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

FORM 10-K

☒ 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

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file number: 001-38869

HOOKIPA PHARMA INC.

(Exact name of registrant as specified in its charter)

Delaware	**81-5395687**
(State of Other Jurisdiction of incorporation or Organization)	(I.R.S. Employer Identification No.)
350 Fifth Avenue, 72nd Floor, Suite 7240 **New York, New York**	**10118**
(Address of principal executive offices)	(Zip code)

Registrant's telephone number, including area code: +43 1 890 63 60

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

Title of Each Class	**Trading Symbol(s)**	**Name Of Each Exchange On Which Registered**
Common Stock, $0.0001 Par Value per Share	**HOOK**	**The Nasdaq Capital Market**

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

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

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

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

Indicate by check mark whether the Registrant has submitted electronically; every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.0405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

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

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

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

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

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

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

Based on the closing price as reported on the Nasdaq Global Select Market, the aggregate market value of the Registrant's Common Stock held by non-affiliates on June 30, 2024 (the last business day of the Registrant's most recently completed second fiscal quarter) was approximately $57.0 million. Shares of Common Stock held by each executive officer and director and by each shareholder affiliated with a director or an executive officer have been excluded from this calculation because such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes. The number of outstanding shares of the Registrant's Common Stock as of February 24, 2025 was 9,659,522 shares and 2,399,517 shares of Class A common stock outstanding, each $0.0001 par value per share.

Documents Incorporated by Reference

If the Registrant's Definitive Proxy Statement relating to the 2025 Annual General Meeting of Shareholders (the "Proxy Statement") is filed with the Commission within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, then portions of the Proxy Statement will be incorporated by reference into Part III of this Annual Report on Form 10-K. If the Proxy Statement is not filed within such 120-day period, then the Registrant will file an amendment to this Annual Report within such 120-day period that will contain the information required to be included or incorporated by reference into Part III of this Annual Report.

Auditor Firm Id: 1259 Auditor Name: PwC Wirtschaftsprüfung GmbH Auditor Location: Vienna, Austria

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, including "Business" in Part I Item I and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II Item 7, contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements may be identified by such forward-looking terminology as "may," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue" or the negative of these terms or other comparable terminology. Our forward-looking statements are based on a series of expectations, assumptions, estimates and projections about our company, are not guarantees of future results or performance and involve substantial risks and uncertainty. We may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements. Our business and our forward-looking statements involve substantial known and unknown risks and uncertainties, including the risks and uncertainties inherent in our statements regarding:

- the success, cost and timing of our product development activities and clinical trials;
- the substantial doubt regarding our ability to continue as a going concern;
- the timing, scope or likelihood of regulatory filings and approvals, including timing of Investigational New Drug Application and Biological Licensing Application filings for our current and future product candidates, and final U.S. Food and Drug Administration, European Medicines Agency or other foreign regulatory authority approval of our current and future product candidates;
- our ability to develop and advance our current product candidates and programs into, and successfully complete, clinical studies;
- our manufacturing, commercialization and marketing capabilities and strategy;
- the potential benefits of and our ability to maintain our collaboration with Gilead Sciences, Inc. and establish or maintain future collaborations or strategic relationships or obtain additional funding;
- the rate and degree of market acceptance and clinical utility of our current and future product candidates;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering our non-replicating and replicating technologies and the product candidates based on these technologies, the validity of intellectual property rights held by third parties, and our ability not to infringe, misappropriate or otherwise violate any third-party intellectual property rights;
- future agreements with third parties in connection with the commercialization of our product candidates and any other approved product;
- regulatory developments in the United States and foreign countries;
- competitive companies and technologies in our industry and the success of competing therapies that are or may become available;
- our ability to attract and retain key scientific or management personnel;
- our ability to obtain funding for our operations, including funding necessary to complete further development and commercialization of our product candidates;

- the accuracy of our estimates of our annual total addressable market, future revenue, expenses, capital requirements and needs for additional financing;
- our expectations about market trends; and
- our ability to comply with Nasdaq listing rules.

All of our forward-looking statements are as of the date of this Annual Report on Form 10-K only. In each case, actual results may differ materially from such forward-looking information. We can give no assurance that such expectations or forward-looking statements will prove to be correct. An occurrence of or any material adverse change in one or more of the risk factors or risks and uncertainties referred to in this Annual Report on Form 10-K or included in our other public disclosures or our other periodic reports or other documents or filings filed with or furnished to the Securities and Exchange Commission could materially and adversely affect our business, prospects, financial condition and results of operations. Except as required by law, we do not undertake or plan to update or revise any such forward-looking statements to reflect actual results, changes in plans, assumptions, estimates or projections or other circumstances affecting such forward-looking statements occurring after the date of this Annual Report on Form 10-K, even if such results, changes or circumstances make it clear that any forward-looking information will not be realized. Any public statements or disclosures by us following this Annual Report on Form 10-K that modify or impact any of the forward-looking statements contained in this Annual Report on Form 10-K will be deemed to modify or supersede such statements in this Annual Report on Form 10-K.

Investors and others should note that we announce material financial information to our investors using our investor relations website (https://ir.hookipapharma.com/), Securities and Exchange Commission ("SEC") filings, press releases, public conference calls and webcasts. We use these channels, as well as social media, to communicate with our members and the public about our company, our services and other issues. It is possible that the information we post on social media could be deemed to be material information. Therefore, we encourage investors, the media, and others interested in our company to review the information we post on the U.S. social media channels listed on our investor relations website.

Note Regarding Trademarks

This 10-K report includes trademarks and trade names that are the property of other organizations. Solely for convenience, trademarks and trade names referred to in this 10-K report appear without the ® symbols, but those references are not intended to indicate that we will not assert, to the fullest extent under applicable law, our rights, or that the applicable owner will not assert its rights, to these trademarks and trade names. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies. All trademarks, trade names and service marks appearing in 10-K report are the property of their respective owners.

Unless otherwise indicated or the context otherwise requires, all references in this 10-K report to "HOOKIPA Pharma", "HOOKIPA", the "Company", "we", "our", "ours", "us" or similar terms refer to HOOKIPA Pharma Inc. and our consolidated subsidiaries.

Summary Risk Factors

Our business is subject to numerous risks and uncertainties, including those described in Item 1A "Risk Factors". These risk factors include, but are not limited to the following:

- We are a clinical-stage biopharmaceutical company with no approved products and a limited operating history. We have incurred significant losses since inception. We expect to incur losses for at least the next several years and may never achieve or maintain profitability.

- There is substantial doubt regarding our ability to continue as a going concern. We will need to raise substantial additional funding, which may not be available on acceptable terms, if at all, to be able to continue as a going concern and advance any our product candidates. Failure to obtain capital when needed may force us to delay, limit or terminate our product development efforts or other operations. Raising additional capital may dilute our existing shareholders, restrict our operations or cause us to relinquish valuable rights.

- Our strategic refocus and the associated workforce reduction announced in January 2024 and additional workforce reductions implemented in September 2024 and November 2024 may not result in anticipated cost savings, which could result in total costs and expenses that are greater than expected, potentially disrupting our business.

- We will require substantial additional financing and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations.

- If we are unable to advance our current or future product candidates into and through clinical trials, obtain marketing approval and ultimately commercialize any product candidates we develop, or experience significant delays in doing so, our business will be materially harmed.

- The regulatory approval processes of the U.S. Food and Drug Administration ("FDA"), the European Medicines Agency ("EMA"), the European Commission, and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

- Failure or perceived failure to comply with existing or future laws, regulations, contracts, self-regulatory schemes, standards, and other obligations related to data privacy and security (including security incidents) could harm our business. Compliance or the actual or perceived failure to comply with such obligations could increase the costs of our products and services, limit their use or adoption, and otherwise negatively affect our operating results and business.

- Our product candidates are based on a novel approach to the treatment of cancer and infectious diseases, which makes it difficult to predict the time and cost of product candidate development.

- Our product candidates may cause serious adverse events, undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, require expansion of the trial size, limit their commercial potential or result in significant negative consequence.

- We are fully dependent on our collaboration with Gilead Sciences, Inc. ("Gilead") for the development of our hepatitis B virus program, rely on funding from Gilead for development of our human immunodeficiency virus program, and may depend on Gilead or additional third parties for the development and commercialization of our other programs and future product candidates. Our current and future collaborators may control aspects of our clinical trials, which could result in delays or other obstacles in the commercialization of the product candidates we develop. If our collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

- Our rights to develop and commercialize our product candidates are subject, in part, to the terms and conditions of licenses granted to us by others, and, if we fail to comply with our obligations under these arrangements or resolve related disputes, we could lose such intellectual property rights or owe damages to the licensor of such intellectual property.

- If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market.

- We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.

PART I

Item 1. Business

Overview

We are a clinical-stage biopharmaceutical company developing a new class of immunotherapeutics based on our proprietary arenavirus platform that is designed to target and amplify T cell and immune responses to fight diseases. Our replicating and non-replicating technologies are engineered to induce robust and durable antigen-specific CD8+ T cell responses and pathogen-neutralizing antibodies. We believe that our technologies can meaningfully leverage the human immune system therapeutic purposes by inducing CD8+ T cell response levels previously not achieved by other immune therapy approaches.

We are building a proprietary immuno-oncology pipeline utilizing our replicating technology. Our oncology portfolio targets oncoviral cancer antigens and next-generation antigens and includes two primary programs in development:

- HB-700 is a novel, next-generation multi-KRAS mutant-targeting, investigational immunotherapy for the treatment of KRAS mutated cancers, including lung, colorectal and pancreatic cancers, which received Investigational New Drug Application ("IND") clearance from the Food and Drug Administration ("FDA") in April 2024 and is Phase 1 ready.

- Eseba-vec (also known as HB-200) is an investigational immunotherapeutic agent in clinical development for the treatment of Human Papillomavirus 16-positive ("HPV16+") head and neck cancers with enrollment completed in a Phase 1/2 clinical trial. Further clinical development activities were paused as of November 2024.

We also have a third oncology program, HB-300, targeting self-antigens for the treatment of prostate cancer, which the Company paused further development in January 2024, to conserve capital and ensure pipeline success and operational efficiency.

Additionally, we are developing infectious disease therapies in partnership with other companies. Our Hepatitis B ("HBV") program, HB-400, and our Human Immunodeficiency Virus ("HIV") program, HB-500, are being developed in a partnership with Gilead. Both programs are in Phase 1 clinical development.

Significant Recent Events

Restructuring Plan

On November 18, 2024, we approved a plan to continue to improve our cost structure and operating efficiency, which includes a reduction in our workforce by approximately 80% of our then-current employee base (the "Restructuring Plan"). The Company began the implementation of the Restructuring Plan in the fourth quarter of 2024 and expects the Restructuring Plan to be substantially completed by the end of the first half of 2025. The Restructuring Plan includes the closing and consolidation of office and laboratories in Vienna, Austria, does not include social plan or severance payments and it is planned that the affected employees will continue to work throughout their termination period.

In connection with the Restructuring Plan, in an effort to rebalance our cost structure in alignment with our strategic refocus and development of the oncology portfolio, we also announced that we would pause clinical development in our eseba-vec program for the treatment of HPV16+ head and neck cancers, including an early

termination of the Phase 1/2 clinical trial for the treatment of HPV16+ cancers. The early termination of our Phase 1/2 clinical trial for the treatment of HPV16+ was not due to lack of efficacy or adverse safety profiles. While we will continue to seek partnering opportunities for the eseba-vec program, we will focus primarily on progressing the Phase 1-ready HB-700 program for the treatment of KRAS mutant cancers and our Gilead-partnered programs.

Research Incentives Receivables

We participate in a research incentive program provided by the Austrian government under which we are entitled to reimbursement of a percentage of qualifying research and development expenses and capital expenditures incurred in Austria. In February 2025, we received a payment of $19.8 million related to the research incentive program including the receivable of $17.3 million from Austrian research incentive program for the years 2022 and 2023.

Potential Combination of Poolbeg Pharma plc and HOOKIPA

On January 2, 2025, we and Poolbeg Pharma plc ("Poolbeg") released an announcement pursuant to Rule 2.4 of the U.K. City Code on Takeovers and Mergers (the "Code") that we and Poolbeg entered into non-binding discussions for the potential acquisition of the entire issued share capital of Poolbeg (the "Potential Combination") to create a clinical-stage biopharmaceutical company focused on developing and commercializing innovative medicines for critical unmet medical needs, with a special focus on next-generation immunotherapies for the treatment of cancer and other serious diseases. On February 20, 2025, we issued an announcement pursuant to Rule 2.8 of the Code disclosing that our board of directors determined that it does not intend to make an offer for Poolbeg under Rule 2.7 of the Code. Accordingly, our non-binding discussions with Poolbeg related to the Potential Combination have been terminated.

2024 Highlights

In 2024, we executed on several key areas across our pipeline. The highlights include:

Oncology:

- Eseba-vec (HB-200) in combination with pembrolizumab: EMA has granted PRIME designation for eseba-vec in combination with pembrolizumab for the treatment of patients with HPV16-positive recurrent/metastatic PD-L1 CPS ≥ 20 oropharyngeal squamous cell carcinoma in the first line setting. We presented positive preliminary Phase 2 data in patients with recurrent/metastatic HPV16+ head and neck cancers in the first line setting in June 2024 at American Society of Clinical Oncology ("ASCO") and additional patient data in November 2024 at the Society for Immunotherapy for Cancer ("SITC") Congress 2024.
    - Data showed 52% objective response rate for 25 evaluable checkpoint inhibitor ("CPI")-naïve patients. These data represent an approximate doubling of the response rate (19 to 26 percent) reported for pembrolizumab monotherapy in historical clinical trials.
    - In an effort to rebalance the Company's cost structure, we decided to pause clinical development of the eseba-vec program for the treatment of Human Papillomavirus 16-positive ("HPV16+") head and neck cancers, including an early termination of the ongoing Phase 1/2 clinical trial for the treatment of HPV16+ cancers. The early termination is not due to lack of efficacy or adverse safety profiles. We will continue to seek partnering opportunities for the eseba-vec program.
- HB-700: HB-700 is a novel, next-generation multi-KRAS mutant-targeting, investigational immunotherapy with antigen specific T cell activation designed to induce deep, durable and robust anti-tumor cell activity. HB-700 targets five of the most prevalent KRAS mutations and has a strong preclinical Proof of Concept ("POC") package with large addressable populations in non-small cell lung cancer ("NSCLC"), colorectal cancer ("CRC") and pancreatic ductal adenocarcinoma ("PDAC").

HB-700 is Phase 1-ready, with nonclinical development and clinical trial material manufacturing completed. HB-700 is derisked by clinical POC with platform asset eseba-vec (HB-200).

Infectious Disease: Gilead-Partnered Programs

- HB-400: In August 2023, the Journal of Infectious Disease published peer-reviewed preclinical data on HB-400. The data showed that HB-400 induced robust, HBV-specific T cell and antibody responses in non-human primates and cleared detectable serum HBV antigens in a mouse model for chronic HBV infection, with near elimination of detectable HBV antigen positive hepatocytes in the liver. A Phase 1b clinical trial led by Gilead completed enrollment with 83 participants, and primary completion of the trial is expected in the first half of 2025.

- HB-500: In November 2023, we received FDA clearance of our IND application for HB-500 and started the Phase 1b trial in the second quarter of 2024. The first person was dosed on July 1, 2024, resulting in the achievement of a $5.0 million milestone payment which was received on July 25, 2024. The Phase 1b trial completed enrollment in January 2025, with 30 participants enrolled across five sites in the United States, and primary completion of the Phase 1b trial of HB-500 is expected in the second half of 2025.

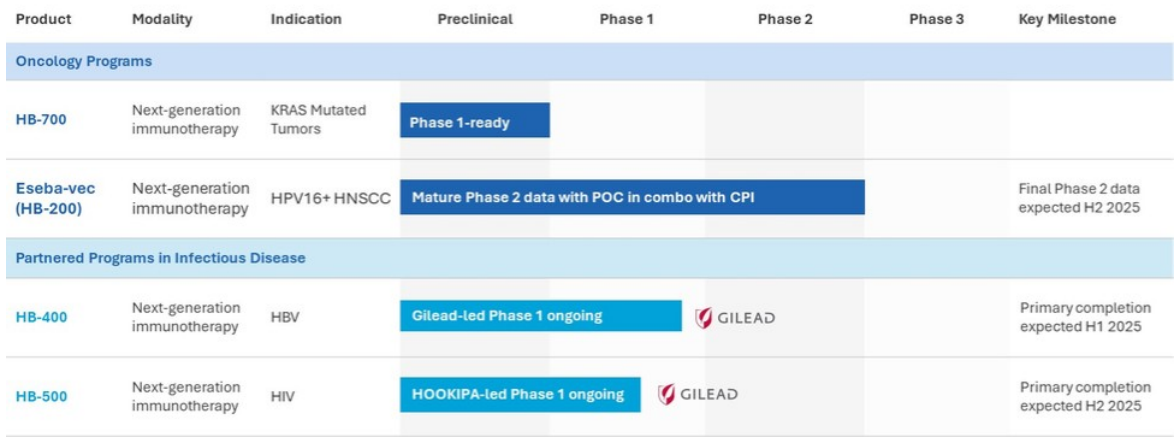
Financial Highlights:

- In April 2024, we received a $10.0 million milestone payment under our now-terminated HB-700 collaboration agreement with F. Hoffmann-La Roche Ltd. and Hoffmann-La Roche Inc. (collectively referred to as "Roche"). The success-based milestone payment was achieved in connection with our submission of an IND application for HB-700 for the treatment of KRAS mutated tumors.

- In July 2024, we received a $5.0 million milestone payment under our HB-500 collaboration agreement with Gilead. The success-based milestone payment reflected the achievement of the first person dosed in a Phase 1b clinical trial of HB-500.

Our Pipeline

We are leveraging our modular arenavirus platform to develop the following product candidates for multiple cancers and infectious diseases:



Background

The immune system is designed to protect the human body from infections and cancers. Infections can be generally defined as the proliferation of foreign microorganisms such as bacteria, viruses, and parasites in a patient's body resulting in clinical manifestations of disease. Cancer can be generally defined as the uncontrolled proliferation of native cells resulting in disease. In both cases, the immune system recognizes and destroys microorganisms, infected cells and cancers by targeting specific proteins, or antigens, as well as their immunogenic sub parts, which are referred to as epitopes.

The innate immune system is the body's first line of defense and enables a rapid, short-lived and nonspecific response. In contrast, the adaptive immune system utilizes highly specialized immune cells called lymphocytes that have been selected to recognize specific foreign antigens. Although it takes longer to mobilize, the adaptive immune system is capable of providing long term, more effective immunity against specific pathogens by being able to recall prior antigen exposure and mounting a very powerful and specific response.

In order for the adaptive immune system to function effectively, the innate immune system must first present disease specific antigens to a subset of lymphocytes called T cells in order to "instruct" the T cells as to which antigen they must recognize. The T cell population consists of CD8+ T cells, those that kill virus infected and cancer cells by releasing cytotoxic proteins, and CD4+ T cells that help or stimulate additional parts of the immune system such as B cells that produce antibodies. Antigen presentation to T cells is mediated by antigen-presenting cells ("APCs"), such as dendritic cells.

Our Technology Platform

Our proprietary platform is based on engineering arenaviruses to carry and deliver virus-specific or tumor-specific genes to APCs, such as dendritic cells, which are natural activators of CD8+ T cells. Arenaviruses have been used for decades to stimulate potent CD8+ T cells responses in preclinical research. Our co-founder, Rolf Zinkernagel, was awarded a Nobel Prize in Physiology or Medicine for his arenavirus-based work on how CD8+ T cells recognize virus infected cells.

Arenaviruses have several important advantages, which we believe represent the optimal characteristics for an antigen specific immunotherapy. Specifically, they:

- have the ability to induce a robust CD8+ T cell response by directly targeting and activating APCs, such as dendritic cells, which are the most efficient antigen presenting cells of the body;
- have the ability to induce a robust antibody response to disease specific target antigens;
- are not efficiently neutralized by vector specific antibodies, which may facilitate repeat administration;
- do not require an adjuvant to stimulate the immune system; and
- have been observed to be well tolerated in preclinical studies and clinical trials.

The arenavirus family is comprised of over 30 currently known species, many of which we believe have potential therapeutic applications. Our systemic and reproduceable approach features two technologies capable of delivering disease-specific antigens for the treatment of disease. Our non-replicating technology is designed to induce a strong immune response for therapeutic use against infectious disease. Our replicating technology is engineered to produce an even more powerful immune response, which we are currently exploring in therapeutic infectious diseases as well as oncology indications. In preclinical studies, our replicating technology was able to reprogram the immune system such that more than half of the body's CD8+ T cells focused on a specific cancer self-antigen target without observed serious adverse events. We observed the ability of HB-200 monotherapy to induce robust, high-quality and durable antigen-specific CD8+ T cell responses in our HB-200 clinical trial in human patients. We have designed our platform to

be modular in nature to allow substitution of antigens to target a broad range of infectious diseases and cancers. We have a robust intellectual property portfolio for our suite of arenaviruses with issued patents and patent applications related to our non-replicating technology as well as issued patents and patent applications for our replicating technology. We believe the breadth and depth of our intellectual property portfolio is a strategic asset that has the potential to provide us with a significant competitive advantage.

We believe that our arenavirus platform approach gives us a unique and powerful way to tap into the biology of the immune system and reprogram it by instructing APCs, such as dendritic cells, to express antigens that direct the immune system to the desired targets. Our product candidates are designed to deliver full length proteins to activate T cells and B cells to produce a robust immune response through natural means, avoiding the use of artificial ex vivo constructs such as CAR-T cells and related approaches that bypass the immune system's normal control mechanisms. Although these latter approaches have shown clinical activity, they have the potential to cause life threatening side effects, including cytokine release syndrome. In addition, we believe that our immunotherapy approach is simpler, more straightforward and cost effective to manufacture and administer than CAR-T cells or other patient derived cellular approaches.

Our non-replicating and replicating technologies utilize both a Lymphocytic Choriomeningitis Virus ("LCMV") and a Pichinde Virus ("PICV"), two species of arenaviruses, as a backbone of the product candidates we are developing. LCMV is principally carried and secreted by wild mice, with human infection being secondary to such exposure and uncommon. Approximately 2% to 5% of individuals in industrialized countries have circulating antibodies against LCMV, which indicates prior exposure in these individuals. Individuals infected with LCMV typically remain asymptomatic or may present with a nonspecific and self-resolving flu-like illness. PICV is principally carried and secreted by Colombian rice rats (oryzomys albigularis) and is a nonpathogenic virus that does not cause disease in humans.

Non-Replicating Technology Overview

Our proprietary non-replicating technology disables arenavirus replication by substituting one of its four structural genes with the gene for a desired antigen. The modified, non-replicating arenavirus is able to directly infect individual APCs, such as dendritic cells, and deliver proteins that serve as antigens to activate the immune system but is not able to replicate and infect additional cells in the body.

Advantages of Non-Replicating Technology

Based on the preclinical and clinical data that we have generated to date, we believe our non-replicating technology supports the benefits of our arenavirus platform approach. Specifically, in preclinical studies and clinical trials this technology has demonstrated that it is well tolerated and has the following additional benefits:

Robust CD8+ T cell Response as Well as Pathogen Neutralization Response. Our non-replicating technology is designed to induce a robust CD8+ T cell and pathogen neutralizing response to fight disease. We believe our technology results in an immuno-therapeutic approach with potential for greater potency than existing treatments.

Immunological Memory and Protection Against Challenge. Our non-replicating technology has shown the ability to trigger a robust and long term CD8+ T cell response of at least 12 months in humans. Furthermore, in various animal models non-replicating vector immunization resulted in protection against infectious challenge.

Reduced Neutralization of Vector Specific Antibodies. The reduced neutralization of vector specific antibodies facilitates repeat administration.

Replicating Technology Overview

Our proprietary replicating technology was designed to provide the beneficial properties of our non-replicating technology but to induce an even more robust immune response. Unlike naturally occurring arenaviruses which have two

genomic segments, our replicating constructs were engineered to have three segments to allow for the introduction of genomic space in which to insert additional target antigens of choice. As a result of the larger genome, the virus' ability to replicate is reduced (attenuated).

Advantages of our Replicating Technology

Based on our preclinical data, we believe our replicating technology shows all the benefits of the non-replicating technology and the following additional benefits:

Quantitatively: Even More Robust CD8+ T Cell Response. In animal studies, our replicating technology has shown to induce a CD8+ T cell response that directs more than 50% of a body's T cells, which is approximately ten times greater than the response induced by our non-replicating technology, to focus on a single target of choice. Robust CD8+ T cell response data have been demonstrated in our Phase 1/2 clinical study of HB-200. We believe our technology results in an immunotherapeutic approach with potential for greater potency than existing therapeutic treatments.

Qualitatively: Immunological Memory and Protection Against Challenge. Our replicating technology has shown the ability to trigger a long term CD8+ T cell response. Furthermore, in various animal models replicating immunization resulted in complete tumor remission after a single treatment and protection against a cancer re-challenge months after primary treatment.

The additional benefits noted above are attributable to our technology's ability to replicate. This allows it to infect not only APCs, such as dendritic cells, but also lymphoid stromal cells, which are immune support cells found in lymph nodes and the spleen. Infection of lymphoid stromal cells results in the release of a signaling protein which further drives the proliferation and differentiation of CD8+ T cells. This mechanism has the potential to generate ten fold more antigen specific CD8+ T cells as compared to viral delivery systems that are unable to trigger this pathway. Furthermore, we believe our replicating technologies may also be synergistic with other approved immuno-oncology agents and currently are conducting a clinical trial of our replicating technology in combination with checkpoint inhibitors.

In additional preclinical models, including a mouse melanoma model and a cancer testis self-antigen cancer model, we again demonstrated the ability of sequential administration of replicating PICV and LCMV constructs to direct up to 50% of a body's T cells to focus on a single target of choice.

Advantages of sequential administration of replicating PICV and replicating LCMV

Although arenaviruses typically do not induce significant vector neutralizing antibodies ("nAbs") in mice, anti-vector cytotoxic T lymphocyte ("CTL") responses were found to curtail immunogenicity when the same arenavirus vectors were administered for prime and boost injections. On repeat administration, vector backbone-specific responses often dominate over responses to the encoded transgene. This is especially true for tumor self-antigens. In contrast, administering an alternating sequence of two vectorized arenaviruses of distant genealogical relationship (such as a combination of Old World LCMV vectors and New World PICV vectors) impedes efficient boosting of vector backbone-directed CTL responses and focuses immune responses on the common transgene cargo. Applying this strategy in mice, alternating vector therapy using a LCMV vector (HB-201) and a PICV vector (HB-202) induced HPV16 E7/E6-specific CD8+ T cell responses that accounted for up to 50% of circulating CD8+ T cells, with similar levels observed when targeting tumor self-antigens such as P1A. Furthermore, and as observed in our other studies, mice with eliminated tumors demonstrated resistance to a tumor rechallenge. Consistent with these preclinical results, we observed significantly higher HPV-16 E7/E6 specific T cell responses induced by the HB-202/HB201 two vector therapy as compared to HB-201 single vector therapy in the H-200-001 clinical Phase 1/2 study.

Our Product Candidates

HB-700 for Targeting Mutated KRAS in Pancreatic, Colorectal and Lung Cancers

Targeting Shared Neoantigens

KRAS is a gene that acts as an on/off switch for cell growth as it is a key regulator of cell proliferation and survival. When there is a mutation, or error, in the gene, cells can grow out of control. KRAS is one of the most frequently mutated proto-oncogenes with respective mutations found in approximately 30% of all human cancers. KRAS mutations are most frequently found in pancreatic cancer (85% to 90%), colorectal cancer (approximately 40%) and lung cancer (approximately 32%). However, the spectrum of mutations mainly alter amino acid position 12 (G12D, G12V, G12R, and G12C) and position 13 (G13D), rendering these mutations an attractive target for immunotherapy. We designed our KRAS targeted therapy for patients suffering from pancreatic adenocarcinoma ("PAAD"), colorectal cancer ("CRC") and lung adenocarcinoma ("LUAD") and carrying one or more of the five most prevalent G12D, G12V, G12R, and G12C and position 13 G13D mutations. Our arenavirus technology enables us to integrate all five mutations into one single-vector, which allows our product to potentially be a single therapeutic targeting multiple large cancer indications.

