied over time we determine an appropriate method of measuring progress for purposes of recognizing revenue.

Consideration associated with at-risk substantive performance milestones is recognized as revenue when it is probable that a significant reversal of the cumulative revenue recognized will not occur.

For arrangements that include sales-based royalties, including milestone payments based on sales thresholds, and for which the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, we have not recognized any royalty revenue resulting from any of our arrangements.

The accounting for these arrangements requires us to develop estimates and assumptions that require judgment. These estimates may include items such as forecasted revenues or costs, development timelines, discount rates, and probabilities of technical and regulatory success. Actual results may differ materially from those estimates.

See Note 5, Revenues, for more information.

Research and Development Expenses

R&D costs are expensed as incurred and primarily include: salaries, benefits and other staff-related costs; facilities and overhead costs; third-party service provider costs for preclinical and clinical studies; laboratory supplies and equipment maintenance costs; consulting; payments under collaborative and other arrangements including milestone payments, licenses and fees; expense reimbursements to collaboration partners; and other related expenses. Under certain collaborative arrangements, we are reimbursed for a portion of the R&D expenses, including costs of drug supplies. When these R&D expenses are incurred under a reimbursement or cost sharing model with a collaboration partner, we record the related reimbursements as a reduction of R&D expense in our Consolidated Statements of Operations. Acquired in-process R&D projects with no alternative future use are recorded in R&D expense upon acquisition.

Net payment or reimbursement of R&D costs is recognized when the obligations are incurred and as we become entitled to the cost recovery. See Note 4, License and collaboration agreements, for more information.

Clinical trial costs are a significant component of R&D expenses. Our clinical studies are primarily performed by third-party CROs. We monitor levels of performance under each significant contract including the extent of patient enrollment and other activities and accrue costs for clinical studies performed over the service periods specified in the contract. We adjust our estimates, if required, based upon our ongoing review of the level of effort and costs actually incurred by the CROs. All of our material CRO contracts are terminable by us upon written notice, and we are generally only liable for actual services completed by the CRO and certain noncancellable expenses incurred at termination.

General and Administrative Expenses

G&A expenses relate to: finance; human resources; legal and other administrative activities which consist primarily of salaries, benefits and other staff-related costs; facilities and overhead costs; legal expenses; and other general and administrative costs. G&A expenses also include cost recoveries associated with collaborative R&D arrangements.

Stock-Based Compensation

We provide stock-based compensation in the form of various types of equity-based awards, including Restricted Stock Units ("RSUs") and stock options. The fair values of RSUs and stock options, which are subject to service conditions and vesting, are recognized as compensation expense on a straight-line basis over the service period net of forfeitures as they occur. See Note 8, Stock-based compensation, for more information.

Income Taxes

We provide for income taxes under the asset and liability method. Current income tax expense or benefit represents the amount of income taxes expected to be payable or refundable for the current year. Deferred income tax assets and liabilities are determined based on differences between the financial statement reporting and tax bases of assets and liabilities and net operating loss and credit carryforwards, measured using the enacted tax rates and laws that will be in effect when such items are expected to reverse. Deferred income tax assets are reduced, as necessary, by a valuation allowance when we determine it is more likely than not that some or all of the tax benefits will not be realized.

We recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained upon examination by tax authorities. We assess all material positions taken in any income tax return, including all significant uncertain positions, in all tax years that are still subject to assessment or challenge by relevant taxing authorities. As of each balance sheet date, unresolved uncertain tax positions must be reassessed, and we will determine whether (i) the factors underlying the sustainability assertion have changed and (ii) the amount of the recognized tax benefit is still appropriate.

We include any penalties and interest expense related to income taxes as a component of other expense and interest income, net, as necessary.

See Note 6, Income taxes, for more information.

Cash Equivalents

Cash equivalents consist of marketable securities having an original maturity of three months or less at the time of purchase.

Marketable Securities

We consider our interest-bearing securities investment portfolio as available-for-sale, and accordingly, these investments are recorded at fair value, with unrealized gains and losses recorded in Accumulated Other Comprehensive Income. See Note 10, Cash, cash equivalents and marketable securities, and Note 16, Fair value measurements, for more information.

Property and Equipment

Property and equipment is recorded at cost and depreciated using the straight-line method over the estimated useful lives of the assets, ranging from three to ten years . Leasehold improvements are amortized over the shorter of their estimated useful lives or the related lease term. We review property and equipment for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. See Note 11, Property and equipment, for more information.

Leases

We determine whether an arrangement is or contains a lease at contract inception. Operating lease right-of-use assets and lease liabilities are recognized at the commencement date based on the present value of the lease payments over the lease term, which is the non-cancelable period stated in the contract adjusted for any options to extend or terminate when it is reasonably certain that we will exercise that option. Right-of-use assets are adjusted for prepaid lease payments, lease incentives and initial direct costs incurred. Operating lease expense for the minimum lease payments is recognized on a straight-line basis over the lease term and includes both lease and non-lease components due to our election account for these components as a single lease component. When our operating leases do not provide an implicit interest rate, we generally utilize our incremental borrowing rate, based on the information available at the commencement date to determine the lease liability. We do not recognize the right-of-use assets and liabilities for leases with lease terms of one year or less with payments recognized as operating expenses on a straight-line basis over the lease term.

We sublease parts of our facilities to third parties and recognize sublease income on a straight-line basis over the sublease term. We evaluate the underlying assets for impairment at sublease inception.

See Note 14, Leases, for more information.

Fair Value of Financial Instruments

We apply fair value accounting for all financial and non-financial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis. We define fair value as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining the fair value measurements for assets and liabilities which are required to be recorded at fair value, we consider the principal or most advantageous market in which we would transact and the market-based risk measurements or assumptions that market participants would use in pricing the asset or liability, such as risks inherent in valuation techniques, transfer restrictions and credit risks. See Note 16, Fair value measurements, for more information.

Other Significant Accounting Policies

Our other significant accounting policies are described in the remaining appropriate notes to the Consolidated Financial Statements.

Recent Accounting Pronouncements

Adopted in the Current Period

In November 2023, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2023-07 — Segment Reporting (Topic 280) — Improvements to Reportable Segment Disclosures. This ASU expands segment disclosure requirements, primarily through enhanced disclosure requirements for significant segment expenses. The ASU does not change how a public entity identifies its operating segments, aggregates them or applies the quantitative thresholds to determine its reportable segments. The additional disclosure requirements apply to all public entities that are required to report segment information, including those with only one reportable segment. Early adoption is permitted, and the standard requires retrospective application to all prior period presented. There was no impact on our reportable segments identified and additional required disclosures have been included in Note 18.

Not Yet Adopted

In November 2024, the FASB issued ASU 2024-03 — Income Statement — Reporting Comprehensive Income — Expense Disaggregation Disclosures (Subtopic 220-40) — Disaggregation of Income Statement Expenses. This ASU requires disclosure, in the notes to financial statements, of specified information about certain costs and expenses. We plan to adopt this guidance beginning with our 2027 Annual Report to be filed in early 2028 and all quarterly and Annual Reports thereafter. We expect the adoption of this standard to result in increased disclosures in our Notes to Consolidated Financial Statements.

Note 3. Related party - Gilead Sciences, Inc.

In 2020, we and Gilead entered into the Gilead Collaboration Agreement, the Stock Purchase Agreement, and the Investor Rights Agreement.

The Gilead Collaboration Agreement was amended in 2021, in 2023, in the first quarter 2024 and in the second quarter 2024 (the "Fourth Gilead Collaboration Agreement Amendment").

The Stock Purchase Agreement was amended in 2021, in 2023, and was amended and restated in the first quarter 2024.

The Investor Rights Agreement was amended in 2022 and was amended and restated in the first quarter 2024.

We refer to these agreements collectively as the Gilead Agreements.

Stock Purchase and Investor Rights Agreements

In 2020, under the Stock Purchase Agreement, Gilead purchased 6.0 million shares of our common stock for total gross proceeds of $ 200 million, of which $ 91 million was determined to be a premium on the purchase of common stock and allocated to the performance obligations created by the Gilead Collaboration Agreement as deferred revenue, see Note 5, Revenues, for more information.

In 2021, under the First Stock Purchase Agreement Amendment, Gilead purchased 5.7 million shares of our common stock for total gross proceeds of $ 220 million.

In 2023, under the Second Stock Purchase Agreement Amendment, Gilead purchased 1.0 million shares of our common stock for total gross proceeds of $ 20 million.

In 2024, under the Third Stock Purchase Agreement Amendment, Gilead purchased 15.2 million shares of our common stock for total gross proceeds of $ 320 million, of which $ 87 million was determined to be a premium on the purchase of common stock and allocated to the performance obligations created by the Third Gilead Collaboration Agreement Amendment as deferred revenue, see Note 5, Revenues, for more information.

Gilead has the right under the Stock Purchase Agreement and the related amendments to purchase, at its option until July 2025, up to a maximum of 35 % of the Company's then-outstanding voting common stock, at a purchase price equal to the greater of a 20 % premium to market (based on a trailing five-day average closing price at option exercise) or the $ 33.54 initial purchase price. Based on the value of our common stock at each contract closing, the right to purchase additional shares had no value. Under the Investor Rights Agreement entered into in 2020 and subsequent amendments, Gilead has: the right to designate three members of our board of directors; registration rights for shares that it purchases; and pro rata participation rights in certain future financings. Gilead has exercised its rights to appoint all three board members and we have registered all shares purchased to date.

As of December 31, 2024, Gilead held approximately 32.6 % of our outstanding common stock arising from purchases in our 2020 public offering and purchases under the Stock Purchase Agreement and the related amendments. See Note 19, Subsequent events, for additional information regarding our February 2025 common stock offering.

Collaboration Agreements

In 2020, we entered into the Gilead Collaboration Agreement, which gave Gilead an exclusive license to develop and commercialize zimberelimab (the anti PD-1 program) in certain markets and time-limited options to acquire exclusive licenses to develop and commercialize any of our then-current and future clinical programs arising during the 10 -year collaboration term, contingent upon $ 100 million option continuation payments payable on each of the second, fourth, sixth and eighth anniversaries of the agreement. Upon closing of the transaction in 2020, Gilead made an upfront payment of $ 175 million.

In 2021, we entered into the First Gilead Collaboration Agreement Amendment pursuant to which Gilead exercised its option to three programs—providing Gilead with exclusive licenses to develop and commercialize domvanalimab and AB308 (collectively, the anti-TIGIT program), etrumadenant (the adenosine receptor antagonist program) and quemliclustat (the CD73 program), in certain markets—for a total payment of $ 725 million that was received in 2022. The amendment also (i) provided for a slight reduction in the royalties for these three programs, such that Gilead will pay us tiered royalties as a percentage of revenues ranging from the mid-teens to the low twenties; and (ii) removed the $ 100 million option continuation payment that was otherwise due on the second anniversary of the Gilead Collaboration Agreement. With respect to domvanalimab, we are also eligible to receive up to $ 500 million in potential U.S. regulatory approval milestones.

Gilead's option, on a program-by-program basis, will expire after a prescribed period following the achievement of a clinical development milestone in such program and our delivery to Gilead of the requisite data package. Gilead may exercise its option to any program at any time prior to expiration of the option and will pay Arcus an option fee of $ 150 million per program.

For each program that Gilead opts in to, both companies will co-develop and equally share global development costs, subject to certain opt-out rights that we have, caps on our spending and related subsequent adjustments, and certain other exceptions. For each program, provided we have not exercised our opt-out rights, we have the option to co-promote in the U.S. with equal sharing of related profits and losses. Gilead has the right to exclusively commercialize outside of the U.S., subject to the rights of our existing partners in any territories and will pay us tiered royalties as a percentage of revenues ranging from the high teens to the low twenties.

Under the First Gilead Collaboration Agreement Amendment, Gilead also has option rights to two oncology research programs for which we will lead discovery and early development activities. With respect to these two research programs, Gilead has the right to exercise its option, on a program-by-program basis, either (i) upon our completion of certain IND-enabling activities for an option payment of $ 60 million or (ii) following the achievement of a clinical development milestone for an option payment of $ 150 million.

In 2023, we entered into the Second Gilead Collaboration Agreement Amendment pursuant to which we expanded our collaboration to provide Gilead with options to license up to four jointly selected research-stage programs that target inflammatory diseases for which we will lead discovery and early development activities. We will receive an upfront payment of $ 17.5 million for each initiated program and Gilead will have an option to license each program at two separate, prespecified time points. For the first two research programs, Gilead has the right, on a program-by-program basis, either (i) to exercise its option upon our completion of certain IND-enabling activities for an option payment of $ 45 million or (ii) to extend its option and exercise it following the achievement of a clinical development milestone for an option payment of $ 150 million. If Gilead exercises its option at the earlier time point for the first two programs, we would be eligible to receive up to $ 375 million in regulatory and commercial milestone payments as well as tiered royalties for each optioned program. For any other program option exercise by Gilead, the parties would have rights to co-develop and share global development costs and to co-commercialize and share profits in the U.S. for that program. We received a total upfront payment of $ 35 million for an initial two research programs in 2023. Gilead's options to the other two research programs, expire unless the programs are selected prior to May 2025, as amended under the Fourth Gilead Collaboration Agreement Amendment.

In the first quarter 2024, we entered into the Third Gilead Collaboration Agreement Amendment. The Third Gilead Collaboration Agreement Amendment, among other things, (i) requires Gilead to pay the $ 100 million option continuation payment due on the fourth anniversary of the Gilead Collaboration Agreement, which was received in the third quarter 2024 (ii) provides that we will operationalize and fund the Phase 3 PRISM-1 study evaluating quemliclustat in pancreatic cancer subject to Gilead's right to reinstate the study as part of the parties' joint development activities upon regulatory approval, (iii) provides that we will solely fund our share of PACIFIC-8, subject to Gilead’s right to reinstate PACIFIC-8 as part of the parties’ joint development activities for the TIGIT Program in the first quarter of 2026, and (iv) provides that we will fund certain other activities. All other terms of the existing collaboration agreements, remain unchanged.

As of December 31, 2024, Gilead has licenses to domvanalimab, AB308, etrumadenant, quemliclustat and zimberelimab. In February 2025, Gilead's time-limited exclusive option rights to our HIF-2α program (including casdatifan) expired.

For the years ended December 31, 2024, 2023 and 2022; we recognized revenue under the Gilead Agreements of $ 243 million, $ 112 million and $ 107 million, respectively and net reimbursements from Gilead recognized as reductions in R&D expense of $ 39 million, $ 110 million and $ 132 million, respectively. For the years ended December 31, 2024 and 2022, respectively, we recognized net payments to Gilead in G&A expense of $ 2 million and net reimbursements from Gilead as reductions in G&A expense of $ 1 million.

At December 31, 2024 and 2023, we had a net receivable of $ 6 million and $ 20 million, respectively, recorded in Receivable from collaboration partners on our Consolidated Balance Sheets. At December 31, 2023, we had $ 6 million recorded in Other noncurrent assets on our Consolidated Balance Sheets.

For a more detailed discussion on revenues recognized under the Gilead Agreements, see Note 5, Revenues, for more information.

Note 4. License and collaborations

We enter into licensing agreements, strategic collaborations and other similar arrangements with third parties for the development and commercialization of certain investigational products. These arrangements: may be collaborative and involve two or more parties who are active participants in the operating activities of the collaboration and are exposed to significant risks and rewards depending on the commercial success of the activities; are performed with no guarantee of either technological or commercial success; and are each unique in nature. Such arrangements may include: non-refundable upfront payments; payments for options to acquire certain rights; potential development and regulatory milestone payments and/or sales-based milestone payments; royalty payments; revenue or profit-sharing arrangements; expense reimbursements; and cost-sharing arrangements. See Note 2, Summary of significant accounting policies, for additional discussion of how revenues are recognized under these types of arrangements.

Operating expenses for costs incurred pursuant to these arrangements are reported in their respective expense line items in the Consolidated Statements of Operations, net of any payments due to or reimbursements due from our collaboration partners, with such reimbursements being recognized at the time the party becomes obligated to pay. Our significant arrangements are discussed below.

Gilead Collaboration

See Note 3, Related party - Gilead Sciences, Inc., for more information.

Taiho Collaboration

In 2017, we entered into an agreement with Taiho under which we granted them exclusive options to programs arising over a five-year period which ended in September 2022 for an upfront payment of $ 35 million. Upon an option exercise of a program, Taiho would obtain exclusive development and commercialization rights to investigational products under the program for the Taiho Territory.

For each option that Taiho exercises, they will be obligated to make a payment of $ 3 million to $ 15 million, depending on the development stage of the optioned program. Upon exercise, Taiho is solely responsible for continued development and commercialization in the Taiho Territory. In addition, for each optioned program we would be eligible to receive clinical and regulatory milestones of up to $ 130 million and commercial milestone payments of up to $ 145 million with the achievement of certain sales thresholds in the Taiho Territory. We will also receive royalties ranging from high single-digits to mid-teens on net sales of licensed products in the Taiho Territory. Royalties will be payable by product and country commencing on the first commercial sale and ending upon the later of: (a) 10 years; and (b) expiration of the last-to-expire valid claim of our patents covering the manufacture, use or sale.

As of December 31, 2024, Taiho has licenses for the Taiho Territory to (i) etrumadenant (the adenosine receptor antagonist program); (ii) zimberelimab (the anti PD-1 program); (iii) domvanalimab and AB308 (the anti-TIGIT program); and (iv) quemliclustat (the CD73 program), for which Taiho exercised its option and made an option payment of $ 15 million in the third quarter 2024.

During 2022, Taiho opted to participate in two global Phase 3 trials of domvanalimab and zimberelimab combinations, STAR-121 and STAR-221, and became obligated to reimburse us for their portion of the global study costs, and to make milestone payments contingent upon successfully satisfying the related clinical milestones. During the year ended December 31, 2023, the clinical milestones for domvanalimab and zimberelimab for the STAR-221 study were met and Taiho became obligated to pay us $ 28 million which has been fully received. In the first quarter 2024, the clinical milestones for domvanalimab and zimberelimab for the STAR-121 study were met and Taiho became obligated to pay us $ 26 million, of which $ 16 million was received in the first quarter 2024. The remaining $ 10 million was received in January 2025. Due to the nature of this arrangement, these clinical milestones were determined to be advance cost sharing payments for a portion of the global study R&D costs under the collaboration and are deferred and recognized as a reduction in R&D expense as the related global studies are performed, calculated as an estimated percentage of completion based on the estimated total effort for the programs.

In October 2024, Taiho opted to participate in the global Phase 3 trial of quemliclustat, PRISM-1, and became obligated to reimburse us for their portion of the global study costs and in February 2025, Taiho dosed their first patient in Japan for PRISM-1, and became obligated to make milestone payments totaling $ 19 million.

For the years ended December 31, 2024, 2023 and 2022, we recognized revenue of $ 15 million, $ 5 million and $ 5 million, respectively. For the years ended December 31, 2024 and 2023 we recognized net reimbursements from Taiho of $ 28 million and $ 8 million, respectively, recognized as a reduction in R&D expense under this arrangement. At December 31, 2024 and 2023, we had $ 14 million and $ 18 million, respectively, related to this arrangement recorded in Receivable from collaboration partners on our Consolidated Balance Sheets. At December 31, 2024, we had liabilities of

$ 36 million related to certain advance cost sharing payments under this arrangement recorded in Other liabilities, allocated between current and noncurrent based on the expected timing of future recognition.

AstraZeneca Collaboration

In 2020, we entered into a collaboration with AstraZeneca to evaluate domvanalimab, our investigational anti-TIGIT antibody, in combination with AstraZeneca's durvalumab in a registrational Phase 3 clinical trial in patients with unresectable Stage 3 NSCLC, known as the PACIFIC-8 trial. The terms of this agreement were amended in the first quarter 2024. Under the collaboration, as amended, each company will retain existing rights to their respective molecules and any future commercial economics. AstraZeneca will conduct the trial, and each company will supply their respective investigational product to support the trial. We may incur milestones of up to $ 24 million upon the achievement of certain clinical trial progress milestones or under certain circumstances if the agreement is terminated early and we will reimburse AstraZeneca annually for a portion of the trial costs. The portion of the costs that we consider to be unavoidable are accrued as incurred and milestones that are deemed probable of occurring are accrued in advance of the achievement of the milestone.

Prior to January 2024, the PACIFIC-8 trial formed part of the Arcus and Gilead joint development program for domvanalimab and our portion of the trial costs were shared with Gilead. At December 31, 2023, we had recognized amounts due from Gilead for these shared costs of $ 6 million, recorded in Other noncurrent assets on our Consolidated Balance Sheet. Under the Third Gilead Collaboration Agreement Amendment, we agreed to solely fund our share of PACIFIC-8, subject to Gilead's right to reinstate PACIFIC-8 as part of the parties' joint development activities for the TIGIT Program in the first quarter of 2026. For the year ended December 31, 2024, we incurred $ 6 million of R&D expense reflecting our additional share of incurred costs to date.

In October 2024, we entered into a clinical collaboration with AstraZeneca to evaluate casdatifan, our investigational HIF-2α inhibitor, in combination with volrustomig, AstraZeneca's investigational PD-1/CTLA-4 bispecific antibody, in IO-naive patients with ccRCC. AstraZeneca will operationalize the study. Under the collaboration, each company will retain existing rights to their respective molecules and any future commercial economics. AstraZeneca will conduct the trial, and each company will supply their respective investigational product to support the phase 1b trial.

For the years ended December 31, 2024, 2023, and 2022, we recognized as R&D expense $ 14 million, $ 6 million, and $ 4 million, respectively, under this arrangement. At December 31, 2024, we have recognized a total liability of $ 26 million related to our obligation to AstraZeneca, recorded in Other current liabilities and Other noncurrent liabilities on our Consolidated Balance Sheets based on the expected timing of payment. At December 31, 2023, we have recognized a liability of $ 11 million, which is recorded in Other noncurrent liabilities on our Consolidated Balance Sheets.

WuXi Biologics License – anti-PD-1

In 2017, we entered into an agreement with WuXi Biologics which, as amended, provides us with exclusive rights to (i) develop, use and manufacture products that include an anti-PD-1 antibody, including zimberelimab, worldwide and (ii) commercialize any such products worldwide, except in Greater China. Under this agreement, as of December 31, 2024 we may incur (i) regulatory milestone payments of up to $ 50 million for zimberelimab, and commercialization milestone payments of up to $ 375 million, (ii) tiered royalties that range from the high single-digits to low teens on net sales of the licensed products and (iii) fees related to any sublicenses.

For the years ended December 31, 2024, 2023, and 2022, we did not have any milestones or royalties due under this arrangement.

WuXi Biologics License – anti-CD39

In 2020, we entered into an agreement with WuXi Biologics, under which we obtained the exclusive worldwide license to develop and commercialize anti-CD39 antibodies discovered under this arrangement. As of December 31, 2024 we may incur additional clinical and regulatory milestone payments of up to $ 14 million and royalty payments in the low single digits on net sales of the licensed products under this agreement.

For the years ended December 31, 2023 and 2022, we incurred development milestones of $ 1 million and $ 2 million, respectively, related to this agreement, which were recognized as R&D expense.

Abmuno License

In 2016, we entered into an agreement with Abmuno, under which we obtained the exclusive worldwide license to develop, use, manufacture, and commercialize products that include an anti-TIGIT antibody, including domvanalimab. Under this agreement, as of December 31, 2024 we may incur additional clinical, regulatory and commercialization milestone payments of up to $ 88 million.

For the year ended December 31, 2022, we incurred development milestones of $ 5 million related to this agreement, which were recorded as R&D expense.

Note 5. Revenues

The following table summarizes our revenues by collaboration, category of revenue, and the method of recognition (in millions):

			Year Ended December 31,		
	Over time	Point in time	2024	2023	2022
Gilead Collaboration					
License and R&D services	*		$ 207	$ 75	$ 74
R&D services	*		8	4	—
Access rights	*		28	33	33
Taiho Collaboration					
License revenue		*	15	—	—
Other	*		—	5	5
Total revenues			$ 258	$ 117	$ 112
Total revenues from collaborations			$ 207	$ 80	$ 74
Total revenues from a customer			$ 51	$ 37	$ 38

Revenues from Gilead accounted for 94 %, 96 % and 96 % of Total revenues for the years ended December 31, 2024, 2023 and 2022, respectively.

The following table summarizes the revenue recognized as a result of changes in the deferred revenue balance (in millions):

	Year Ended December 31,		
	2024	2023	2022
Revenue recognized from amounts in deferred revenue at the beginning of the period	$ 243	$ 108	$ 112

We had $ 319 million and $ 398 million of deferred revenue remaining on our Consolidated Balance Sheets at December 31, 2024 and 2023, respectively, allocated between current and noncurrent based on the expected timing of future recognition.

Revenue from the Gilead Collaboration

In January 2024, we entered into the Third Gilead Collaboration Agreement Amendment, which we determined was a change in scope and price of the original contract and we accounted for this contract modification as both a modification of the existing contract and the creation of a new contract. Under the applicable accounting rules for such contract modifications, we did not adjust the accounting for completed performance obligations that were distinct from the modified goods or services. However, we adjusted revenue previously recognized to reflect the effect of the contract modification due to the updated estimated transaction price allocated to the partially satisfied performance obligations and the updated measure of progress as of the modification date. Accordingly, we allocated the transaction price to the remaining performance obligations (both from the existing contract and the modification) and recognized a cumulative catch-up to revenue of $ 107 million based on the updated transaction price and measure of progress for the partially satisfied performance obligations. This cumulative catch-up reduced net loss per share, basic and diluted, in the year ended December 31, 2024 by $ 1.19 , see Note 3, Related party - Gilead Sciences, Inc., for more information.

The following table summarizes the transaction price (in millions):

Transaction price	Amount
Premium from Third Stock Purchase Agreement Amendment	$ 87
Option continuation payment received in the third quarter of 2024	100
Deferred revenue as of January 2024	335
Total transaction price	$ 522

Our assessment of the updated transaction price for the Third Gilead Collaboration Agreement Amendment included an analysis of amounts we expected to receive, which at contract amendment consisted of: $ 100 million option continuation payment that Gilead committed to and paid in the third quarter of 2024 for continued access to our pipeline; $ 87 million allocated from the premium from the Third Stock Purchase agreement; and $ 335 million deferred revenue remaining from the First Gilead Collaboration Agreement Amendment effective December 2021. We determined the entire $ 522 million to be the allocable transaction price as of the amendment closing date, due to the history of timely payments by Gilead.

The following table summarizes the allocation of the transaction price to the performance obligations (in millions):

Allocation to performance obligations	Distinct	Combined	Amount
Etrumadenant - License and R&D services		*	$ 210
Quemliclustat - License and R&D services		*	168
Domvanalimab - R&D services	*		33
Access rights	*		57
Option continuation periods	*		20
Rights to certain studies	*		34
Total allocated transaction price			$ 522

We accounted for each performance obligation as follows:

Etrumadenant – License and R&D Services

Under the Gilead Collaboration Agreement, Gilead obtained an option to the exclusive rights to our adenosine receptor program, etrumadenant, in exchange for an option payment of $ 250 million, if exercised.

Effective December 2021, under the First Gilead Collaboration Agreement Amendment, Gilead exercised the option and obtained an exclusive license to etrumadenant and we were also obligated to perform further R&D services for Gilead related to etrumadenant. We determined that the license and R&D services were combined at the inception of the agreement based on an evaluation of the delivery of the license, due to the early stage of the technology and the specialized nature of our know-how. We determined the standalone selling price of the license using a discounted cash flow method and the R&D services using an expected cost-plus margin approach. We recognize the amounts allocated to the combined license and services as the performance obligation is satisfied, calculated as an estimated percentage of completion based on management's estimated total effort for the program. Prior to the closing of the Third Gilead Collaboration Agreement Amendment, we had $ 129 million of deferred revenue on our Consolidated Balance Sheet related to this performance obligation.

Effective January 2024, under the Third Gilead Collaboration Agreement Amendment, this performance obligation was partially satisfied and there were no changes to the scope of the related R&D service obligation as a result of the amendment. We allocated the updated transaction price to this performance obligation based on the standalone selling price and adjusted revenue based on an updated measure of progress, which resulted in a cumulative catch-up of revenue of $ 14 million.

We recognized $ 47 million, $ 52 million, and $ 34 million in the years ended December 31, 2024, 2023 and 2022, respectively, within License and development services revenue in our Consolidated Statements of Operations. At December 31, 2024 and 2023, we had $ 166 million and $ 133 million, respectively, of deferred revenue remaining on our Consolidated Balance Sheet related to this performance obligation.

Quemliclustat – License and R&D Services

Under the Gilead Collaboration Agreement, Gilead obtained an option to the exclusive rights to our CD73 program, quemliclustat, in exchange for an option payment of $ 200 million, if exercised.

Effective December 2021, under the First Gilead Collaboration Agreement Amendment, Gilead exercised the option and obtained an exclusive license to quemliclustat and we were also obligated to perform further R&D services for Gilead related to quemliclustat. We determined that the license and R&D services were combined at the inception of the agreement based on an evaluation of the delivery of the license, due to the early stage of the technology and the specialized nature of our know-how. We determined the standalone selling price of the license using a discounted cash flow method and the R&D services using an expected cost-plus margin approach. We recognize the amounts allocated to the combined license and services as the performance obligation is satisfied, calculated as an estimated percentage of completion based on management's estimated total effort for the program. Prior to the closing of the Third Gilead Collaboration Agreement Amendment, we had $ 130 million of deferred revenue on our Consolidated Balance Sheet related to this performance obligation.

Effective January 2024, under the Third Gilead Collaboration Agreement Amendment, this performance obligation was partially satisfied and there was a reduction to the scope of the related R&D service obligation as a result of the amendment. Specifically, the amendment provides that we will independently initiate, operationalize and fund a Phase 3 study to evaluate quemliclustat in pancreatic cancer, which reduces our estimated obligation to perform further R&D services for Gilead related to quemliclustat under the collaboration. We allocated the updated transaction price to this performance obligation based on the standalone selling price and adjusted revenue based on an updated measure of progress which resulted in cumulative catch-up of revenue of $ 88 million.

We recognized $ 147 million, $ 17 million, and $ 26 million in the years ended December 31, 2024, 2023 and 2022, respectively, within License and development service revenue in our Consolidated Statements of Operations. At December 31, 2024 and 2023, we had $ 23 million and $ 132 million, respectively, of deferred revenue remaining on our Consolidated Balance Sheet related to this performance obligation.

Domvanalimab – R&D Services

Under the First Gilead Collaboration Agreement Amendment, we determined that we retain a separate performance obligation to perform further R&D services for Gilead related to domvanalimab. The standalone selling price of this obligation was determined using an expected cost-plus margin approach. We recognize the amounts allocated to these services as the performance obligation is satisfied, calculated as an estimated percentage of completion based on management's estimated total effort for the program. Prior to the closing of the Third Gilead Collaboration Agreement Amendment, we had $ 25 million of deferred revenue on our Consolidated Balance Sheet related to this performance obligation.

Effective January 2024, under the Third Gilead Collaboration Agreement Amendment, this performance obligation was partially satisfied and there were no significant changes to the scope of this obligation as a result of the amendment. We allocated the updated transaction price to this performance obligation based on the standalone selling price and adjusted revenue based on an updated measure of progress which resulted in cumulative catch-up of revenue of $ 5 million.

We recognized $ 13 million, $ 5 million, and $ 5 million in the years ended December 31, 2024, 2023, and 2022, respectively, within License and development services revenue in our Consolidated Statements of Operations. At December 31, 2024 and 2023, we had $ 21 million and $ 25 million, respectively, of deferred revenue remaining on our Consolidated Balance Sheet related to this performance obligation.

Zimberelimab – R&D and Commercialization Services

Under the First Gilead Collaboration Agreement Amendment, we determined that we retained separate performance obligations to perform further R&D and commercialization services for Gilead related to zimberelimab, as a monotherapy and in combination with other agents. The standalone selling price of these obligations were determined using an expected cost-plus margin approach. We recognize the amounts allocated to these services as the performance obligations are satisfied, calculated as an estimated percentage of completion based on management's estimated total effort for the program.

We recognized $ 1 million and $ 9 million for R&D and commercialization services in the years ended December 31, 2023 and 2022, respectively, within License and development service revenue in our Consolidated Statements of Operations. At December 31, 2023, the performance obligation was fully satisfied and all revenue has been recognized.