An early proof of concept for targeting KRAS mutations via CD8+ T cells was reported by Tran et al in 2016. Tran targeted a KRAS mutation on position 12 (G12D) in a patient with metastatic CRC by tumor infiltrating lymphocyte ("TILs"); Tran demonstrated objective regression of all seven lung metastatic lesions from underlying CRC after the infusion of KRAS G12D-directed tumor infiltrating lymphocytes. More recently, small molecule inhibitors targeting mutated KRAS were developed and have shown promising results in clinical trials. However, those targeted therapies are limited to a single, specific KRAS mutation (KRAS G12C), which is frequently found in LUAD (approximately 50% of the late-stage cancers). However, KRAS G12C is underrepresented in PAAD and CRC when compared to other KRAS mutations such as G12D, G12V, G12R and G13D, which are much more frequently found (greater than 60% and greater than 90% in advanced CRC or PAAD, respectively).

Pancreatic cancer is considered one of the most lethal malignancies. Overall, approximately 500,000 new cases of pancreatic cancer per year are recorded globally. Incidence, prevalence and mortality for pancreatic cancer has increased by more than 50% during the last 25 years. Pancreatic cancer accounts for 1.8% of all cancers but causes 4.6% of all cancer deaths and pancreatic cancer deaths are expected to double by the year 2060. The high mortality rate can be explained in part as pancreatic cancer typically remains silent, not causing signs or symptoms for a long time. When patients become symptomatic, the cancer has usually reached an advanced and incurable stage. According to the American Cancer Society, the overall 5-year survival rate for pancreatic cancer is approximately 9%. 97% of patients with metastatic cancer (i.e., stage IV) are expected to die within 5 years after diagnosis. Additional effective therapies are therefore urgently needed.

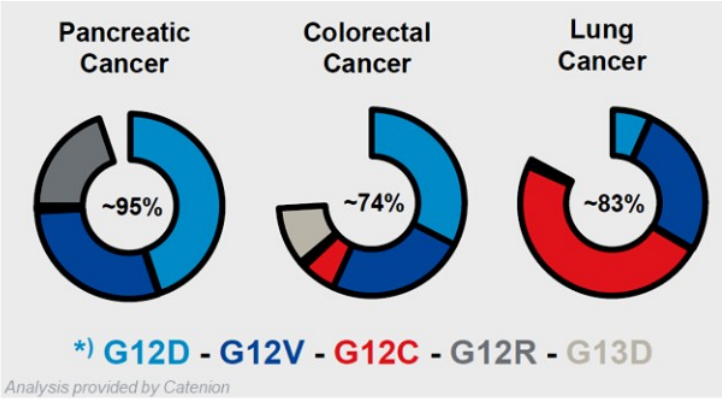
Colorectal cancer is the third most diagnosed malignancy worldwide and the second leading cause of cancer death. The incidence of colorectal cancer was estimated at 1.9 million cases in 2020, causing 0.9 million deaths worldwide. The incidence is higher in highly developed countries and it is increasing in middle- and low-income countries due to westernization. The death rate from colorectal cancer in 2018 was approximately 55%. The 5-year survival rate of patients with localized stage colorectal cancer is 90%. About 38% of patients are diagnosed at this early stage. If the cancer has spread to surrounding tissues or organs and/or the regional lymph nodes, the 5-year survival rate is 72%. If the cancer has metastasized to distant parts of the body, the 5-year survival rate is less than 15%. The advancements made in understanding colorectal cancer pathophysiology have led to increased treatment options, including endoscopic and surgical excision, radiotherapy, immunotherapy, palliative chemotherapy, targeted therapy, and extensive surgery and local ablative therapies for metastases. These treatments have prolonged overall survival and screening through endoscopy also greatly enhanced the early detection, leading to good prospects of a cure. Although the prospect for colorectal cancer therapy is generally good, the increasing number of cases and rising incidence among younger generations still poses a heavy financial burden and a public health challenge.

Lung cancer is the most common cause of cancer death worldwide, with an estimated 1.6 million deaths annually. Approximately 85% of lung cancer patients suffer from a subgroup called non-small cell lung cancer

("NSCLC"), of which LUAD and lung squamous cell carcinoma are the most common subtypes. LUAD represents approximately 40% of NSCLC and is the most common primary lung cancer diagnosed in the United States. Despite new treatments, the 5-year survival rate is only 12% to 15%.

Our Solution: HB-700 for KRAS Mutated Cancers

HB-700 is based on our replicating arenavirus platform and was designed for treatment of cancers encoding mutated KRAS, especially KRAS-mutated pancreatic, colorectal, and lung cancers. HB-700 is a replicating dual-vector therapy that has been engineered to encode fragments encoding multiple KRAS mutations found in these three cancers, specifically KRAS mutations G12D, G12V, G12R, G12C and G13D. By simultaneously targeting these five most common mutations, we believe HB-700 has the potential to benefit more patients than single mutation inhibitors. Potential coverage of KRAS mutations of important cancer indications by our product candidate HB-700 is illustrated in the following graph:



Similar to our other immuno-oncology candidate therapies, we can deliver HB-700 by simple infusion; HB-700 is designed to target APCs, such as dendritic cells, without the need for cellular isolation or *ex vivo* processing. Since induction of KRAS mutation-specific CD8+ T cells is the mode of action of this investigational therapy, and administration of alternating LCMV- and PICV-based vectors have been shown to induce unprecedented tumor antigen-specific CD8+ T cell levels in the context of our HB-200 program, we have designed HB-700 to potentially maximize HB-700-induced CD8+ T cell responses by using replicating vectors based on both LCMV and PICV in a sequential dosing regimen.

In October 2022, we announced a strategic collaboration and license agreement with Roche to develop HB-700 for KRAS-mutated cancers. Through the collaboration, we have conducted research and early clinical development for HB-700.

In February 2023, we achieved a $10.0 million milestone payment under our HB-700 collaboration agreement with Roche. The success-based milestone payment reflected the start of the HB-700 manufacturing process to support a Phase 1 clinical trial.

On January 25, 2024, we received written notice (the "Notice") from Roche of their decision to terminate the Research Collaboration and License Agreement ("Roche Collaboration Agreement") dated October 18, 2022. Roche's decision to terminate the Roche Collaboration Agreement was made according to Roche's right to terminate without cause, acknowledging that we had met all go-forward criteria under the Roche Collaboration Agreement.

Pursuant to the terms of the Collaboration Agreement and the Notice, the Collaboration Agreement was terminated on April 25, 2024. We received the final milestone payment associated with an IND submission to the FDA which occurred in April 2024. Effective April 25, 2024, we regained full control of the associated intellectual property

portfolio and have full collaboration and licensing rights for the HB-700 program. After the termination of the Roche Collaboration Agreement, and except as disclosed above, there is no other material relationship between the Company and Roche.

Nonclinical development and clinical trial material manufacturing for HB-700 has been completed. HB-700 is derisked by clinical proof of concept with platform asset eseba-vec (HB-200).

Eseba-vec (HB-200) Program for the Treatment of HPV16+ Cancers

The eseba-vec (also known as HB-200) program is our first program in oncology and the first clinical exploration of our replicating arenaviral vector-based technology. The eseba-vec program is composed of potential therapeutic agents for people with cancers caused by the Human Papillomavirus ("HPV"), specifically HPV16+.

All of our current product candidates are alternating, dual-vector arenaviral immunotherapies. Eseba-vec is a targeted dual vector arenaviral-based immunotherapy that uses alternating sequential injections of a LCMV vector and a PICV vector, both expressing the E7E6 fusion protein specific to HPV16+ cells. The two components of our eseba-vec program are referred to as HB-201 (LCMV) and HB-202 (PICV).

HPV-Positive Cancers

HPV is estimated to cause about 5% of cancers worldwide, including approximately 99% of cervical cancers, up to 60% of HNSCC, 70% of vaginal cancers and 88% of anal cancers. While most infections with HPV are cleared from the body with no lasting consequences, in some cases, HPV DNA becomes integrated into chromosomal DNA. When host cells take up this DNA, they express the HPV E6 and E7 proteins. The expression of these proteins can lead to alterations in cell cycle control, which in turn predisposes these cells to become cancerous.

HPV infection is linked to several cancer types, including HNSCC which is now the 8th most common cancer affecting men in the United States (Siegel et al. 2023). The high incidence rate of HNSCC is largely due to a rising epidemic of oropharyngeal squamous cell carcinoma ("OPSCC") associated with HPV (Price & Cohen 2012). The median overall survival ("OS") for R/M HNSCC remains less than 15 months despite modern chemotherapy, targeted agents, and recent immunotherapy. The high-risk genotype HPV 16 accounts for 88% of HPV+ OPSCC cases in the United States (Chaturvedi et al. 2011) and for more than 50% of HPV+ cases found in other head and neck anatomical locations (Abogunrin et al. 2014; Vokes et al. 2015). In 2023, an estimated 54,540 new cases of head and neck cancers were diagnosed in the United States alone, with anticipated deaths estimated at 11,580 (Siegel et al. 2023).

While there is no T cell therapy approved for HNSCC, retrospective analyses have shown that patients' outcomes are improved for those with high levels of CD8+ T cells in tumors as compared to patients with low levels. In many cases, the survival rate of patients with higher levels is more than double that of patients with lower levels of CD8+ T cells.

Our Solution: Eseba-vec Program

Eseba-vec alternates the administration of both HB-201 (LCMV) and HB-202 (PICV) attenuated viral vectors, which on their own are replicating-based therapeutics expressing a non-oncogenic, but highly antigenic, E7E6 fusion protein from HPV16. We have observed strong immunogenicity and robust antitumor activity in mouse models for LCMV alone as well as for the sequential administration of LCMV and PICV.

Relevance of E6 and E7 as Tumor Antigens

Integration of HPV viral sequences into the genome of a cell can result in the introduction of E6 and E7 oncoproteins. They are present in cells that become cancerous and play a critical role in interfering with cellular processes and interrupting normal tumor suppressor functions.

Profiling of immune cells isolated from patients with HPV16+ tumors has identified E6 and E7 specific T cells, indicating that the E6 and E7 proteins are immunogenic, meaning that they trigger antigen specific CD8+ T cell responses. Because both E6 and E7 are highly expressed in tumor cells and are absent in normal cells, they are ideal candidates for use as targets of tumor directed active immunization.

Eseba-vec Clinical Trial

In March 2024 EMA granted PRIME designation for eseba-vec in combination with pembrolizumab for the treatment of patients with HPV16-positive recurrent/metastatic PD-L1 CPS ≥ 20 oropharyngeal squamous cell carcinoma in the first line setting. Eseba-vec was being evaluated in a Phase 1/2 clinical trial for the treatment of HPV16+ cancers until November, 2024. The Phase 1/2 trial explored, in multiple arms, several dose levels and administration regimens across multiple HPV16+ cancer indications. The Company has published interim data readouts at key scientific conferences dating back to 2021. Interim data readouts from 2021 to 2022 have shaped further the study design and protocol.

Most recently, there has been data published on two key components of the trial:

- Phase 1 evaluation of HB-200 as a monotherapy in second or later-line R/M setting of HPV16+ cancers; and

- Phase 2 evaluation of HB-200 in combination with pembrolizumab in the first line R/M setting of HPV16+ OPSCC.

In an effort to rebalance the Company's cost structure, we decided to pause clinical development in the eseba-vec program, including an early termination of the Phase 1/2 clinical trial. The early termination was not due to lack of efficacy or adverse safety profiles. Enrollment of the Phase 1/2 trial was completed in October 2024, and we expect final Phase 2 data in the second half of 2025. The planned pivotal randomized Phase 2/3 trial was not started and did not enroll patients. We will continue to seek partnering opportunities for the eseba-vec program.

Clinical Results: HB-200 Monotherapy in Second or Later-Line Setting

In November 2023, we presented updated Phase 1 monotherapy data for HB-200 in the second or later-line R/M setting of HPV16+ cancer at the Society for Immunotherapy of Cancer annual congress (Abstract #679).

As of March 31, 2023, in the Phase 1 portion of the study, 93 patients with any HPV16+ cancer (72 HNSCC and 21 non-HNSCC) were enrolled to receive HB-200 therapy (LCMV 1-vector therapy or PICV/LCMV alternating 2-vector therapy). Patients were heavily pretreated with a median of three prior anticancer systemic therapies (range 1-11). The recommended phase 2 dose ("RP2D") and regimen for HB-200 monotherapy was previously determined to be alternating 2-vector therapy IV at dose level 3 (PICV 1×107 RCV FFU, LCMV 5×107 RCV FFU). The reported efficacy and clinical biomarker data focused on the 41 patients with HPV16+ HNSCC treated with HB-200 alternating 2-vector therapy, especially 29 patients with HPV16+ HNSCC treated with HB-200 alternating 2-vector therapy at the RP2D (DL3) or one dose lower than the RP2D (RP2D-1, DL2).

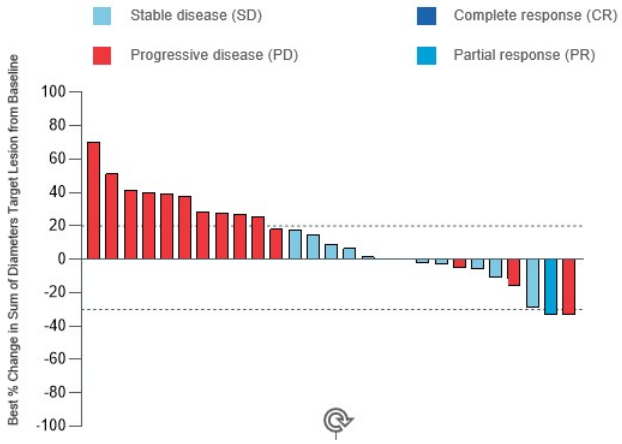
Safety and Tolerability

Across all patients treated, the safety profile with HB-200 monotherapy was generally favorable. The majority of reported adverse events ("AEs") were mild to moderate (Grade 1 or Grade 2) with the most common AEs being flu-like symptoms. Across the 93 patients treated in Phase 1, 11.8% of patients reported grade ≥3 treatment related adverse events ("TRAEs"), 2.2% of patients had treatment discontinuation due to TRAEs, and no treatment-related deaths occurred, as shown below. Safety data were generally comparable to checkpoint inhibitor monotherapy in the later-line HNSCC setting.

Clinical Activity

The intent to treat population ("ITT") of 29 patients with HPV16+ HNSCC were treated at the RP2D and RP2D-1 of HB-200 alternating 2-vector monotherapy, with 27 patients evaluable with ≥1 tumor efficacy scan. Importantly, HB-200 demonstrated clinical activity and tumor shrinkage as a monotherapy in a very difficult to treat and immune checkpoint resistant patient population that we believe has the potential to be best-in-class. Among the evaluable patient population, the disease control rate was 44% (1 confirmed partial response "PR" and 11 stable disease "SD"), and 33% of patients had tumor shrinkage in the target lesions (Figure 1). Overall survival data is still maturing with a median OS of ~13 months and a median follow-up time of 6.3 months for the 29 patients as of August 7, 2023. Two patients (patient #1 and #2) had paired biopsies available. High levels of circulating E6-E7–specific CD8+ T cells and increased tumor infiltration of CD8+ lymphocytes were seen in these 2 patients, who also demonstrated clinical benefit / disease control (Figures 1-4).

Figure 1. Best percent change in sum of target lesions and overall response per RECIST v1.1 for patients with HNSCC treated at the RP2D or RP2D-1 of HB-202/HB-201 alternating 2-vector monotherapy



Biomarker and Translational Results

Augmentation of tumor-specific T cells was observed in 100% of patients tested across all 4 dose levels (N = 35 tested out of 41 HNSCC patients receiving HB-200 alternating 2-vector therapy) (Figure 2B):

- Up to 48% of all CD8+ T cells in blood were specific for the tumor antigen (i.e., HPV16 E6 & E7), with a median specificity of 2.0% (Figure 2A).

- Figure 2C illustrates one representative patient with HNSCC (Patient #1) from DL3 cohort with tumor-specific CD8+ T cell responses measured by ICS, E6-E7–specific IFN-γ+ CD8+ T cells increasing from 0% at baseline to 10% after 2 doses of HB-200.

Figure 2. High levels of circulating E6-E7–specific CD8+ T-cells in HNSCC patients treated with HB-202/HB-201 alternating 2-vector therapy at all DLs tested

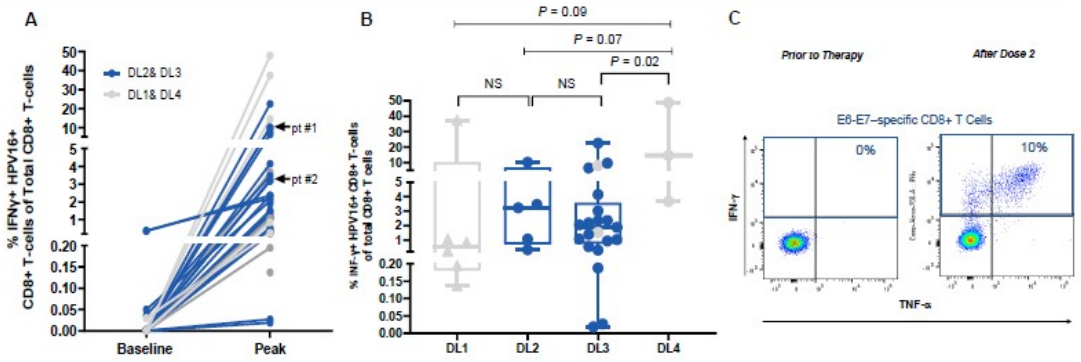


Figure 2. HPV16 E6-E7–specific T cell responses in HNSCC patients treated with HB-200 alternating 2-vector therapy.
A. Baseline and peak IFN-γ+ HPV16 E6-E7 T cell response measured by ICS. Peak responses were typically observed post 2 doses of HB-200 (N = 35/41 HNSCC patients receiving HB-200 alternating 2-vector therapy across DL1-4).
B. Box plots are representing IFN-γ+ HPV16 E6-E7 T cell response measured by ICS per DL (N = 35/41). Box and whiskers represent minimum, maximum and median. DL1 = PICV 1×106, LCMV 5×106 RCV FFU; DL2 (RP2D-1) = PICV 1×107, LCMV 5×106 RCV FFU; DL3 (RP2D) = PICV 1×107, LCMV 5×107 RCV FFU; DL4 = PICV 1×108, LCMV 5×106 RCV FFU. Patients from DL2 & DL3 with available PBMC samples are highlighted (N = 26/29)
C. Representative pseudo-color plots (Patient #1) with the frequencies of double-positive IFN-γ+ TNF-α+ cells gated on CD8+ T cells at baseline and post 2 doses of HB-200.

Importantly, HB-200 showcased durability and functionality of tumor-specific CD8+ T cells (N = 35/41 HNSCC patients receiving alternating 2-vector therapy) and infiltration of CD8+ T cells in tumors upon therapy in patients with paired biopsies (N = 13 tested out of 93 patients in Phase 1) (Figure 3):

- Results showed rapid induction of tumor-specific T cells, sustained for more than 8 months and increasing in polyfunctionality during treatment (Figure 3A).
- Patients with increased CD8+ T cell influx in tumors during HB-200 treatment tended to show clinical benefit (stable disease vs. progressive disease) (Figure 3B).

Figure 3. Rapid induction of functional and long-lasting CD8+ T cell responses & association of tumor-infiltrating CD8+ T cells with best overall response

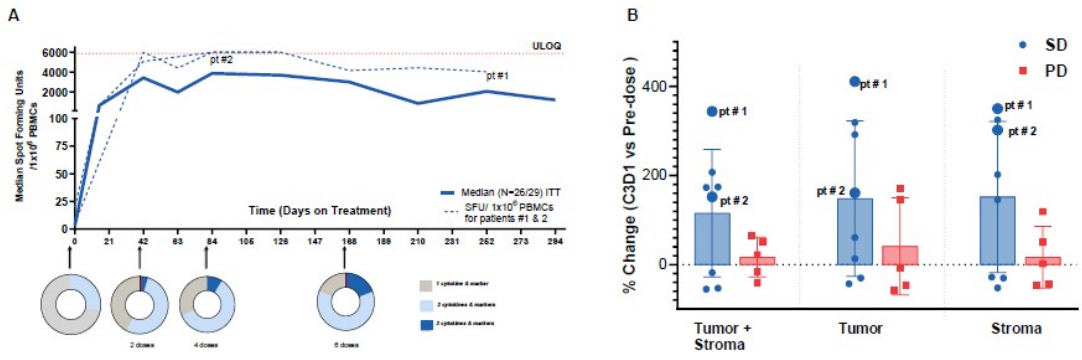


Figure 3.
A. Median of circulating E6-E7–specific T cells over time measured by ELISpot (solid line shows median SFU/1 x 106 PBMCs and dashed lines indicate Patient #1 and #2 in the case report in Figure 4). Pie charts below graph show percentage of tumor-specific T cells expressing the indicated number of cytokines/markers (IFN-γ, TNF-a, CD107a, IL-2) measured by ICS in available PBMCs from HNSCC patients undergoing HB-202/HB-201 alternating 2-vector therapy at DL2 & DL3 at the corresponding timepoints (N = 26/29).
B. Percent change in tumor-infiltrating CD8+ T cells pre and post HB-200 treatment in patients with disease control (blue) and progressive disease (red) measured by IF IHC. Mean ± SD. Data shown are all patients with available paired biopsies, which includes patients from all groups explored in the study (N = 13 out of 93 total patients enrolled in Phase 1).

Paired tumor biopsies of two HNSCC patients treated with HB-200 2-vector therapy at DL2 or DL3 were available for analysis (pt #1 & pt #2 Figure 3B):

- Tumor-specific T cell responses were induced rapidly and remained at high levels throughout therapy in these 2 patients (Figure 3A), both of whom also exhibited clinical benefit (stable disease / disease control) (Figure 4A).
- In these patients, HB-200 therapy induced high levels of tumor-specific CD8+ T cells in the circulation (Figure 2A and 3A), as well as elevated CD8+ T cell numbers in tumors (Figure 3B & 4C).
- The patients with disease control exhibited only small increases or modest reductions in ctDNA levels (Figure 4B), with respective best percent change in target lesions -29% (pt #1) and -11% (pt #2) (Figure 1).

Figure 4. Association of T cell response with best overall response

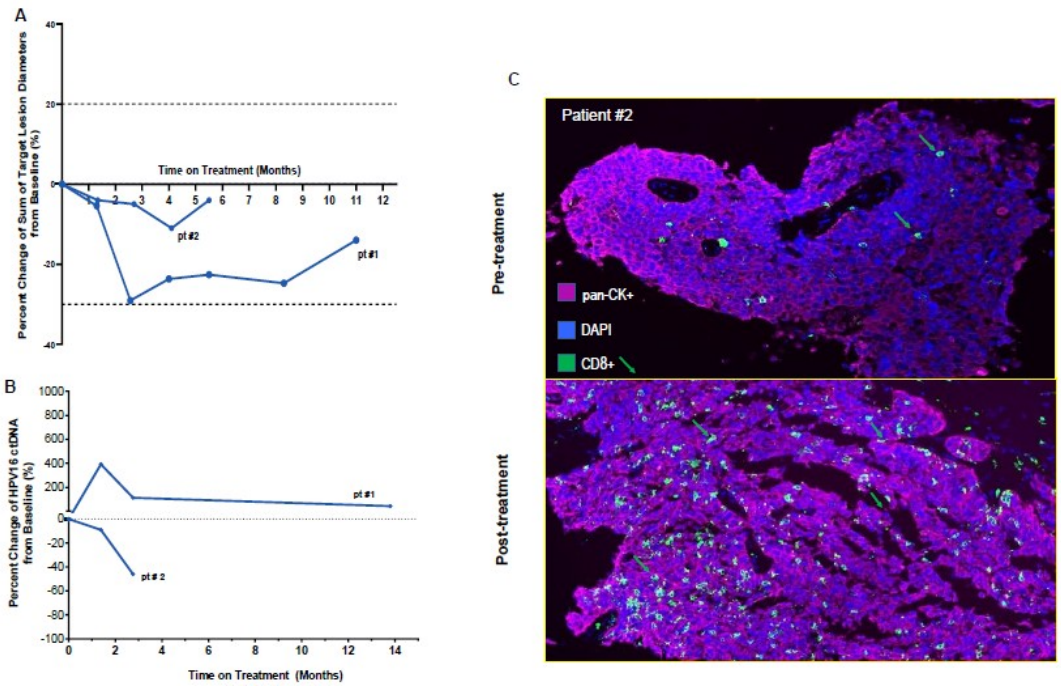


Figure 4. Tumor response, HPV16 ctDNA, and TILs in 2 patients with stable disease who received HB-200 alternating 2-vector therapy.
A. Percent change in sum of target lesion diameters from baseline over time in Patient #1 and #2.

B. Percent change in circulating HPV16 DNA from baseline in Patient #1 and #2.
C. TILs in tumor tissue from Patient #2 with best overall response of stable disease. Tissues were analyzed by Multiplex IF IHC Vectra® Polaris™ and HALO® Quantification to determine expression of immune markers (CD8, DAPI, and PanCK).

Clinical Results: Eseba-vec in Combination with Pembrolizumab in the First Line Setting

In November 2024, we presented updated Phase 2 data for eseba-vec in combination with pembrolizumab in the first line setting at the SITC annual congress (Late Breaking Abstract Number: 1480). As of September 30, 2024, 66 participants were treated with eseba-vec in combination with pembrolizumab (55/66 treated at the selected Phase 3 dose and 11/66 at a higher dose of eseba-vec). 30/66 (45.5%) participants remained on treatment, 15/66 (22.7%) were in long-term follow-up, and 21/66 (31.8%) discontinued the study. The majority of participants had metastatic disease (~70-80%), with the oropharynx as the primary cancer site (>90%). ~45% had a smoking history. 34/66 (51.5%) had a tumor with PD-L1 CPS ≥20. Baseline characteristics were similar across subpopulations by PD-L1 CPS status.

Baseline Characteristics (All Treated Participants)	**PD-L1 CPS ≥1 (N = 66)**	**PD-L1 CPS ≥20 (N = 34)**
Age, years, median (range)	64 (38–76)	68 (38–76)
Gender, male, n (%)	62 (93.9)	30 (88.2)
Race, white, n (%)	59 (89.4)	31 (91.2)
Smoking history, n (%)	30 (45.5)	15 (44.1)
ECOG PS, n (%)		
0	48 (72.7)	23 (67.6)
1	18 (27.3)	11 (32.4)
Metastatic, n (%)	51 (77.3)	24 (70.6)
Locally recurrent only, n (%)	15 (22.7)	10 (29.4)
Primary site, n (%)		
Oropharynx	64 (97.0)	32 (94.1)
Hypopharynx	1 (1.5)	1 (2.9)
Unknown	1 (1.5)	1 (2.9)
Prior definitive radiation ± chemotherapy, n (%)		
Prior radiation treatment, n (%)	62 (93.9)	31 (91.2)
Prior platinum use, n (%)	50 (75.8)	24 (70.6)
Prior CPI use, n (%)	3 (4.5)	1 (2.9)

Safety and Tolerability

Eseba-vec in combination with pembrolizumab demonstrated a favorable safety profile with manageable toxicity. The majority of TRAEs were mild to moderate in severity, with only 7.6% serious events. Very few participants (4.5%) had TRAEs leading to discontinuation. One TRAE led to death in a participant who also received concomitant chemotherapy (carboplatin and 5-FU) in error in addition to eseba-vec and pembrolizumab (documented as critical protocol deviation). The most common TRAEs were grade 1-2 flu-like disease/symptoms, which were mostly short-lived, transient, and observed within a few days after the first administration.