Access Rights and Option Continuation Periods

Under the First Gilead Collaboration Agreement Amendment, Gilead has exclusive access to our current programs as well as the future programs for a period of ten years , contingent upon option continuation payments totaling $ 300 million, consisting of a $ 100 million payment on each of the fourth, sixth, and eighth anniversaries of the Gilead Collaboration Agreement. Prior to the closing of the Third Gilead Collaboration Agreement Amendment, we had $ 51 million of deferred revenue on our Consolidated Balance Sheet related to these performance obligations.

Effective January 2024, under the Third Gilead Collaboration Agreement Amendment, Gilead agreed to pay the $ 100 million option continuation payment due on the fourth anniversary of the Gilead Collaboration Agreement, which occurred and was received in the third quarter of 2024, and we included this payment in the transaction price. By exercising this right Gilead's exclusive access to our current programs as well as any future programs is extended to 2026. We determined that as of the closing date in January 2024, Gilead is not obligated to make the remaining contingent payments totaling $ 200 million due on the sixth and eighth anniversaries of the Gilead Collaboration Agreement and accordingly, we have excluded these payments from the transaction price. Failure to pay the non-obligatory option continuation payments will result in Gilead's loss of certain rights to access and obtain licenses to the programs arising from our R&D pipeline.

The standalone selling price of the ongoing R&D pipeline access and the option continuation material rights were determined using an expected cost-plus margin approach, with the option continuation material rights probability-adjusted for the likelihood of exercise. We use a time-elapsed input method to measure progress toward satisfying the access rights performance obligation, which is the method we believe most faithfully depicts the Company's performance in transferring the promised services during the time period in which Gilead has access to our R&D pipeline. Accordingly, the revenue allocated to the initial four-year access rights performance obligation is being recognized using this input method over the remaining period through July 2024, and for the access rights continuation, over the two-year period commencing July 2024. For the remaining access rights option continuation periods commencing on the sixth, and eighth, anniversaries of the agreement, if Gilead elects to exercise their option, we will recognize the revenue allocated to that option together with the $ 100 million continuation payment over the new minimum access period or immediately if the option lapses.

We recognized $ 28 million, $ 33 million, and $ 33 million in the years ended December 31, 2024, 2023, and 2022, respectively, within Other collaboration revenue in our Consolidated Statements of Operations. At December 31, 2024 and 2023, we had $ 52 million and $ 54 million, respectively, of deferred revenue on our Consolidated Balance Sheet related to these performance obligations.

Rights to Certain Studies

Effective January 2024, under the Third Gilead Collaboration Agreement Amendment, we will solely fund certain studies, but Gilead retains exclusive rights to reinstate into the collaboration each study at specified time-points for a payment. We have determined that these are material rights and we estimated the standalone selling price of these performance obligations using a discounted cash flow method probability-adjusted for the likelihood of exercise. We will recognize the amount allocated to each right if and when the related study is reinstated into the parties' co-development plans or if the option lapses.

At December 31, 2024, we had $ 34 million of deferred revenue remaining on our Consolidated Balance Sheet related to these performance obligations.

Inflammation Programs - R&D Services

In addition to the amendments noted above, in May 2023, we entered into the Second Gilead Collaboration Agreement Amendment pursuant to which we expanded our collaboration to provide Gilead with options to license up to four jointly selected research-stage programs that target inflammatory diseases for which we will lead discovery and early development activities, see Note 3, Related party - Gilead Sciences, Inc., for more information. In 2023, we received a total upfront payment of $ 35 million for an initial two jointly selected research-stage programs. We determined that the Second Gilead Collaboration Agreement Amendment represented a separate contract and, at the amendment closing date, we allocated the transaction price of $ 35 million to the performance obligations created as of the date of this amendment.

The following table summarizes the allocation of the transaction price to the performance obligations (in millions):

Allocation to performance obligations	Distinct	Amount
Inflammation target 1 - R&D services	*	$ 18
Inflammation target 2 - R&D services	*	17
Total allocated transaction price		$ 35

We determined that we have separate performance obligations to perform R&D services for Gilead related to discovery and early development activities for each research program for which they have made an upfront payment. The standalone selling prices of these obligations were determined using an expected cost-plus margin approach. We recognize the amounts allocated to these services as the performance obligation is satisfied, calculated as an estimated percentage of completion based on management's estimated total effort for the program. The options to acquire additional licenses or services did not result in additional performance obligations because they did not provide a material right at contract inception, primarily due to the very early stages of the programs.

We recognized revenue of $ 8 million and $ 4 million for the years ended December 31, 2024 and 2023, respectively, within Other collaboration revenue in our Consolidated Statements of Operations. At December 31, 2024 and 2023, we had $ 23 million and $ 31 million, respectively, of deferred revenue remaining on our Consolidated Balance Sheet related to these performance obligations.

Revenue from the Taiho Collaboration

Quemliclustat - License

In July 2024, Taiho exercised its option under the agreement we entered into in 2017 and obtained an exclusive license for quemliclustat (the CD73 program) for the Taiho Territory for an option payment of $ 15 million which was received in the third quarter 2024.

We determined that this license was the only performance obligation and we recognized upon delivery the full $ 15 million of revenue in the year ended December 31, 2024 within License and development services revenue in our Consolidated Statements of Operations.

Capitalized Costs to Obtain Contracts

We incurred $ 8 million of costs in the first quarter 2024 to obtain the Third Gilead Collaboration Agreement Amendment, Third Stock Purchase Agreement Amendment and the Second Investor Rights Agreement Amendment, which consisted of consultant fees that were payable upon the successful completion of the agreements. We determined that $ 5 million of these costs were related to the Third Stock Purchase Agreement Amendment which were recognized as offering costs in additional paid-in capital. The remaining costs were combined with $ 3 million in capitalized costs that remained from the initial Gilead Collaboration Agreement and subsequent amendments, and the total was allocated to the various remaining performance obligations, to be recognized as the underlying performance obligations are satisfied and revenue is recognized.

For the years ended December 31, 2024, 2023, and 2022, we recognized $ 3 million, $ 1 million, and $ 4 million, respectively, of expense in G&A expense. At each of December 31, 2024 and 2023, we had $ 3 million in capitalized costs to obtain the contracts, allocated between Prepaid expenses and other current assets and Other noncurrent assets in our Consolidated Balance Sheets based on the expected timing of future recognition.

Note 6. Income taxes

Loss before income taxes included the following (in millions):

	Year Ended December 31,		
	2024	2023	2022
Domestic	$ (283)	$ (301)	$ (267)
Foreign	1	—	1
Loss before income taxes	$ (282)	$ (301)	$ (266)

The provision for income taxes included the following (in millions):

	Year Ended December 31,		
	2024	2023	2022
Current provision:			
Federal	$ —	$ 4	$ —
State	1	2	1
Total income tax expense	$ 1	$ 6	$ 1

The reconciliation between the federal statutory income tax rate and our effective tax rate was as follows:

	Year Ended December 31,		
	2024	2023	2022
Federal statutory income tax rate	21.0 %	21.0 %	21.0 %
State taxes, net of federal benefit	— %	(0.7)%	(0.1)%
Equity investment	4.1 %	0.4 %	0.9 %
Research and development credits	5.4 %	5.2 %	3.1 %
Change in valuation allowance	(28.1)%	(26.3)%	(24.5)%
Stock based compensation	(1.9)%	(2.1)%	0.1 %
Non-deductible expenses and other	(0.7)%	0.5 %	(0.6)%
Provision for income taxes	(0.2)%	(2.0)%	(0.1)%

Deferred income taxes reflect the net tax effects of (a) temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, and (b) operating losses and tax credit carryforwards.

Significant components of our deferred tax assets and liabilities were as follows (in millions):

	Year Ended December 31,	
	2024	2023
Deferred tax assets:		
Federal and state net operating loss carryforwards	$ 5	$ 1
Research and development credits carryforwards	42	26
Stock-based compensation	27	21
Depreciation and amortization	3	3
Deferred revenue	45	66
Lease liability	24	26
Capitalized research and development costs	178	109
Other	6	1
Total deferred tax assets	330	253
Deferred tax liabilities:		
Right-of-use assets	(14)	(20)
Total deferred tax liabilities	(14)	(20)
Less valuation allowance	(316)	(233)
Net deferred tax assets (liabilities)	$ —	$ —

The accounting for deferred taxes involves the evaluation of a number of factors concerning the realizability of net deferred tax assets. We considered factors such as our history of operating losses, the nature of our deferred tax assets, and the timing, likelihood and amount, if any, of future taxable income during the periods in which those temporary differences and carryforwards become deductible, including amounts that may arise under the collaboration agreements with Gilead and related program opt-ins. As a result of our evaluation of these factors, including the uncertainty that exists with respect to the option fees and milestone payments, we do not believe that it is more likely than not that the deferred tax assets will be realized. Accordingly, a full valuation allowance has been established and no deferred tax asset is shown in the accompanying Consolidated Balance Sheets. The valuation allowance increased by approximately $ 83 million for the years ended December 31, 2024 and 2023.

The U.S. enacted the Tax Cuts and Jobs Act in December 2017, which requires companies to capitalize all of their R&D costs for U.S. tax purposes, including software development costs, incurred in tax years beginning after December 21,2021. Beginning in 2022, for tax purposes we began capitalizing and amortizing R&D costs over a five-year period for domestic research and a fifteen-year period for international research rather than expensing these costs immediately.

At December 31, 2024, we have federal net operating losses of $ 1 3 million that have no expiration date and research tax credits of approximately $ 41 million that begin to expire in 2041. We also have state NOLs of approximately $ 34 million that begin to expire in 2035, and state research tax credits of approximately $ 20 million that have no expiration date, and foreign research tax credits of approximately $ 3 million that have no expiration date. Use of the U.S. federal and state NOLs and credit carryforwards may be subject to a substantial annual limitation due to the ownership change provisions of U.S. tax law, as defined in IRC Sections 382 and 383, and similar state provisions. The annual limitation may result in the expiration of NOLs and credits before use. We have determined that an ownership change, as defined under IRC Section 382, occurred in previous years. While we do not expect these ownership changes to result in the expiration of net operating loss and credit carryforwards prior to utilization, we are subject to an annual limitation on the use of its tax attributes. The limitation on the use of net operating loss and credit carryforwards could reduce our ability to use a portion of the tax attributes to offset future taxable income.

We have not been audited by the Internal Revenue Service, any state or foreign tax authority. We are subject to taxation in the U.S. and in Australia. Due to net operating loss and research credit carryforwards, all of our tax years, from 2015 to 2024, remain open to U.S. federal and California state tax examinations. In addition, our fiscal years from 2020 to 2024 are open to examination in Australia.

Uncertain Tax Positions

We follow the provisions of FASB Accounting Standards Codification 740-10, *Accounting for Uncertainty in Income Taxes* , which prescribe a comprehensive model for the recognition, measurement, presentation and disclosure in financial statements of uncertain tax positions that have been taken or are expected to be taken on a tax return. No liability related to uncertain tax positions is recorded in the Consolidated Financial Statements. The reserve for unrecognized tax benefits was approximately $ 19 million and $ 13 million at December 31, 2024, and 2023, respectively.

Due to the full valuation allowance at December 31, 2024 and 2023, current adjustments to the unrecognized tax benefit will have no impact on our effective income tax rate; any adjustments made after the valuation allowance is released will have an impact on the tax rate.

Interest and penalties related to unrecognized tax benefits are included in the provision for income taxes. There were no material interest or penalties accrued at December 31, 2024 or 2023.

The following table summarizes the activity related to our unrecognized tax benefits (in millions):

	Year Ended December 31,	
	2024	2023
Beginning balance	$ 13	$ 8
Additions for tax positions taken in prior year	1	2
Additions for tax positions taken in current year	5	3
Ending balance	$ 19	$ 13

As of December 31, 2024, the total amount of gross unrecognized tax benefits was $ 19 million, of which, if recognized, none would impact our effective tax rate. We do not anticipate material changes to our uncertain tax positions through the next 12 months.

Note 7. Net loss per share

The computation of basic net loss per share is based on the weighted-average number of our common shares outstanding during the period. The computation of diluted net loss per share is based on the weighted-average number of our common shares and dilutive potential common shares, which primarily include shares that may be issued under our stock option, RSU, and Employee Stock Purchase Plans ("ESPP") (collectively, "dilutive securities") as determined under the treasury stock method.

The following table sets forth the computation of basic and diluted net loss per share (in millions, except per share data):

	Year Ended December 31,		
	2024	2023	2022
Net loss (Numerator):			
Net loss	$ (283)	$ (307)	$ (267)
Weighted-average shares (Denominator):			
Weighted-average shares for basic and diluted EPS	90.1	74.0	72.0
Net loss per share			
Basic and diluted	$ (3.14)	$ (4.15)	$ (3.71)

The following table summarizes potentially dilutive securities excluded from the computation of diluted net loss per share calculations because they would have been antidilutive (in millions):

	At December 31,		
	2024	2023	2022
Common stock options issued and outstanding	15.5	13.5	12.0
Restricted stock units issued	2.2	1.5	1.3
Employee Stock Purchase Plan shares	0.3	0.3	0.2
Total potential dilutive securities	18.0	15.3	13.5

We have also excluded the effect of Gilead's right to purchase additional shares of our common stock from the calculation as these rights had no intrinsic value at December 31, 2024, 2023 or 2022.

Note 8. Stock-based compensation

Stock-based compensation expense

The following table reflects the components of stock-based compensation expense recognized in our Consolidated Statements of Operations (in millions):

	Year Ended December 31,		
	2024	2023	2022
Research and development	$ 38	$ 35	$ 33
General and administrative	38	38	32
Total stock-based compensation	$ 76	$ 73	$ 65

As of December 31, 2024, unrecognized compensation costs related to non-vested stock option awards and RSUs totaled $ 54 million and $ 38 million, respectively, and is expected to be recognized over a weighted average period of 2.3 years and 2.6 years, respectively.

Stock Plans

We grant awards to employees and nonemployees under a series of equity incentive plans (collectively, the "Stock Plans"). Awards under our Stock Plans are made with newly issued shares reserved for this purpose.

2020 Stock Plan

In 2020, we adopted the 2020 Inducement Plan (the "2020 Stock Plan") for the award of stock options and other equity-based awards as an inducement to eligible individuals to enter into employment with us. As of December 31, 2024, there were 2.6 million shares available for grant under this plan.

2015 Stock Plan and 2018 Equity Incentive Plan

In 2015, we adopted the 2015 Stock Plan, which we replaced in 2018 with the 2018 Equity Incentive Plan (the "2018 Equity Incentive Plan"). Any outstanding awards under the 2015 Stock Plan that subsequently expire, lapse unexercised or are forfeited to us are added to the shares reserved for issuance under the 2018 Equity Incentive Plan. The number of shares reserved for issuance will automatically increase on January 1 of each year by a number equal to or the smaller of (i) 3.6 million shares, (ii) 4 % of the shares of common stock outstanding on the last business day of the prior fiscal year, or (iii) an amount as determined by the board of directors. As of December 31, 2024, there were 3.7 million shares available for grant under this plan. On January 1, 2025, the number of shares available for issuance under the 2018 Equity Incentive Plan automatically increased by 3.6 million.

Employee Stock Purchase Plan

In 2018, we adopted the 2018 Employee Stock Purchase Plan (the "2018 ESPP"). The 2018 ESPP provides eligible employees with the opportunity to purchase shares of common stock through payroll deductions at a price equal to 85 % of the lower of the fair market value per share on the first trading day of the applicable 24-month offering period or on the applicable purchase date. Employees are limited to a maximum purchase limit of 3,000 shares on each purchase date or $ 25,000 of shares purchased in a calendar year based on the stock price on the first day of the offering period. The 2018 ESPP is intended to constitute an “employee stock purchase plan” under IRC Section 423(b). The 2018 ESPP may be terminated by our board of directors at any time. The number of shares reserved for issuance will automatically increase on January 1 of each year by a number equal to or the smaller of (i) 1.1 million shares, (ii) 1 % of the shares of common stock outstanding on the last business day of the prior fiscal year, or (iii) an amount as determined by the board of directors. As of December 31, 2024, there were 2.7 million shares available for purchase under this plan. On January 1, 2025, the number of shares available for purchase under this Plan automatically increased by 0.9 million shares.