All Participants (N = 66)	Treatment-Emergent AEs, n (%)	Treatment-Related AEs, n (%)
Any event	63 (95.5)	60 (90.9)
Grade ≥3	30 (45.5)	14 (21.2)
Serious	15 (22.7)	5 (7.6)
Leading to discontinuation of eseba-vec	4 (6.1)	3 (4.5)[a]
Leading to discontinuation of pembrolizumab	5 (7.6)	4 (6.1)[b]
Deaths	3 (4.5)	1 (1.5)[c]

a. One participant with grade 3 checkpoint inhibitor pneumonitis (related to pembrolizumab), one participant with grade 1 cytopenia (related to eseba-vec and pembrolizumab) along with unrelated events of grade 3 transaminitis and grade 2 abdominal pain, one participant with grade 2 pneumonitis (related to pembrolizumab).
b. Above-mentioned AEs and a grade 3 event of worsening pruritus (related to pembrolizumab) leading to discontinuation of pembrolizumab but continuation of eseba-vec.
c. Grade 5 hepatitis fulminant was reported as related to HB-202 and pembrolizumab per investigator assessment, where the participant also received chemotherapy (carboplatin and 5-FU) in error.

Table: Safety summary

Treatment-Related AE, Preferred Term (N = 66)	All Grades, n (%)	Grade ≥3, n (%)
Fatigue	28 (42.4)	0 (0.0)
Influenza-like illness	23 (34.8)	1 (1.5)
Nausea	20 (30.3)	0 (0.0)
Pyrexia	20 (30.3)	0 (0.0)
Chills	17 (25.8)	2 (3.0)
Headache	17 (25.8)	1 (1.5)
Myalgia	11 (16.7)	0 (0.0)
Vomiting	10 (15.2)	0 (0.0)
Platelet count decreased	8 (12.1)	0 (0.0)
Arthralgia	8 (12.1)	0 (0.0)
Pruritus	7 (10.6)	1 (1.5)

Table: Most common treatment-related adverse events (incidence ≥10%)

Clinical Activity

Among 55/66 participants with a minimum of 18 weeks of treatment from first dose until the data cutoff date, 27/55 had a PD-L1 CPS ≥20. 25/27 participants had at least one post-baseline tumor scan (evaluable) and were assessed for best overall response per RECIST v1.1. Two participants were excluded; 1 discontinued due to COVID-19-related death and 1 withdrew consent prior to the first efficacy scan.

The preliminary data showed a 52% confirmed objective response rate ("ORR") and disease control rate ("DCR") of 80% across 25 evaluable patients with PD-L1 CPS ≥20. Best overall response for the evaluable population included four patients with a confirmed complete response, eight patients with confirmed partial responses and one patient with an unconfirmed response. The preliminary data showed sustained disease control in the majority of patients with 66.7% of confirmed responses ongoing at data cutoff date of September 30, 2024. Preliminary progression-free survival ("PFS") and overall survival ("OS") are encouraging but the data are still maturing. As of the data cutoff date, the median PFS is 16.3 months (5.4 – NR). OS follow-up time is 11.1 months, with 7/27 deaths and a 12-month OS rate of 83%.

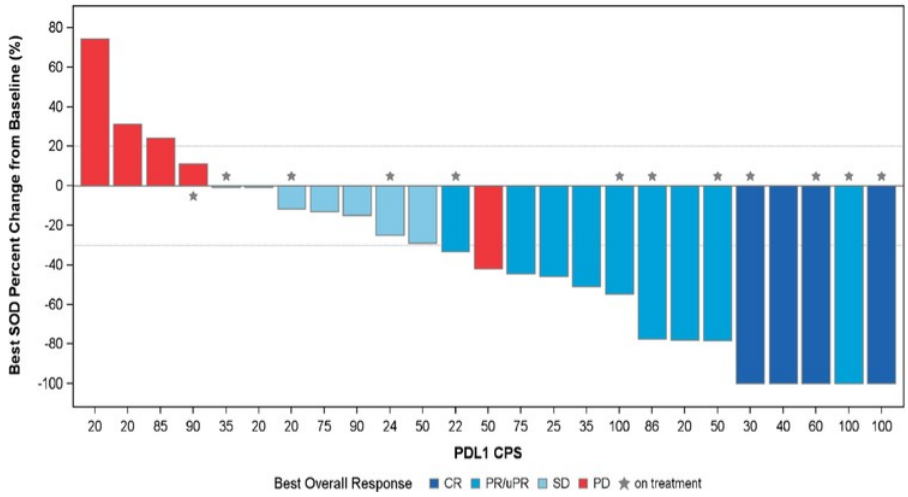


Figure: Best percent change in sum of target lesions from baseline and best overall response per RECIST v1.1 in evaluable participants with PD-L1 CPS ≥20 (N=25)

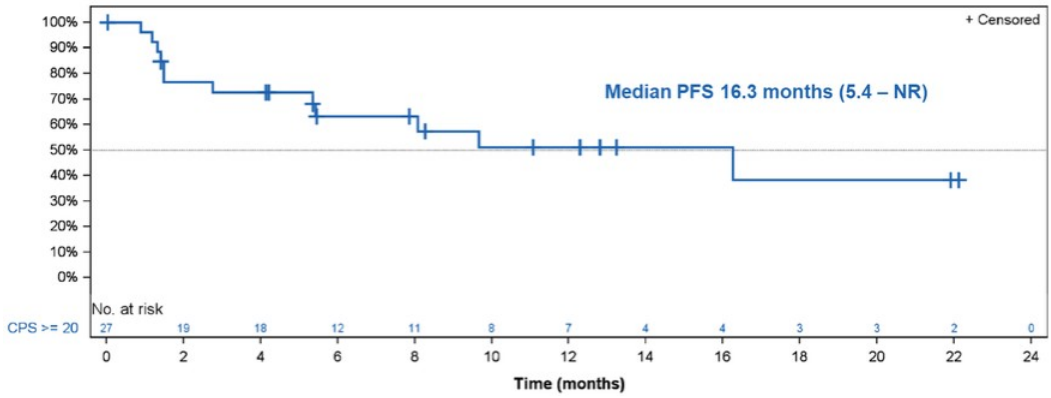


Figure: Progression-free survival in participants with PD-L1 CPS ≥20 (N=27)

Biomarker and Translational Results

Importantly, the data showed significant activation of antigen-specific CD8+ T cells, the body's primary driver of tumor killing activity. Out of 18 patients with available peripheral blood mononuclear cells ("PMBC") samples, all

patients showed an increase of tumor antigen-specific circulating HPV16+ CD8+ T cells. HPV-16 E7E6 specific T cell responses were strongly elevated already two weeks after the first administration of the therapy (mean: 16 SFU/10^6 PBMCs prior to therapy versus 657 SFU/106 PBMCs two weeks after the first administration) and remained at high levels throughout the therapy. Mean HPV-16 E7E6 specific T cell response post vector administration varied between 657 and 4737 SFU/10^6 PBMCs (for timepoints with >1 patient analyzed).

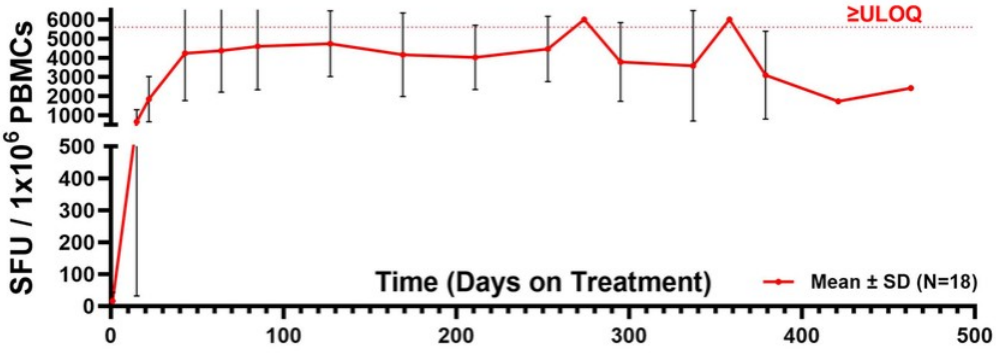


Figure: Circulating HPV16-specific CD8+ T cell response in participants with PD-L1 CPS ≥20 (N=18). Line graph represents the mean SFU/10^6 PBMCs of E7E6-specific T cells over time. PBMCs were stimulated for 24 hours with overlapping HPV16 E7E6 peptides and analyzed by IFN-γ ELISpot assay.

Combining eseba-vec with pembrolizumab resulted in an approximately 2-fold increase in response rates over historical data reported for pembrolizumab monotherapy, and suggests a meaningful improvement in participants with 1L HPV16+ PD-L1 CPS ≥20 R/M HNSCC. Clinical activity is supported by a rapid, robust, and durable tumor antigen specific T-cell response. The rate, depth, and durability of responses were accompanied by encouraging preliminary PFS and OS, suggesting a meaningful contribution of eseba-vec to pembrolizumab in 1L treatment. The differentiated benefit observed is supported by biological plausibility: high PD-L1 expressing tumors are more permissive of infiltration by HPV-specific T cells. The combination showed a manageable safety profile and no significant toxicities beyond those observed with either eseba-vec or pembrolizumab alone. The Phase 3 eseba-vec dose in combination with pembrolizumab has been determined; however, we have paused further development of the eseba-vec program and the planned pivotal randomized Phase 2/3 trial was not started and did not enroll patients. We will continue to seek partnering opportunities for the eseba-vec program.

HB-300 Program for Prostate Cancer

Targeting Self Antigens

Our viral vectors may be appropriate for any antigen where a T cell response may be therapeutically meaningful. We have shown in multiple preclinical models that replicating product candidates are active in generating robust immune responses to tumor self antigens and that this response results in decreased tumor growth and an increase in survival rates.

Prostate cancer provides a unique treatment opportunity for immunotherapy because prostate cancer cells express a number of tumor specific antigens that serve as potential targets. HB-300 is an alternating, dual-vector replicating arenaviral immunotherapy which uses LCMV and PICV as arenaviral backbones, with each expressing two well-defined self antigens of prostate cancer, prostatic acid phosphatase (“PAP”) and prostate specific antigen (“PSA”), designated HB-301 and HB-302, respectively.

In February 2023, we opened a first-in-human Phase 1/2, multinational, multicenter, open-label study of HB-302/HB-301 alternating dual-vector therapy in participants with mCRPC (NCT05553639). Derived from clinical and

translational data of the HB-200 program, HB-302/HB-301, the alternating dual-vector therapy was administered intravenously every three weeks (Q3W) for the first five doses and every 6 weeks (Q6W) from the fifth dose and onward. HB-302 was administered first, followed three or six weeks later by HB-301.

As of December 31, 2023, we had completed enrollment of the Phase 1 dose escalation cohorts. The Study Safety Committee deemed that HB-300 was generally safe and well-tolerated in both dose escalation cohorts. Initial analysis of target antigen-specific T cell responses – using direct ELISPOT without pre-expansion of T cells – in ten patients between dose level 1 (N=5) and dose level 2 (N=5) indicated a 15- to 26-fold increase of target antigen specific T cells in 30% of patients (3/10).

In March 2024, in line with our previously announced strategy to prioritize the development of eseba-vec, we terminated the Phase 1/2 study of HB-300 and utilized the associated capital and resources for the advancement of our eseba-vec program.

Infectious Disease Pipeline Highlights

Our platform is also uniquely positioned to provide value from the therapeutic use against infectious diseases. We plan to continue developing infectious disease therapies in partnership with other companies.

Our collaboration with Gilead to develop functional cures for chronic HBV and HIV infections has become our main driver of our infectious disease pipeline progress. We entered into our collaboration and licensing agreement (the "Gilead Collaboration Agreement") with Gilead in June 2018. To date, we have received $51.2 million in upfront and milestone payments and $43.0 million of cost reimbursements from Gilead. Both programs have completed preclinical research and are currently in a Phase 1 clinical trial.

In July 2024, we announced the achievement of a $5.0 million milestone payment for the first person dosed in a Phase 1b clinical trial of HB-500, an investigational therapeutic vaccine for the treatment of HIV. The Phase 1b clinical trial will evaluate the safety and tolerability, reactogenicity, and immunogenicity to repeated doses of HB-500 in participants with HIV on suppressive antiretroviral treatment. The Phase 1b design comprises two dose escalation cohorts that will be randomized to receive HB-500 or placebo. The first participant was dosed on July 1, 2024, enrollment of 30 participants was completed in January 2025, and primary completion is expected in the second half of 2025. We are responsible for advancing the HIV program through the completion of a Phase 1b clinical trial. Gilead retains an exclusive right (the "Option") to take back the rights for the HIV program, including further research, development and commercialization. If Gilead elects to exercise the Option, we will be entitled to a $10.0 million program completion fee.

In January 2023, we announced the achievement of a $5.0 million milestone payment for the completion and delivery of a regulatory support package for Gilead's Phase 1 clinical trial of the HBV therapeutic vaccine developed under the Gilead Collaboration Agreement. The first participant in the Phase 1 clinical trial being conducted by Gilead was dosed in 2023, enrollment of 83 participants has been completed and primary completion of the trial is expected in the first half of 2025. The preclinical data on the HBV vaccine as a potential component for a curative regimen were presented at the American Association for the Study of Liver Diseases ("AASLD") in November 2022 and was selected by AASLD as a "Best of the Liver Meeting" highlight. These data were published in The Journal of Infectious Disease in August of 2023. Gilead is solely responsible for further development and commercialization of the HBV product candidate.

In February 2022, we signed an amended and restated collaboration agreement (the "Restated Gilead Collaboration Agreement") which revised the terms only for the HIV program, whereby we took on development responsibilities for the HIV program through a Phase 1b clinical trial and Gilead provides funding through a combination of an initiation payment of $15.0 million, a milestone payment of $5.0 million and equity contributions of up to $35.0 million. In November 2023, we announced FDA clearance of our IND application for the treatment of HIV. The first participant with HIV in a Phase 1b trial was dosed on July 1, 2024, enrollment has been completed, and primary completion is expected in the second half of 2025. Additionally, Nature Partner Journals published peer-reviewed preclinical data for the program. Data show that HB-500 was well tolerated and generated robust, high-quality and

durable immune responses (antigen-specific T cells and antibodies) in non-human primates, and arenaviral therapeutic vaccination significantly reduced SIV viral load and clinical illness in those animals compared to placebo.

In December 2023, we received approximately $26.25 million from Gilead's purchases of our common stock under the Stock Purchase Agreement with Gilead entered into in connection with the Restated Gilead Collaboration Agreement. We have the right, subject to certain terms and conditions, to sell an additional approximately $8.75 million of common stock to Gilead as pro-rata participation in potential future equity raises.

Infectious Disease: In Collaboration with Gilead

HB-400 for the Treatment of HBV

HB-400 Preclinical Data Package for Hepatitis B Virus Cure Program

In collaboration with Gilead Sciences, Inc. a HBV-specific immunotherapy consisting of 2 non-replicating arenavirus vectors derived from PICV (HB-402 or GS-2829) and 2 non-replicating arenavirus vectors derived from LCMV (HB-401 or GS-6779) was developed. The immunotherapy is intended to utilize the patient`s own immune system to induce a strong cellular and antibody response against HBV.

Arenavirus vectors were constructed to encode three different HBV antigens: HBV Core, Pol (an inactivated version of the HBV polymerase) and HBV surface antigen ("HBsAg"). Alternating immunizations with GS-2829 and GS-6779 induced high magnitude HBV T cell responses, with PICV vectors driving high anti-HBs antibody titers. Dose schedule optimization in macaques achieved strong polyfunctional CD8+ T cell responses with balanced specificity for core, HBsAg, and polymerase and high titer anti-HBs antibodies. In an HBV efficacy model (AAV-HBV mice), GS-2829 and GS-6779 were efficacious in animals with low pre-treatment serum HBsAg. Based on these results, GS-2829 and GS-6779 could become central components of cure regimens.

HB-400 Clinical Development

The results of the preclinical studies, and the association of strong CD8+ T cell responses and anti-HBsAg antibodies with immune clearance and long-term control of chronic hepatitis B virus ("CHBV") (Boni 2012, Hoogeveen 2022, Yip 2018), provide a strong rationale for clinical development of HB-400.

A Phase 1a/1b study (GS-US-642-5670 / NCT05770895) was designed to evaluate the safety and immunogenicity of HB-402 and HB-401 healthy volunteers and participants with CHB. This study is led by Gilead, has completed enrollment with 83 participants and primary completion of the trial is expected in the first half of 2025.

HB-500 for the Treatment of HIV

HB-500 Preclinical Data Package for HIV Cure Program

In collaboration with Gilead a preclinical study in a NHP model of HIV infection was conducted. The model uses Simian immunodeficiency virus ("SIV") as a surrogate virus for HIV. The study showed that immunization of naïve rhesus macaques with arenavirus-derived vaccine vectors encoding Simian immunodeficiency virus (SIVSME543 Gag, Env, and Pol) immunogens was safe, immunogenic, and efficacious. Immunization induced robust SIV-specific CD8+ and CD4+ T cell responses with expanded cellular breadth, polyfunctionality, and Env-binding antibodies with antibody-dependent cellular cytotoxicity. Vaccinated animals had significant reductions in median SIV viral load (1.45-log10 copies/mL) after SIVMAC251 challenge compared with placebo. Peak viral control correlated with the breadth of Gag-specific T cells and tier 1 neutralizing antibodies. These results support clinical investigation of arenavirus-based vectors as a central component of therapeutic vaccination for HIV cure.

HB-500 Clinical Development

In 2024 a Phase 1b clinical trial (NCT06430905) evaluating the safety and tolerability, reactogenicity, and immunogenicity to repeated doses of HB-500 in participants with HIV on suppressive antiretroviral treatment was started. The Phase 1b design comprises two dose escalation cohorts that will be randomized to receive HB-500 or placebo. The first participant was dosed on July 1, 2024, full enrollment of 30 participants was completed in January 2025 and primary completion of the trial is expected in the second half of 2025. Under the collaboration agreement with Gilead, we received a $5.0 million milestone payment associated with dosing of the first subject in this trial in July 2024.

Intellectual Property

Our success depends, in part, on our ability to obtain and maintain intellectual property protection for our product candidates, technology and knowhow, to defend and enforce our intellectual property rights, in particular, our patent rights, to preserve the confidentiality of our knowhow and trade secrets, and to operate without infringing the proprietary rights of others. We seek to protect our product candidates and technologies by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. We also rely on trade secrets, knowhow, continuing technological innovation and in-licensing of third-party intellectual property to develop and maintain our proprietary position. We, or our collaborators and licensors, file patent applications directed to our key product candidates in an effort to establish intellectual property positions to protect our product candidates as well as uses of our product candidates for the prevention and/or treatment of diseases.

As of January 13, 2025, we are the owner, co-owner or exclusive licensee to 13 issued U.S. patents and 12 pending U.S. patent applications, one pending international Patent Cooperation Treaty ("PCT") application, two pending U.S. provisional patent applications, and approximately 210 issued foreign patents and approximately 90 foreign patent applications. These patents and patent applications are related to our technologies concerned with the arenavirus-based immunization systems, non-replicating and replicating, our product candidates and various development programs, which are directed to the use of these immunization systems for the treatment and/or prevention of various infectious diseases or cancer, and certain clinical uses of our current or future product candidates in oncology. The issued patents and pending patent applications contain claims directed to various aspects of our work, including compositions of matter, methods of treatment and prevention, methods of producing certain compositions, and use of our product candidates in combination with certain other therapeutics.

Non-Replicating Technology Portfolio

Our patent portfolio related to our non-replicating technology includes a patent family exclusively licensed to us from the University of Zurich. This patent family includes five patents granted in the United States and patents granted in Europe (validated in Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom), Canada, China, India, Hong Kong, Macao and Japan. This patent family also includes pending applications in the United States, Europe, and Hong Kong. The granted patents and pending applications related to our non-replicating technology are expected to expire no earlier than 2028, not giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. Our non-replicating technology is being employed or may be employed in one or more of the product candidates or programs described herein.

Replicating Technology Portfolio

We are the owner or exclusive licensee to proprietary patent positions related to our replicating technology. Our patent portfolio related to our replicating technology includes a patent family exclusively licensed from the University of Geneva. This patent family includes a patent granted in the United States and patents granted in Europe (validated in Albania, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Macedonia, Malta, Monaco, Norway, Poland,

Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland/LI, The Netherlands, Turkey and the United Kingdom), Australia, Canada, Hong Kong, India and Japan. The European patent in this family (European Patent No. 3218504) was opposed by a third party in April 2021. The opposition was dismissed, and the patent was maintained as granted by the European Patent Office ("EPO") in an oral proceeding on May 9, 2023. This patent family also includes pending applications in the United States, Europe, Australia, Japan, China and Hong Kong. The granted United States patent from the first patent family related to our replicating technology is expected to expire in April 2037 due to patent term adjustment. The granted patents in Europe, Australia, Canada, Hong Kong, India and Japan, and the pending applications are expected to expire in 2035, not giving effect to any potential patent term extensions or patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. The second patent family in our replicating platform portfolio is jointly owned by us and the University of Basel. The rights of the University of Basel under this patent family are exclusively licensed to us. This second patent family includes patents granted in Australia, China, Hong Kong, Japan, Macao, Eurasia, India, Israel, Japan, Korea, Mexico, and Singapore. This patent family also includes pending applications in various countries, including in the United States, Europe, Eurasia, Hong Kong, Korea, China, Australia, New Zealand, Mexico, Japan, Brazil, Singapore, India, and Israel. The granted patents and the pending applications are expected to expire in 2037, not giving effect to any potential patent term extensions or patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. Our replicating technology is being employed or may be employed in one or more of the product candidates or programs described herein.

Oncology Technology Portfolio

For the application of our non-replicating and replicating technologies in oncology, we own three patent families relating to potential clinical uses of our product candidates, such as combination treatments. One of the patent families includes a patent granted in the United States and patents granted in Europe (validated in Albania, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Macedonia, Malta, Monaco, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland/LI, The Netherlands, Turkey and the United Kingdom), Hong Kong, Australia, China, Macao, India and Japan. This patent family also includes pending applications in the United States, Europe, Canada, India and Hong Kong. A second patent family includes a patent granted in China and pending applications in the United States, Europe, Australia, and Hong Kong. The third patent family includes pending applications in the United States and Europe. The granted patents and pending applications within the three patent families are expected to expire between 2036 and 2043, not giving effect to any potential patent term extensions or patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

Eseba-vec (HPV16+ Head and Neck Squamous Cell Carcinoma)

HB-201 and HB-202, the two components of our eseba-vec product candidate, rely on our replicating technology and, depending on their clinical implementation, may relate to one or more applications in our oncology patent portfolio. In addition to the replicating and oncology patent portfolios, we own two patent families that relate more specifically to our HB-200 product candidate. The first patent family includes two patents granted in the United States and patents granted in Australia, China, Macao, India and Japan with claims directed to compositions of matter. This patent family also includes pending applications in the United States, Europe, Australia, Canada, China, India, Japan and Hong Kong. The second patent family includes pending applications in the United States, Europe, Eurasia, Australia, Brazil, Canada, China, Costa Rica, Hong Kong, India, Israel, Japan, Korea, Mexico, New Zealand, Peru, Singapore, South Africa relating to HB-200 treatment regimens. Excluding the replicating and oncology patent portfolios, the granted patents and pending applications specifically related to our HB-200 product candidate are expected to expire in 2036 and 2041, respectively, not giving effect to any potential patent term extensions or patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

HB-700 (KRAS Mutated Tumors)

Our HB-700 product candidate relies on our replicating technology and, depending on its clinical implementation, may relate to one or more applications in our oncology patent portfolio. In addition to the replicating

and oncology patent portfolios, we currently own one patent family that more specifically relates to our HB-700 product candidate. This patent family includes pending applications in the United States, Europe, Australia, Canada, China, Hong Kong, India, Israel, Japan, Korea, Mexico, New Zealand, Singapore, Argentina, and Taiwan. The pending applications specifically related to our HB-700 product candidate are expected to expire in 2042, not giving effect to any potential patent term extensions or patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

HB-300 (Prostate Cancer)

Our HB-300 product candidate relies on our replicating technology and, depending on its clinical implementation, may relate to one or more applications in our oncology patent portfolio. In addition to the replicating and oncology patent portfolios, we currently own one patent family that more specifically relates to our HB-300 product candidate. This patent family includes pending applications in the United States, Europe, Hong Kong, Australia, Brazil, Canada, China, India, Israel, Japan, Korea, Mexico, New Zealand, and Singapore. The pending applications specifically related to our HB-300 product candidate are expected to expire in 2042, not giving effect to any potential patent term extensions or patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

HB-400 (Hepatitis B Virus)

Our HB-400 product candidate, codeveloped with Gilead, is in Phase 1b clinical trial and is being built on our non-replicating technology. In addition to the non-replicating patent portfolio, we own one patent family that relates to the use of our platform technologies for prevention and treatment of HBV. This patent family includes patents granted in the United States, Europe (validated in Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland/LI, The Netherlands, Turkey and the United Kingdom), Australia, China, Hong Kong, Macao, Mexico, Japan, India, Israel, and New Zealand. This patent family also includes pending applications in the United States, Europe, Australia, Brazil, Canada, China, India, Israel, Japan, Hong Kong, Korea, Mexico, New Zealand and Singapore. Excluding the non-replicating patent portfolio, the granted patents and pending applications related to the HBV program are expected to expire in 2036, not giving effect to any potential patent term extensions or patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

HB-500 (HIV)

Our HB-500 product candidate, codeveloped with Gilead, is in Phase 1b clinical development and is being built on our replicating technology. In February 2022, we signed an amended and restated collaboration agreement, wherein we assumed development responsibilities through the end of Phase 1b. In November 2023, our investigational new drug application was cleared by the FDA, and the Phase 1b trial was started in the second quarter of 2024. The first participant was dosed on July 1, 2024, and enrollment of 30 patients was completed in January 2025. We currently do not own any patents or patent applications that more specifically relate to an HIV program outside of the replicating patent portfolio.

The actual term of any patent that may issue from the above described patent applications claiming one of our product candidates could be longer than described above due to patent term adjustment or patent term extension, if available, or shorter if we are required to file terminal disclaimers. The term of individual patents depends upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, the patent term is 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country.

Our ability to maintain and solidify our proprietary position for our product candidates and technologies will depend on our success in obtaining effective patent claims and enforcing those claims once granted. We do not know whether any of our patent applications will result in the issuance of any patents, or what the scope of the claims in any future issued patents may be. Our issued patents and those that may issue in the future, or those licensed to us, may be challenged, invalidated, narrowed, rendered unenforceable or circumvented, which could limit our ability to stop

competitors from marketing identical or substantially similar products or could reduce the length of term of patent protection that we may have for our products. With respect to patents and patent applications licensed to us, our licensors may have the right to terminate our licenses if we fail to comply with our obligations under the applicable license agreement. In addition, the claims granted in any of our issued patents may not provide us with advantages against competitors with similar products or technology. Furthermore, our competitors may independently develop technologies that are similar or identical to technology developed by us but that do not infringe our patents or other intellectual property. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, by the time that any of our product candidates or those developed by our collaborators can be commercialized, our key patent may have expired or may only continue to remain in force for a short period following commercialization, thereby reducing the usefulness of the patent.

We seek to protect our proprietary technology and processes, in part, by confidentiality agreements with our employees, consultants, scientific advisors and other contractors. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants or contractors use technology or know-how owned by others in their work for us, disputes may arise as to the rights in related inventions. For this and more comprehensive risks related to our intellectual property, see "Risk Factors—Risks Related to Our Intellectual Property."

Gilead Collaboration Agreement and Stock Purchase Agreement

Overview

On June 4, 2018, we entered into the Gilead Collaboration Agreement, with Gilead to collaborate on preclinical research programs to evaluate potential vaccine products using or incorporating our replicating and non-replicating technology platforms for the treatment, cure, diagnosis, or prevention of HBV or HIV, which we refer to, collectively, as the Field.

Pursuant to the Gilead Collaboration Agreement, we granted Gilead an exclusive, worldwide, royalty bearing license to our knowhow and our owned and in-licensed patent rights (including those patent rights in-licensed from the University of Geneva, the University of Basel, and the University of Zurich) that are necessary or reasonably useful for researching, developing, manufacturing or commercializing products that contain a vaccine that uses our replicating or non-replicating technology platforms for expressing one or more HIV or HBV antigens, which foregoing knowhow and patent rights we refer to as the Licensed Technology (and each such product a Licensed Product), for the purpose of researching, developing, manufacturing and commercializing Licensed Products for uses in the Field.

Pursuant to the Gilead Collaboration Agreement, we will own all new intellectual property conceived or created out of the activities conducted under the Gilead Collaboration Agreement that specifically relate to the replicating and non-replicating technology platforms. Gilead will own all other intellectual property rights conceived or created out of the activities conducted under the Gilead Collaboration Agreement.

On February 15, 2022, we entered into the Restated Gilead Collaboration Agreement, which altered key aspects of the collaboration pertaining to the HIV therapeutic. Specifically, we assumed responsibility for advancing the HIV program through to the end of a Phase 1b clinical program, and Gilead retains an exclusive right, the Option, for further development thereafter. Pursuant to the Option, Gilead has the exclusive right to take back the development rights for such HIV program candidates and to further research, develop, and commercialize such candidates in accordance with the terms and conditions of the Restated Gilead Collaboration Agreement. Gilead may exercise the Option at any time, but no later than 60 days after the receipt of a data package containing pre-clinical, clinical, chemistry and manufacturing control, regulatory and other data specified by the Restated Gilead Collaboration Agreement in return for an option exercise fee of $10.0 million.

If the Option is not exercised by Gilead during the term of the Option, or if Gilead provides written notice to us of its intention to not exercise the Option, then the terms of the Restated Gilead Collaboration Agreement will be deemed terminated with respect to the HIV Development Plan and HIV Licensed Products (each as defined in the Restated Gilead Collaboration Agreement), and the Field and rights granted under the Restated Gilead Collaboration

Agreement will be limited to the HBV indication. Furthermore, if the Option expires or is terminated, the non-competition and right of first negotiations terms contained in the Restated Gilead Collaboration Agreement and summarized below will not be applicable to the development for HIV indications. In the event the Option is not exercised, we and Gilead will work in good faith to enter into a license agreement pursuant to which Gilead will grant us a milestone and/or royalty-bearing license under certain Gilead owned intellectual property necessary or reasonably useful to allow us to research, develop, manufacture and commercialize HIV product candidates as of the date on which the Option is declined.

Financial support from Gilead to us includes a $15.0 million non-refundable initiation fee and $35.0 million equity commitment pursuant to the Stock Purchase Agreement. In December 2023, the Stock Purchase Agreement was amended. As of December 31, 2024, we have received approximately $26.25 million from Gilead's purchases of our common stock under the terms of this equity commitment. Under the amended terms we have the right to sell an additional $8.75 million of common stock to Gilead as pro-rata participation with an equity financing (either public or private) at the offer price of the financing. Our option to sell these shares to Gilead expires on December 20, 2025.

Pursuant to the Gilead Collaboration Agreement, in the event we offer a license or other rights to the Licensed Technology to a third party to research, develop, manufacture or commercialize a Licensed Product outside of the Field before June 4, 2028, we are required to offer Gilead a right of first negotiation for the same rights to the Licensed Technology in such field offered to the third party. If the Option expires or is terminated, the right of first negotiations terms contained in the Restated Gilead Collaboration Agreement will not be applicable to the development for HIV indications.

Financial Terms

Upon execution of the Gilead Collaboration Agreement, Gilead paid us a one-time upfront fee of $10.0 million, and through to December 31, 2024, we received $16.2 million in milestone payments for the achievement of pre-clinical research milestones, a $5.0 million milestone payment for the completion and delivery of a regulatory support package for HB-400, and a $5.0 million milestone payment for the first person dosed in a Phase 1b clinical trial of HB-500.

Upon execution of the Restated Gilead Collaboration Agreement, we became entitled to a program initiation fee of $15.0 million. In addition, we are eligible for up to $140.0 million in developmental milestone payments for the HBV program and $50.0 million in commercialization milestone payments for the HBV program. If Gilead exercises the Option, we are eligible for up to a further $167.5 million in developmental milestone payments for the HIV program, inclusive of the $10.0 million program completion fee payable upon Option exercise, and $65.0 million in commercialization milestone payments for the HIV program. Upon the commercialization of a Licensed Product, if ever, we are eligible to receive tiered royalties of a high single-digit to mid-teens percentage on the worldwide net sales of each HBV Licensed Product, and royalties of a mid-single-digit to 10% of worldwide net sales of each HIV Licensed Product, if the Option is exercised. The royalty payments are subject to reduction under specified conditions set forth in the Gilead Collaboration Agreement.

In addition, Gilead is obligated to pay us for all out-of-pocket costs incurred by us in connection with the HBV programs, including CMO related costs, to the extent contemplated under the research plans and research budget. In December 2019, Gilead agreed to expand the reimbursement for our resources allocated to the collaboration.

Termination

Either party may terminate for the uncured breach of the other party and upon the other party filing for bankruptcy, reorganization, liquidation, or receivership proceedings. On a program-by-program basis, at any time after the expiration or termination of the collaboration term for such program, Gilead may terminate the Restated Gilead Collaboration Agreement with respect to such program or on a product by product or a country-by-country basis upon prior written notice. If the Restated Gilead Collaboration Agreement is not otherwise terminated prior to the expiration of the last to expire royalty term, upon such expiration the license granted to Gilead will continue in effect, but will be fully paid-up, royalty free, perpetual, and irrevocable.

Supply Agreement

In December 2020, we entered into a Clinical Supply Agreement with Gilead. Under the terms of the Clinical Supply Agreement, we provide Gilead with drug product for use in proof-of-concept clinical trials associated with the Licensed Products designated under the Gilead Collaboration Agreement. We receive reimbursement at an agreed cost in accordance with the terms of the Restated Gilead Collaboration Agreement. Clinical supply of a potential Phase 3 clinical trial will be regulated in a separate supply agreement.

Stock Purchase Agreement

In connection with the Restated Gilead Collaboration Agreement, on February 15, 2022, the Effective Date, we entered into the Stock Purchase Agreement with Gilead. Pursuant to, and subject to the terms and conditions of, the Stock Purchase Agreement, Gilead will be required, at our option, to purchase up to $35,000,000 of our common stock, the proceeds of which we intend to use to fund additional research and development activities of our HIV program. On the Effective Date, Gilead purchased an initial amount of 166,666 unregistered shares of our common stock in exchange for approximately $5.0 million at a purchase price per share equal to $3.00. On December 20, 2023, the parties amended the terms of the Stock Purchase Agreement and Gilead purchased 1,500,000 shares of our common stock in exchange for approximately $21.25 million in cash at a purchase price per share equal to $14.167. Pursuant to the terms of the Stock Purchase Agreement, we may require Gilead to purchase the balance of the $8.75 million of common stock as participation in potential future equity raises. Our ability to sell shares of our common stock to Gilead are subject to specified limitations, including compliance with Nasdaq Rule 5635(d) and continued compliance with the Nasdaq listing rules. The Stock Purchase Agreement also prohibits Gilead from purchasing shares of our common stock if such purchase would result in Gilead being a beneficial owner of more than 19.9% of the total number of our then-issued and outstanding shares of common stock.

The Stock Purchase Agreement may be terminated: (1) by Gilead (a) any time an Event of Default (as defined in the Stock Purchase Agreement) exists or (b) if we suspend, terminate or otherwise cease to perform our obligations under the HIV Development Plan; (2) automatically if Gilead exercises its Option pursuant to the Restated Gilead Collaboration Agreement; (3) by us for any reason; (4) automatically on the date that we sell and Gilead purchases the full $35.0 million of common stock; or (5) automatically on December 20, 2025.

Pursuant to the terms of the Stock Purchase Agreement, we and Gilead agreed to enter into a registration rights agreement obligating us to file a registration statement on Form S-3 to register for resale any additional purchases of common stock within four months of any additional purchases of common stock by Gilead.

Roche Collaboration Agreement

On October 18, 2022, we entered into the Roche Collaboration Agreement, with Roche, to (i) grant Roche an exclusive license to research, develop, manufacture and commercialize our pre-clinical HB-700 cancer program, an arenaviral immunotherapeutic for KRAS-mutated cancers, and (ii) grant Roche an exclusive option right to exclusively license for research, development manufacturing and commercialization, a second, novel arenaviral immunotherapeutic program targeting undisclosed cancer antigens (collectively UCAs or UCA Program). Pursuant to the Roche Collaboration Agreement, we received a non-refundable upfront payment of $25.0 million, we have received $10.0 million in milestone payments for the achievement of a GMP manufacturing milestone under the HB-700 program and we have received $10.0 million in milestone payments associated with an IND submission for the HB-700 program.

On January 25, 2024, Roche terminated the Collaboration Agreement without cause, effective as of April 25, 2024. We received a final milestone payment associated with an IND submission. to the FDA, which occurred in April 2024. Effective April 25, 2024, we regained full control of the associated intellectual property portfolio and have full collaboration and licensing rights for the HB-700 program.

License Agreements

University of Geneva License Agreement

In February 2017, we entered into an Exclusive License Agreement with the University of Geneva, the Geneva Agreement. Pursuant to the Geneva Agreement, the University of Geneva granted us a worldwide, exclusive license to use the University of Geneva's technology titled "method for vaccine delivery" and the patent rights in the subject matter of U.S. Provisional Patent Application No. 62/079,493 and PCT Patent Application No. PCT/EP2015/076458, each titled "Tri-Segmented Arenaviruses as Vaccine Vectors," including any patents that claim priority thereto, the Geneva Licensed Patent Rights, to make, have made, to use and have used, to sell and have sold, to commercialize and have commercialized products, the manufacture, use, or sale of which would infringe a claim of the Geneva Licensed Patent Rights, each a Geneva Licensed Product.

Pursuant to the terms of the Geneva Agreement, we are obligated to use reasonable efforts to develop and make commercially available Geneva Licensed Products. We were also required to provide proof to the University of Geneva that we have filed an IND or an equivalent application for a Geneva Licensed Product within seven years of the effective date of the Geneva Agreement. In June 2019 we informed the University of Geneva about the filing of an IND for a Geneva Licensed Product. The University of Geneva can terminate the Geneva Agreement if we stop the development and/or exploitation of the technology licensed by the University of Geneva to us.

Starting with the third anniversary of the effective date of the Geneva Agreement, we are required to pay the University of Geneva a nominal annual fee, which is deductible from any milestone payments, royalties or sublicense payments payable by us to the University of Geneva during the same fiscal year. We are required to pay the University of Geneva, subject to the achievement by us of specified development and regulatory milestones, payments aggregating up to CHF 290,000 per Geneva Licensed Product. While the Geneva Agreement remains in effect, we are required to pay the University of Geneva low single digit royalties on aggregate net sales of Geneva Licensed Products sold by us. We must also pay the University of Geneva percentages ranging from the low single digits to 10%, decreasing as a Geneva Licensed Product proceeds through development stages, of any consideration we receive from sublicensees, depending on the timing of such sublicense. We are also responsible for the prosecution and maintenance of the Geneva Licensed Patents Rights, including the costs related thereto.

Unless earlier terminated, the Geneva Agreement remains in effect until the expiration of the last to expire of the Geneva Licensed Patent Rights. Following the expiry of the Geneva Agreement due to the last to expire of the Geneva Licensed Patent Rights, we will have a fully paid-up, royalty-free right to use, sell and commercialize Geneva Licensed Products. We or the University of Geneva may terminate the Geneva Agreement for the other party's breach that remains uncured after 60 days' notice. We may terminate the Geneva Agreement for convenience upon prior notice. The University of Geneva may terminate the Geneva Agreement if we cease to carry on our business or become insolvent.

University of Basel License Agreement

In January 2017, we entered into an Exclusive License Agreement with the University of Basel, the Basel Agreement. Pursuant to the Basel Agreement, the University of Basel granted us a worldwide, exclusive license under the University of Basel's share in U.S. Provisional Patent Application No. 62/338,400, titled "Tri-segmented Pichinde viruses as vaccine vectors," including any patents that claim priority thereto, the Basel Licensed Patent Rights to use the technology titled "tri-segmented Pichinde viruses as vaccine vectors" as covered by the Basel Licensed Patent Rights, to make and have made, to use and have used, to sell and have sold, to commercialize and have commercialized products, the manufacture, use, sale, or importation of which would infringe a claim of the Basel Licensed Patent Rights, each a Basel Licensed Product.

Pursuant to the terms of the Basel Agreement, we are obligated to use reasonable efforts to develop and make commercially available Basel Licensed Products. Beginning on February 28, 2018, and for as long as we have not effected a first commercial use of a Basel Licensed Product, we are required to provide the University of Basel with an annual report detailing our efforts to develop Basel Licensed Products.

We are required to pay the University of Basel, subject to the achievement of specified development and regulatory milestones, payments aggregating up to CHF 265,000 per Basel Licensed Product. While the Basel Agreement remains in effect, we are required to pay the University of Basel low single digit royalties on net sales of Basel Licensed Products. We must also pay the University of Basel a low to high single digit percentage, decreasing as a Basel Licensed Product proceeds through development stages, of any consideration we receive from sublicensees, depending on the timing of such sublicense. We are also responsible for the prosecution and maintenance of the Basel Licensed Patent Rights, and the costs related thereto.

Unless earlier terminated, the Basel Agreement remains in effect until the expiration of the last to expire of the Basel Licensed Patent Rights. Following the expiry of the Basel Agreement due to the last to expire of the Basel Licensed Patent Rights, we will have a fully paid-up, royalty-free right to use, sell and commercialize Basel Licensed Products. We or the University of Basel may terminate the agreement for the other party's breach that remains uncured after 60 days' notice. We may terminate the Basel Agreement for convenience upon prior notice. The University of Basel may terminate the Basel Agreement if we cease to pay for the costs associated with prosecution and maintenance of the Basel Licensed Patent Rights.

University of Basel Split License Agreement

In October 2020, we entered into an Exclusive License Agreement with the University of Basel, hereinafter referred to as the Basel Split Agreement, pursuant to which the University of Basel granted us a worldwide, exclusive license to proprietary patent positions related to a novel molecular strategy to vectorize arenavirus genomes, hereinafter referred to as the Basel Licensed Split Patent Rights. Pursuant to the Basel Split Agreement, the University of Basel further granted us a worldwide, exclusive license under the University of Basel's share in jointly owned patent applications related to certain improvements developed under the Basel Split Agreement, hereinafter referred to as the Improvement Patent Rights. Pursuant to the Basel Split Agreement, we were responsible for the prosecution and maintenance of the Basel Licensed Split Patent Rights and the Improvement Patent Rights, and all costs related thereto.

On June 27, 2024, we terminated the Basel Split Agreement, effective as of October 1, 2024. Effective as of October 1, 2024, the University of Basel took over the responsibility for the filing, prosecution and maintenance of the Basel Licensed Split Patent Rights as well as the Improvement Patent Rights. Each party under the terminated Basel Split Agreement is granted by the other party a non-exclusive, royalty-free, fully-paid up license to such other party's share in the jointly owned Improvement Patent Rights, with the right to grant non-exclusive sublicenses to affiliates and third parties.

University of Zurich License Agreement

In October 2011, we entered into a License Agreement with the University of Zurich, the Zurich Agreement. Pursuant to the Zurich Agreement, the University of Zurich granted us a worldwide, exclusive license to PCT Patent Application No. PCT/EP/08/010994, titled "Propagation deficient arenavirus vectors," the Zurich Licensed Patent Rights, to make and have made, use, sell, offer for sale, and import products that fall within the scope of the Zurich Licensed Patent Rights, each a Zurich Licensed Product and to practice the Zurich Licensed Patent Rights and methods that fall within the scope of the Zurich Licensed Patent Rights, each a Zurich Licensed Method.

Pursuant to the terms of the Zurich Agreement, we are obligated to diligently proceed with the development, manufacture, and sale of, and the obtaining of government approvals for the manufacture, use and sale of, suitable Zurich Licensed Products in the United States, Japan and certain European countries. If we fail to use commercially reasonable efforts to do the foregoing, the University of Zurich can demand a written development and marketing plan. Failure of the parties to agree on a development and marketing plan entitles the University of Zurich to terminate the Zurich Agreement. Beginning on January 1, 2012, and ending on the date of the first commercial sale of a Zurich Licensed Product, we are required to provide the University of Zurich with an annual report detailing our efforts to develop and test Zurich Licensed Products and to use the Zurich Licensed Patent Rights and Zurich Licensed Methods.

In consideration for the license granted to us under the Zurich Agreement, we issued 26,744 shares with a nominal value of EUR 2,297 of our common stock to the University of Zurich and agreed to provide them certain

antidilution rights, which rights have subsequently expired. We are required to pay the University of Zurich low single digit royalties on net sales of Zurich Licensed Products or Zurich Licensed Methods. We must also pay the University of Zurich percentages ranging from the mid-single digits to 20% of any sublicense fees and consideration we receive from sublicensees, depending on the amount of fees received from sublicensees and the cumulative monetary value of the consideration and fees received from all sublicensees. We are responsible for the prosecution and maintenance of the Zurich Licensed Patent Rights, and the costs related thereto.

Unless earlier terminated, the Zurich Agreement remains in effect on a country-by-country basis until the expiration of the last to expire of the Zurich Licensed Patent Rights in such country. The University of Zurich may terminate the agreement for our uncured breach of any of the terms of the Zurich Agreement or if we oppose or dispute the validity of any of the Zurich Licensed Patent Rights, or assist a third party to do the same. If we fail to use commercially reasonable efforts to market and develop the Zurich Licensed Products in certain countries, and if we fail to agree with the University of Zurich on any amendments to our development and marketing plans within the time specified in the Zurich Agreement upon such demand for amendments from the University of Zurich, the University of Zurich may terminate the Zurich Agreement. We may terminate the Zurich Agreement for convenience upon prior notice. The Zurich Agreement automatically terminates if we file a petition for bankruptcy, insolvency, or reorganization relating to bankruptcy or insolvency, or in the event of an adjudication that we have become bankrupt or insolvent.

National Institutes of Health License Agreement

In September 2013, we entered into a Biological Materials License Agreement with the National Institutes of Health ("NIH") which was subsequently amended in April 2017, July 2018, January 2021, and May 2021, hereinafter referred to as the NIH Agreement. Pursuant to the NIH Agreement, the NIH granted us a worldwide, nonexclusive license to make, have made, import and use certain cells and cell clones developed at the Vaccine Research Center of the NIH (the "NIH Licensed Products") to manufacture viral vectors based on our proprietary arenavirus-based vectors.

Pursuant to the terms of the NIH Agreement, we are required to provide the NIH with an annual report which states the number and description of NIH Licensed Products made or otherwise disposed of. We are further responsible for obtaining and maintaining any required third-party license for the background rights for the commercial use of the respective cells and cell clones.

In consideration of the license granted to us pursuant to the NIH Agreement, we paid the NIH a low six figure and a mid-five figure issue royalty, upon execution of the NIH Agreement and the first amendment, respectively. We must also pay the NIH 10% of any consideration we receive from sublicensees. We must also pay the NIH low five figure to mid six figure annual royalty payments, increasing as our most developed product candidate manufactured from NIH Licensed Products proceeds through development stages.

Unless earlier terminated, the NIH Agreement remains in effect for a term of 20 years from the effective date. We have the option to extend the term of the agreement for additional one year periods, upon prior notice to the NIH. The NIH may terminate the NIH Agreement if we are in default in performing any material obligation under the NIH Agreement and do not remedy such default within a specified period upon notice thereof. We may terminate the NIH Agreement for convenience upon prior notice.

University of Minnesota License Agreement

In October 2022, we entered into a Non-Exclusive License Agreement with the Regents of the University of Minnesota (the "Minnesota Agreement"). Pursuant to the Minnesota Agreement, the University of Minnesota granted us a worldwide, non-exclusive license under the University of Minnesota's rights in the subject matter of PCT Patent Application No. PCT/US2015/051337 including any patents that claim priority thereto (the "Minnesota Licensed Patent Rights") to make, have made, sell, have sold, offer to sell, have offered to sell, commercialize, have commercialized, import, have imported, export, have exported, use, have used and otherwise exploit products that are covered by a valid claim of the Minnesota Licensed Patent Rights (and simultaneously covered by a claim of the University of Geneva patent related to our replicating technology which is exclusively licensed to us), (each, a "Minnesota Licensed Product").

We paid the University of Minnesota a low six figure amount upon entering into the agreement and are required to pay a non-material annual maintenance fee, and, upon commercialization of the first Minnesota Licensed Product, an annual minimum royalty which is creditable against royalties payable in the same year. We are required to pay the University of Minnesota, subject to the achievement of specified regulatory and commercial milestones, payments aggregating up to $2,750,000 per Minnesota Licensed Product. While the Minnesota Agreement remains in effect, we are required to pay the University of Minnesota royalties on aggregate net sales of Minnesota Licensed Products, of a generally below single digit percentage.

We must also pay the University of Minnesota low single digit percentages of certain considerations we receive from sublicensees, subject to pre-defined minimum and maximum payments in the range of a mid five figure amount to a mid six figure amount. We further have to pay the University of Minnesota a nominal amount if we assign the Minnesota Agreement as part of a change of control.

Unless earlier terminated, the Minnesota Agreement remains in effect until the expiration of the last to expire of the Minnesota Licensed Patent Rights. Following the expiry of the Minnesota Agreement due to the last to expire of the Minnesota Licensed Patent Rights, we will have a fully paid-up, royalty-free right to use, sell and commercialize Minnesota Licensed Products. We or the University of Minnesota may terminate the Minnesota Agreement for the other party's breach that remains uncured after 30 days' notice. We may terminate the Minnesota Agreement for convenience upon prior notice. The University of Minnesota may terminate the Minnesota Agreement if we cease operations, become insolvent, enter into any bankruptcy, receivership, or similar proceeding, or attempt to use the Minnesota Licensed Patent Rights as collateral for any debt.

Competition

The biotechnology and pharmaceutical industries have made substantial investments in recent years into the rapid development of novel immunotherapies for the treatment of a range of pathologies, including infectious diseases and cancers.

Competition arises from multiple sources, including large and specialty pharmaceutical, biopharmaceutical and biotechnology companies, academic research institutions and governmental agencies and public and private research institutions. Our competitors compete with us on the level of the technologies employed to target various therapeutic areas, such as adoptive cell therapies and active immunization technologies, or on the level of development of product candidates. In addition, many small biotechnology companies have formed collaborations with large, established companies to (i) obtain support for their research, development and commercialization of products or (ii) combine several treatment approaches to develop longer lasting or more efficacious treatments that may potentially directly compete with our current or future product candidates. We anticipate that we will continue to face increasing competition as new therapies and combinations thereof, technologies, and data emerge within the field of immunotherapy and, furthermore, within the treatment of infectious diseases and cancers.

In addition to the current standard of care treatments for patients with infectious diseases or cancers, numerous commercial and academic preclinical studies and clinical trials are being undertaken by a large number of parties to assess novel technologies and product candidates in the field of immunotherapy. Results from these studies and trials have fueled increasing levels of interest in the field of immunotherapy.

Our competitors in the development of product candidates in our lead immunooncology indication of therapies for mutated KRAS and HPV+ cancers, include, among others, companies such as Elicio Therapeutics, BioNTech, PDS Biotech, TCR Cure, Transgene and Ultimovacs.

Companies developing technology that competes directly or indirectly with our technology include Abalos GmbH, which is developing mammarenavirus vectors for cancer, and companies developing oncolytic viruses, bispecific antibodies, engineered cell therapies, tumor specific antigens, and other active immunization technologies including, among others, Adaptimmune PLC, BioNTech, CureVac AG, Merck & Co., Moderna, Novartis, Replimune Group, Inc., Roche and Turnstone Biologics Inc.

Many of our competitors, either alone or in combination with their respective strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, the regulatory approval process, and marketing than we do. Mergers and acquisition activity in the pharmaceutical, biopharmaceutical and biotechnology sector is likely to result in greater resource concentration among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through sizeable collaborative arrangements with established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if one or more of our competitors develop and commercialize products that are safer, more effective, better tolerated, or of greater convenience or economic benefit than our proposed product offering. Our competitors also may be in a position to obtain FDA or other regulatory approval for their products more rapidly, resulting in a stronger or dominant market position before we are able to enter the market. The key competitive factors affecting the success of all of our programs are likely to be product safety, efficacy, convenience and treatment cost.

Manufacturing

We have been establishing robust manufacturing processes, reliable assays and strong supply agreements for all of the components used in our product candidates to support ongoing and planned clinical trials. These include the components for our non-replicating technology based and replicating technology based product candidates. For GMP production and testing we rely on qualified CMOs and CLOs to produce and test our clinical material. We require that our suppliers produce and test bulk drug substances and finished drug products in accordance with cGMP, and all other applicable laws and regulations. We continue to build and maintain agreements with manufacturers that include confidentiality and intellectual property provisions to protect our proprietary rights related to our product candidates. Currently we do not own or operate manufacturing facilities.

Government Regulation

Government authorities in the United States at the federal, state and local level and in other countries regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, recordkeeping, promotion, advertising, distribution, post approval monitoring and reporting, marketing and export and import of biological products, such as those developed from our non-replicating and replicating technologies and any other product candidates we develop. Generally, before a new drug or biologic can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority.

U.S. Biological Product Development

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (“FDCA”) and its implementing regulations and biologics under the FDCA, the Public Health Service Act (“PHSA”) and their implementing regulations. Both drugs and biologics also are subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state and local statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or post market may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA’s refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, untitled or warning letters, product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Our product candidates and any future biological product candidates we develop must be approved by the FDA through a biologics license application (BLA) process before they may be legally marketed in the United States. The

BLA is a request for approval to market the biologic for one or more specified indications and must contain proof of safety, purity and potency. The FDA review and approval process generally involves the following:

1. Completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with GLP requirements;

2. Submission to the FDA of an IND, which must become effective before human clinical trials may begin;

3. Approval by an Institutional Review Board (IRB) or independent ethics committee at each clinical trial site before each trial may be initiated;

4. Performance of adequate and well controlled human clinical trials in accordance with applicable IND regulations, good clinical practice (GCP) requirements and other clinical trial related regulations to establish the safety and efficacy of the investigational product for each proposed indication;

5. Submission to the FDA of a BLA;

6. A determination by the FDA within 60 days of its receipt of a BLA to accept the filing for review;

7. Satisfactory completion of an FDA preapproval inspection of the manufacturing facility or facilities where the biologic will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the biologic's identity, strength, quality and purity;

8. Potential FDA audit of the clinical trial sites that generated the data in support of the BLA; and

9. FDA review and approval of the BLA, including, where applicable, consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the biologic in the United States.

The preclinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, or at all.

Preclinical Studies and IND

Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as in vitro and animal studies to assess the potential for adverse events and in some cases to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies.

An IND sponsor must submit the results of the preclinical studies, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before human clinical trials may begin. Some long-term preclinical testing may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time, the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical Trials

The clinical stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols

detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Further, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries.

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

Clinical trials generally are conducted in three sequential phases, known as Phase 1, Phase 2 and Phase 3, and may overlap.

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the product candidate.

- Phase 2 clinical trials involve studies in disease affected patients to determine the dose required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, possible adverse effects and safety risks are identified, and a preliminary evaluation of efficacy is conducted.

- Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product labeling.

Post approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of a BLA. Failure to exhibit due diligence with regard to conducting required Phase 4 clinical trials could result in withdrawal of approval for products.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators fifteen days after the trial sponsor determines the information qualifies for reporting for serious and unexpected suspected adverse events, findings from other studies or animal or in vitro testing that suggest a significant risk for human subjects and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must also notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than seven calendar days after the sponsor's initial receipt of the information.

Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biologic has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as

a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated check points based on access to certain data from the trial. Concurrent with clinical trials, companies usually complete additional animal studies and also must develop additional information about the chemistry and physical characteristics of the biologic as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product and, among other things, companies must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidates do not undergo unacceptable deterioration over their shelf life.