Restricted Stock Units

We grant RSUs to our employees and directors under the 2018 Equity Incentive Plan. The RSUs vest annually or quarterly over four years for employees and annually for directors. The following table summarizes information regarding our RSUs for the year ended December 31, 2024:

	Total RSUs (in millions)	Weighted Average Grant Date Fair Value Per Share
Nonvested at December 31, 2023	1.5	$ 25.43
RSUs granted	2.0	$ 15.55
RSUs vested	(1.1)	$ 23.64
RSUs forfeited or canceled	(0.2)	$ 18.36
Nonvested at December 31, 2024	2.2	$ 18.07

The total fair value of shares at vesting date during the years ended December 31, 2024, 2023 and 2022 was $ 19 million, $ 13 million and $ 12 million, respectively.

Stock Options

The exercise price of stock options is set at the closing price of our common stock on the grant date, and the related number of shares granted is fixed at that point in time. Awards expire 10 years from the date of grant. The following table summarizes information regarding our stock options for the year ended December 31, 2024:

	Shares Subject to Outstanding Options (in millions)	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in millions)
Outstanding at December 31, 2023	13.5	$ 21.31		
Options granted	2.8	$ 15.61		
Options exercised	(0.3)	$ 11.45		
Options forfeited or canceled	(0.5)	$ 25.57		
Outstanding at December 31, 2024	15.5	$ 20.31	6.61	$ 19
Options vested and expected to vest as of December 31, 2024	15.5	$ 20.31	6.61	$ 19
Options exercisable as of December 31, 2024	11.3	$ 20.47	5.90	$ 19

During the years ended December 31, 2024, 2023 and 2022, the intrinsic value of shares exercised was $ 1 million, $ 3 million, and $ 26 million, respectively.

Valuation Assumptions for Stock Options and Employee Stock Purchase Plan

We utilize the Black-Scholes pricing model to estimate the fair value of stock options and shares issued under our 2018 ESPP. The following table summarizes the key assumptions used to calculate the fair value and the resulting weighted-average grant date fair value of stock options granted:

	Year Ended December 31,		
Stock Options	**2024**	**2023**	**2022**
Weighted average closing price of our common stock on grant date	$ 15.61	$ 21.21	$ 30.37
Risk-free interest rate	3.6 % - 4.4 %	3.6 % - 4.6 %	2.4 % - 4.0 %
Expected term (in years)	6.02	6.02	6.02
Volatility	77.2 % - 77.4 %	77.7 % - 79.1 %	76.5 % - 79.3 %
Dividend yield	— %	— %	— %
Weighted average fair value of stock options granted	$ 10.91	$ 14.81	$ 20.75

	Year Ended December 31,		
ESPP	**2024**	**2023**	**2022**
Risk-free interest rate	4.1 % - 5.4 %	4.3 % - 5.4 %	1.6 % - 4.7 %
Expected term (in years)	0.5 - 2	0.5 - 2	0.5 - 2
Volatility	59.0 % - 70.0 %	61.1 % - 86.9 %	68.9 % - 82.5 %
Dividend yield	— %	— %	— %

Weighted average closing price of our common stock on grant date — Our awards are valued based on the closing price of our common stock on the grant date.

Risk-free interest rate — The risk-free rate assumption is based on the U.S. treasury yield in effect at the time of grant for instruments with maturities similar to the expected term of our stock options.

Expected term — We use the “simplified method” for estimating the expected term of options, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option (generally 10 years).

Volatility — Our estimate of expected volatility is based on the historical volatility of our common stock price. Prior to 2023, due to our limited operating history and a lack of company specific historical and implied volatility data, our estimate of expected volatility included the historical volatility of a group of similar publicly traded companies. The historical volatility data was computed using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the stock-based awards.

Dividend yield — We have not issued any dividends in our history and do not expect to issue dividends over the life of the options.

Note 9. Defined contribution plan

We have a 401(k) defined contribution plan for all our employees which allows tax-deferred salary deductions. The Company matches, at its discretion, employee contributions. For the years ended December 31, 2024, 2023, and 2022, we made contributions of $ 3 million, $ 3 million and $ 2 million, respectively, to the plan.

Note 10. Cash, cash equivalents and marketable securities

The following table summarizes the amortized cost, gross unrealized gains and losses and the fair value of our cash, cash equivalents and marketable securities, all of which are considered available for sale, by type of securities (in millions):

Types of securities as of December 31, 2024	Amortized Cost	Unrealized Gain	Unrealized Loss	Fair Value
Money market funds	$ 120	$ —	$ —	$ 120
U.S. treasury securities	251	—	—	251
Corporate securities and commercial paper	592	—	—	592
U.S. government agency securities	5	—	—	5
Certificate of deposit	24	—	—	24
Total cash, cash equivalents and marketable securities	$ 992	$ —	$ —	$ 992

Types of securities as of December 31, 2023	Amortized Cost	Unrealized Gain	Unrealized Loss	Fair Value
Money market funds	$ 85	$ —	$ —	$ 85
U.S. treasury securities	213	1	(1)	213
Corporate securities and commercial paper	471	—	—	471
U.S. government agency securities	90	—	—	90
Certificate of deposit	7	—	—	7
Total cash, cash equivalents and marketable securities	$ 866	$ 1	$ (1)	$ 866

The following table summarizes the fair values of our cash, cash equivalents and marketable securities by location in the Consolidated Balance Sheets and contractual maturity (in millions):

Location in Consolidated Balance Sheets	Contractual Maturity	As of December 31, 2024	As of December 31, 2023
Cash and cash equivalents	—	$ 150	$ 127
Marketable securities	Within one year	828	632
Long-term marketable securities	Between one and three years	14	107
Total cash, cash equivalents and marketable securities		$ 992	$ 866

Realized gains or losses recognized on the sale of available-for-sale marketable securities were not material for the years ended December 31, 2024, 2023 and 2022. Realized gains and losses are included in Interest and other income, net, in the Consolidated Statements of Operations. The cost of a security sold is determined using the specific-identification method.

We limit the credit risk associated with our investments by placing them with banks and institutions we believe are highly credit worthy and investing in highly rated investments. We held a total of 54 and 105 positions in securities which were in unrealized loss positions as of December 31, 2024 and 2023, respectively. We do not intend to sell our securities with unrealized loss positions and have concluded we will not be required to sell the securities before recovery of the amortized cost for the investment at maturity. No credit related losses have been recognized for any of the periods presented.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash within the Consolidated Balance Sheets to the total shown in the Consolidated Statements of Cash Flows (in millions):

	As of December 31,	
	2024	2023
Cash and cash equivalents	$ 150	$ 127
Restricted cash (included in Other noncurrent assets)	3	3
Total cash, cash equivalents and restricted cash	$ 153	$ 130

Restricted cash at December 31, 2024 and 2023 represents cash balances held as security in connection with our facility lease agreements.

Note 11. Property and equipment

Property and equipment, net was all located in the U.S. and consisted of the following (in millions):

	Useful Life (in years)	As of December 31,	
		2024	2023
Leasehold improvements	5 - 10	$ 56	$ 54
Scientific equipment	5	27	24
Furniture and equipment	3 - 5	4	3
Construction in progress	—	1	1
Property and equipment, gross		88	82
Less: Accumulated depreciation and amortization		(41)	(31)
Property and equipment, net		$ 47	$ 51

Note 12. Consolidated balance sheet components

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following (in millions):

	As of December 31,	
	2024	2023
Prepaid expenses and other assets	$ 13	$ 30
Accrued interest receivable	5	4
Total prepaid expenses and other current assets	$ 18	$ 34

Other Current Liabilities

Other current liabilities consisted of the following (in millions):

	As of December 31,	
	2024	2023
Accrued research and development	$ 65	$ 36
Accrued personnel expenses	31	26
Income taxes payable	1	—
Current portion of lease liabilities	12	11
Other	14	3
Total other current liabilities	$ 123	$ 76

Note 13. Long-term deb t

The following table summarizes our borrowings (in millions):

	As of December 31,	
	2024	2023
Long-term debt, non-current (Contractual maturity 2029)	$ 50	$ —
Unamortized discounts and issuance costs	(2)	—
Total long-term debt	$ 48	$ —

On August 27, 2024, we and Hercules entered into a loan and security agreement (the "Hercules Agreement"), under which Hercules agreed to lend us up to $ 250 million in term loans in various tranches subject to minimum draw requirements for each tranche. Under the terms of this agreement, $ 50 million was drawn at closing and an additional $ 100 million is committed and fully available at our sole option in minimum increments of $ 25 million. A second tranche of $ 100 million will be available subject to future approval by Hercules.

The Hercules Agreement has an initial maturity date of September 1, 2029 which is extendable by 12 months, at our discretion subject to the achievement of certain regulatory milestones related to our product candidates. Repayment of the principal amount will be in 13 monthly installments commencing September 1, 2028, if not extended. The term loans have an interest only period for the first 48 months from the agreement date and bear interest at a rate equal to the greater of (i) 10.45 % or (ii) the prime rate plus 1.95 %. We may prepay all or any portion of the outstanding term loans at any time, subject to a prepayment fee of: (i) 3.00 % of the principal amount prepaid if the prepayment occurs prior to the first anniversary of the funding date; (ii) 2.00 % of the principal amount prepaid if the prepayment occurs on or after the first anniversary of the funding date and prior to the second anniversary of the funding date; or (iii) 1.00 % of the principal amount prepaid thereafter. The agreement also has an upfront facility fee of $ 1 million and an end of term charge of 7.75 % of the total amount borrowed.

The Hercules Agreement contains customary affirmative and negative covenants, including covenants that limit or restrict our ability to incur liens, incur indebtedness, make investments, pay dividends, merge or consolidate, dispose of assets, and enter into transactions with affiliates, subject to customary exceptions. We are also required to maintain a minimum cash balance of 50 % of the funded amount if our market capitalization were to fall below a certain threshold which will be reduced in the event of certain regulatory approvals of our product candidates. We do not have covenant requirements associated with this agreement until October 1, 2026.

The Hercules Agreement is secured by a first priority security interest in substantially all of our assets, excluding intellectual property. The Hercules Agreement also contains customary events of default terms, including payment defaults, breaches of covenants, bankruptcy and insolvency events, cross-defaults to other indebtedness, material adverse events, and the occurrence of a change of control. Upon the occurrence of an event of default, Hercules may declare all outstanding obligations under the Hercules Agreement to be immediately due and payable and exercise any or all of its rights and remedies, including foreclosure on the collateral securing the term loans.

The aggregate future minimum payments including principal payments and the end of term charge, due under the Hercules Agreement, are as follows (in millions):

Maturity Date	Amount
2028	$ 15
2029	39
Total payments	$ 54

During the year ended December 31, 2024, we recognized $ 2 million of interest expense at an effective interest rate of 13.39 %, including amortization of the debt discount and issuance costs. As of December 31, 2024, we had borrowed $ 50 million under the Hercules Agreement and had $ 200 million of additional borrowing capacity, of which $ 100 million is subject to additional approval by Hercules.

Note 14. Leases

We lease our corporate headquarters, which includes approximately 151,000 square feet of executive offices, R&D, and business operations, in Hayward, California. We also lease approximately 109,000 square feet of office space in Brisbane, California. Both leases: are non-cancelable; extend through 2031; have two options, at our sole discretion, to extend each lease term for a period of eight years ; and require monthly lease payments that are subject to annual increases throughout the lease term.

Subleases

We subleased approximately 31,000 square feet of our Brisbane office to a third-party which commenced in October 2023. This sublease included a tenant improvement allowance to be paid by us of $ 9 million, which was fully paid at December 31, 2024. This sublease is non-cancelable and extends through 2028, with the sublessee having options to extend the lease term.

We have also subleased approximately 19,000 square feet of our Brisbane office to a third-party which commenced in December 2024. This sublease is non-cancelable and extends through 2031.

We will receive payments from our subleases of approximately $ 3 million per year through 2028, which is then reduced to approximately $ 1 million per year through 2031.

Income from our subleases is recognized on a straight-line basis as reduction of rent expense within G&A. For the year ended December 31, 2024, we recorded gross sublease income totaling $ 3 million.

Operating leases

At December 31, 2024 and 2023, our lease portfolio had a weighted average remaining term of 7 years and 8 years, respectively, and a weighted average discount rate of 5.2 % for both periods.

The following table summarizes information related to our leases, all of which are classified as operating (in millions):

	As of December 31,	
Location in Consolidated Balance Sheets	2024	2023
Assets:		
Other noncurrent assets - right-of-use assets	$ 65	$ 92
Liabilities:		
Other current liabilities - net current operating lease liabilities	$ 12	$ 11
Other noncurrent liabilities - noncurrent operating lease liabilities	$ 99	$ 110

In the first quarter of 2024, we evaluated our plans for a portion of our office space that we expected to sublease, and identified indicators of impairment to certain right-of-use assets associated with the leased space where the asset value was determined to be non-recoverable based upon a discounted cash flow analysis, resulting in an impairment charge of $ 20 million for the year ended December 31, 2024.

For the years ended December 31, 2024, 2023 and 2022, we incurred lease expense of $ 17 million, $ 18 million, and $ 18 million, respectively. Lease costs include rent expense, which consists primarily of our proportionate share of operating expenses, property taxes, and insurance which we have elected to include in lease costs.

The following table summarizes our cash and non-cash information related to our operating leases (in millions):

	Year Ended December 31,		
	2024	2023	2022
Cash paid for amounts included in measurement of lease liabilities	$ 17	$ 15	$ 11
Cash received from tenant improvement allowances	$ —	$ 9	$ 8
Right-of-use assets obtained in exchange for new operating lease liabilities	$ —	$ —	$ 3
Recognition of tenant improvement allowance receivable included in Other current liabilities	$ —	$ 4	$ 6

The following table summarizes our future minimum lease payments at December 31, 2024 (in millions):

Year Ending December 31,	Operating Leases
2025	$ 17
2026	18
2027	18
2028	19
2029	19
Thereafter	42
Total undiscounted future minimum lease payments	$ 133
Less: Imputed interest	(22)
Total present value of lease liabilities	$ 111

As of December 31, 2024, we have provided deposits for letters of credit totaling $ 3 million to secure our obligations under our leases, which are included in Other noncurrent assets on the Consolidated Balance Sheets.

Note 15. Stockholders' equity

Common Stock

We are authorized to issue up to 400.0 million shares of common stock.

Gilead Stock Purchase Agreement

In 2023, under the Second Stock Purchase Agreement, Gilead purchased 1.0 million shares of our common stock at the closing day purchase price of $ 19.26 per share for total gross proceeds of $ 20 million.

In 2024, under the Third Stock Purchase Agreement Amendment, Gilead purchased 15.2 million shares of our common stock at a price of $ 21.00 per share for total gross proceeds of $ 320 million. Of the $ 320 million equity investment, $ 87 million was determined to be a premium on the purchase of common stock and allocated to the performance obligations created by the Third Gilead Collaboration Agreement Amendment, see Note 5, Revenues, for more information. Net proceeds from Gilead's equity investment were $ 228 million after allocating the premium and deducting direct offering expenses of $ 5 million.

At-the-Market Facility

In 2023, we entered into an equity distribution agreement pursuant to which we may, from time to time, sell shares of our common stock, par value $ 0.0001 per share, having an aggregate offering price of up to $ 200 million. During the year ended December 31, 2023, we issued and sold under this agreement 0.2 million shares of our common stock for total net proceeds of $ 5 million.

Preferred Stock

We have authorized 10.0 million shares of preferred stock, par value $ 0.0001 . There was no preferred stock outstanding as of December 31, 2024 and 2023.

See Note 19, Subsequent events, for additional information on stock issuances that occurred in February 2025.