FDA Review Process

Following completion of the clinical trials, data are analyzed to assess whether the investigational product is safe and effective for the proposed indicated use or uses. The results of preclinical studies and clinical trials are then submitted to the FDA as part of a BLA, along with proposed labeling, chemistry and manufacturing information to ensure product quality and other relevant data. The BLA may include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings. Data may come from company sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety, purity and potency of the investigational product to the satisfaction of FDA. FDA approval of a BLA must be obtained before a biologic may be marketed in the United States.

Under the Prescription Drug User Fee Act (PDUFA) as amended, each BLA must be accompanied by a user fee. The FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA reviews all submitted BLAs before it accepts them for filing and may request additional information rather than accepting the BLA for filing. The FDA decides whether to accept a BLA for filing within 60 days of receipt, and such decision could include a refusal to file by the FDA. Once the submission is accepted for filing, the FDA begins an in-depth review of the BLA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has ten months, from the filing date, in which to complete its initial review of an original BLA and respond to the applicant, and six months from the filing date of an original BLA designated for priority review. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs, and the review process is often extended by FDA requests for additional information or clarification.

Before approving a BLA, the FDA will conduct a preapproval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP requirements. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA also may audit data from clinical trials to ensure compliance with GCP requirements. Additionally, the FDA may refer applications for novel products or products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by recommendations of an advisory committee, but it considers such recommendations when making decisions on approval. The FDA likely will reanalyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. After the FDA evaluates a BLA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the biologic with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A Complete Response Letter usually describes all of the specific deficiencies in the BLA identified by the FDA. The Complete Response Letter may require additional clinical data, pivotal Phase 3 clinical trial(s) as well as other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies

identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data.

Orphan Drug Designation

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

Orphan drug designation for a biologic must be requested before submitting a BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety or providing a major contribution to patient care or in instances of drug supply issues. Competitors, however, may receive approval of either a different product for the same indication or the same product for a different indication but that could be used off label in the orphan indication. Orphan drug exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval before we do for the same product, as defined by the FDA, for the same indication we are seeking approval, or if our product is determined to be contained within the scope of the competitor's product for the same indication or disease. If one of our products designated as an orphan drug receives marketing approval for an indication broader than that which is designated, it may not be entitled to orphan drug exclusivity. Orphan drug status in the European Union (EU) has similar, but not identical, requirements and benefits.

Expedited Development and Review Programs

FDA provides programs intended to facilitate and expedite development and review of new products that are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs are referred to as fast-track designation, breakthrough therapy designation, priority review, and accelerated approval. These designations are not mutually exclusive, and a product candidate may qualify for one or more of these programs.

The fast-track program is intended to expedite or facilitate the process for reviewing new drugs and biologics that meet certain criteria. Specifically, new drugs and biologics are eligible for fast-track designation if they are intended to treat a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast-track designation applies to both the product and the specific indication for which it is being studied. The sponsor of a biologic can request the FDA to designate the product for fast-track status any time before receiving BLA approval, but ideally no later than the pre-BLA meeting.

A product that receives fast-track program designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it treats a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biologic designated for priority review in an effort to facilitate the review.

A product may also be eligible for accelerated approval, if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate 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. As a condition of approval, the FDA may require that a sponsor of a drug or biologic receiving accelerated approval perform adequate and well controlled post marketing clinical trials. Under the Food and Drug Omnibus Reform Act of 2022 (FDORA), the FDA is now permitted to require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. Sponsors are also required to send updates to the FDA every 180 days on the status of such studies, including progress toward enrollment targets, and the FDA must promptly post this information publicly. Under FDORA, the FDA has increased authority for expedited procedures to withdraw approval of a drug or indication approved under accelerated approval if, for example, the sponsor fails to conduct such studies in a timely manner and send the necessary updates to the FDA, or if a confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, the FDA generally requires, unless otherwise informed by the agency, pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Additionally, a drug or biologic may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints. The benefits of breakthrough therapy designation include the same benefits as fast-track designation, plus intensive guidance from the FDA to ensure an efficient drug development program.

Fast-track designation, priority review, accelerated approval and breakthrough therapy designation do not change the standards for approval, but may expedite the development or approval process.

Pediatric Information

Under the Pediatric Research Equity Act (PREA), a BLA or supplement to a BLA must contain data to assess the safety and efficacy of the biologic for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. The Food and Drug Administration Safety and Innovation Act (FDASIA) amended the FDCA to require that a sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan (PSP) within 60 days of an end of Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 study. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials as well as other clinical development programs.

Post Marketing Requirements

Following approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and recordkeeping activities, reporting of adverse experiences, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as “off label use”) and limitations on industry sponsored scientific and educational activities. Although physicians may prescribe legally available products for off label uses, manufacturers may not market or promote such uses. Prescription drug and biologic promotional materials must be submitted to the FDA in conjunction with their first use. Further, if there are any modifications to the biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and

obtain FDA approval of a new BLA or BLA supplement, which may require the development of additional data or preclinical studies and clinical trials.

The FDA may also place other conditions on approvals including the requirement for a Risk Evaluation and Mitigation Strategy (REMS) to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve the BLA without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

FDA regulations require that products be manufactured in specific facilities and in accordance with cGMP regulations. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved drugs or biologics are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws, including applicable product tracking and tracing requirements. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violations, including failure to conform to cGMP regulations, could result in enforcement actions, and the discovery of post approval problems with a product may result in restrictions on a product, manufacturer or holder of an approved BLA, including recall.

Other U.S. Healthcare Laws

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, including the Centers for Medicare & Medicaid Services (“CMS”), other divisions of the Department of Health and Human Services (HHS), the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments.

Healthcare providers, physicians and third party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third party payors and customers can expose pharmaceutical manufactures to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Antikickback Statute and the federal False Claims Act (FCA) which may constrain the business or financial arrangements and relationships through which companies sell, market and distribute pharmaceutical products. In addition, transparency laws and patient privacy regulations by federal and state governments and by governments in foreign jurisdictions can apply to the manufacturing, sales, promotion and other activities of pharmaceutical manufactures. These laws include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, the purchase, lease, order, arrangement, or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that 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 or federal civil monetary penalties;

- the federal civil and criminal false claims laws and civil monetary penalty laws, such as the FCA, which impose criminal and civil penalties and authorize civil whistleblower or qui tam actions, against individuals or entities for, among other things: knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; knowingly making, using or causing to be made or used, a false statement of record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;

- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) which created new federal criminal statutes that prohibit a person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious, or fraudulent statements or representations in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH) and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates, independent contractors or agents of covered entities, that perform services for them that involve the creation, maintenance, receipt, use, or disclosure of, individually identifiable health information relating to the privacy, security and transmission of individually identifiable health information, as well as their covered subcontractors. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, there may be additional federal, state and non-U.S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts;

- the U.S. federal transparency requirements under the Affordable Care Act (ACA) including the provision commonly referred to as the Physician Payments Sunshine Act, and its implementing regulations, which requires applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other licensed health care practitioners and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;

- federal price reporting laws, which require manufacturers to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on approved products; and

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Additionally, we are subject to state and foreign equivalents of each of the healthcare laws and regulations described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many U.S. states have adopted laws similar to the federal Anti-Kickback Statute and FCA, and may apply to our business practices, including, but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental payors, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state and require the registration of pharmaceutical sales representatives. State and foreign laws, including for example the EU General Data Protection Regulation (EU GDPR), also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement, we could be subject to penalties. Finally, there are state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations with respect to certain laws. Federal and state enforcement bodies have recently increased 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. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect our business in an adverse way. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

Ensuring our business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time and resource consuming and can divert a company's attention from the business.

The failure to comply with any of these laws or regulatory requirements may subject companies to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as 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. Any action for violation of these laws, even if successfully defended, could cause a pharmaceutical company to incur significant legal expenses and divert management's attention from the operation of the business. Further, defending against any such actions can be costly and time consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, our ability to operate our business and our results of operations could be adversely affected.

U.S. Healthcare Reform

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in 2010, the ACA was passed, which substantially changed the way healthcare is financed by both

governmental and private insurers and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, subjects biological products to potential competition by lower cost biosimilars, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and creates a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition to coverage under Medicare Part D for the manufacturer's outpatient drugs.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which remain in effect through 2032, absent additional congressional action. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers will be further reduced starting in 2025 absent further legislation.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives which could limit the amounts that federal and state governments will pay for healthcare products and services and result in reduced demand for certain pharmaceutical products or additional pricing pressures.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs.

The Inflation Reduction Act of 2022 (IRA) includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket spending cap for Medicare Part D beneficiaries from $7,050 to $2,000 starting in 2025, thereby effectively eliminating the coverage gap; impose new manufacturer financial liability on certain drugs under Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost single source biologics that have been on the market for 11 years (the "Medicare Drug Price Negotiation Program); require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay until January 1, 2032 the implementation of the HHS rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare Drug Price Negotiation Program, but only if they have one rare disease designation and for which the only approved indication is for that disease or condition. If a product receives multiple rare disease designations or has multiple approved indications, it may not qualify for the orphan drug exemption. These provisions began to take effect progressively starting in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon prices of the first ten drugs that were subject to price negotiations, although the Medicare Drug Price Negotiation Program is currently subject to legal challenges. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program.. Further, on December 7, 2023 an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act was announced. 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.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

In the United States, there has also been a lot of legislative activity at the state level with respect to privacy regulation. For example, in California, the California Consumer Privacy Act of 2018, as amended by the California

Privacy Rights Act of 2020 (“CPRA”) (collectively the “CCPA”), broadly defines personal information and creates individual privacy rights and protections for California consumers (as defined in the law), places increased privacy and security obligations on entities handling personal data of consumers or households, and provides for civil penalties for violations and a private right of action for data breaches. The CCPA requires covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices, and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. While there is an exception for protected health information that is subject to HIPAA and clinical trial regulations, the CCPA may impact our business activities if we become a "Business" regulated by the scope of the CCPA. Additionally, as of January 1, 2023, the effective date for the CPRA’s amendments to the CCPA, California has a new state agency that is vested with authority to implement and enforce the CCPA. In addition to the CCPA, numerous other U.S. states – including Virginia, Colorado, Connecticut, and Utah – have enacted comprehensive privacy laws that are substantially similar in scope and contain many of the same requirements and exceptions as the CCPA, including exemptions for clinical trial data and limited obligations for entities regulated by HIPAA. In addition, Congress regularly contemplates passing comprehensive privacy legislation at the federal level, reflecting a trend toward more stringent privacy legislation in the U.S., which trend may accelerate in the future. The effects of the CCPA, and other similar state or federal laws, are potentially significant and may require us to modify our data processing practices and policies and to incur substantial costs and potential liability in an effort to comply with such legislation. The existence of comprehensive privacy laws in different states in the country could make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance.

U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of our product candidates and any future product candidates we develop, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch Waxman Amendments. The Hatch Waxman Amendments permit restoration of the patent term of up to five years as compensation for patent term lost during product development and FDA regulatory review process. Patent term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product’s approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office (USPTO) in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

An abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA licensed reference biological product was created by the Biologics Price Competition and Innovation Act of 2009. Biosimilarity, which requires that the biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, animal studies and a clinical trial or trials. Interchangeability requires that a biological product be biosimilar to the reference product and that the product can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times to an individual, that the product and the reference product may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product without such alternation or switch. A reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. “First licensure” typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure of the

biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity, or potency. Therefore, one must determine whether a new product includes a modification to the structure of a previously licensed product that results in a change in safety, purity, or potency to assess whether the licensure of the new product is a first licensure that triggers its own period of exclusivity. Whether a subsequent application, if approved, warrants exclusivity as the "first licensure" of a biological product is determined on a case-by-case basis with data submitted by the sponsor.

Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing regulatory exclusivity periods. This six-month exclusivity may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA issued "Written Request" for such a trial.

European Union Drug Development

In the EU our future products also may be subject to extensive regulatory requirements. As in the United States, medicinal products can be marketed only if a marketing authorization from the competent regulatory authorities has been obtained.

Similar to the United States, the various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls. In April 2014, the EU adopted the new Clinical Trials Regulation (EU) No 536/2014 (CTR), which entered into application on January 31, 2022, repealing and replacing the Clinical Trials Directive 2001/20/EC (CTD). The CTR foresaw a three-year transition period that ended on January 31, 2025. Since this date, all new or ongoing trials are subject to the provisions of the CTR.

The CTR aims to simplify and streamline the approval of clinical trials in the EU, simplify adverse-event reporting procedures, improve the supervision of clinical trials and increase transparency. The main characteristics of the regulation include: a streamlined application procedure via a single-entry point through the Clinical Trials Information System ("CTIS"); a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I assessment is led by the competent authorities of a reference Member State selected by the trial sponsor and relates to clinical trial aspects that are considered to be scientifically harmonized across EU Member States. This assessment is then submitted to the competent authorities of all concerned Member States in which the trial is to be conducted for their review. Part II is assessed separately by the competent authorities and Ethics Committees in each Member State concerned. Individual EU Member States retain the power to authorize the conduct of clinical trials on their territory. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure continues to be governed by the national law of the concerned EU Member State. However, overall related timelines are defined by the Regulation.

European Union Drug Review and Approval

In the EU, medicinal products can only be commercialized after obtaining a marketing authorization ("MA"). To obtain an MA for a product in the EU, an applicant must submit a Marketing Authorization Application, or MAA, either under a centralized procedure administered by the European Medicines Agency, or EMA, or one of the procedures administered by the competent authorities of EU Member States (decentralized procedure, national procedure or mutual recognition procedure). An MA may be granted only to an applicant established in the EU.

The centralized procedure provides for the grant of a single MA is issued by the European Commission, based on the opinion of the Committee for Medicinal Products for Human Use ("CHMP") of the EMA, that is valid throughout the entire territory of the European Economic Area ("EEA") (which comprises the 27 EU Member States, Iceland, Liechtenstein and Norway). The centralized procedure is mandatory for certain types of products, such as medicines produced by biotechnological processes, products designated as orphan medicinal products, advanced therapy medicines (i.e. gene therapy, somatic cell therapy or tissue engineered medicines) and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases. The centralized procedure is optional for products containing a new active

substance indicated for the treatment of other diseases and products not yet authorized in the EU, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EEA.

Under the centralized procedure, the CHMP is responsible for conducting the initial assessment of a product and for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing MA. Under the centralized procedure in the EU, the maximum timeframe for the evaluation of an MAA by the EMA is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP. Clock stops may extend the timeframe of evaluation of an MAA considerably beyond 210 days. Where the CHMP gives a positive opinion, it provides the opinion together with supporting documentation to the European Commission, who adopts the final decision in relation to a MAA, which is issued within 67 days of receipt of the EMA's opinion. Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of major public health interest, particularly from the point of view of therapeutic innovation. If the CHMP accepts such request, the time limit of 210 days will be reduced to 150 days, excluding clock stops, but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that the application is no longer appropriate to conduct an accelerated assessment.

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

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

Under the above-described procedures, before granting the MA, the European Commission or the competent authorities of the EU Member States make an assessment of the risk benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

An MA has, in principle, an initial validity of five years. The MA may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the EU Member State in which the original MA was granted. To support the application, the MA holder must provide the EMA or the competent authority with a consolidated version of the Common Technical Document providing up-to-date data concerning the quality, safety and efficacy of the product, including all variations introduced since the MA was granted, at least nine months before the MA ceases to be valid. The European Commission or the competent authorities of the EU Member States may decide on justified grounds relating to pharmacovigilance, to proceed with one further five year renewal period for the MA. Once subsequently definitively renewed, the MA shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the EU market (for a centralized MA) or on the market of the authorizing EU Member State within three years after authorization ceases to be valid (the so-called sunset clause).

Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the Priority Medicines, or PRIME, scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. PRIME is a voluntary

scheme aimed at enhancing the EMA's support for the development of medicinal products that target unmet medical needs. Eligible products must target conditions for which there is an unmet medical need (there is no satisfactory method of diagnosis, prevention or treatment in the EU or, if there is, the new medicinal product will bring a major therapeutic advantage) and they must demonstrate the potential to address the unmet medical need by introducing new methods of therapy or improving existing ones. Benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted.

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

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

Advanced Therapy Medicinal Products in the European Union

Advanced Therapy Medicinal Products ("ATMPs"), include gene therapy products as well as somatic cell therapy products and tissue engineered products. The grant of marketing authorization in the EU for products containing viable human tissues or cells such as gene therapy medicinal products is governed by Regulation (EC) No. 1394/2007 on ATMPs, read in combination with Directive (EC) No. 2001/83 of the European Parliament and of the Council, commonly known as the Community code on medicinal products. Regulation (EC) No. 1394/2007 establishes specific rules concerning the authorization, supervision and pharmacovigilance of gene therapy medicinal products, somatic cell therapy medicinal products and tissue engineered products. Manufacturers of advanced therapy medicinal products must demonstrate the quality, safety and efficacy of their products to the EMA which is required to provide an opinion regarding the application for marketing authorization. The European Commission grants or refuses marketing authorization in light of the opinion delivered by the EMA.

Products made from substances of human origin must also comply with Regulation (EU) 2024/1938 on standards of quality and safety for substances of human origin intended for human application. This Regulation describes the conditions and quality requirements which must be applied when sourcing the substances of human origin intended for manufacturing of such medicinal products and removed divergences between EU Member States that were present under the (now repealed) Directive (EC) No. 2004/23.

European Union Pediatric Development

In the EU, Regulation (EC) No 1901/2006 provides that all MAAs for new medicinal products have to include the results of trials conducted in the pediatric population, in compliance with a pediatric investigation plan, or PIP, agreed with the EMA's Pediatric Committee ("PDCO"). The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the medicinal product for which MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures provided in the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all EU Member States and study results are included in the product information, even when negative, the product is eligible for a six-month extension to the Supplementary Protection Certificate ("SPC") if any is in effect at the time of authorization or, in the case of orphan medicinal products, a two-year extension of orphan market exclusivity.

European Union Data and Market Exclusivities

In the EU, innovative medicinal products qualify for eight years of data exclusivity upon grant of an MA and an additional two years of market exclusivity. The data exclusivity, if granted, prevents generic or biosimilar applicants from referencing the innovator's preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar MA in the EU, during a period of eight years from the date on which the reference product was first authorized in the EU. During the additional two-year period of market exclusivity, a generic or biosimilar MAA can be submitted, and the innovator's data may be referenced, but no generic or biosimilar product can be placed on the EU market until the expiration of the market exclusivity. The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are determined to bring a significant clinical benefit in comparison with currently approved therapies. There is no guarantee that a product will be considered by the EU's regulatory authorities to be an innovative medicinal product, and products may not qualify for data exclusivity.

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

European Union Orphan Designation and Exclusivity

In the EU, medicinal products can be designated as an orphan medicinal product by the European Commission, following the opinion of the EMA's Committee for Orphan Medicinal Products if the sponsor of a product can establish that: (1) the product is intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions; (2) either (i) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (ii) it is unlikely that the marketing of the product, without the benefits derived from orphan status, would generate sufficient return in the EU to justify the necessary investment in its development; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or, if a method exists, the product would be a significant benefit to those affected by that condition.

An application for the designation of a medicinal product as an orphan medicinal product must be submitted at any stage of development of the medicinal product but before filing of an MAA. An MA for an orphan medicinal product may only include indications designated as orphan. For non-orphan indications treated with the same active pharmaceutical ingredient, a separate marketing authorization has to be sought.

In the EU, orphan designation entitles a party to financial incentives such as reduction of fees or fee waivers, protocol assistance, and access to the centralized marketing authorization procedure. Upon grant of a marketing

authorization, orphan medicinal products are entitled to a ten-year period of market exclusivity for the approved therapeutic indication, which means that the EMA cannot accept another marketing authorization application or accept an application to extend for a "similar product" and the European Commission cannot grant a marketing authorization for the same indication for a period of ten years. A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed PIP. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan medicinal product designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The market exclusivity period may be reduced to six years if the orphan designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, an MA may be granted to a similar medicinal product with the same orphan indication during the 10 year period if (i) it is established that a similar medicinal product is safer, more effective or otherwise clinically superior to the original orphan medicinal product; (ii) the marketing authorization holder of the authorized orphan product consents to a second original orphan medicinal product application; or (iii) the marketing authorization holder of the authorized orphan product cannot supply enough orphan medicinal product. A company may also voluntarily remove a product from the register of orphan products. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Manufacturing Regulation in the EU

In addition to an MA, various other requirements apply to the manufacturing and placing on the EU market of medicinal products. The manufacturing of medicinal products in the EU requires a manufacturing authorization and import of medicinal products into the EU requires a manufacturing authorization allowing for import. The manufacturing authorization holder must comply with various requirements set out in the applicable EU laws, regulations and guidance, including EU cGMP standards. Similarly, the distribution of medicinal products within the EU is subject to compliance with the applicable EU laws, regulations and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of EU Member States. Marketing authorization holders and/or manufacturing and import authorization, or MA holders and/or distribution authorization holders may be subject to civil, criminal or administrative sanctions, including suspension of manufacturing authorization, in case of non-compliance with the EU or EU Member States' requirements applicable to the manufacturing of medicinal products.

If an MA for a medicinal product in the EU is obtained, the holder of the MA is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. These include:

- Compliance with the EU's stringent pharmacovigilance or safety reporting rules must be ensured. These rules can impose post-authorization studies and additional monitoring obligations. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports ("PSURs").

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

- In the EU, the advertising and promotion of medicinal products are subject to both EU and EU Member States' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. General requirements for advertising and promotion of medicinal products, such as direct-to-consumer advertising of prescription medicinal products are established in EU law. However, the details are governed by regulations in individual EU Member States and can differ from one country to another. For example,

applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics, or SmPC, which may require approval by the competent national authorities in connection with an MA. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU.

- Much like the Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. In addition, payments made to physicians in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization as well as the regulatory authorities of the individual EU Member States. Outside the United States, interactions between pharmaceutical companies and health care professionals including the provision of benefits or advantages to physicians, are also governed by strict laws, such as national anti-bribery laws of European countries such as the Bribery Act 2010 in the UK, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

The aforementioned EU rules are generally applicable in the European Economic Area (EEA) which consists of the EU Member States, plus Norway, Liechtenstein and Iceland.

European Data Collection

The collection and use of personal health data in the EEA is governed by the EU GDPR. The EU GDPR applies to any company established in the EEA and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. The EU GDPR enhances data protection obligations for data controllers of personal data, including stringent requirements relating to the consent of data subjects, expanded disclosures about how personal data is used, requirements to conduct privacy impact assessments for "high risk" processing, limitations on retention of personal data, mandatory data breach notification and "privacy by design" requirements, and creates direct obligations on service providers acting as data processors.

In addition, further to the United Kingdom's exit from the European Union on January 31, 2020, the EU GDPR ceased to apply in the United Kingdom at the end of the transition period on December 31, 2020. However, as of January 1, 2021, the United Kingdom's European Union (Withdrawal) Act 2018 incorporated the EU GDPR (as it existed on December 31, 2020 but subject to certain UK specific amendments) into UK law, referred to as the UK GDPR. The UK GDPR and the UK Data Protection Act 2018 set out the United Kingdom's data protection regime, which is independent from but substantially aligned to the European Union's data protection regime. Although the EU GDPR and the UK GDPR currently impose substantially similar obligations, it is possible that over time the UK GDPR could become less aligned with the EU GDPR. The UK government has announced plans to reform the data protection legal framework in the UK in the Data Protection and Digital Information Bill. The potential misalignment between future UK laws and regulations and EU laws and regulations could add legal risk, uncertainty, complexity and cost to our handling of EU/UK personal information and our privacy and data security compliance programs and could require us to implement different compliance measures for the UK and the EU. Non-compliance with the UK GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher. Although the UK is regarded as a third country under the EU GDPR, the EC has issued a decision recognizing the UK as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the EU to the UK remain unrestricted. Like the EU GDPR, the UK GDPR restricts personal data transfers outside the United Kingdom to countries not regarded by the United Kingdom as providing adequate protection. The UK government has confirmed that personal data transfers from the United Kingdom to the EEA remain free flowing. To enable the transfer of personal data outside of the EEA or the UK, adequate safeguards must be implemented in compliance with EU and UK data protection laws. There are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EU's Standard Contractual Clauses, the UK's International Data Transfer Agreement /

Addendum, and the EU-U.S. Data Privacy Framework and the UK Extension thereto (which allows for transfers for relevant U.S.-based organizations who self-certify compliance and participate in the Framework). However, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States.

Failure to comply with the requirements of the EU GDPR or UK GDPR and the related national data protection laws of the EEA Member States may result in fines up to €20 million or 4% of a company's global annual revenues for the preceding financial year, whichever is higher. Moreover, the EU GDPR and UK GDPR grant data subjects the right to claim material and non-material damages resulting from infringement of the EU GDPR or UK GDPR. Given the breadth and depth of changes in data protection obligations, maintaining compliance with the EU GDPR and UK GDPR, will require significant time, resources and expense, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. This may be onerous and adversely affect our business, financial condition, results of operations and prospects.

Brexit and the Regulatory Framework in the United Kingdom

The United Kingdom's, or UK, withdrawal from the EU on January 31, 2020, commonly referred to as Brexit, has changed the regulatory relationship between the UK and the EU. The Medicines and Healthcare products Regulatory Agency, or MHRA, is now the UK's standalone regulator for medicinal products and medical devices. The United Kingdom is now a third country to the EU.

The UK regulatory framework in relation to clinical trials is governed by the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended, which is derived from the CTD, as implemented into UK national law through secondary legislation. On January 17, 2022, the MHRA launched an eight-week consultation on reframing the UK legislation for clinical trials, and which aimed to streamline clinical trials approvals, enable innovation, enhance clinical trials transparency, enable greater risk proportionality, and promote patient and public involvement in clinical trials. The UK Government published its response to the consultation on March 21, 2023 confirming that it would bring forward changes to the legislation. The UK Government published its response to the consultation on March 21, 2023, confirming that it would bring forward changes to the legislation and such changes were laid in parliament on December 12, 2024. These resulting legislative amendments will, if implemented in their current form, bring the UK into closer alignment with the CTR. In October 2023, the MHRA announced a new Notification Scheme for clinical trials which enables a more streamlined and risk-proportionate approach to initial clinical trial applications for Phase 4 and low-risk Phase 3 clinical trial applications.

Marketing authorizations in the United Kingdom are governed by the Human Medicines Regulations (SI 2012/1916), as amended. Since January 1, 2021, an applicant for the EU's centralized procedure marketing authorization can no longer be established in the United Kingdom. As a result, since this date, companies established in the United Kingdom cannot use the EU's centralized procedure. In order to obtain a United Kingdom MA to commercialize products in the United Kingdom, an applicant must be established in the United Kingdom and must follow one of the United Kingdom national authorization procedures or one of the remaining post-Brexit international cooperation procedures. Applications are governed by the Human Medicines Regulations (SI 2012/1916) and are made electronically through the MHRA Submissions Portal. The MHRA has introduced changes to national licensing procedures, including procedures to prioritize access to new medicines that will benefit patients, a 150-day assessment (subject to clock-stops) and a rolling review procedure. The rolling-review procedure permits the separate or joint submission of quality, non-clinical, and clinical data to the MHRA which can be reviewed on a rolling basis. After an application under the rolling-review procedure has been validated, the decision should be received within 100 days (subject to clock-stops).

In addition, since January 1, 2024, the MHRA may rely on the International Recognition Procedure ("IRP"), when reviewing certain types of MAAs. Pursuant to the IRP, the MHRA will take into account the expertise and decision-making of trusted regulatory partners (e.g., the regulatory in Australia, Canada, Switzerland, Singapore, Japan, the U.S.A. and the EU). The MHRA will conduct a targeted assessment of IRP applications but retain the authority to reject applications if the evidence provided is considered insufficiently robust. The IRP allows medicinal products approved by such trusted regulatory partners that meet certain criteria to undergo a fast-tracked MHRA review to obtain and/or update a MA in the United Kingdom.