Note 16. Fair value measurements

We determine the fair value of financial and non-financial assets and liabilities using the fair value hierarchy, which establishes three levels of inputs that may be used to measure fair value, as follows:

- Level 1 inputs include unadjusted quoted prices in active markets for identical assets or liabilities;
- Level 2 inputs include observable inputs other than Level 1 inputs, such as quoted prices for similar assets or liabilities; quoted prices for identical or similar assets or liabilities 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 asset or liability; and
- Level 3 inputs include unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the underlying asset or liability. Our Level 3 assets and liabilities include those whose fair value measurements are determined using pricing models, discounted cash flow methodologies or similar valuation techniques and significant management judgment or estimation.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

The following tables summarize the types of assets and liabilities measured at fair value on a recurring basis by level within the fair value hierarchy (in millions):

Fair value measurement as of December 31, 2024	Level 1	Level 2	Level 3	Total
Assets				
Money market funds	$ 120	$ —	$ —	$ 120
U.S. treasury securities	—	251	—	251
Corporate securities and commercial paper	—	592	—	592
U.S. government agency obligations	—	5	—	5
Certificate of deposit	—	24	—	24
Total assets measured at fair value	$ 120	$ 872	$ —	$ 992
Liabilities				
Liability for sale of future royalties	$ —	$ —	$ 21	$ 21
Total liabilities measured at fair value	$ —	$ —	$ 21	$ 21

Fair value measurement as of December 31, 2023	Level 1	Level 2	Level 3	Total
Assets				
Money market funds	$ 85	$ —	$ —	$ 85
U.S. treasury securities	—	213	—	213
Corporate securities and commercial paper	—	471	—	471
U.S. government agency obligations	—	90	—	90
Certificate of deposit	—	7	—	7
Total assets measured at fair value	$ 85	$ 781	$ —	$ 866
Liabilities				
Liability for sale of future royalties	$ —	$ —	$ 19	$ 19
Total liabilities measured at fair value	$ —	$ —	$ 19	$ 19

Liability for sale of future royalties

In 2021, we entered into an agreement with BVF, under which BVF funded the discovery and development of compounds for the treatment of inflammatory diseases (the "BVF Program") for $ 15 million in non-refundable payments which were paid in 2021 and 2022. In return, we are obligated to perform R&D activities in the BVF Program; make contingent payments upon the achievement of certain clinical and regulatory milestones of up to $ 73 million or $ 160 million depending on whether the BVF Program is solely developed by us or with Gilead if they opt-in under the Gilead Collaboration Agreement; and pay mid- to high-single digit royalties on any net product sales generated by the BVF Program.

We account for the BVF agreement as a liability primarily because we have significant continuing involvement in generating the cash flows due to BVF. The liability is recorded at fair value by using probability-adjusted discounted cash flows and is revalued each reporting period until the related contingencies have been resolved. The fair value measurement is based on significant unobservable inputs that are reviewed quarterly by management and include, as applicable, estimated probabilities and the timing of achieving specified development, regulatory and commercial milestones as well as estimated annual sales. Significant changes that increase or decrease the probabilities of achieving the related development, regulatory and commercial events or that shorten or lengthen the time required to achieve such events or that increase or decrease estimated annual sales would result in corresponding increases or decreases in the fair values of the obligations, as applicable. Changes in the fair value of this liability related to interest accretion are recognized in Non-operating income (expense) in the Consolidated Statements of Operations.

During the second quarter of 2023, new preclinical information from our BVF Program led to revised assumptions which decreased the estimated probabilities of success and delayed the projected timing of achieving specified development, regulatory and commercial milestones and commercial sales. These changes in estimates are accounted for prospectively and resulted in a decrease in the imputed effective interest rate on the unamortized portion of the liability to 10.1 % commencing with the quarter ended June 30, 2023, compared to 20.6 % for the quarters ended March 31, 2023 and prior. The impact of this change on the non-cash interest expense for the year ended December 31, 2024 was not material when compared to the prior year periods. The liability for sale of future royalties is reported in Other noncurrent liabilities in the Consolidated Balance Sheets and changes were as follows (in millions):

	Year Ended December 31	
	2024	2023
Beginning balance	$ 19	$ 17
Interest accretion	2	2
Ending balance	$ 21	$ 19

Long-term debt

As of December 31, 2024, the estimated fair value of our long-term debt approximated the carrying amount. The fair value of the long-term debt was estimated for disclosure purposes only and was determined based on other inputs that are observable, and thus categorized as Level 2 in the fair value hierarchy.

Note 17. Commitments

Long-term debt

We are obligated to make principal loan payments and an end of term charge under the loan and security agreement with Hercules. See Note 13, Long-term debt, for more information.

Standby letters of credit

We have standby letters of credit up to an aggregate of $ 3 million provided as collateral for our leases. The letters of credit are secured by $ 3 million in deposits classified as restricted cash and included in Other noncurrent assets on the Consolidated Balance Sheet. At December 31, 2024 the standby letters of credit were not drawn down.

Purchase commitments

We have contractual arrangements with CROs and suppliers. These contracts are generally cancellable on 30 days' notice and the obligations under these contracts arise as the services are performed.

Indemnification

As permitted under Delaware law and in accordance with our bylaws, we are required to indemnify our officers and directors for certain events or occurrences while the officer or director is or was serving in such capacity. We are also party to indemnification agreements with our directors and officers. We believe the fair value of the indemnification rights and agreements is minimal and accordingly, we have not recorded any liabilities as of December 31, 2024 and 2023.

Note 18. Segments of business

We operate and manage our business as one reportable and operating segment, which is the business of developing and commercializing highly differentiated therapies that have a meaningful impact on patients. Our chief operating decision maker ("CODM") is the Chief Executive Officer, who decides how to allocate resources and assesses segment performance based on net loss reported on the Consolidated Income Statements.

The table below is a summary of the segment net loss, including significant segment expenses (in millions):

	Year Ended December 31, 2024	Year Ended December 31, 2023	Year Ended December 31, 2022
Total revenues	$ 258	$ 117	$ 112
Less:			
Late-stage development programs [1]	252	168	124
Early-stage development and preclinical programs [2]	132	128	145
Compensation and personnel costs	250	223	189
Depreciation and amortization	10	8	6
Impairment of long-lived assets	20	—	—
Interest income, net	(48)	(39)	(13)
Income tax expense	1	6	1
Other segment items [3]	89	92	89
Partnership reimbursements	(165)	(162)	(162)
Segment net loss and Consolidated net loss	$ (283)	$ (307)	$ (267)

(1) R&D expenses incurred related to a Phase 3 clinical program intended to result in registration of a new product. This includes all unallocated program-level expense not directly attributable to a specific clinical trial once a molecule enters into one or more Phase 3 clinical trials.

(2) R&D expenses incurred for activities ranging from early-stage R&D and preclinical to Phase 2 clinical trials. This includes all unallocated program-level expense not directly attributable to a specific clinical trial unless the related program has entered into one or more Phase 3 clinical trials.

(3) Other segment items includes non-allocated program costs and other G&A costs.

Total segment assets at December 31, 2024, 2023 and 2022 were $ 1.2 billion, $ 1.1 billion, and $ 1.3 billion, respectively.

Note 19. Subsequent events

In February 2025, we announced that Gilead's time-limited exclusive option rights to our HIF-2α program (including casdatifan) have expired. As a result, Gilead has no future rights to casdatifan and we retain full global development and commercial rights, subject to Taiho’s option right for the Taiho Territory.

In February 2025, we sold through an underwritten offering, 13.6 million shares of our common stock at price of $ 11.00 per share, for total gross proceeds of approximately $ 150 million, before deducting underwriting discounts, commissions and offering expenses. Gilead acquired 1.4 million shares of our common stock through this offering and held approximately 29.7 % of our common stock as of February 19, 2025.

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 maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Securities Exchange Act of 1934 ("Exchange Act") reports is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission, and that such information is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within an organization have been detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met.

As of the end of the period covered by this Annual Report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-15. Based upon, and as of the date of, this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over our financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f). Our management, with the participation of our principal executive officer and principal financial officer, conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2024. Our assessment was based on criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control Integrated − Framework (2013).

Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our internal control over financial reporting includes those policies and procedures that:

1. pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;
2. provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and board of directors; and
3. provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

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

Based on our evaluation under the framework in Internal Control − Integrated Framework, management concluded that our internal control over financial reporting was effective as of December 31, 2024.

Our independent registered public accounting firm, Ernst & Young LLP, has audited our Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K and have issued a report on our internal control over financial reporting as of December 31, 2024. Their report on the audit of internal control over financial reporting appears below.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Arcus Biosciences, Inc.

Opinion on Internal Control Over Financial Reporting

We have audited Arcus Biosciences, Inc.'s internal control over financial reporting as of December 31, 2024, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Arcus Biosciences, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2024, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the 2024 consolidated financial statements of the Company and our report dated February 25, 2025 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

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

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

/s/ Ernst & Young LLP

San Mateo, California
February 25, 2025

Item 9B. Other Information

Rule 10b5-1 Trading Arrangements

None of our directors or officers adopted , modified or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement during the quarter ended December 31, 2024, as such terms are defined under Item 408(a) of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item will be set forth in our proxy statement to be filed with the Securities and Exchange Commission within 120 days after the end of our fiscal year ended December 31, 2024 (our "Proxy Statement") and is incorporated into this Annual Report on Form 10-K by reference, specifically:

- Information regarding our directors and any persons nominated to become a director, as well as with respect to some other required board matters, is set forth under Proposal 1 entitled "Election of Directors" and under the caption "Corporate Governance."
- Information regarding our audit committee and our designated "audit committee financial expert" is set forth under the caption "Corporate Governance."
- Information regarding Section 16(a) beneficial ownership reporting compliance, if any, will be set forth under the caption "Delinquent Section 16(a) Reports."
- Information regarding procedures by which stockholders may recommend nominees to our board of directors is set forth under the caption "Nominating and Corporate Governance Committee" under "Corporate Governance."
- Information regarding our executive officers is set forth under "Executive Officers."

We have adopted a Code of Conduct and Ethics that applies to all directors, officers and employees of the Company, which is available on our website at www.arcusbio.com. If we make any substantive amendments to our Code of Conduct and Ethics or grant any waivers to our directors or executive officers, we will disclose it on our website or in a Current Report on Form 8-K.

We have adopted an insider trading policy governing the purchase, sale and other dispositions of our securities by our directors and employees that are designed to promote compliance with insider trading laws, rules and regulations, as well as procedures designed to further the foregoing purposes. A copy of our insider trading policy is filed with this Annual Report on Form 10-K as Exhibit 19.1.

Item 11. Executive Compensation

The information required by this Item will be set forth in our Proxy Statement under the captions "Executive Compensation," "Compensation of Directors" and "Compensation Committee Interlocks and Insider Participation" and is incorporated into this Annual Report on Form 10-K by reference.

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

The information required by this Item will be set forth in our Proxy Statement under the caption "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" and is incorporated into this Annual Report on Form 10-K by reference.

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

The information required by this Item will be set forth in our Proxy Statement under the captions "Related Person Transactions" and "Corporate Governance" and is incorporated into this Annual Report on Form 10-K by reference.

Item 14. Principal Accounting Fees and Services

The information required by this Item will be set forth in our Proxy Statement under the Proposal with the caption "Ratification of Appointment of Independent Registered Public Accounting Firm" and is incorporated into this Annual Report on Form 10-K by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) The following documents are filed as part of this Annual Report on Form 10-K:

(1) Financial Statements

See Index to Consolidated Financial Statements at Item 8 herein.

(2) Financial Statement Schedules

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

(3) Exhibits.

See Exhibit Index following Item 16 below.

Item 16. Form 10-K Summary

None.

Exhibit Index

Exhibit Number	Exhibit Description	Incorporated by Reference			
		Form	File No	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation.	10-Q	001-38419	3.1	May 9, 2018
3.2	Amended and Restated Bylaws.	8-K	001-38419	3.1	May 26, 2020
4.1	Reference is made to Exhibits 3.1 and 3.2				
4.2	Description of Common Stock.	10-K	001-38419	4.3	February 25, 2021
10.1	Non-Employee Director Compensation Program	8-K	001-38419	10.1	June 6, 2024
10.2[A]	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers.	S-1	333-223086	10.1	February 16, 2018
10.3[A]	Arcus Biosciences, Inc. Management Cash Incentive Plan.	S-1	333-223086	10.13	February 16, 2018
10.4[A]	Arcus Biosciences, Inc. Severance Benefits Plan.	10-K	001-38419	10.4	February 21, 2024
10.5[A]	Amended and Restated Letter Agreement, dated February 14, 2018, between the Registrant and Terry Rosen, Ph.D.	S-1	333-223086	10.5	February 16, 2018
10.6[A]	Amended and Restated Letter Agreement, dated February 14, 2018, between the Registrant and Juan Carlos Jaen, Ph.D.	S-1	333-223086	10.6	February 16, 2018
10.7[A]	Offer letter by and between Arcus Biosciences, Inc. and Jennifer Jarrett dated September 10, 2020.	10-Q	001-38419	10.2	November 5, 2020
10.8[A]	Offer letter by and between Arcus Biosciences, Inc. and Robert C. Goeltz II dated June 30, 2020.	10-Q	001-38419	10.1	November 5, 2020
10.9[A*]	Letter Agreement, dated January 13, 2025, between the Registrant and Richard Markus, MD., Ph.D.				
10.10[A]	Arcus Biosciences, Inc. 2015 Stock Plan and forms of agreements thereunder.	S-1/A	333-223086	10.2	March 5, 2018
10.11[A]	Arcus Biosciences, Inc. 2018 Equity Incentive Plan (including form agreements for use before January 1, 2021).	S-1/A	333-223086	10.3	March 5, 2018
10.12[A]	Form of Stock Option Notice and Agreement under 2018 Equity Incentive Plan (for use from January 1, 2021).	10-K	001-38419	10.36	February 25, 2021
10.13[A]	Form of RSU Notice and Agreement under 2018 Equity Incentive Plan (for use from January 1, 2021).	10-K	001-38419	10.37	February 25, 2021
10.14[A]	Arcus Biosciences, Inc. 2018 Employee Stock Purchase Plan.	S-1/A	001-38419	10.4	March 5, 2018
10.15[A]	Arcus Biosciences, Inc. Amended and Restated 2020 Inducement Plan.	10-K	001-38419	10.18	February 23, 2022
10.16[A]	Form of Stock Option Grant Notice (2020 Inducement Plan).	10-K	001-38419	10.26	March 5, 2020
10.17[A]	Form of Restricted Stock Unit Grant Notice (2020 Inducement Plan).	10-K	001-38419	10.27	March 5, 2020

10.18	Lease, dated September 30, 2015, between the Registrant and Hayward Point Eden I Limited Partnership, as amended on July 22, 2016 and October 12, 2017.	S-1	333-223086	10.8	February 16, 2018
10.19	Third Amendment dated June 26, 2020 to the Lease agreement dated September 30, 2015 between Arcus Biosciences, Inc. and Hayward Point Eden I Limited Partnership.	10-Q	001-38419	10.4	August 6, 2020
10.20	Fourth Amendment dated October 16, 2020 to the Lease agreement dated September 30, 2015 between Arcus Biosciences, Inc. and Hayward Point Eden I Limited Partnership.	10-Q	001-38419	10.3	November 5, 2020
10.21	Fifth Amendment dated April 1, 2021 to the Lease agreement dated September 30, 2015 between Arcus Biosciences, Inc. and Hayward Point Eden I Limited Partnership.	10-Q	001-38419	10.2	May 5, 2021
10.22[B]	License Agreement, dated December 8, 2016, between Arcus Biosciences, Inc. and Abmuno Therapeutics LLC.	S-1	333-223086	10.10	February 16, 2018
10.23[B]	License Agreement, dated August 16, 2017, between Arcus Biosciences, Inc. and WuXi Biologics (Cayman) Inc.	S-1	333-223086	10.11	February 16, 2018
10.24[C]	Amendment No. 1 dated June 27, 2019 to the License Agreement dated August 16, 2017 between Arcus Biosciences, Inc. and WuXi Biologics (Cayman) Inc.	10-Q	001-38419	10.2	August 6, 2019
10.25[C]	Amendment No. 2 dated March 2, 2020 to the License Agreement dated August 16, 2017 between Arcus Biosciences, Inc. and WuXi Biologics (Cayman) Inc.	10-K	001-38419	10.28	March 5, 2020
10.26[C]	Amendment No. 3 dated May 10, 2021 to the License Agreement dated August 16, 2017 between Arcus Biosciences, Inc. and WuXi Biologics (Cayman) Inc.	10-Q	001-38419	10.2	August 5, 2021
10.27[C]	Amendment No. 4 dated December 30, 2022 to the License Agreement dated August 16, 2017 between Arcus Biosciences, Inc. and WuXi Biologics (Cayman) Inc.	10-K	001-38419	10.28	February 28, 2023
10.28	Assignment Agreement dated November 10, 2020 by and among Arcus Biosciences, Inc., WuXi Biologics (Cayman) Inc. and WuXi Biologics Ireland Limited to the License Agreement dated August 16, 2017.	10-K	001-38419	10.35	February 25, 2021
10.29[B]	Option and License Agreement, dated September 19, 2017, between Arcus Biosciences, Inc. and Taiho Pharmaceutical Co., Ltd.	S-1	333-223086	10.12	February 16, 2018
10.30[B]	Amendment No. 1 to Option and License Agreement, dated September 19, 2017, between Arcus Biosciences, Inc. and Taiho Pharmaceutical Co, Ltd.	10-Q	001-38419	10.1	November 8, 2018
10.31[C]	Memorandum, dated July 27, 2023, between Arcus Biosciences, Inc. and Taiho Pharmaceutical Co., LTD.	10-Q	001-38419	10.1	November 7, 2023