Applications should be decided within a maximum of 60 days if there are no major objections identified that cannot be resolved within such 60 day period and the approval from the trusted regulatory partner selected has been granted within the previous 2 years or if there are such major objections identified or such approval hasn't been granted within the previous 2 years within 110 days. Applicants can submit initial MAAs to the IRP but the procedure can also be used throughout the lifecycle of a product for post-authorization procedures including line extensions, variations and renewals.

All existing marketing authorizations of the EU for centrally authorized products were automatically converted or grandfathered into the United Kingdom's marketing authorization, effective in Great Britain only, free of charge on January 1, 2021, unless the marketing authorization holder opted-out of this possibility. Northern Ireland remained within the scope of authorizations of the EU in relation to centrally authorized medicinal products until January 1, 2025. However, on January 1, 2025, a new arrangement as part of the so-called "Windsor Framework" came into effect and reintegrated Northern Ireland under the regulatory authority of the MHRA with respect to medicinal products. The Windsor Framework removes EU licensing processes and EU labelling and serialization requirements in relation to Northern Ireland and introduces a UK-wide licensing process for medicines.

There is no pre-marketing authorization orphan designation for medicinal products in the UK. Instead, the MHRA reviews applications for orphan designation in parallel to the corresponding marketing authorization application. The criteria are essentially the same as those in the EU, but have been tailored for the market. This includes the criterion that prevalence of the condition in the United Kingdom, rather than the EU, must not be more than five in 10,000. Upon the grant of a marketing authorization with orphan status, the medicinal product will benefit from up to 10 years of market exclusivity from similar products in the approved orphan indication. The start of this market exclusivity period will be set from the date of first approval of the product in the United Kingdom.

Rest of the World Regulation

For other countries outside of the EU and the United States, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. Additionally, the clinical trials must be conducted in accordance with GCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. In addition, many jurisdictions outside of Europe are also considering and/or enacting comprehensive data protection legislation. These laws impose stringent requirements applicable to our collection, use and processing of personal data including identifiable health information.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Coverage and Reimbursement

Sales of our products, when and if approved, will depend, in part, on the extent to which our products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS, an agency within the HHS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. However, no uniform policy of coverage and reimbursement for drug or biological products exists in the United States. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of our products will be made on a payor by payor basis. As a result, coverage determination is often a time consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. Factors payors consider in determining reimbursement are based on whether the product 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.

The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government paid health care costs, including price controls, restrictions on reimbursement and requirements for substitution of biosimilars for branded prescription drugs. For example, the ACA contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal healthcare programs. Adoption of general controls and measures, coupled with the tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceutical drugs.

The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the HHS as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. The ACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs from 15.1% of average manufacturer price (AMP), to 23.1% of AMP and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The ACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by enlarging the population potentially eligible for Medicaid drug benefits.

As noted above, the marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide coverage and reimbursement. Obtaining coverage and reimbursement for newly approved drugs and biologics is a time consuming and costly process, and coverage may be more limited than the purposes for which a drug is approved by the FDA or comparable foreign regulatory authorities. Assuming coverage is obtained for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require copayments that patients find unacceptably high. Additionally, coverage policies and third-party reimbursement rates may change at any time. 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 their prescription drugs. Patients are unlikely to use products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of prescribed products.

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

In addition, in most foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the EU provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Other EU Member States allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. In addition, some EU Member States may require the completion of

additional studies that compare the cost-effectiveness of a particular medicinal product candidate to currently available therapies. This Health Technology Assessment, or HTA, process is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The HTA Regulation has applied from January 12, 2025 although it will enter into force iteratively and initially apply to new active substances to treat cancer and to all advanced therapy medicinal products (ATMPs), it will then be expanded to orphan medicinal products in January 2028, and to all centrally authorized medicinal products as of 2030. Selected high-risk medical devices will also be assessed under the HTA Regulation as of 2026. The HTA Regulation is intended to harmonize the clinical benefit assessment of HTA across the EU and permits EU Member States to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected. In light of the fact that the United Kingdom has left the EU, Regulation No 2021/2282 on HTA does not apply in the United Kingdom. However, the UK Medicines and Healthcare products Regulation Agency ("MHRA") is working with UK HTA bodies and other national organizations, such as the Scottish Medicines Consortium ("SMC"), the National Institute for Health and Care Excellence ("NICE"), and the All-Wales Medicines Strategy Group, to introduce new pathways supporting innovative approaches to the safe, timely and efficient development of medicinal products, including, effective as of March 31, 2025, relaunching the Innovative Licensing and Access Pathway with more predicable timelines and closer involvement of the National Health Service.

There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the EU do not follow price structures of the United States and generally prices tend to be significantly lower.

Human Capital Resources

As of January 31, 2025, we had 82 full-time employees and 5 part-time employees which include employees affected by the Restructuring Plan that will continue to work throughout their termination period. Of our 87 full and part-time employees, 25, or 28.7%, have Ph.D. or M.D. degrees and 65, or 74.7%, are engaged in research and development activities. Pursuant to Austrian law, all of our Austrian employees are covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. To further drive attraction and retention of our high-quality, experienced, and diverse workforce, we invest in the physical, emotional, and financial well-being of our employees. The principal purposes of our equity incentive plans are to attract, retain and reward personnel through the granting of stock-based compensation awards in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Corporate History

We were originally incorporated as Hookipa Biotech AG under the laws of Austria in 2011. In February 2017, we reorganized to become a corporation under the laws of the State of Delaware as Hookipa Biotech, Inc., which was a wholly-owned subsidiary of Hookipa Biotech AG. In June 2018, Hookipa Biotech, Inc. changed its name to HOOKIPA Pharma Inc. and acquired all of the shares of Hookipa Biotech AG, now Hookipa Biotech GmbH.

Available Information

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, proxy statements, and other information, including amendments and exhibits to such reports, filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, are available free of charge on our website located at www.hookipapharma.com, as soon as reasonably practicable after they are filed with or furnished to the SEC. These reports are also available at the SEC's Internet website at www.sec.gov.

A copy of our Corporate Governance Guidelines, Code of Conduct and the charters of the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee are posted on our website, www.hookipapharma.com, under the heading "Corporate Governance."

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Annual Report on Form 10-K, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

Risks Related to Our Financial Position and Capital Needs

We are a clinical-stage biopharmaceutical company with no approved products and a limited operating history. We have incurred significant losses since inception. We expect to incur losses for at least the next several years and may never achieve or maintain profitability.

We are a clinical stage biopharmaceutical company with no approved products and a limited operating history. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale and have not generated any revenue from product sales. To date, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, undertaking preclinical studies and clinical trials of our product candidates, securing related intellectual property rights and conducting discovery, research and development activities for our programs. As a result, we are not profitable and have incurred losses in each period since our inception in 2011. For the years ended December 31, 2023 and 2024, we reported a net loss of $81.6 million and $43.5 million, respectively. As of December 31, 2024, we had an accumulated deficit of $412.8 million. We expect to continue to incur significant losses for the foreseeable future. We anticipate that our expenses will increase substantially if, and as, we:

- pursue the clinical and preclinical development of our current and future product candidates;
- leverage our technologies to advance product candidates into preclinical and clinical development;
- seek regulatory approvals for product candidates that successfully complete clinical trials, if any;
- attract, hire, and retain additional clinical, quality control and scientific personnel;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company;

- establish our manufacturing capabilities through third parties or by ourselves and scale-up manufacturing to provide adequate supply for clinical trials and commercialization;
- expand and protect our intellectual property portfolio;
- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly;
- acquire or in-license other product candidates and technologies.

Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates and we may never generate revenue that is significant or large enough to achieve profitability. We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Accordingly, our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company also could cause you to lose all or part of your investment.

There is substantial doubt regarding our ability to continue as a going concern. We will need to raise substantial additional funding, which may not be available on acceptable terms, if at all, to be able to continue as a going concern and advance any our product candidates. Failure to obtain capital when needed may force us to delay, limit or terminate our product development efforts or other operations. Raising additional capital may dilute our existing shareholders, restrict our operations or cause us to relinquish valuable rights.

There is substantial doubt regarding our ability to continue as a going concern. Our continued existence is dependent upon our ability to obtain additional capital. As of December 31, 2024, we had cash, cash equivalents and restricted cash of approximately $39.9 million. In February 2025, we received a payment of $19.8 million related to receivables from Austrian research incentive program. Our management believes that such cash, cash equivalents and restricted cash will not be sufficient to fund our operating expenses and capital requirements for one year after the date that the financial statements are issued, whether or not we curtail efforts with respect to certain of our product candidates. We will require significant additional funding to advance any of our product candidates beyond the short term.

We are seeking funds through collaborations, strategic alliances, or licensing arrangements with third parties, and such agreements may impact rights to our product candidates or technologies, future revenue streams, research programs or products candidates or to grant licenses on terms that may not be favorable to us. Such arrangements will limit our participation in the success of any of our product candidates that receive regulatory approval.

We may also seek to raise such capital through public or private equity, royalty financing or debt financing. Raising funds in the current economic environment is challenging and financing may not be available in sufficient amounts or on acceptable terms, if at all. The issuance of additional securities, whether equity or debt, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities may dilute the ownership of existing shareholders. Incurring debt would result in increased fixed payment obligations, and we may agree to restrictive covenants, such as limitations on our ability to incur additional debt or limitations on our ability to acquire, sell or license intellectual property rights that could impede our ability to conduct our business.

We will require substantial additional financing and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations.

Since our inception, we have invested a significant portion of our efforts and financial resources in research and development activities for our non-replicating and replicating technologies and our product candidates derived from these technologies. Preclinical studies and clinical trials and additional research and development activities will require substantial funds to complete. We believe that we will continue to expend substantial resources for the foreseeable future in connection with the development of our current product candidates and programs, any future product candidates we may choose to pursue, when we begin to develop our own manufacturing capabilities and other corporate uses. These expenditures will include costs associated with conducting preclinical studies and clinical trials, obtaining regulatory approvals, and manufacturing and supply, as well as marketing and selling any products approved for sale. Our expenses could increase beyond our current expectations if other unanticipated costs arise or if the FDA, the EMA, or other comparable foreign regulatory authorities requires us to perform clinical trials and other studies in addition to those that we currently anticipate. Because the outcome of any preclinical study or clinical trial is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our current or future product candidates. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce or terminate our research and development programs or future commercialization efforts.

As of December 31, 2024, we had $39.9 million in cash, cash equivalents and restricted cash. Our management believes that such cash, cash equivalents and restricted cash will not be sufficient to fund our operating expenses and capital requirements for one year after the date the financial statements are issued, whether or not we curtail efforts with respect to certain of our current and future product candidates. We will require significant additional funding to advance any of our product candidates beyond the short term and to sustain our operations. Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing our current and future product candidates and programs, and of conducting preclinical studies and clinical trials;
- the number and development requirements of other product candidates that we may pursue, and other indications for our current product candidates that we may pursue;
- our ability to achieve efficiencies and expected cost reductions in connection with our recent strategic refocus;
- the stability, scale and yields of our future manufacturing process as we scaleup production and formulation of our product candidates for later stages of development and commercialization;
- the timing of, and the costs involved in, obtaining regulatory and marketing approvals and developing our ability to establish sales and marketing capabilities, if any, for our current and future product candidates we develop if clinical trials are successful;
- the success of our collaborations with Gilead;
- our ability to establish and maintain collaborations, strategic licensing or other arrangements and the financial terms of such agreements. For example, in January 2024 Roche notified us of their decision to terminate their collaboration agreement with us;
- the cost of commercialization activities for our current and future product candidates that we may develop, whether alone or with a collaborator;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;

- the timing, receipt and amount of sales of, or royalties on, our future products, if any; and
- the emergence of competing oncology and infectious disease therapies and other adverse market developments.

Other than the Stock Purchase Agreement and our collaboration agreements with Gilead, we do not have any committed external source of funds or other support for our development efforts.

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

Until we can generate sufficient product and royalty revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements and grant funding.

If we raise additional capital through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest will be diluted. For example, in December 2023 we entered into an Amended and Restated Stock Purchase Agreement with Gilead pursuant to which we issued and sold 15,000,000 shares of unregistered common stock to Gilead for approximately $21.25 million, and we may require Gilead to purchase up to approximately $8.75 million of additional share of common stock. In addition, in May 2023 we completed a public offering in which we issued and sold 22,900,768 shares of common stock and 15,268 shares of Series A-2 convertible preferred stock, which are convertible into common stock on a 1,000 to one basis, pursuant to our shelf registration statement on Form S-3 (File No. 333-266104) for net proceeds of $46.3 million. If we raise additional capital through debt financing, we would be subject to fixed payment obligations and may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us.

If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, reduce or terminate our product development or future commercialization efforts or grant rights to third parties to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders if we issue equity securities, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We may evaluate various acquisitions and strategic partnerships, including acquiring complementary products, intellectual property rights, technologies, or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integration;

- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology or products sufficient to meet our objectives in undertaking the acquisition.

In addition, if we undertake acquisitions, we may incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense.

We have obtained funding from an agency of the Austrian government that contains certain covenants that may restrict our operations.

In the past, we have contracted numerous funding agreements with an agency of the Austrian government to partially finance our research and development programs, such as personnel costs, material costs, third-party services, travel expenses and research and development infrastructure use. These funding agreements include both below market rate loans and grants, which are subject to various criteria linked to certain terms and conditions as well as certain costs attributable to the respective funded research and development program. We have committed to reporting obligations and to obtain the approval for significant changes in the cost structure of the funded research and development programs. If we were to breach these contractual obligations, we may be held liable by the agency of the Austrian government for damages incurred by such agencies resulting from the breach of contract and we could be required to reimburse in full the funding granted by such agencies.

As of December 31, 2024, we have no outstanding loans related to these funding agreements. A final principal repayment of $1.1 million was made in the year ended December 31, 2024.

Further, pursuant to the general terms of each grant, the agency is entitled to re-evaluate the funding granted to us in case of a fundamental change in our ownership structure if such change no longer ensures that the purpose of the funding can be achieved. Any such re-evaluation could negatively impact the funding that we receive or have received from the agency or that we may receive in the future from other agencies of the Austrian government.

Risks Related to Our Business and Industry

If we are unable to advance our current or future product candidates into and through clinical trials, obtain marketing approval and ultimately commercialize any product candidates we develop, or experience significant delays in doing so, our business will be materially harmed.

All of our product candidates are in early stages of development, including our lead product candidate, eseba-vec (formerly HB-200), and as such will require extensive preclinical and clinical testing. We cannot predict with any certainty if or when we might submit an IND, or BLA, or comparable foreign applications, for regulatory approval for any of our product candidates or whether any such IND or BLA, or comparable foreign applications, will be accepted for review by the FDA or comparable foreign regulatory authority, or subsequently whether any such IND will go into effect or BLA will be approved upon review, or whether comparable foreign applications will fulfill the related milestones.

We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. For example, in 2024 we announced a strategic refocus to prioritize HB-700 and Gilead-partnered programs in infectious disease and to pause development activities related to HB-300 and most other preclinical research activities. In connection with this strategic refocus, we implemented an approximately 30%

reduction in our workforce and discontinued our GMP manufacturing facility project. In January 2024 Roche notified us of their decision to terminate the collaboration and licensing agreement for HB-700 in KRAS mutated cancers, despite acknowledging we had met all go-forward criteria under the agreement.

Our ability to generate product revenues, which we do not expect to occur for several years, if ever, will depend heavily on the successful development and eventual commercialization of the product candidates we develop, which may never occur. Before we are able to generate any revenues from product sales, our current product candidates, and any future product candidates we develop, will require additional preclinical and clinical development, management of clinical, preclinical and manufacturing activities, marketing approval in the United States and other markets, demonstrating effectiveness to pricing and reimbursement authorities, obtaining sufficient manufacturing supply for both clinical development and commercial production, building of a commercial organization, and substantial investment and significant marketing efforts. The success of our current and future product candidates will depend on several factors, including the following:

- successful completion of preclinical studies and clinical trials;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- acceptance of INDs and comparable foreign applications for our planned clinical trials or future clinical trials;
- successful enrollment and completion of clinical trials;
- successful data from our clinical program that support an acceptable risk-benefit profile of our product candidates in the intended populations;
- receipt and maintenance of regulatory and marketing approvals from applicable regulatory authorities;
- scale-up of our manufacturing processes and formulation of our product candidates for later stages of development and commercialization;
- establishing our own manufacturing capabilities or agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if our product candidates are approved;
- entry into collaborations to further the development of our product candidates;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates;
- successfully launching commercial sales of our product candidates, if and when approved;
- acceptance of the product candidate’s benefits and uses, if and when approved, by patients, the medical community and third-party payors;
- the prevalence and severity of adverse events experienced with our product candidates;
- maintaining a continued acceptable safety profile of the product candidates following approval;
- effectively competing with other therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors; and

- qualifying for, maintaining, enforcing and defending intellectual property rights and claims.

We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator. If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize the product candidates we develop, which would materially harm our business.

The regulatory approval processes of the FDA, the EMA and the European Commission and other comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval from the FDA, the European Commission and other comparable foreign regulatory authorities is unpredictable, but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate, and it is possible that none of our current or future product candidates will ever obtain regulatory approval.

Our current and future product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA, the EMA or other comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, the EMA or the European Commission or other comparable foreign regulatory authorities that a product candidate is safe, pure and potent or effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA, the EMA and the European Commission or other comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA, the EMA or the European Commission or other comparable foreign regulatory authorities may disagree with our interpretation of data from clinical trials or preclinical studies;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA to the FDA, or similar foreign submission to the EMA or other comparable foreign regulatory authority, or to obtain approval in the United States, the European Union or elsewhere;
- the supply or quality of materials for product candidates we develop or other materials necessary to conduct clinical trials may be insufficient or inadequate;
- the FDA, the EMA the European Commission, competent authorities of EU Member States or other comparable foreign regulatory authorities may, as applicable, find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and

- the approval policies or regulations of the FDA, the EMA and the European Commission or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of clinical trial results may result in our failing to obtain regulatory approval to market any product candidate we develop, which would significantly harm our business, results of operations and prospects.

We have conducted, and intend to conduct, clinical trials of certain of our product candidates outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA, including compliance with all applicable U.S. laws and regulations. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with GCP, including review and approval by an independent ethics committee and informed consent from subjects. The study population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. In general, the patient population for any clinical trials conducted outside of the United States must be representative of the population for whom we intend to label the product in the United States. There can be no assurance the FDA will accept data from trials conducted outside of the United States. Comparable risks apply abroad in relation to the data that was generated in the United States which we intend to leverage for purposes of obtaining regulatory authorizations abroad. There can be no assurance that foreign regulatory authorities will accept data from trials conducted outside of their territory.

The FDA, the EMA and the European Commission and other comparable foreign regulatory authorities have discretion in the approval process and determining when or whether regulatory approval will be obtained for any product candidate that we develop. Even if we believe the data collected from future clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA, the European Commission or any other comparable foreign regulatory authorities.

Even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Our clinical trials may fail to demonstrate adequately the safety and efficacy of any of our product candidates, which would prevent or delay regulatory approval and commercialization.

Before obtaining regulatory approvals for the commercial sale of our product candidates, including eseba-vec, HB-400, HB-500, HB-700 and any other future product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process, and, because our product candidates are in an early stage of development, there is a high risk of failure and we may never succeed in developing marketable products.

Clinical trials that we may conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. If the results of our ongoing or future clinical trials are inconclusive with respect to the efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be delayed in obtaining marketing approval, if at all.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue from future drug sales and regulatory and commercialization milestones. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates, if approved, or allow our competitors to bring comparable products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business, financial condition, results of operations and prospects.

Even if the trials are successfully completed, clinical data are often susceptible to varying interpretations and analyses, and we cannot guarantee that the FDA, the EMA and the European Commission, or other comparable foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. We cannot guarantee that the FDA, the EMA and the European Commission or other comparable foreign regulatory authorities will view our product candidates as having efficacy even if positive results are observed in our clinical trials. To the extent that the results of the trials are not satisfactory to the FDA, the EMA and the European Commission or other comparable foreign regulatory authorities for support of a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

Our preclinical programs may experience delays or our product candidates may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these product candidates on a timely basis or at all, which would have an adverse effect on our business.

Certain of our product candidates and all of our next generation product candidates are still in the preclinical development stage, and the risk of failure of preclinical programs is high. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies to obtain regulatory clearance to initiate human clinical trials, including based on INDs in the United States and clinical trial applications in Europe. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA, the competent authorities of EU Member States or other regulatory authorities will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our product candidates. As a result, we cannot be sure that submission of INDs or similar applications will result in the FDA, the competent authorities of EU Member States or other comparable foreign regulatory authorities allowing clinical trials to begin.

We have in the past, and may in the future, encounter challenges in collecting, transporting and analyzing clinical blood samples, which could cause delays or prevent the approval of our drug candidates.

Interim, top line and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to regulatory audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim, top line or preliminary data from our clinical trials. We may decide to conduct an interim analysis of the data after a certain number or percentage of patients have been enrolled, or after only a part of the full follow-up period but before completion of the trial. Similarly, we may report top line or preliminary results of primary and key secondary endpoints before the final trial results are completed. Preliminary, top line and interim data from our clinical trials may change as more patient data or analyses become available. Preliminary, top line or interim data from our clinical trials are not necessarily predictive of final results and are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues, more patient data become available, and we issue our final clinical trial report. These data also remain subject to verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, preliminary, interim and top line data should be viewed with caution until the final data are available. Material adverse changes in the final data compared to the interim data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our interim, topline or preliminary analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular

program, the approvability or commercialization of the particular product candidate and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

Results of earlier studies and trials of our product candidates may not be predictive of future trial results.

Success in preclinical studies and early clinical trials does not ensure that later clinical trials will be successful. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Even if we are able to commence clinical trials, issues may arise that could suspend or terminate such clinical trials. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in clinical trials, even after positive results in earlier preclinical studies or clinical trials. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. Notwithstanding any potential promising results in earlier studies and trials, we cannot be certain that we will not face similar setbacks. In addition, the results of our preclinical animal studies, including our oncology mouse studies and animal studies, may not be predictive of the results of outcomes in human clinical trials. For example, our oncology product candidates that are in preclinical development may demonstrate different chemical and biological properties in patients than they do in laboratory animal studies or may interact with human biological systems in unforeseen or harmful ways.

Our replicating technology is early in clinical development and could therefore prove to be unsafe.

Our replicating technology is an attenuated viral vector technology. If our technology causes unexpected side effects that are not tolerable in the treatment of the relevant patient group, the further development of the product candidate and any other potential products based on the replicating technology may be significantly limited or become impossible. Although clinical trials of onco-viral therapies have supported their role as a potential treatment for cancer, there is the risk of uncontrolled replication in vivo and possible transmission to patients' contacts, such as other patients and health care workers. In recent years, clinical trials to address these concerns have been conducted. Any such transmission by our product candidates or a competitor would have an adverse impact on our future research and development efforts.

Our product candidates are based on a novel approach to the treatment of cancer, which makes it difficult to predict the time and cost of product candidate development.

We have concentrated all of our research and development efforts on product candidates based on our non-replicating and replicating technologies, and our future success depends on the successful development of this therapeutic approach. Our non-replicating and replicating technologies utilize arenaviruses to activate CD8+ T cells and induce pathogen-neutralizing antibodies. There are no approved products that utilize the arenavirus. Because our non-replicating and replicating technologies are novel, regulatory agencies may lack experience with product candidates which may lengthen the regulatory review process, increase our development costs and delay or prevent commercialization of our product candidates. We have not yet succeeded and may not succeed in demonstrating safety and efficacy for any of our product candidates in ongoing or late-stage clinical trials or in obtaining marketing approval thereafter.

In addition, our vectors are live, gene-modified organisms for which the FDA, the EU and other comparable foreign regulatory authorities and other public health authorities, such as the Centers of Disease Control and Prevention and hospitals involved in clinical studies, have established additional safety and contagion rules and procedures, which could establish additional hurdles for the development, manufacture or use of our vectors. These hurdles may lead to delays in the conduct of clinical trials or in obtaining regulatory approvals for further development, manufacturing or commercialization of our product candidates. We may also experience delays in transferring our process to commercial partners, which may prevent us from completing our clinical trials or commercializing our product candidates on a timely or profitable basis, if at all.

Since the number of patients that we plan to dose in some of our planned clinical trials is small, the results from such clinical trials, once completed, may be less reliable than results achieved in larger clinical trials, which may hinder our efforts to obtain regulatory approval for our product candidates.

A trial design that is considered appropriate for regulatory approval includes a sufficiently large sample size with appropriate statistical power, as well as proper control of bias, to allow a meaningful interpretation of the results. Future trials of eseba-vec or other product candidates may similarly enroll a small number of patients although some trials will require the enrollment of more patients. The preliminary results of trials with smaller sample sizes can be disproportionately influenced by the impact the treatment had on a few individuals, which limits the ability to generalize the results across a broader community, making the trial results less reliable than trials with a larger number of patients. As a result, there may be less certainty that such product candidates would achieve a statistically significant effect in any future clinical trials. If we conduct any future clinical trials, we may not achieve a statistically significant result or the same level of statistical significance, if any, that would have been possible to achieve in a larger trial.

Our product candidates may cause serious adverse events, undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, require expansion of the trial size, limit their commercial potential or result in significant negative consequences.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities, including IRBs or ethics committees, to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, the European Commission or other comparable foreign regulatory authorities. Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of subjects and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the drug. Because of our dose escalation design for our clinical trials, undesirable side effects could also result in an expansion in the size of our clinical trials, increasing the expected costs and timeline of our clinical trials. Additionally, results of our trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. If we do observe severe side effects in our clinical trials, our ongoing clinical trials may be halted or put on clinical hold prior to completion if there is an unacceptable safety risk for patients.

If unacceptable toxicities arise in the development of our product candidates, we could suspend or terminate our trials or the FDA, the competent authorities of EU Member States or other comparable foreign regulatory authorities, or local regulatory authorities such as IRBs or ethics committees, could order us to cease clinical trials. Competent national health authorities, such as the FDA or the European Commission, could also deny approval of our product candidates for any or all targeted indications. Even if the side effects presented do not preclude the product from obtaining or maintaining marketing approval, treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our product candidates, if approved, to understand the side effect profile of these technologies for both our planned clinical trials and upon any commercialization of any product candidates, if approved. Inadequate training in recognizing or managing the potential side effects of our technologies could result in patient deaths. Any of these occurrences may harm our business, financial condition and prospects significantly.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;

- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- the novel nature of the technology underlying our product candidates which may not be known to or be negatively perceived by clinical trial investigators or patients;
- our ability to obtain and maintain patient consents;
- the risk that patients enrolled in clinical trials will drop out of the trials before the manufacturing and infusion of our product candidates or trial completion; and
- current or potential pandemics that may limit patients, principal investigators or staff or clinical site availability (e.g. the recent COVID-19 pandemic).

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates or similar areas, and this competition will reduce the number and types of patients available to us because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Moreover, because our product candidates represent a departure from more commonly used methods for the treatment of infectious diseases and cancers, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy and hematopoietic stem cell transplantation, rather than enroll patients in any future clinical trial. Additionally, because some of our clinical trials will be in patients with relapsed or refractory cancer, the patients are typically in the late stages of the disease and may experience disease progression independent from our product candidates, making them unevaluable for purposes of the trial and requiring additional enrollment.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our ongoing and planned clinical trials, which could prevent completion or commencement of these trials and adversely affect our ability to advance the development of our product candidates.

We have limited experience as a company conducting clinical trials.

We have limited experience as a company in conducting clinical trials. In part because of this lack of experience, we cannot be certain that our ongoing clinical trials will be completed on time or if our planned clinical trials will begin at all. Large scale trials would require significant additional financial and management resources and reliance on third-party clinical investigators, contract research organizations (CROs), or consultants. Relying on third-party clinical investigators or CROs may force us to encounter delays that are outside of our control.

The market opportunities for our oncology product candidates may be limited to those patients who are ineligible for or have failed prior treatments.

Cancer therapies are characterized as first line, second line, or third line, and the FDA and comparable foreign regulatory authorities often approve new therapies initially only for a particular line of use. When cancer is detected early enough, first line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first line therapy, usually chemotherapy, antibody drugs, tumor-targeted small molecules, hormone therapy, radiation

therapy, surgery, or a combination of these, proves unsuccessful, second line therapy may be administered. Second line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor-targeted small molecules, or a combination of these. Third line therapies can include hematopoietic stem cell transplantation in certain cancers, chemotherapy, antibody drugs, and small molecule tumor-targeted therapies, more invasive forms of surgery, and new revolutionary technologies. We expect to initially seek approval of our product candidates in most instances at least as a third line therapy, for use in patients with relapsed or refractory metastatic cancer. Subsequently, for those product candidates that prove to be sufficiently safe and beneficial, if any, we would expect to seek approval as a second line therapy and potentially as a first line therapy, but there is no guarantee that our product candidates, even if approved as a third or subsequent line of therapy, would be approved for an earlier line of therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

If the market opportunities for our product candidates are smaller than we believe they are, even assuming approval of a drug candidate, our business may suffer.

Our projections of both the number of people who have the infectious diseases and cancers we are targeting, as well as the subset of people with these infectious diseases and cancers in a position to receive a particular line of therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, commissioned reports, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new therapies may change the estimated incidence or prevalence of these cancers. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. Even if we obtain significant market share for our product candidates within our addressable patient population, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications, including use as first or second line therapy.

Even if we obtain regulatory approval of our product candidates, the products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers, third-party payors and others in the medical community.

The use of an arenavirus for the treatment of infectious diseases and tumors is a recent development and may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers and others in the medical community. Various factors will influence whether our product candidates, if approved, are accepted in the market, including:

- the clinical indications for which our product candidates are approved;
- physicians, hospitals, cancer treatment centers and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- the prevalence and severity of any side effects for virus-based therapeutic products, in particular, other prime-boost therapies;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA or comparable foreign regulatory authorities;
- the timing of market introduction of our product candidates as well as competitive products;

- the cost of treatment in relation to alternative treatments;
- the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

In addition, although we are not utilizing fully replication competent live virus vectors, our replicating technology uses a replication attenuated vector and adverse publicity due to the ethical and social controversies surrounding the therapeutic use of such technologies, and reported side effects from any clinical trials using these technologies or the failure of such trials to demonstrate that these therapies are safe and effective may limit market acceptance of our product candidates. If our product candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers, third-party payors or others in the medical community, we will not be able to generate significant revenue and we may not become profitable.

Even if we, or any future collaborators, are able to commercialize any product candidate that we, or they, develop, the product may become subject to unfavorable pricing laws, regulations or third-party payor coverage and reimbursement policies, any of which could harm our business.

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. These third-party payors decide which medications they will pay for and establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford many types of treatments. Sales of these or other product candidates that we may identify will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. See “Item 1. Business – Government Regulation – Coverage and Reimbursement.”

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement.

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.

Additionally, we, or our collaborators may develop companion diagnostic tests for use with our product candidates. We, or our collaborators, will be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we may seek for our product candidates. While we have not yet developed

any companion diagnostic tests for our product candidates, if we do, there is significant uncertainty regarding our ability to obtain coverage and adequate reimbursement for the same reasons applicable to our product candidates.

In addition, the requirements governing drug pricing vary widely from country to country. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. For example, the European Union provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. An EU Member State may approve a specific price for the medicinal product, it may refuse to reimburse a product at the price set by the manufacturer or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Many EU Member States also periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. Moreover, in order to obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. This Health Technology Assessment ("HTA") of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the European Union do not follow price structures of the U.S. and generally prices tend to be significantly lower.

We cannot predict whether we will receive reimbursement from third-party payors for any product we may successfully commercialize in the future. Any reimbursement we may receive might not be adequate for use to generate significant revenue and we may not become profitable.

We are developing, and in the future may develop, other product candidates, in combination with other therapies, which exposes us to additional risks.

Our eseba-vec program is being developed to be used in combination with or without an approved checkpoint inhibitor, a currently approved cancer therapy. In the future, we may develop other product candidates to be used with one or more currently approved cancer therapies. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or similar regulatory authorities outside of the United States could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. Combination therapies are commonly used for the treatment of cancer, and we would be subject to similar risks if we develop any of our product candidates for use in combination with other drugs or for indications other than cancer. This could result in our own products being removed from the market or being less successful commercially. In addition, if the results from our combination trials are not significantly better than results from the existing therapy that we are combining with, then regulatory authorities, clinical investigators, physicians and patients may perceive our product candidates negatively, which could adversely affect enrollment in our clinical trials, approval by regulatory authorities or commercial adoption of our product candidates, if approved.

We may also evaluate our future product candidates in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA or similar regulatory authorities outside of the United States. We will not be able to market any product candidate we develop in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval.

If the FDA or similar regulatory authorities outside of the United States do not approve these other drugs or revoke their approval of, or if safety, efficacy, manufacturing, or supply issues arise with, the drugs we choose to evaluate in combination with any product candidate we develop, we may be unable to obtain approval.

Negative developments in the field of immuno-oncology and virus-based therapies could damage public perception of any of our product candidates and negatively affect our business.

The commercial success of product candidates based on our replicating technology will depend in part on public acceptance of the use of cancer immunotherapies. Adverse events in the eseba-vec program or our other product candidates based on our replicating technology or in clinical trials of others developing similar products and the resulting publicity, as well as any other negative developments in the field of immuno-oncology that may occur in the future, including in connection with competitor therapies, could result in a decrease in demand for any product candidates based on our replicating technology that we may develop. These events could also result in the suspension, discontinuation, or clinical hold of or modification to our clinical trials. If public perception is influenced by claims that the use of cancer immunotherapies is unsafe, whether related to our therapies or those of our competitors, our product candidates may not be accepted by the general public or the medical community and potential clinical trial subjects may be discouraged from enrolling in our clinical trials. In addition, responses by national or state governments to negative public perception may result in new legislation or regulations that could limit our ability to develop or commercialize any product candidates, obtain or maintain regulatory approval or otherwise achieve profitability. More restrictive statutory regimes, government regulations or negative public opinion would have an adverse effect on our business, financial condition, prospects and results of operations and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop. As a result, we may not be able to continue or may be delayed in conducting our development programs.

Our product candidates consist of a modified virus. Adverse developments in clinical trials of other immunotherapy products based on viruses, like oncolytic viruses, may result in a disproportionately negative effect for our non-replicating and replicating technologies as compared to other products in the field of infectious disease and immuno-oncology that are not based on viruses. Future negative developments in the biopharmaceutical industry could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our products. Any increased scrutiny could delay or increase the costs of obtaining marketing approval for our product candidates.

We may not be successful in our efforts to identify and successfully commercialize additional product candidates.

Part of our strategy involves identifying novel product candidates. We have developed a pipeline of product candidates and intend to pursue clinical development of additional product candidates utilizing our non-replicating and replicating technologies. The process by which we identify product candidates may fail to yield product candidates for clinical development for a number of reasons, including those discussed in these risk factors and also:

- we may not be able to assemble sufficient resources to acquire or discover additional product candidates;
- competitors may develop alternatives that render our potential product candidates obsolete or less attractive;
- potential product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- potential product candidates may, on further study, be shown to have harmful side effects, toxicities or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance;
- potential product candidates may not be effective in treating their targeted diseases or symptoms;
- the market for a potential product candidate may change so that the continued development of that product candidate is no longer reasonable;

- a potential product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; or

- the regulatory pathway for a potential product candidate is highly complex and difficult to navigate successfully or economically.

Developing, obtaining regulatory approval for and commercializing additional product candidates will require substantial additional funding and is prone to the risks of failure inherent in medical product development. We cannot provide you with any assurance that we will be able to successfully advance any of these additional product candidates through the development process.

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

We may choose to focus our efforts on and allocate resources to a potential product candidate that ultimately proves to be unsuccessful, or to license or purchase a marketed product that does not meet our financial expectations. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases that may later prove to have greater commercial potential, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we are unable to evaluate the commercial potential or target market for a particular product candidate, identify and successfully commercialize additional suitable product candidates, this would adversely impact our business strategy and our financial position.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biopharmaceutical industry is characterized by intense competition and rapid innovation. Our competitors may be able to develop other products or drugs that are able to achieve similar or better results. Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations and well-established sales forces. In addition, many of these competitors are active in seeking patent protection and licensing arrangements in anticipation of collecting royalties for use of technology that they have developed. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel therapeutics or to in-license novel therapeutics that could make the product candidates that we develop obsolete. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products. We believe the key competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety, tolerability, reliability, convenience of use, price and reimbursement.

In immuno-oncology for HPV16+ and mutated KRAS cancers, we face competition from companies such as BioNtech AG, Cue Biopharma, Inc., PDS Biotechnology Corporation and Elicio Therapeutics Inc. Even if we obtain regulatory approval of our product candidates, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our product candidates. In addition, other immuno-oncology companies are developing the following technologies, including, but not limited to, neoantigens, bispecific antibodies, engineered cell therapies and tumor specific antigens in areas outside of HPV16+ cancers.

We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- our inability to commercialize any product candidate;
- decreased demand for our product candidates or products that we may develop;
- reputational damage;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources; and
- a decline in our share price.

Failure to obtain or retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with corporate collaborators. Although we have clinical trial insurance, our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. In the future, we may be unable to maintain this insurance coverage, or we may not be able to obtain additional or replacement insurance at a reasonable cost, if at all. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

A variety of risks associated with operating our business internationally could materially adversely affect our business.

Many of our employees and a significant portion of our operations are located outside the United States, including in Vienna, Austria. In addition, we plan to seek regulatory approval of our product candidates outside of the United States and, accordingly, we expect that we, and any potential collaborators in those jurisdictions, will be subject to additional risks related to operating in foreign countries, including:

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls, and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act of 1977 (FCPA), Office of Foreign Assets Control Anti-Money Laundering Program as required by the Bank Secrecy Act and its implementing regulations, or comparable foreign laws;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States; and
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad.

These and other risks associated with our planned international operations may materially adversely affect our ability to attain or maintain profitable operations.

Natural disasters, geopolitical unrest, war, terrorism, public health issues or other catastrophic events could disrupt the supply, delivery or demand of products and reduce our ability to access capital, which could negatively affect our operations and performance.

We are subject to the risk of disruption by earthquakes, floods and other natural disasters, fire, power shortages, geopolitical unrest, war, terrorist attacks and other hostile acts, public health issues, epidemics or pandemics and other events beyond our control and the control of the third parties on which we depend. Any of these catastrophic events, whether in the United States, Europe or abroad, may have a strong negative impact on the global economy, our employees, facilities, partners, suppliers, distributors or customers, and could decrease demand for our products, create delays and inefficiencies in our supply chain and make it difficult or impossible for us to continue preclinical studies or clinical trials, seek and receive approval for any of our product candidates by the FDA and comparable foreign regulatory authorities, or deliver products to our customers. Further, disruption of global financial markets and a recession or market correction, including as a result of any resurgence of the coronavirus pandemic, the ongoing military

conflict between Russia and Ukraine and the related sanctions imposed against Russia, any escalation of the conflict in Israel and the Gaza Strip, and other global macroeconomic factors, could reduce our ability to access capital, which could, in the future, negatively affect our business.

Our business may be adversely affected by a pandemic, epidemic or outbreak of an infectious disease, such as the recent coronavirus pandemic or other emerging global health threats on business and operations.

Our business could be adversely affected by health epidemics in regions where we have concentrations of clinical trial sites or other business activities and could cause significant disruption in the operations of third-party contract manufacturers and contract research organizations upon whom we rely, as well as our ability to recruit patients for our clinical trials. For example, the recent coronavirus pandemic had unpredictable impacts on global societies, economies, financial markets, and business practices around the world, and caused temporary delays and disruptions in our clinical development operations.

We currently have no marketing and sales organization and have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, if approved, we may not be able to generate product revenue.

We currently have no sales, marketing or distribution capabilities and have no experience in marketing products. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, undertaking preclinical studies and clinical trials of product candidates, securing related intellectual property rights and conducting discovery, research and development activities for our programs. We intend to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other biotechnology and pharmaceutical companies to recruit, hire, train and retain marketing and sales personnel. There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. In addition, there can be no assurance that we will be able to develop inhouse sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the United States or overseas.

Insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, employment practices liability, property, umbrella, and directors' and officers' insurance.

Insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

We also expect that firming of the insurance market will make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any

significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

Exchange rate fluctuations may materially affect our results of operations and financial conditions.

Owing to the international scope of our operations, fluctuations in exchange rates, particularly between the U.S. dollar and the euro, may adversely affect us. Although we are incorporated in Delaware in the United States, we have significant research and development operations in Austria, and source third-party manufacturing, consulting and other services in the European Union. As a result, our business and the price of our common stock may be affected by fluctuations in foreign exchange rates, which may have a significant impact on our results of operations and cash flows from period to period. Currently, we do not have any exchange rate hedging arrangements in place.

Risks Related to Our Reliance on Third Parties

We are fully dependent on our collaboration with Gilead for the development of our HBV programs, rely on funding from Gilead for development of our human immunodeficiency virus program, and may depend on Gilead or additional third parties for the development and commercialization of our other programs and future product candidates. Our current and future collaborators may control aspects of our clinical trials, which could result in delays or other obstacles in the commercialization of the product candidates we develop. If our collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates

We are currently party to collaborations with Gilead to help expand and advance our pipeline of candidates. In the future, we may form or seek other strategic alliances, joint ventures, or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to product candidates we develop.

Our current collaborations pose, and potential future collaborations involving our product candidates may pose, the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs or license arrangements based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as a strategic transaction that may divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, including technology we in-license, products that compete directly or indirectly with our products or product candidates;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- collaborators may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;

- collaborators may not properly enforce, maintain or defend our intellectual property rights or may use our proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation, or other intellectual property proceedings;

- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;

- disputes may arise between a collaborator and us that cause the delay or termination of the research, development or commercialization of the product candidate, or that result in costly litigation or arbitration that diverts management attention and resources;

- if a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated;

- collaboration agreements may restrict our right to independently pursue new product candidates. For example, under the Gilead Collaboration Agreement, we are prohibited from, directly or indirectly, researching, developing, manufacturing or commercializing product candidates targeted to HBV and with respect to HIV so long as Gilead's option for the program has not expired; and

- collaborations may be terminated by the collaborator (such as the termination of the Roche Collaboration Agreement by Roche), and, if terminated, we may suffer reputational harm, find it more difficult to attract new collaborators and be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

As a result, if we enter into additional collaboration agreements and strategic partnerships, or license our intellectual property, products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to any product candidate we develop could delay the development and commercialization of our other product candidates, which would harm our business prospects, financial condition, and results of operations.

We may seek to establish additional collaborations, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

The advancement of our product candidates and development programs and the potential commercialization of our current and future product candidates will require substantial additional cash to fund expenses. For some of our programs, we may decide to collaborate with additional biotechnology and pharmaceutical companies with respect to development and potential commercialization. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business. We will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of any product candidates we may seek to develop with them. We cannot predict the success of any collaboration that we have entered into or will enter into. For example, in January 2024 Roche notified us of their decision to terminate the Roche Collaboration Agreement despite acknowledging we had met all go-forward criteria under the agreement.

We face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for other collaborations will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the progress of our clinical trials, the likelihood of approval by the FDA or similar regulatory

authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Further, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for future product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view them as having the requisite potential to demonstrate safety and efficacy.

We may also be restricted under existing collaboration agreements from entering into future agreements on certain terms with potential collaborators. For example, under the Restated Gilead Collaboration Agreement, we have granted worldwide exclusive rights to Gilead for using our technologies to develop treatments for HBV, and during the term of the agreement we will be restricted from granting similar rights to other parties. This exclusivity could limit our ability to enter into strategic collaborations with future collaborators.

In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

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

We rely and will continue to rely on third parties to conduct our clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.

We depend and will continue to depend upon independent investigators and collaborators, such as medical institutions, CROs, CMOs and strategic partners to conduct our preclinical studies and clinical trials under agreements with us. We expect to have to negotiate budgets and contracts with CROs, trial sites and CMOs which may result in delays to our development timelines and increased costs. We will rely heavily on these third parties over the course of our clinical trials, and we control only certain aspects of their activities. As a result, we have less direct control over the conduct, timing and completion of these clinical trials and the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff.

Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, our clinical trials must be conducted with biologic product produced under current good manufacturing practices (cGMP) regulations and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if

any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our clinical trials are and will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing, clinical and nonclinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies or other drug development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Switching or adding third parties to conduct our clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines.

We rely and expect to continue to rely on third parties to manufacture our clinical product supplies, and we may rely on third parties for at least a portion of the manufacturing process of our product candidates, if approved. Our business could be harmed if those third parties fail to provide us with sufficient quantities of clinical product supplies or product candidates or fail to do so at acceptable quality levels or prices.

We do not currently own any facility that may be used as our clinical-scale manufacturing and processing facility and must currently rely on outside vendors to manufacture our product candidates. We have not yet caused our product candidates to be manufactured or processed on a commercial scale and may not be able to do so for any of our product candidates.

The manufacture of biological drug products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of biologic products often encounter difficulties in production, particularly in scaling up or out, validating the production process and assuring high reliability of the manufacturing process, including the absence of contamination. These problems include logistics and shipping, difficulties with production costs and yields, quality control, including lot consistency, stability of the product, product testing, operator error and availability of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. We have encountered problems with our third party manufacturers in the past, including delays and low yields, and there can be no assurance that we will not encounter similar or other difficulties in the future.

Furthermore, if contaminants are discovered in our supply of our product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability failures or other issues relating to the manufacture of our product candidates will not occur in the future.

Our reliance on a limited number of third-party manufacturers exposes us to the following risks:

- the production process for our product candidates is complex and requires specific know-how that only a limited number of CMOs can provide, as a result, we compete with other companies in the field for the scarce capacities of these organizations and may not be able to secure sufficient manufacturing capacity when needed;

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA and comparable foreign regulatory authorities must inspect any manufacturers for cGMP compliance as part of our marketing application;

- a new manufacturer would have to be educated in, or develop substantially equivalent processes for, the production of our product candidates;
- a change in manufacturers or certain changes in manufacturing processes/procedures will require that we conduct a manufacturing comparability study to verify that any new manufacturer or manufacturing process/procedure will produce our product candidate according to the specifications previously submitted to the FDA or other regulatory authority, to which we may be unsuccessful;
- manufacturers may have little or no experience with viral vector products and therefore may require a significant amount of support from us in order to implement and maintain the infrastructure and processes required to manufacture our product candidates;
- manufacturers might be unable to timely manufacture our product candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately;
- manufacturers may not perform as agreed, may not devote sufficient resources to our product candidates or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store, and distribute our products, if any;
- manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state and foreign regulatory authorities to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards, of which we have limited control over;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our product candidates;
- manufacturers could breach or terminate their agreements with us;
- raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available timely or may not be suitable or acceptable for use due to material or component defects;
- manufacturers and critical suppliers may be subject to risks related to cyber-attacks that could cause disruptions in manufacturing;
- manufacturers and critical suppliers may be subject to inclement weather, as well as natural or manmade disasters; and
- manufacturers may have unacceptable or inconsistent product quality success rates and yields, and we have no direct control over our contract manufacturers' ability to maintain adequate quality control, quality assurance and qualified personnel.

Any of these risks could delay or prevent the completion of our clinical trials or the approval of any of our product candidates by the FDA and comparable foreign regulatory authorities, result in higher costs or adversely impact commercialization of our product candidates. In addition, we will rely on third parties to perform certain specification tests on our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm and the FDA and comparable foreign regulatory authorities could place significant restrictions on our company until deficiencies are remedied.

Despite our efforts to audit and verify regulatory compliance, one or more of our third-party manufacturing vendors may be found on regulatory inspection by the FDA, competent authorities of EU Member States or other comparable foreign regulatory authorities to be noncompliant with cGMP regulations. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including shutdown of the third-party vendor or invalidation of drug product lots or processes, fines, injunctions, civil penalties, delays, suspension, variation or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products, if approved, and significantly harm our business, financial condition, results of operations and prospects.

If our third-party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by our manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

Risks Related to Government Regulation

Even if we receive regulatory approval of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a (REMS) in order to approve our product candidates, which could entail 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. Comparable foreign regulatory authorities may impose similar requirements.

Additionally, under the Food and Drug Omnibus Reform Act of 2022 (FDORA), sponsors of approved drugs and biologics must provide six months' notice to the FDA of any changes in marketing status, such as the withdrawal of a drug, and failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product's ability to be marketed.

In addition, if the FDA, the European Commission or another comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for any such approved product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or

manufacturing processes, or our or our distributors', licensees' or co-marketers' failure to comply with changes to regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning or untitled letters or holds on clinical trials;
- suspension of any ongoing clinical trials;
- refusal by the FDA, the European Commission or other comparable foreign regulatory authorities to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention, refusal to permit the import or export of our product candidates, or request that we initiate a product recall;
- injunctions or the imposition of civil or criminal penalties or monetary fines; and
- requiring us to conduct additional clinical trials, change our product labeling or submit additional applications for marketing authorization.

The FDA's, the EMA's and the European Commission and other comparable foreign regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. As an example, the regulatory landscape related to clinical trials in the EU has evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. The CTR permits trial sponsors to make a single submission to both the competent authority and an ethics committee in each EU Member State, leading to a single decision for each EU Member State. The assessment procedure for the authorization of clinical trials has been harmonized as well, including a joint assessment of some elements of the application by all EU Member States in which the trial is to be conducted, and a separate assessment by each EU Member State with respect to specific requirements related to its own territory, including ethics rules. Each EU Member State's decision is communicated to the sponsor through a centralized EU portal, the Clinical Trial Information System, or CTIS. The CTR provides a three-year transition period. The extent to which ongoing clinical trials will be governed by the CTR varies. As of January 31, 2025, all ongoing trials are subject to the provisions of the CTR. The CTR will apply to clinical trials from an earlier date if the related clinical trial application was made on the basis of the CTR or if the clinical trial has already transitioned to the CTR framework before January 31, 2025. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. 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 lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

If any of these events occurs, our ability to commercialize such product candidate may be impaired, and we may incur substantial additional expense to comply with regulatory requirements, which could adversely affect our business, financial condition and results of operations.

The impact of recent healthcare reform legislation and other changes in the healthcare industry and in healthcare spending on us is currently unknown, and may adversely affect our business model.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability, or the ability of our collaborators, to profitably sell any products for which we obtain marketing approval. We expect that current laws, as well as other

healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or our collaborators, may receive for any approved products. See "Business – Other U.S. Healthcare Laws." We cannot predict the initiatives that may be adopted in the future.

The continuing efforts of the government, insurance companies, managed care organizations and other payers of healthcare services to contain or reduce costs of healthcare may adversely affect:

- the demand for any of our product candidates, if approved;
- the ability to set a price that we believe is fair for any of our product candidates, if approved;
- our ability to generate revenues and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

In December 2021, Regulation No 2021/2282 on HTA amending Directive 2011/24/EU, was adopted in the EU. This Regulation, which entered into force in January 2022 and into application on January 12, 2025. It is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The Regulation foresees a three-year transitional period and will permit EU Member States to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected. In light of the fact that the United Kingdom has left the EU, Regulation No 2021/2282 on HTA will not apply in the United Kingdom. However, the UK Medicines and Healthcare products Regulation Agency ("MHRA") is working with UK HTA bodies and other national organizations, such as the Scottish Medicines Consortium ("SMC"), the National Institute for Health and Care Excellence ("NICE"), and the All-Wales Medicines Strategy Group, to introduce new pathways supporting innovative approaches to the safe, timely and efficient development of medicinal products.

In addition, on April 26, 2023, the European Commission adopted a proposal for a new Directive and Regulation to revise the existing pharmaceutical legislation and on April 10, 2024, the Parliament adopted its related position. The proposed revisions remain to be agreed and adopted by the European Council. In addition, on December 1, 2024, a new European Commission took office. The proposal could, therefore, still be subject to revisions. If adopted in the form proposed, the recent European Commission proposals to revise the existing EU laws governing authorization of medicinal products may result in a decrease in data and market exclusivity opportunities for our product candidates in the EU and make them open to generic or biosimilar competition earlier than is currently the case with a related reduction in reimbursement status.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical and biologic products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements. Compliance with new requirements may increase our operational expenses and impose significant administrative burdens. As a result of these and other new proposals, we may need to change our current manner of operation, which could have a material adverse effect on our

business, financial condition, and results of operations. Any reduction in reimbursement from Medicare or other government healthcare programs may result in a similar reduction in payments from private payors.

The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products. Legislative and regulatory proposals may also impact our regulatory and commercial prospects, expand post-approval requirements, and restrict sales and promotional activities. We cannot predict the extent to which our business may be affected by these or other potential future legislative or regulatory developments, whether regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be, particularly in light of the recent U.S. Presidential and Congressional elections. Such future price controls or other changes in pricing regulation or negative publicity related to the pricing of pharmaceutical drugs generally could restrict the amount that we are able to charge for our future products, which would adversely affect our anticipated revenue and results of operations. See "Business – U.S. Healthcare Reform."

We expect that the healthcare reform measures that have been adopted and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

The FDA or comparable foreign regulatory authorities could require the clearance, CE marking or approval of a companion diagnostic device as a condition of approval for our product candidates. Failure to successfully validate, develop and obtain regulatory clearance or approval for companion diagnostics on a timely basis or at all could harm our drug development strategy.

Our success may depend, in part, on the development and commercialization of companion diagnostic tests to select patients for our drug candidates. If safe and effective use of any of our product candidates depends on an in vitro diagnostic that is not otherwise commercially available, then the FDA generally will require approval or clearance of that diagnostic, known as a companion diagnostic, at the same time that the FDA approves our product candidates. The process of obtaining or creating such diagnostic is time consuming and costly. Foreign regulatory authorities may impose comparable requirements.

Companion diagnostics, which provide information that is essential for the safe and effective use of a corresponding therapeutic product, are subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and require separate regulatory approval from therapeutic approval prior to commercialization. The FDA previously has required in vitro companion diagnostics intended to select the patients who will respond to a product candidate to obtain pre-market approval (PMA), simultaneously with approval of the therapeutic candidate. The PMA process, including the gathering of preclinical and clinical data and the submission 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 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. After a device is placed on the market, it remains subject to significant regulatory requirements, including requirements governing development, testing, manufacturing, distribution, marketing, promotion, labeling, import, export, record-keeping, and adverse event reporting. We will be subject to additional obligations and regimes with respect to such companion diagnostic tests with regulators outside the United States.

In the EEA, companion diagnostics are deemed to be in vitro diagnostic medical devices, or IVDs, and are governed by Regulation 2017/746, or IVDR, which entered into application on May 26, 2022, repealing and replacing Directive 98/79/EC. The IVDR defines a companion diagnostic as a device which is essential for the safe and effective use of a corresponding medicinal product to: (a) identify, before and/or during treatment, patients who are most likely to benefit from the corresponding medicinal product; or (b) identify, before and/or during treatment, patients likely to be at increased risk of serious adverse reactions as a result of treatment with the corresponding medicinal product. The IVDR and its associated guidance documents and harmonized standards govern, among other things, device design and

development, preclinical and clinical or performance testing, premarket conformity assessment, registration and listing, manufacturing, labeling, storage, claims, sales and distribution, export and import and post-market surveillance, vigilance, and market surveillance. IVDs, including companion diagnostics, must conform with the general safety and performance requirements, or GSPR, of the IVDR. Compliance with these requirements is a prerequisite to be able to affix the CE mark to devices, without which they cannot be marketed or sold in the EEA. To demonstrate compliance with the GSPR laid down in Annex I to the IVDR, and obtain the right to affix the CE mark, IVD manufacturers must conduct a conformity assessment procedure, which varies according to the type of IVD and its classification. Companion diagnostics must undergo a conformity assessment by a Notified Body. Depending on the relevant conformity assessment procedure, the Notified Body audits and examines the technical documentation and the quality system for the manufacture, design and final inspection of the medical devices. The Notified Body issues a CE Certificate of Conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the GSPRs. If the related medicinal product has, or is in the process of, been authorized through the centralized procedure for the authorization of medicinal products, the notified body will, before it can issue a CE Certificate of Conformity, be required to seek a scientific opinion from the EMA on the suitability of the companion diagnostic for use in relation to the medicinal product concerned. For medicinal products that have or are in the process of authorization through any other route provided in EU legislation, the Notified Body must seek the opinion of the national competent authority of an EU Member State. The CE Certificate of Conformity and the related conformity assessment process entitles the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related EC Declaration of Conformity.