10.32[C]	Option, License and Collaboration Agreement dated May 27, 2020 between Arcus Biosciences, Inc. and Gilead Sciences, Inc.	10-Q	001-38419	10.1	August 6, 2020
10.33[C]	Amendment No. 1 to the Option, License and Collaboration Agreement between Arcus Biosciences, Inc. and Gilead Sciences, Inc., dated November 17, 2021	10-K	001-38419	10.34	February 23, 2022
10.34[C]	Amendment No. 2 to the Option, License and Collaboration Agreement between Arcus Biosciences, Inc. and Gilead Sciences, Inc., dated May 15, 2023.	10-Q	001-38419	10.1	August 7, 2023
10.35[C]	Amendment No. 3 to the Option, License and Collaboration Agreement between Arcus Biosciences, Inc. and Gilead Sciences, Inc., dated January 29, 2024.	10-Q	001-38419	10.1	May 8, 2024
10.36[C]	Amendment No. 4 to the Option, License and Collaboration Agreement between Arcus Biosciences, Inc. and Gilead Sciences, Inc., dated May 10, 2024.	10-Q	001-38419	10.1	August 8, 2024
10.37[C]	Letter Agreement with Gilead Sciences, Inc., dated July 1, 2022.	10-Q	001-38419	10.2	August 3, 2022
10.38[C]	Third Amended and Restated Common Stock Purchase Agreement, dated January 29, 2024 between Arcus Biosciences, Inc. and Gilead Sciences, Inc.	SC 13D/A	005-90423	99.1	January 31, 2024
10.39[C]	Amended and Restated Investor Rights Agreement dated January 29, 2024 between Arcus Biosciences, Inc. and Gilead Sciences, Inc.	SC 13D/A	005-90423	99.2	January 31, 2024
10.40	Equity Distribution Agreement, dated as of February 28, 2023, by and among the Registrant, Goldman Sachs & Co. LLC and SVB Securities LLC.	S-3	333-270132	1.2	February 28, 2023
10.41	Loan & Security Agreement, between the Registrant, Hercules Capital, Inc. and the lenders listed therein, dated August 27, 2024	10-Q	001-38419	10.1	February 28, 2023
10.42*[A]	Separation Agreement, between the Registrant and Dimitry Nuyten, dated January 16, 2025.				
19.1*	Insider Trading Policy.				
23.1*	Consent of independent registered public accounting firm.				
24.1*	Power of Attorney (included on signature page to this Annual Report).				
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				

31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1†	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2†	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
97.1	Compensation Clawback Policy.	10-K	001-38419	97.1	February 21, 2024
101.INS	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)				

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* Filed herewith.

A Indicates management contract or compensatory plan or arrangement.

B The Company has been granted confidential treatment for certain portions of this exhibit. The omitted portions have been filed separately with the SEC.

C This exhibit omits certain information the Company deems immaterial and either of the type that it treats as confidential or would be competitively harmful if disclosed.

† This certification is deemed not filed for purposes of section 18 of the Exchange Act, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

SIGNATURES

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

ARCUS BIOSCIENCES, INC.

Date: February 25, 2025

By: /s/ Terry Rosen

Terry Rosen, Ph.D.

Chief Executive Officer

(Principal Executive Officer and Duly Authorized Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS that each person whose signature appears below constitutes and appoints Terry Rosen, Ph.D. and Robert C. Goeltz II, and each of them, his or her true and lawful attorneys-in-fact and agents, each with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that each of said attorneys-in-fact and agents or their substitute or substitutes may lawfully do or cause to be done by virtue hereof. Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Annual Report on Form 10-K 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/ Terry Rosen	Chief Executive Officer and Director	February 25, 2025
Terry Rosen, Ph.D.	(Principal Executive Officer)	
/s/ Robert C. Goeltz II	Chief Financial Officer	February 25, 2025
Robert C. Goeltz II	(Principal Financial Officer)	
/s/ Alexander Azoy	Chief Accounting Officer	February 25, 2025
Alexander Azoy	(Principal Accounting Officer)	
/s/ Dietmar Berger	Director	February 25, 2025
Dietmar Berger, M.D., Ph.D.		
/s/ Kathryn Falberg	Director	February 25, 2025
Kathryn Falberg		
/s/ Linda Higgins	Director	February 25, 2025
Linda Higgins, Ph.D.		
/s/ Yasunori Kaneko	Director	February 25, 2025
Yasunori Kaneko, M.D.		
/s/ David Lacey	Director	February 25, 2025
David Lacey, M.D.		
/s/ Nicole Lambert	Director	February 25, 2025
Nicole Lambert		
/s/ Patrick Machado	Director	February 25, 2025
Patrick Machado, J.D.		
/s/ Johanna Mercier	Director	February 25, 2025
Johanna Mercier		
/s/ Andrew Perlman	Director	February 25, 2025
Andrew Perlman, M.D., Ph.D.		
/s/ Antoni Ribas	Director	February 25, 2025
Antoni Ribas, M.D., Ph.D.		

January 13, 2025

Richard Markus, M.D., Ph.D.
[ADDRESS]

Dear Richard:

On behalf of Arcus Biosciences, Inc. (“Arcus” or the “Company”), I am pleased to invite you to join the Company in the role of Chief Medical Officer, reporting initially to Terry Rosen, CEO. Once you begin, Terry can provide you with additional information regarding your role and responsibilities. We believe this position creates an extraordinary opportunity to contribute to the success of Arcus, and we look forward to you joining our exceptional team.

Below are details of the compensation and benefits program we offer, as well as other terms of your employment with Arcus. Should you have any questions regarding any part of this offer, or wish to receive additional details, please let us know and we can provide more information for you. Your annual base salary will be $600,000, less payroll deductions and all required tax withholdings, paid twice monthly in the form of 24 pay periods per year.

You will receive a payment of $100,000, less required tax withholding, payable as soon as practical following your start date (the “Sign-On Bonus”). Notwithstanding the foregoing, the Sign-On Bonus will not be earned to any extent as of the date of payment and will only become earned if you remain employed by the Company through the 18-month anniversary of your start date. Should you voluntarily resign from Arcus within eighteen (18) months of your start date, you agree to repay the pro-rated portion of the payment based on the number of whole months you were employed by the Company prior to your resignation, such payment to be made on or within 30 days following your termination of employment. You hereby authorize the Company to deduct up to the amount of any such payment from your final paycheck, provided, that any such deduction shall not reduce your final paycheck beyond minimum wage for the period covered by such paycheck.

You will be eligible to participate in the Company’s 2025 annual bonus program at a rate up to 45% of your annual base salary, prorated for any partial year, if your first day of employment with the Company is on or before September 30th. Bonuses are typically paid in the first quarter following the year in which the bonus was earned.

An important component of your compensation includes the opportunity for ownership in the Company. To that end, subject to the approval of our Compensation Committee, Arcus will grant you an option to purchase 305,328 shares of the Company’s Common Stock (the “Option”) and 75,193 restricted stock units (RSUs). The Option will have an exercise price equal to the fair market value as of the effective date of grant (typically the 8th or the 23rd of a month after your start date), with 1/48th of the Option vesting each month. The RSUs will vest over four years, with one-quarter (1/4) of the RSUs vesting annually. Vesting of the Option and RSUs will continue until they are fully vested or you are no longer a service provider to the Company, whichever occurs first. The Option and RSUs will be subject to the terms and conditions of the equity plan pursuant to which they are granted and the equity award agreement issued thereunder. The Option and RSUs represent a material inducement for you to accept this offer of employment with the Company.

You will be eligible for the Company's Severance Benefits Plan on the terms therein. Arcus further provides all eligible employees with a comprehensive benefits program, including but not limited to medical, dental, vision, life insurance, and long-term disability. Your medical, dental and vision benefits will be effective the first of the month following your date of hire. If your hire date is the first of the month, your medical benefits will be effective that day. You will have the opportunity to participate in these benefits for you and your eligible dependents, if you choose to enroll them. In addition, we will provide a comprehensive matching 401(k) program, Employee Stock Purchase Plan, and Health Care and Dependent Care Flexible Spending Accounts. Arcus also provides time-off benefits, including designated Company holidays, three weeks of vacation accrued throughout the year, two personal holidays and sick leave pursuant to Company policy. The Company may change its organization, compensation, and its benefits from time to time in its discretion. There is a formal performance review period once a year.

Your start date will be as soon as practical, as agreed between us as part of your acceptance of this offer, on or around January 31, 2025.

As a condition of your employment, you will be required to abide by the Company's policies and procedures. You also agree to read, sign and comply with the Company's Proprietary Information and Inventions Agreement.

In your work for the Company, you will be expected to not make any unauthorized use of, or disclose, the confidential information or materials, including trade secrets, of any former employer or other third party to whom you owe an obligation of confidentiality. Rather, you will be expected to use only that information generally known and used by persons with training and experience comparable to your own, which information is common knowledge in the industry or otherwise legally available in the public domain, or which is otherwise provided or developed by the Company. By accepting employment with the Company, you are representing to us that you will be able to perform your duties within the guidelines described in this paragraph. You represent further that you have disclosed to the Company any contract you have signed which may restrict your activities on behalf of the Company in any manner.

This offer is contingent upon our verification of your employment history, education credentials, and successful completion of a background check. Any intentional misrepresentation concerning these items may result in actions up to and including revocation of this offer or termination of your employment at Arcus.

Your employment relationship is at-will. Accordingly, you may terminate your employment with the Company at any time and for any reason whatsoever simply by notifying the Company. Likewise, the Company may terminate your employment at any time and for any reason, with or without cause or advance notice. This letter will reflect the final, total and complete agreement between you and the Company regarding how your employment may be terminated. Only the CEO and President of the Company have the authority to change the "at-will" nature of your employment, which also is only binding if done in writing.

You and the Company mutually agree that pursuant to the Federal Arbitration Act, 9 U.S.C. §1-16, and to the fullest extent permitted by applicable law, you will submit solely to final, binding and confidential arbitration any and all disputes, claims, or causes of action arising from or relating to this offer letter; your employment with the Company (including all statutory claims); or the termination of your

employment with the Company (including all statutory claims). BY AGREEING TO THIS ARBITRATION PROCEDURE, BOTH YOU AND THE COMPANY WAIVE THE RIGHT TO RESOLVE ANY SUCH DISPUTES THROUGH A TRIAL BY JURY OR JUDGE OR THROUGH AN ADMINISTRATIVE PROCEEDING. The Arbitrator will have the sole and exclusive authority to determine whether a dispute, claim or cause of action is subject to arbitration and to determine any procedural questions that grow out of such disputes, claims or causes of action. All claims, disputes, or causes of action under this section, whether by you or the Company, must be brought solely in an individual capacity, and will not be brought as a plaintiff (or claimant) or class member in any purported class or representative proceeding, nor joined or consolidated with the claims of any other person or entity. The Arbitrator may not consolidate the claims of more than one person or entity, and may not preside over any form of representative or class proceeding. To the extent that the preceding sentences in this paragraph are found to violate applicable law or are otherwise found unenforceable, any claim(s) alleged or brought on behalf of a class will proceed in a court of law rather than by arbitration. Any arbitration proceeding under this paragraph will be presided over by a single arbitrator and conducted by JAMS, Inc. ("JAMS") under the then applicable JAMS rules for the resolution of employment disputes (available upon request and also currently available at http://www.jamsadr.com/rules-employment-arbitration/). You and the Company both have the right to be represented by legal counsel at any arbitration proceeding, at each party's own expense. The Arbitrator will: (a) have the authority to compel adequate discovery for the resolution of the dispute; (b) issue a written arbitration decision, to include the arbitrator's essential findings and conclusions and a statement of the award; and (c) be authorized to award any or all remedies that you or the Company would be entitled to seek in a court of law. The Company will pay all JAMS arbitration fees in excess of the amount of court fees that would be required of you if the dispute were decided in a court of law. This section will not apply to any action or claim that cannot be subject to mandatory arbitration as a matter of law, including, without limitation, claims brought pursuant to the California Private Attorneys General Act of 2004, as amended, the California Fair Employment and Housing Act, as amended, and the California Labor Code, as amended, to the extent such claims are not permitted by applicable law to be submitted to mandatory arbitration and such applicable law is not preempted by the Federal Arbitration Act or otherwise invalid. Nothing in this section is intended to prevent either you or the Company from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration. Any final award in any arbitration proceeding hereunder may be entered as a judgment in the federal and state courts of any competent jurisdiction and enforced accordingly.

This letter, together with your Proprietary Information and Inventions Agreement, forms the complete and exclusive statement of your agreement with the Company with respect to the subject matter hereof. The terms of this letter supersede any other representations or agreements made to you by any party, whether oral or written. This agreement is to be governed by the laws of the state of California without reference to its conflicts of law principles. Should any provision contained in this agreement, for any reason, be held invalid or unenforceable in any respect, this invalidity or unenforceability will not affect the other provisions of this agreement, and such provision will be construed and enforced so as to render it valid and enforceable consistent with the general intent of the parties insofar as possible under applicable law. Regarding the enforcement of this agreement, no waiver of any right hereunder will be effective unless it is in writing. This agreement may be executed in more than one counterpart, and signatures transmitted electronically will be deemed equivalent to originals. As required by law, this offer is subject to satisfactory proof of your identity and right to work in the United States.

If you wish to accept employment at the Company under the terms described above, please sign and date this letter and the Proprietary Information and Inventions Agreement and return them to me by January 15, 2025. Please note this offer, if not accepted by you, will expire on January 15, 2025.

Arcus is an ambitious undertaking, and we fully expect our company to become a force in the discovery, development and commercialization of novel therapies for the treatment of cancer. To this end, we are assembling a team of uniquely qualified individuals with extraordinary knowledge, skills and drive. We look forward to your acceptance and to a productive and enjoyable working relationship.

Sincerely,

/s/ Terry Rosen, Ph.D.
Terry Rosen, Ph.D.
CEO

Understood and Accepted:

/s/ Richard Markus, M.D., Ph.D. 1/13/2025
Richard Markus, M.D., Ph.D. Date

Exhibit A – Employee Proprietary Information & Inventions Agreement

EXHIBIT 10.42

January 16, 2025

Dimitry Nuyten, MD, Ph.D.
[ADDRESS]

Dear Dimitry:

This letter sets forth the substance of the separation agreement (the "**Agreement**") that Arcus Biosciences (the "**Company**") is offering to you to aid in your employment transition.

1. Separation. Your last day of work with the Company and your employment termination date will be January 31, 2025 (the "**Separation Date**").

2. Accrued Salary and Paid Time Off. On the Separation Date, the Company will pay you all accrued salary and all accrued and unused vacation/earned through the Separation Date, subject to standard payroll deductions and withholdings. You are entitled to this payment by law.

3. Severance Payment. Pursuant to the Severance Benefits Plan, if you timely sign this Agreement, allow it to become effective, and comply with your obligations under it (collectively, the "**Severance Preconditions**"), then the Company will pay you, as severance, the equivalent of twelve (12) months of your base salary in effect as of the Separation Date, subject to standard payroll deductions and withholdings. Furthermore, although the Company has no obligation to do so, provided that you satisfy the Severance Preconditions, the Company will further pay you, as severance, $250,000 in consideration of your 2024 annual bonus. These amounts will be paid in a lump sum within fifteen (15) days after the Effective Date (as defined below).

4. Health Insurance. To the extent provided by the federal COBRA law or, if applicable, state insurance laws, and by the Company's current group health insurance policies, you will be eligible to continue your group health insurance benefits at your own expense following the Separation Date. Later, you may be able to convert to an individual policy through the provider of the Company's health insurance, if you wish. You will be provided with a separate notice describing your rights and obligations under COBRA and a form for electing COBRA coverage. Pursuant to the Severance Benefits Plan and provided that you satisfy the Severance Preconditions set forth above and timely elect continued coverage under COBRA, then the Company will pay your COBRA premiums to continue your health insurance coverage (including coverage for eligible dependents, if applicable) through the period (the "**COBRA Premium Period**") starting on the Separation Date and ending on the earliest to occur of: (i) January 31, 2026; (ii) the date you become eligible for group health insurance coverage through a new employer; or (iii) the date you cease to be eligible for COBRA coverage for any reason. In the event you become covered under another employer's group health plan or otherwise cease to be eligible for COBRA during the COBRA Premium Period, you must immediately notify the Company in writing. Notwithstanding the foregoing, if the Company determines in its sole discretion that it cannot provide the foregoing subsidy of COBRA coverage without potentially violating or causing the Company to incur additional expense as a result of noncompliance with applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company instead will pay you a taxable monthly payment for the COBRA Premium Period in an amount equal to the monthly COBRA premium that you would be required to pay to continue the

group health coverage in effect on your Separation Date for you and your eligible dependents pursuant to the Company's health insurance plans in which you and your eligible dependents participated as of your Separation Date (which amount shall be based on the premium for the first month of COBRA coverage).

5. Stock Options. Under the terms of your stock option agreement and the applicable plan documents, vesting of your stock options will cease as of the Separation Date. Your right to exercise any vested shares, and all other rights and obligations with respect to your stock options(s), will be as set forth in your stock option agreements, grant notices and applicable plan documents.

6. OUTPLACEMENT SERVICES. The Company will provide you with six (6) months of outplacement services. You may begin utilizing such benefits upon execution of this Agreement.

7. Other Compensation or Benefits. You acknowledge that, except as expressly provided in this Agreement, you have not earned and will not receive from the Company any additional compensation (including base salary, bonus, incentive compensation, or equity), severance, or benefits before or after the Separation Date, with the exception of any vested right you may have under the express terms of a written ERISA-qualified benefit plan (e.g., 401(k) account) or any vested stock options.

8. Expense Reimbursements. You agree that, within thirty (30) days after the Separation Date, you will submit your final documented expense reimbursement statement reflecting all business expenses you incurred through the Separation Date, if any, for which you seek reimbursement. The Company will reimburse you for these expenses pursuant to its regular business practice.

9. Release of Claims.

1. General Release of Claims. In exchange for the consideration provided to you under this Agreement to which you would not otherwise be entitled, you hereby generally and completely release the Company, and its affiliated, related, parent and subsidiary entities, and its and their current and former directors, officers, employees, shareholders, partners, agents, attorneys, predecessors, successors, insurers, affiliates, and assigns from any and all claims, liabilities, demands, causes of action, and obligations, both known and unknown, arising from or in any way related to events, acts, conduct, or omissions occurring at any time prior to and including the date you sign this Agreement.

2. Scope of Release. This general release includes, but is not limited to: (i) all claims arising from or in any way related to your employment with the Company or the termination of that employment; (ii) all claims related to your compensation or benefits from the Company, including salary, bonuses, commissions, vacation pay, expense reimbursements, severance pay, fringe benefits, stock, stock options, or any other ownership, equity, or profits interests in the Company; (iii) all claims for breach of contract, wrongful termination, and breach of the implied covenant of good faith and fair dealing; (iv) all tort claims, including claims for fraud, defamation, emotional distress, and discharge in violation of public policy; and (v) all federal, state, and local statutory claims, including claims for discrimination, harassment,

retaliation, attorneys' fees, or other claims arising under the federal Civil Rights Act of 1964 (as amended), the federal Americans with Disabilities Act of 1990, the California Labor Code (as amended), the California Family Rights Act, the Age Discrimination in Employment Act ("**ADEA**") and the California Fair Employment and Housing Act (as amended). **You acknowledge that you have been advised, as required by California Government Code Section 12964.5(b)(4), that you have the right to consult an attorney regarding this Agreement and that you were given a reasonable time period of not less than five business days in which to do so.** You further acknowledge and agree that, in the event you sign this Agreement prior to the end of the reasonable time period provided by the Company, your decision to accept such shortening of time is knowing and voluntary and is not induced by the Company through fraud, misrepresentation, or a threat to withdraw or alter the offer prior to the expiration of the reasonable time period, or by providing different terms to employees who sign such an agreement prior to the expiration of the time period.

3. ADEA Release. You acknowledge that you are knowingly and voluntarily waiving and releasing any rights you have under the ADEA, and that the consideration given for the waiver and releases you have given in this Agreement is in addition to anything of value to which you were already entitled. You further acknowledge that you have been advised, as required by the ADEA, that: (i) your waiver and release does not apply to any rights or claims arising after the date you sign this Agreement; (ii) you should consult with an attorney prior to signing this Agreement (although you may choose voluntarily not to do so); (iii) you have twenty-one (21) days to consider this Agreement (although you may choose voluntarily to sign it sooner); (iv) you have seven (7) days following the date you sign this Agreement to revoke this Agreement (in a written revocation sent to the Company); and (v) this Agreement will not be effective until the date upon which the revocation period has expired, which will be the eighth day after you sign this Agreement provided that you do not revoke it (the "**Effective Date**").

4. Section 1542 Waiver. In giving the release herein, which includes claims which may be unknown to you at present, you acknowledge that you have read and understand Section 1542 of the California Civil Code, which reads as follows: **"A general release does not extend to claims that the creditor or releasing party does not know or suspect to exist in his or her favor at the time of executing the release and that, if known by him or her, would have materially affected his or her settlement with the debtor or released party."** You hereby expressly waive and relinquish all rights and benefits under that section and any law of any other jurisdiction of similar effect with respect to your release of claims herein, including but not limited to your release of unknown claims.

5. Exceptions. Notwithstanding the foregoing, you are not releasing the Company hereby from: (i) any obligation to indemnify you pursuant to the Articles and Bylaws of the Company, any valid fully executed indemnification agreement with the Company, applicable law, or applicable directors and officers liability insurance; (ii) any claims that cannot be waived by law; or (iii) any claims for breach of this Agreement.

6. Protected Rights. You understand that nothing in this Agreement limits your ability to file a charge or complaint with the Equal Employment Opportunity Commission, the Department of Labor, the National Labor Relations Board, the Occupational Safety and Health Administration, the California Department of Fair Employment and Housing, the Securities and Exchange Commission or any other federal, state or local governmental agency or commission ("**Government Agencies**"). You further understand this Agreement does not limit your ability to communicate with any Government Agencies or otherwise participate in any investigation or proceeding that may be conducted by any Government Agency, including providing documents or other information, without notice to the Company. While this Agreement does not limit your right to receive an award for information provided to the Securities and Exchange Commission, you understand and agree that, to maximum extent permitted by law, you are otherwise waiving any and all rights you may have to individual relief based on any claims that you have released and any rights you have waived by signing this Agreement. Nothing in this Agreement (i) prevents you from discussing or disclosing information about unlawful acts in the workplace, such as harassment or discrimination or any other conduct that you have reason to believe is unlawful; or (ii) waives any rights you may have under Section 7 of the National Labor Relations Act to engage in protected concerted activity, including speech.

7. Return of Company Property. You represent and warrant that you have returned to the Company all Company documents (and all copies thereof) and other Company property in your possession or control, including, but not limited to, Company files, notes, drawings, records, plans, forecasts, reports, studies, analyses, proposals, agreements, drafts, financial and operational information, research and development information, sales and marketing information, customer lists, prospect information, pipeline reports, sales reports, personnel information, specifications, code, software, databases, computer-recorded information, tangible property and equipment (including, but not limited to, computing and electronic devices, mobile telephones, servers), credit cards, entry cards, identification badges and keys; and any materials of any kind which contain or embody any proprietary or confidential information of the Company (and all reproductions or embodiments thereof in whole or in part). You further represent that you have made a diligent search to locate any such documents, property and information. If you have used any personally owned computer or other electronic device, server, or e-mail system to receive, store, review, prepare or transmit any Company confidential or proprietary data, materials or information, within five (5) days after the Separation Date, you shall provide the Company with a computer-useable copy of such information and then permanently delete and expunge such Company confidential or proprietary information from those systems; and you agree to provide the Company access to your system as requested to verify that the necessary copying and/or deletion is completed. **Your timely compliance with this paragraph is a condition to your receipt of the severance benefits provided under this Agreement.**

8. Confidential Information Obligations. You acknowledge and reaffirm your continuing obligations under your Proprietary Information and Inventions Agreement, a copy of which is attached hereto as Exhibit A and incorporated herein by reference.

9. Confidentiality. The provisions of this Agreement will be held in strictest confidence by you and will not be publicized or disclosed by you in any manner whatsoever; *provided, however,* that: (a) you may disclose this Agreement in confidence to your immediate

family and to your attorneys, accountants, tax preparers and financial advisors; (b) you may disclose this Agreement insofar as such disclosure may be necessary to enforce its terms or as otherwise required by law; and (c) you may disclose this Agreement to the extent permitted by the "Protected Rights" Section above or in furtherance of your rights under Section 7 of the National Labor Relations Act.

10. Non-disparagement. Except to the extent permitted by the Protected Rights Section above, you agree not to disparage the Company, its officers, directors, employees, shareholders, parents, subsidiaries, affiliates, and agents, in any manner likely to be harmful to its or their business, business reputation, or personal reputation; provided that you may respond accurately and fully to any request for information if required by legal process or in connection with a government investigation. In addition, nothing in this provision or this Agreement prohibits or restrains you from making disclosures protected under the whistleblower provisions of federal or state law or from exercising your rights to engage in protected speech under Section 7 of the National Labor Relations Act, if applicable.

11. No Voluntary Adverse Action. You agree that you will not voluntarily (except in response to legal compulsion or as permitted under the section of this Agreement entitled "Protected Rights") assist any person in bringing or pursuing any proposed or pending litigation, arbitration, administrative claim or other formal proceeding against the Company, its parent or subsidiary entities, affiliates, officers, directors, employees or agents.

12. Cooperation. You agree to cooperate fully with the Company in connection with its actual or contemplated defense, prosecution, or investigation of any claims or demands by or against third parties, or other matters arising from events, acts, or failures to act that occurred during the period of your employment by the Company. Such cooperation includes, without limitation, making yourself available to the Company upon reasonable notice, without subpoena, to provide complete, truthful and accurate information in witness interviews, depositions, and trial testimony. The Company will reimburse you for reasonable out-of-pocket expenses you incur in connection with any such cooperation (excluding foregone wages) and will make reasonable efforts to accommodate your scheduling needs.

13. No Admissions. You understand and agree that the promises and payments in consideration of this Agreement shall not be construed to be an admission of any liability or obligation by the Company to you or to any other person, and that the Company makes no such admission.

14. Representations. You hereby represent that you have: been paid all compensation owed and for all hours worked; received all leave and leave benefits and protections for which you are eligible pursuant to the Family and Medical Leave Act, the California Family Rights Act, or otherwise; and not suffered any on-the-job injury for which you have not already filed a workers' compensation claim.

15. Dispute Resolution. You and the Company agree that any and all disputes, claims, or controversies of any nature whatsoever arising from, or relating to, this Agreement or its interpretation, enforcement, breach, performance or execution, your employment or the termination of such employment (including, but not limited to, any statutory claims) (collectively, "**Claims**", each a "**Claim**"), shall be resolved, pursuant to the Federal Arbitration Act, 9 U.S.C. §1-16, and to the fullest extent permitted by law, by final, binding and confidential arbitration in a mutually acceptable location conducted before a single neutral arbitrator by JAMS, Inc. ("**JAMS**") or its successor, under the then applicable JAMS Arbitration Rules and

Procedures for Employment Disputes (available at http://www.jamsadr.com/rules-employment-arbitration/). **By agreeing to this arbitration procedure, both you and the Company waive the right to have any Claim resolved through a trial by jury or judge or an administrative proceeding.** You will have the right to be represented by legal counsel at any arbitration proceeding, at your own expense. This paragraph shall not apply to any action or claim that cannot be subject to mandatory arbitration as a matter of law, including, without limitation, claims brought pursuant to the California Private Attorneys General Act of 2004, as amended, to the extent such claims are not permitted by applicable law to be submitted to mandatory arbitration and the applicable law(s) are not preempted by the Federal Arbitration Act or otherwise invalid (collectively, the "**Excluded Claims**"). In the event you intend to bring multiple claims, including one of the Excluded Claims listed above, the Excluded Claims may be publicly filed with a court, while any other claims will remain subject to mandatory arbitration. The arbitrator shall have sole authority for determining if a Claim is subject to arbitration, and any other procedural questions related to the dispute and bearing on the final disposition. In addition, the arbitrator shall: (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be available under applicable law in a court proceeding; and (b) issue a written statement signed by the arbitrator regarding the disposition of each claim and the relief, if any, awarded as to each claim, the reasons for the award, and the arbitrator's essential findings and conclusions on which the award is based. The Company shall pay all JAMS arbitration fees. Nothing in this Agreement shall prevent you or the Company from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any arbitration. Any awards or orders in such arbitrations may be entered and enforced as judgments in the federal and state courts of any competent jurisdiction.

16. Miscellaneous. This Agreement, including Exhibit A, constitutes the complete, final and exclusive embodiment of the entire agreement between you and the Company with regard to its subject matter. It is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes any other such promises, warranties or representations. This Agreement may not be modified or amended except in a writing signed by both you and a duly authorized officer of the Company. This Agreement will bind the heirs, personal representatives, successors and assigns of both you and the Company, and inure to the benefit of both you and the Company, their heirs, successors and assigns. If any provision of this Agreement is determined to be invalid or unenforceable, in whole or in part, this determination will not affect any other provision of this Agreement and the provision in question will be modified by the court so as to be rendered enforceable to the fullest extent permitted by law, consistent with the intent of the parties. This Agreement will be deemed to have been entered into and will be construed and enforced in accordance with the laws of the State of California without regard to conflict of laws principles. Any ambiguity in this Agreement shall not be construed against either party as the drafter. Any waiver of a breach of this Agreement shall be in writing and shall not be deemed to be a waiver of any successive breach. This Agreement may be executed in counterparts and electronic or facsimile signatures will suffice as original signatures.

If this Agreement is acceptable to you, please sign below and return the original to me. You have twenty-one (21) calendar days to decide whether to accept this Agreement, and the Company's offer contained herein will automatically expire if you do not sign and return it within that timeframe.

We wish you the best in your future endeavors.

Sincerely,

By: /s/ Terry Rosen, Ph.D.

__
Terry Rosen, Ph.D.
CEO

I have read, understand and agree fully to the foregoing Agreement:

/s/ Dimitry Nuyten, MD, Ph.D.

__
Dimitry Nuyten, MD, Ph.D.

1/17/2025

__
Date

Exhibit A

EMPLOYEE CONFIDENTIAL INFORMATION

AND INVENTIONS ASSIGNMENT AGREEMENT

EXHIBIT 19.1

ARCUS BIOSCIENCES, INC.

Insider Trading Policy

Purpose.

It is illegal for anyone to trade in the securities of a company while in possession of material nonpublic information and in breach of a duty of trust or confidence. It is also illegal to share material nonpublic information with others who may trade on the basis of such information. Companies who fail to take reasonable steps to prevent insider trading can be subject to liability. Arcus Biosciences, Inc. and its subsidiaries (collectively, the "***Company***") have adopted this Insider Trading Policy (the "***Policy***") to prevent insider trading (and allegations of insider trading), to protect the Company's reputation for integrity and ethical conduct and to facilitate compliance with federal and state securities laws.

Scope.

Persons Covered. We expect every employee and director to abide by this Policy. Furthermore, these restrictions also apply to family members who reside with you, anyone else who lives in your household, and family members who do not live in your household but whose transactions in Company securities are directed by you or are subject to your influence or control (such as parents or children who consult with you before they trade in Company securities). You are responsible for ensuring their compliance with this Policy. It is also the policy of the Company that the Company will not engage in transactions in Company securities while aware of material nonpublic information relating to the Company or Company securities. This Policy also applies to any entities controlled by individuals subject to this Policy, including any corporations, limited liability companies, partnerships or trusts, and transactions by these entities should be treated for the purposes of this Policy as if they were for the individual's own account. The Company may determine that this Policy applies to additional persons with access to material nonpublic information, such as contractors or consultants.

This Policy continues to apply even after you have left the Company. If you are aware of material nonpublic information when your employment or service relationship terminates, you may not trade in Company securities until that information has become public or is no longer material.

Companies Covered. This Policy applies to the trading of the Company's securities, as well as the securities of any other company with which we have a business relationship, such as our collaborators, suppliers and other vendors, while in possession of material nonpublic information about such other company obtained in connection with your employment by or service to the Company.

Definition of "Material Nonpublic Information".

Inside information has two important elements—materiality and public availability.

Material Information. Information is material if there is a substantial likelihood that a reasonable investor would consider it important in deciding whether to buy, hold or sell a security. Any information that could reasonably be expected to affect the price of the security is material. Both positive and negative information can be material. Common examples of material information are:

- results or material data from clinical trials or pre-clinical testing, or other significant development milestones;
- significant communications to or from regulatory agencies, or other significant regulatory developments;
- initiation of a new clinical trial for a product candidate or termination of the development of a product candidate;
- any significant changes in our ability to manufacture or supply products or product candidates;
- product recalls or defects;
- acquisitions, licenses, divestitures or sales of any assets;
- entry into new, significant modifications of, or termination of any major strategic relationship;
- financial performance, such as quarterly and year-end operating results;
- restatements of financial results, material impairments, write-offs, or restructurings;
- offerings of additional securities of the Company or debt offerings;
- changes in the Company's liquidity, significant default under or acceleration of any financial obligation;
- cybersecurity or data security incidents;
- significant changes in the Company's senior management; and
- actual or threatened major litigation, or the resolution of such litigation.

It is important to note that materiality may be different for different companies. Information that is not material to the Company may be material to another company.

Nonpublic Information. Nonpublic information is information that is not generally known or available to the public. One common misconception is that material information loses its "nonpublic" status as soon as a press release is issued disclosing the information. In fact, information is considered to be available to the public only when it has been released broadly to the marketplace ***and*** the investing public has had time to absorb the information fully. For purposes of this Policy, information will be considered public one (1) full trading day

following widespread public release of the information, such as through a press release, major newswire service(s) or filing with the U.S. Securities and Exchange Commission ("***SEC***").

Prohibited Activities.

No Trading on Inside Information. You may not trade in the securities of the Company, directly or through family members or other persons or entities, if you are aware of material nonpublic information relating to the Company. Similarly, you may not trade in the securities of any other company if you are aware of material nonpublic information about the other company that you obtained in connection with your employment with or service to the Company.

Trading is meant to broadly encompass all transactions involving the securities of a company, including purchases, sales and other transfers of common stock, options, warrants, preferred stock, debt securities (such as debentures, bonds and notes) and other securities.

*"*Purchase*"* and *"*sale*"* are defined broadly under federal securities law. *"*Purchase*"* includes not only the actual purchase of a security, but also any contract to purchase or otherwise acquire a security. *"*Sale*"* includes not only the actual sale of a security, but also any contract to sell or otherwise dispose of a security. These definitions extend to a broad range of transactions, including conventional cash-for-stock transactions, conversions, the exercise of stock options or warrants, puts, calls, pledging and margin loans, or other derivative securities.

Limited Exception. Limited exceptions are:

- transactions directly with the Company.
- gift transactions for family or estate planning purposes, where securities are gifted to a person or entity subject to this Policy, except that gift transactions involving Company securities are subject to pre-clearance.
- the exercise of a stock option for cash under the Company's Equity Incentive Plans. The trading restrictions do apply, however, to any sale of the underlying stock or to a cashless exercise of the option through a broker (often called a "same-day sale"). Such a transaction entails selling a portion of the underlying stock to cover the costs of exercise and/or withholding taxes.
- the purchase of Company securities made through an employee's participation in the Company's Employee Stock Purchase Plan. The trading restrictions do apply, however, to any subsequent sale of such Company securities.
- transactions under an Approved 10b5-1 Plan (as defined below under the section titled "10b5-1 Plan Requirements").
- transactions that involve merely a change in the form in which you own securities, for example, transfers to certain types of trust. Such transfers may be subject to certain restrictions under the Company's Equity Incentive Plans.

No Tipping. You may not directly or indirectly pass material nonpublic information on to anyone outside the Company unless in accordance with Company policy regarding confidential information or to anyone within the Company, except as reasonably required to facilitate the Company's business activities. You also may not recommend to others the purchase or sale of any securities when you are aware of such information. This practice, known as “tipping,” also violates securities laws and can result in the same civil and criminal penalties that apply to insider trading, even though you did not trade and did not gain any benefit from the other person’s trading.

No Minimums or Exception for Hardship. There is no *de minimis* test. Use of inside information and tipping are as illegal with respect to a few shares of stock as they are with respect to a large number of shares. Furthermore, the existence of a personal financial emergency or hardship does not excuse you from compliance with this Policy.

10b5-1 Plan Requirements.

Notwithstanding the restrictions set forth herein, a transaction will be permitted if it is made under a pre-existing written contract, instruction or plan subject to the following requirements (an “***Approved 10b5-1 Plan***”):

- such contract, instruction or plan specifies the security or securities to be purchased or sold, the number of shares, the prices and/or dates of transactions, or formula(s) for determining the foregoing;
- such contract, instruction or plan designates a third party to execute such purchases and sales outside the control or influence of the person adopting the plan;
- such contract, instruction or plan is entered into by the person in good faith, at a time when he or she is not in possession of material nonpublic information and meets the other requirements or conditions for contracts, instructions, or plans designed to comply with Rule 10b5-1(c) of the Securities Exchange Act of 1934;
- such contract, instruction or plan, or any amendment thereto, has been reviewed and approved by the Securities Compliance Officer prior to being executed;
- if such contract, instruction or plan is being entered into by a director or an “officer,” as defined under Rule 16a-1(f) promulgated under Section 16 of the Securities Exchange Act of 1934 (a “***Section 16 Reporting Person***”), the contract, instruction or plan is entered into prior to the first trade scheduled to be made under such contract, instruction or plan by a number days equal to the earlier of (i) 120 days and (ii) the later of (a) 90 days and (b) the number of days that is two business days after the Company files its Form 10-Q or 10-K for the quarter in which such plan is entered into; and
- if such plan is being entered into by an employee that is not a Section 16 Reporting Person, the contract, instruction or plan is entered into at least 30 days prior to the first trade scheduled to be made under such contract, instruction or plan.

Employees who are not Section 16 Reporting Persons are generally required to use the Company's designated broker for Approved 10b5-1 Plans.

The General Counsel may impose such other conditions on the implementation and operation of an Approved 10b5-1 Plan as the General Counsel deems necessary or advisable.

An individual may only modify an Approved 10b5-1 Plan outside of a blackout period and, in any event, when the individual does not possess material nonpublic information. Modifications to and early terminations of an Approved 10b5-1 Plan are subject to pre-approval by the General Counsel.

The Company also reserves the right from time to time to suspend, discontinue, or otherwise prohibit transactions under an Approved 10b5-1 Plan if the General Counsel or the Board of Directors, in its discretion, determines that such suspension, discontinuation, or other prohibition is in the best interests of the Company.

Compliance of an Approved 10b5-1 Plan with the terms of Rule 10b5-1 and the execution of transactions pursuant to the Approved 10b5-1 Plan are the sole responsibility of the person initiating the Approved 10b5-1 Plan, and none of the Company, the General Counsel, or the Company's other employees assumes any liability for any delay in reviewing and/or refusing to approve a 10b5-1 plan submitted for approval, nor the legality or consequences relating to a person entering into, informing the Company of, or trading under, an Approved 10b5-1 Plan.

Additional Guidance.

Whether or not you have inside information, you should also not engage in any of the following activities with respect to securities of the Company:

- *Short Sales.* This involves the sale of securities that you do not own,*i.e.*, borrowed securities, or that you own but with delayed delivery, *i.e.*, short sales "against the box".
- *Publicly Traded Options*. Examples include puts, calls and other derivative contracts or transactions, on an exchange or in any other organized market.
- *Hedging Transactions.* This involves transactions of the Company's securities, such as prepaid variable forward contracts, equity swaps, collars and exchange funds, or other transactions that hedge or offset, or are designed to hedge or offset, any decrease in the market value of the Company's equity securities.
- *Margin Accounts and Pledges*. This means borrowing from a brokerage firm, bank or other entity in order to purchase Company securities.

Unauthorized Disclosure. Maintaining the confidentiality of Company information is essential for competitive, security and other business reasons, as well as to comply with securities laws. You should treat all information you learn about the Company or its business plans in connection with your employment with (or service to) the Company as confidential and proprietary to the Company. Employees should treat all corporate information with discretion and discuss confidential data ***only*** with those Company employees who have a right and a

need to know. In particular, do not discuss confidential information with relatives, friends or acquaintances. Inadvertent disclosure of confidential or inside information may expose the Company and you to significant risk of investigation and litigation. The timing and nature of the Company's disclosure of material information to outsiders is subject to legal rules, the breach of which could result in substantial liability to you, the Company and its management. Accordingly, it is important that responses to inquiries about the Company by the press, investment analysts or others in the financial community be made on the Company's behalf only through authorized individuals. Please consult the Company's Code of Conduct and Ethics for the list of authorized individuals.

In addition, you are prohibited at ***all*** times from posting any information about the Company, its products or product candidates, its collaborators, suppliers, clinical investigators, patients, competitors or others, as well as any other "material" nonpublic information, in any internet discussion group. This includes, but is not limited to, social media platforms, internet message boards or chat rooms.

Designated Broker. You must hold all securities issued to you by the Company in an account established under your name with the Company's designated broker who, as of the date that this policy was adopted. This includes any options, RSUs, shares purchased under any employee stock purchase plan, or any shares of common stock received upon the exercise of any options or the vesting of any RSUs. The Company generally does not permit transfer of any such securities to a personal broker.

Blackout Periods and Other Procedures.

Event-Specific Blackouts. From time to time, an event may occur that is material to the Company. These event-specific blackouts may apply to only a few individuals with knowledge of the material nonpublic information, or all employees and directors, such as in the event of impending material data from a clinical study. As long as the event remains material and nonpublic, anyone who is subject to the event-specific blackout or otherwise designated by the General Counsel may not trade in the Company's securities. In the event of an event-specific blackout that is not applicable to all employees and directors, the existence of such event-specific blackout will not be announced, other than to those who are subject to the event-specific blackout. Any person made aware of the existence of an event-specific blackout should not disclose the existence of the blackout to any other person, including persons outside the Company. The failure of the General Counsel to designate a person as being subject to an event-specific blackout will not relieve that person of the obligation not to trade while aware of material nonpublic information.

Even if a blackout period is not in effect, at no time may you trade in Company securities if you are aware of material nonpublic information about the Company.

Pre-Clearance Procedure. All directors and employees at the level of Vice President and above must pre-clear all transactions in the Company's securities with the Company's General Counsel. In addition, the General Counsel may designate additional individuals who must also pre-clear their transactions. The General Counsel may not trade in Company securities unless

the Principal Financial Officer has approved the trade in accordance with the procedures set forth in this Addendum.

Penalties for Noncompliance.

The consequences of insider trading can be severe. Both the SEC and the Financial Industry Regulatory Authority (FINRA) investigate, and are very effective in detecting, insider trading. The SEC, together with the Department of Justice, pursues insider trading violations vigorously. Cases have been prosecuted successfully against trading by employees through foreign accounts, trading by family members and friends, and trading involving only a small number of shares.

Failure to comply with this Policy may also subject you to Company-imposed sanctions, including dismissal, whether or not your failure to comply with this Policy results in a violation of law.

Because trading is always judged after the fact with the benefit of hindsight, any uncertainty concerning the materiality of particular information should be resolved in favor of materiality. In other words, in case of doubt, you should not trade.

Reporting & Enforcement.

Violations of the Policy. Anyone who violates this Policy or securities laws may be disciplined, including termination of employment and/or his or her business relationship with the Company, in accordance with local legal requirements. Certain violations of this Policy may be violations of the law, which may result in civil or criminal penalties.

Report Violations. Anyone who violates this Policy or knows of any such violation must promptly report it to the General Counsel.

Questions.

It is your obligation to understand and comply with this Policy. Should you have any questions regarding this Policy, please contact the General Counsel or such individual's designee, who is referred to in this Policy as the Company's General Counsel.

Modification.

The Company is committed to continuously reviewing and updating our policies, and therefore reserves the right to amend this Policy at any time, for any reason, subject to applicable law.

ADDENDUM TO INSIDER TRADING POLICY PRE-CLEARANCE

PROCEDURES

As provided in the Policy, no director, employee at the level of Vice President or above, and such other individuals designated by the General Counsel may trade in Company securities unless they have satisfied the requirements of this Addendum.

1. The person wishing to trade must send an email to[***] with the following information regarding the proposed trade:

    a. Type of security to be traded

    b. Type of trade (purchase or sale)

    c. The proposed date of the transaction

    d. Number of shares or other securities to be traded

    The General Counsel will endeavor to respond to all requests within five (5) business days. All approved trades must be executed within five (5) business days of approval, after which new approval must be obtained.

2. The General Counsel may approve in whole, approve in part, or deny the requested trade via email. The General Counsel is under no obligation to approve a transaction submitted for pre-clearance and may determine not to permit the transaction.

In addition, person must execute a certification that he or she is not aware of material nonpublic information about the Company. In the event the person wishing to trade becomes of aware of any material nonpublic information between the time of his or her request and when the trade is effected, they must immediately notify the General Counsel. The General Counsel may rescind any previously granted approval.

Pre-clearance should not be understood to represent legal advice by the company that a proposed transaction complies with the law. None of the Company, the General Counsel, or the Company's other employees will have any liability for any delay in reviewing, or refusal of, a request for pre-clearance.

ACKNOWLEDGEMENT OF INSIDER TRADING POLICY

I have received and read a copy of the Insider Trading Policy (including the Addendum) ("***Policy***") of Arcus Biosciences, Inc. and its subsidiaries (collectively, the "***Company***"). I hereby agree to comply with the specific requirements of the Policy in all respects during my employment or other service relationship with the Company and for such period of time after termination of my service as provided in the Policy. I understand that my failure to comply in all respects with the Policy is a basis for termination of my employment or other service relationship with the Company.

Signature:____ Printed Name:____ Date:__

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statements (Form S-3 Nos. 333-267822, 333-270132 and 333-277224) of Arcus Biosciences, Inc.,

(2) Registration Statements (Form S-8 Nos. 333-236915, 333-253474 and 333-262929) pertaining to the Arcus Biosciences, Inc. 2018 Equity Incentive Plan, the Arcus Biosciences, Inc. 2018 Employee Stock Purchase Plan, and the Arcus Biosciences, Inc. 2020 Inducement Plan,

(3) Registration Statements (Form S-8 Nos. 333-230074, 333-270114 and 333-277219) pertaining to the Arcus Biosciences, Inc. 2018 Equity Incentive Plan and the Arcus Biosciences, Inc. 2018 Employee Stock Purchase Plan, and

(4) Registration Statement (Form S-8 No. 333-223746) pertaining to the Arcus Biosciences, Inc. Amended and Restated 2015 Stock Plan, the Arcus Biosciences, Inc. 2018 Equity Incentive Plan, and the Arcus Biosciences, Inc. 2018 Employee Stock Purchase Plan;

of our reports dated February 25, 2025, with respect to the consolidated financial statements of Arcus Biosciences, Inc. and the effectiveness of internal control over financial reporting of Arcus Biosciences, Inc. included in this Annual Report on Form 10-K of Arcus Biosciences, Inc. for the year ended December 31, 2024.

/s/ Ernst & Young LLP

San Mateo, California
February 25, 2025

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Terry Rosen, certify that:

1. I have reviewed this Form 10-K of Arcus Biosciences, 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 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 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: February 25, 2025

By: /s/ Terry Rosen

Terry Rosen, Ph.D.

Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Robert C. Goeltz II, certify that:

1. I have reviewed this Form 10-K of Arcus Biosciences, 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 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 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: February 25, 2025

By: /s/ Robert C. Goeltz II

Robert C. Goeltz II

Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION 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 of Arcus Biosciences, Inc. (the "Company") on Form 10-K for the period ending December 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to the best of my 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 result of operations of the Company.

Date: February 25, 2025

By: /s/ Terry Rosen

Terry Rosen, Ph.D.

Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION 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 of Arcus Biosciences, Inc. (the "Company") on Form 10-K for the period ending December 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to the best of my 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 result of operations of the Company.

Date: February 25, 2025

By: /s/ Robert C. Goeltz II

Robert C. Goeltz II

Chief Financial Officer
(Principal Financial Officer)