Given our limited experience in developing and commercializing diagnostics, we do not plan to develop companion diagnostics internally and thus will be dependent on the sustained cooperation and effort of third-party collaborators in developing and obtaining approval for these companion diagnostics. We and our collaborators may encounter difficulties in developing and obtaining approval or CE marking for the companion diagnostics, including issues relating to selectivity/specificity, analytical validation, reproducibility, or clinical validation. Any delay or failure by our collaborators to develop or obtain regulatory approval or CE marking the companion diagnostics could delay or prevent approval of our product candidates. In addition, we, our collaborators or third parties may encounter production difficulties that could constrain the supply of the companion diagnostics, and both they and we may have difficulties gaining acceptance of the use of the companion diagnostics in the medical community. If such companion diagnostics fail to gain market acceptance, it would have an adverse effect on our ability to derive revenues from sales, if any, of any product candidate for which we obtain approval and that requires a companion diagnostic test. In addition, any companion diagnostic collaborator or third party with whom we contract may decide not to commercialize or to discontinue selling or manufacturing the companion diagnostic that we anticipate using in connection with development and commercialization of our product candidates, or our relationship with such collaborator or third party may otherwise terminate. We may not be able to enter into arrangements with another provider to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our product candidates.

We may pursue breakthrough therapy designation from the FDA for our product candidates but such designation may not lead to a faster development or regulatory review or approval process, and it would not increase the likelihood that our product candidates will receive marketing approval.

We may in the future seek breakthrough therapy designation for some of our product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. For compounds that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for accelerated approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead

determine not to make such designation. We cannot be sure that any evaluation we may make of our product candidates as qualifying for breakthrough therapy designation will meet the FDA's expectations. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that such product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

We may seek Fast Track Designation by the FDA for a product candidate that we develop, and we may be unsuccessful. If we are successful, the designation may not actually lead to a faster development or regulatory review or approval process.

We may seek Fast Track Designation for the product candidates we develop. If a product is intended for the treatment of a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, the product sponsor may apply for Fast Track Designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track Designation, as we have for eseba-vec in combination with pembrolizumab, for the treatment of first-line advanced/metastatic HPV16+ HNSCC, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may rescind the Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program.

We may seek Orphan Drug Designation for product candidates we develop, and we may be unsuccessful or may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for market exclusivity.

As part of our business strategy, we may seek Orphan Drug Designation for any product candidates we develop, and we may be unsuccessful. Regulatory authorities in some jurisdictions, including the United States and the European Union, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, Orphan Drug Designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers.

Similarly, in Europe, the European Commission may grant orphan designation after receiving the opinion of the EMA Committee for Orphan Medicinal Products on an orphan designation application. Orphan designation is intended to promote the development of drugs that are intended (i) for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions, (ii) either the conditions affect no more than 5 in 10,000 persons in the EU or without the benefits derived from orphan status, it is unlikely that sales of the product in the EU would be sufficient to justify the necessary investment in developing the product, and (iii) there exists no satisfactory authorized method of diagnosis, prevention, or treatment of the condition that has been authorized in the EU, or even if such method exists, the product will be of significant benefit to those affected by that condition. In the EU, orphan designation entitles a party to a number of incentives, such as protocol assistance, access to the centralized marketing authorization procedure, and potential fee reductions or waivers depending on the status of the sponsor.

Generally, if a drug with an orphan designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug and indication for that time period, except in limited circumstances. Similarly, the EMA cannot accept another marketing authorization application or accept an application to extend for a similar product and the European Commission cannot grant a marketing authorization for the same indication. The applicable period is seven years in the United States and ten years in the EU. The EU exclusivity period can be reduced to six years if, at the end of the fifth year, a drug no longer meets the criteria on the basis of which

it received orphan designation, including where it can be demonstrated on the basis of available evidence that the drug is sufficiently profitable such that market exclusivity is no longer justified or where the prevalence of the condition has increased above the threshold.

Even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product candidate from competition because different therapies can be approved for the same condition and the same therapies can be approved for different conditions but used off-label. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan Drug Designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. Similar considerations apply abroad. While we may seek Orphan Drug Designation for applicable indications for our current and any future product candidates, we may never receive such designations. Even if we do receive such designations, there is no guarantee that we will enjoy the benefits of those designations.

Our business operations and current and future relationships with investigators, health care professionals, consultants, third-party payors and customers will be subject, directly or indirectly, to federal, state and foreign healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, 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.

Although we do not currently have any products on the market, if we obtain FDA approval for our product candidates, and begin commercializing those products in the United States, our operations may be directly, or indirectly through our prescribers, customers and third-party payors, subject to various U.S. federal and state healthcare laws and regulations, including, without limitation, the U.S. federal Anti-Kickback Statute, the U.S. federal civil and criminal false claims laws, the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act (collectively "HIPAA"), and the Physician Payments Sunshine Act and regulations. Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. These laws may impact, among other things, our current business operations, including our clinical research activities, 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. In addition, we may be subject to patient data privacy and security regulation by both the U.S. federal government and the states in which we conduct our business. Finally, we may be subject to additional healthcare, statutory and regulatory requirements and enforcement by comparable foreign regulatory authorities in jurisdictions in which we conduct our business that may affect our ability to operate. See "Business – Other U.S. Healthcare Laws."

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased 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. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource- consuming and can divert a company's attention from the business.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental and regulatory authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may

apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the delay, reduction, termination or curtailment or restructuring of our operations. Further, defending against any such actions can be costly and time-consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business is found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, our ability to operate our business and our results of operations could be adversely affected.

Outside the United States, interactions between pharmaceutical companies and health care professionals are also governed by strict laws, such as national anti-bribery laws of European countries, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is not permitted in the countries that form part of the European Union. Some European Union Member States, and the United Kingdom, through the United Kingdom Bribery Act 2010, have enacted laws explicitly prohibiting the provision of these types of benefits and advantages. Infringements of these laws can result in substantial fines and imprisonment.

Payments made to physicians in certain European Union Member States (e.g., France or Belgium) must be publicly disclosed. Moreover, agreements with physicians may be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual European Union Member States. These requirements are provided in the European Union Member State national laws, industry codes (e.g. the European Federation of Pharmaceutical Industries and Associations Disclosure and Healthcare Professionals Codes) or professional codes of conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of a product candidate in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval for that product candidate in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, in order to market and sell our drugs in the European Union and many other jurisdictions, we, and any collaborators we may have in the future, must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The marketing approval process outside of the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside of the United States, it is required that the drug be approved for reimbursement before the drug can be approved for sale in that country. In some cases, the price that we intend to charge for our products is also subject to regulatory approval. We, and any collaborators we may have in the future, may not obtain approvals from regulatory authorities outside of the United States on a timely basis, if at all.

European data collection and processing is governed by restrictive regulations governing the use, processing and cross-border transfer of personal information.

The collection, use, storage, disclosure, transfer or other processing of personal data, including personal health data regarding individuals in the EEA is governed by the EU GDPR. The EU GDPR is wide ranging in scope and imposes several requirements on companies that process personal data, including requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, notification of data

processing obligations to the competent national data protection authorities and the security and confidentiality of the personal data. Failure to comply with the requirements of the EU GDPR and the related national data protection laws of the EU Member States may result in fines and other administrative penalties, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater, for breach or non-compliance.

In addition, further to the UK's exit from the EU on January 31, 2020, the EU GDPR ceased to apply in the UK at the end of the transition period on December 31, 2020. However, as of January 1, 2021, the UK's European Union (Withdrawal) Act 2018 incorporated the EU GDPR (as it existed on December 31, 2020 but subject to certain UK specific amendments) into UK law, referred to as the UK GDPR. The UK GDPR and the UK Data Protection Act 2018 set out the UK's data protection regime, which is independent from but aligned to the EU's data protection regime. Non-compliance with the UK GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher. Although the EU GDPR and the UK GDPR currently impose substantially similar obligations, it is possible that over time the UK GDPR could become less aligned with the EU GDPR. The UK government has announced plans to reform the data protection legal framework in the UK in its Data (Use and Access) Bill. The potential misalignment between future UK laws and regulations and EU laws and regulations could add legal risk, uncertainty, complexity and cost to our handling of EU/UK personal information and our privacy and data security compliance programs and could require us to implement different compliance measures for the UK and the EU.

The EU GDPR also imposes strict rules on the transfer of personal data out of the EEA, including to the United States. Although the UK is regarded as a third country under the EU GDPR, the EC has now issued a decision recognizing the UK as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the EU to the UK remain unrestricted. Like the EU GDPR, the UK GDPR restricts personal data transfers outside the UK to countries not regarded by the UK as providing adequate protection. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing. To enable the transfer of personal data outside of the EEA or the UK, adequate safeguards must be implemented in compliance with EU and UK data protection laws. There are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EU's Standard Contractual Clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK Extension thereto (which allows for transfers for relevant U.S.-based organizations who self-certify compliance and participate in the Framework). However, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States.

The EU GDPR and UK GDPR also confer a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the EU GDPR and UK GDPR. The EU GDPR and UK GDPR regulations may impose additional responsibility and liability in relation to personal data that we process, and we may be required to put in place additional mechanisms ensuring compliance with these and/or new data protection rules. This may be onerous and adversely affect our business, financial condition, prospects and results of operations. Compliance with the EU GDPR and UK GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities.

Our business activities may be subject to the Foreign Corrupt Practices Act and similar anti-bribery and anti-corruption laws.

Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the U.K. Bribery Act. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. The anti-bribery provisions of the FCPA are enforced primarily by the Department of Justice ("DOJ") and the Securities and Exchange Commission is involved with enforcement of the books and records provisions of the FCPA and may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions. Recently the SEC and DOJ have increased their

FCPA enforcement activities with respect to pharmaceutical companies. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA.

There is no certainty that all of our employees, agents, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of our facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

Our ability to utilize our foreign net operating loss carryforwards may be limited by GILTI taxation introduced through the tax reform.

We have incurred substantial losses during our operating history. We do not anticipate generating revenue from sales of products for the foreseeable future, if ever, and we may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. The tax reform legislation introduced section 951A, a new tax on so-called "global intangible low-taxed income," or GILTI. GILTI applies to income of a controlled foreign corporation (CFC) that is not otherwise subpart F income. Our Austrian subsidiary is expected to be treated as a CFC and GILTI taxation may therefore apply when use of foreign net operating loss carryforwards reduce our foreign income tax to a low level. Tax benefits from the use of our foreign net operating loss carryforwards could be partially offset by U.S. GILTI taxation, which could have an adverse effect on our future results of operations.

Changes to section 174 capitalization rules through the tax reform may impact our ability to immediately deduct research and development expenses, leading to higher taxable income and effective income tax payments even before reaching profitability

The tax reform legislation also altered section 174, by requiring that, beginning with the year 2022, research and development expenses be capitalized and amortized over five years for expenditures incurred in the U.S. and 15 years for expenditures incurred outside the U.S. Therefore, our ability to use research and development expenses to offset revenue in the coming years, may be limited, and we may be required to record taxable income while our business is actually still loss-making. The resulting tax payments could have an adverse effect on our future results of operations.

Risks Related to Our Intellectual Property

Our rights to develop and commercialize our product candidates are subject, in part, to the terms and conditions of licenses granted to us by others, and, if we fail to comply with our obligations under these arrangements or resolve related disputes, we could lose such intellectual property rights or owe damages to the licensor of such intellectual property.

We are dependent on patents, know-how and proprietary technology, both our own and licensed from others. We license patents related to our non-replicating and replicating technologies and certain other intellectual property rights from third parties, including from the University of Geneva, the University of Basel, the University of Zurich and the University of Minnesota and expect in the future to be party to other material license or collaboration agreements. These agreements typically impose numerous obligations, such as diligence and payment obligations, including in relation to revenues we may receive from any sublicenses we grant in respect of the licensed patents. If we fail to comply with our obligations under these agreements, our licensors may have the right to terminate our licenses, in which event we might not be able to develop, manufacture or market any product that is covered by the intellectual property we in-license from such licensor and may face other adverse consequences. These licenses do and future licenses may also

include provisions that impose obligations and restrictions on us that could delay or otherwise negatively impact a transaction that we may wish to enter into.

Disputes may also arise between us and our licensors regarding the license agreements we have with them, including with respect to:

- the proper interpretation of the license agreement terms, including with respect to our right to sublicense patent rights and any other intellectual property rights to third parties and the amount of fees owed to the licensors as a result of such sublicenses;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how created by us and our partners using a combination of our own intellectual property and that licensed from our licensors.

If disputes arise that prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license as we are for intellectual property that we own, which are described below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market.

We rely upon a combination of patents, confidentiality agreements, trade secret protection and license agreements to protect the intellectual property related to our technologies. Such means may afford only limited protection of our intellectual property and may not: (i) prevent our competitors from duplicating our technology or product candidates; (ii) prevent our competitors from gaining access to our proprietary technology; or (iii) permit us to gain or maintain a competitive advantage. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by the third parties to which we grant access to such intellectual property, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. These third parties also may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property-related proceedings that could jeopardize or invalidate our proprietary information and intellectual property. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

Our success depends in large part on our ability to obtain and maintain patent protection with respect to our non-replicating technology, our replicating technology, including our eseba-vec and HB-700 product candidates, the vaccine product candidates we are developing with Gilead for HBV (HB-400) and HIV (HB-500), and other proprietary product candidates. Although we own or license from others certain patents and patent applications that cover some of the foregoing technologies and product candidates, we do not currently own or license from others issued patents covering all of the foregoing technologies and product candidates. Our reliance on patent applications carries certain risks associated with pending patent applications prior to the issuance of patents, as described below. If we do not adequately obtain and protect our intellectual property rights, competitors may be able to erode, negate or preempt any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we file patent applications in the United States and abroad related to our product candidates that are important to our business. The patent application and approval process is expensive and time-consuming and we may not

be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We cannot predict:

- if and when patents will issue from our patent applications;
- the degree and range of protection any patents that we obtain will afford us against competitors, including whether third parties will find ways to invalidate or otherwise circumvent our patents;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; or
- whether we will need to initiate litigation or administrative proceedings related to obtaining, protecting or enforcing our patents, which may be costly whether we win or lose.

We cannot be certain that the claims in our pending patent applications covering composition of matter of our product candidates will be considered patentable by the USPTO or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered patentable by courts in the United States or foreign countries. Certain of our issued patents and pending applications are method of use patents, which protect the use of a product for a specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products "off-label." Although off-label prescriptions may induce or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights may be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries. Even if patents do successfully issue from such applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. If our patents are rendered invalid or unenforceable, or narrowed in scope, the patent coverage afforded our products could be impaired. Such impairment could significantly impede our ability to market our products, negatively affect our competitive position and harm our business and operating results. In addition, changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent or in the same manner as the laws of the United States. For example, patent laws in various jurisdictions, including significant commercial markets such as Europe, restrict the patentability of methods of treatment of the human body more than United States law does. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our patent protection. No assurances can be given that third parties will not create new products or methods that achieve similar results without infringing upon patents we own. If these developments were to occur, it could have an adverse effect on our sales or market position. If the breadth or strength of protection provided by the patents and patent applications we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates.

If we enter into additional collaboration agreements and strategic partnerships or license our product candidates, 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. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the European Union. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent may be extended, and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, 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. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced and could have a material adverse effect on our business.

Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates. Furthermore, for U.S. applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third-party or instituted by the USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. It is also possible for third parties to file observations with various patent offices during the patent application process. Various post grant review proceedings, such as inter partes review and post grant review in the United States and opposition proceedings at the EPO, are available for any interested third party to challenge the patentability of claims issued in patents to us. Some of these procedures are relatively new and can be unpredictable. For example, the EP ’504 Patent, which is owned by the University of Geneva and is exclusively licensed to us, was opposed by a third-party at the EPO. The Opposition Division of the EPO eventually dismissed the opposition and maintained the patent as granted.

In addition to the protection afforded by patents, we seek to rely on trade secret protection, confidentiality agreements, and license agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes that involve proprietary know-how, information, or technology that is not covered by patents. Although we require all of our employees to assign their inventions to us, and require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

Third-party claims of intellectual property infringement may prevent or delay our product discovery and development efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, reexamination, *inter partes* review and post grant review proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As

the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others.

Third parties may assert that we are employing their proprietary technology without authorization. Generally, conducting clinical trials and certain other development activities in the United States is not considered an act of infringement. If and when any of our product candidates are approved by the FDA, a third party may then seek to enforce its patent by filing a patent infringement lawsuit against us. While we are aware of certain third-party patents and applications that relate to similar subject matter as our technologies, we do not believe that any patent claims that could otherwise materially adversely affect commercialization of our product candidates, if approved, are valid and enforceable. We may be incorrect in this belief, or we may not be able to prove it in a litigation. In this regard, patents issued in the United States by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof. There may be third-party patents of which we are currently unaware which cover materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, we may fail to identify relevant patents or incorrectly conclude that a patent is invalid, not enforceable, exhausted, or not infringed by our activities. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, which may not be available on commercially reasonable terms, if at all, or until such patents expire or they are determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license, which may not be available on commercially reasonable terms, if at all, or until such patent expires or is determined to be invalid or unenforceable. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business.

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

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.

Presently we have rights to certain intellectual property, through licenses from third parties and under patents and/or patent applications that we own or will own, related to eseba-vec, HB-700, HB-400, HB-500 and certain other product candidates. Because additional product candidates may require the use of proprietary rights held by third parties, such as the rights to use certain antigens that are, specific to future disease targets, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights. In addition, while we have patent rights directed to certain non-replicating and replicating technologies, we may not be able to obtain intellectual property to all uses of non-replicating and replicating technologies. Our product candidates may also require specific formulations to work effectively and efficiently and rights to such formulations may be held by others. Similarly, efficient production or delivery of our product candidates may also require specific compositions or methods, and the rights to these

compositions or methods may be owned by third parties. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify. Even if we are able to obtain a license to use such intellectual property, it may be non-exclusive, which would not restrict the licensor party from giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. Moreover, the specific antigens that will be used with our product candidates may be covered by the intellectual property rights of others.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure.

For certain of our in-licensed patent rights, such as patent rights in-licensed from the University of Geneva, the University of Basel and the University of Zurich, we may not have the right to file a lawsuit for infringement and may have to rely on a licensor to enforce these rights for us. If we are not able to directly assert our licensed patent rights against infringers or if a licensor does not vigorously prosecute any infringement claims on our behalf, we may have difficulty competing in certain markets where such potential infringers conduct their business, and our commercialization efforts may suffer as a result.

Post-grant proceedings, including interference proceedings, provoked by third parties or brought by the USPTO may be necessary to determine the validity or priority of inventions with respect to our patents or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not agree to a license on commercially reasonable terms or at all. Litigation or post-grant proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

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 this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of our patents and/or patent applications and any patent rights we may obtain in the future. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or the USPTO.

If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that such patent is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, *inter partes* review, post grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidate. Such a loss of patent protection could have a material adverse impact on our business.

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology or pharmaceutical industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the United States continues to adapt to wide-ranging patent reform legislation that became effective starting in 2012. Moreover, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Furthermore, the specific content of patents and patent applications that are necessary to support and interpret patent scope is highly uncertain due to the complex nature of the relevant legal, scientific, and factual issues. Changes in either patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, 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. Changes in the laws and regulations governing patents in other jurisdictions could similarly have an adverse effect on our ability to obtain and effectively enforce our patent rights.

For example, the Biden administration indicated its support for a proposal at the World Trade Organization to waive patent rights with respect to COVID-19 vaccines. Any waiver of our patent or other intellectual property

protection by the U.S. and other foreign governments could have a material adverse effect on our competitive position, business, financial condition and results of operations. For example, recent decisions raise questions regarding the award of patent term adjustment (PTA) for patents in families where related patents have been issued without PTA. Thus, it cannot be said with certainty how PTA will or will not be viewed in the future and whether patent expiration dates may be impacted. In addition, the European patent system is relatively stringent in the type of amendments that are allowed during prosecution, but the complexity and uncertainty of European patent laws has also increased in recent years. For example, in Europe, a new unitary patent system took effect June 1, 2023, which will significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court (UPC). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes. Complying with these laws and regulations could limit our ability to obtain new patents in the future that may be important for our business.

We have less robust intellectual property rights in certain foreign jurisdictions and may not be able to protect our intellectual property rights throughout the world.

Certain of our key patent families have been filed in the United States, as well as in numerous jurisdictions outside the United States. However, our intellectual property rights in certain jurisdictions outside the United States may be less robust. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may export otherwise infringing products to territories where we have patent protection. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. A portion of our patent portfolio is still at an early stage. We will need to decide whether and in which jurisdictions to pursue protection for the various inventions in our portfolio prior to applicable deadlines.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products, 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. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. 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.

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

We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, and contractors. These agreements generally provide that inventions conceived by an employee, consultant, or contractor, as applicable, in the course of rendering services to us will be our exclusive property. However, those agreements may not be honored and may not effectively assign intellectual property rights to us. We may face claims by third parties that our agreements with employees, contractors or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our

ability to capture the commercial value of such intellectual property. Moreover, there may be some circumstances, where we are unable to negotiate for such ownership rights. Disputes regarding ownership or inventorship of intellectual property can also arise in other contexts, such as collaborations and sponsored research. We may be subject to claims that former collaborators or other third parties have an ownership interest in our patents or other intellectual property, including our in-licensed patent rights. If we are subject to a dispute challenging our rights in or to patents or other intellectual property, such a dispute could be expensive and time-consuming. If we are unsuccessful, we could lose valuable rights in intellectual property that we regard as our own.

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

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers or our consultants' or contractors' current or former clients or customers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees from their normal responsibilities. If we are not successful, in addition to paying monetary damages, we could lose access or exclusive access to valuable intellectual property and personnel.

Numerous factors may limit any potential competitive advantage provided by our intellectual property rights.

The degree of future protection afforded by our intellectual property rights, whether owned or in-licensed, is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technologies, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative:

- pending patent applications that we own or license may not lead to issued patents;
- patents, should they issue, that we own or license, may not provide us with any competitive advantages, or may be challenged and held invalid or unenforceable;
- others may be able to develop and/or practice technology that is similar to our technology or aspects of our technology but that is not covered by our owned or in-licensed patents, should any such patents issue;
- third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection;
- we, or our licensors, might not have been the first to make the inventions covered by a pending patent application that we own or license;
- we, or our licensors, might not have been the first to file patent applications covering a particular invention;
- others may independently develop similar or alternative technologies without infringing our intellectual property rights;
- we may not be able to obtain and/or maintain necessary licenses on reasonable terms or at all;
- third parties may assert an ownership interest in our intellectual property, including our in-licensed patent rights, and, if successful, such disputes may preclude us from exercising exclusive rights, or any rights at all, over that intellectual property;
- we may not be able to maintain the confidentiality of our trade secrets or other proprietary information;

- we may not develop or in-license additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business and results of operation.

Risks Related to Employee Matters, Managing Our Growth and Other Risks

The contractual obligations of Daniel Pinschewer to the University of Basel may present conflicts of interest.

Daniel Pinschewer, M.D., Founder and Chief Scientific Officer until March 2020, who served as our Scientific Advisor to the Chief Executive Officer until December 2024, provided research services to us pursuant to a consulting agreement. Dr. Pinschewer is also an employee of the University of Basel where he engages in, among other activities, academic research related to arenaviruses and our technology platform. Pursuant to a separate research service agreement with the University of Basel, the university provides us with on-going services with respect to our technologies, and employs the services of Dr. Pinschewer to perform some of these services. As an employee of the University of Basel, Dr. Pinschewer is subject to the university's rules of conduct, such as confidentiality, academic objectivity and transparency of research with respect to his academic research. As a result of Dr. Pinschewer's obligations to the University of Basel and his previous role as our Scientific Advisor to the Chief Executive Officer, circumstances may arise that could create or appear to create conflicts of interest when, we, the University of Basel or Dr. Pinschewer are faced with decisions that could have different implications for the University of Basel and our company. Additionally, we would not automatically obtain rights to inventions that are developed by Dr. Pinschewer unless the inventions were made in the course of his consulting services to us. Furthermore, other research being conducted by the University of Basel may receive higher priority than research and services related to our technology platform. Any potential disagreement or dispute that may arise with the University of Basel relating to the ownership of Dr. Pinschewer's inventions, conflicts of interest or otherwise may result in a delay or termination of the research, development or commercialization of our product candidates or may have other negative consequences for our company.

We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

We are highly dependent on members of our executive team. Although we have formal employment agreements with our executive officers, any of our executive officers could leave our employment at any time, or within a contractual termination period that is too short to find an adequate replacement. We currently do not have "key person" insurance on any of our employees. The loss of the services of our executive officers or other key employees may adversely impact the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Any significant leadership change or senior management transition involves risk, especially nearly simultaneous changes involving senior level leadership positions. For example, on July 22, 2024, Joern Aldag separated as our Chief Executive Officer and Reinhard Kandera separated as our Chief Financial Officer. In addition, on July 22, 2024, Dr. Malte Peters was appointed as our Chief Executive Officer and Terry Coelho was appointed as our Executive Vice President and Chief Financial Officer. Any failure to effectively transition these senior executive leadership changes or to retain Dr. Peters or Ms. Coelho on our executive team could hinder our strategic planning, business execution and future performance.

Recruiting and retaining qualified employees, consultants and advisors for our business, including scientific and technical personnel, also will be critical to our success. We primarily conduct our operations at our facility in Vienna, Austria. This region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous biotechnology and pharmaceutical companies and academic institutions for skilled individuals. In addition, failure to succeed in preclinical studies, clinical trials or applications for marketing approval may make it more challenging to recruit and retain qualified personnel.

To induce valuable employees to join and remain at our company, in addition to salary and cash incentives, we have provided, and intend to continue to provide, stock options that vest over time. The value of these equity grants that

vest over time to our employees may be significantly affected by movements in the fair market value of our capital stock that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies.

Moreover, many of our employees have become or will soon become vested in a substantial amount of our common stock or a number of common stock options. Our employees may be more likely to leave us if the shares they own have significantly appreciated in value relative to the original purchase prices of the shares, or if the exercise prices of the options that they hold are significantly below the market price of our common stock.

Accordingly, our future success depends on our ability to continue to attract and retain current and additional executive officers and other key employees. The inability to recruit, or the loss of services of certain executives, key employees, consultants or advisors, may impede the progress of our research, development and commercialization objectives and have a material adverse effect on our business, financial condition, results of operations and prospects.

Our strategic refocus and the associated workforce reduction announced in January 2024 and additional workforce reductions implemented in September 2024 and November 2024 may not result in anticipated cost savings, could result in total costs and expenses that are greater than expected and could disrupt our business.

In January 2024, we announced a reduction in workforce by approximately 30% in connection with the strategic refocus of our business to prioritize and focus on our lead assets. The reduction in force was a component of our broader efforts to prioritize the clinical development of our eseba-vec program for the treatment of HPV16+ head and neck cancers and our two Gilead-partnered infectious disease programs, and to pause development activities related to HB-300 and most of our preclinical research activities. In September 2024, in connection with this strategic refocus, we implemented an enterprise-wide initiative intended to improve our business through specialized organizational programs that include targeted cost-savings, including a further reduction in workforce by approximately 20%. Going forward, we may implement further cost-saving initiatives that could result in additional restructuring charges including severance and other employee charges. In November 2024, we approved a plan to continue to improve our cost structure and operating efficiency, including a further reduction in workforce by approximately 80% of our then-current employee base. In connection with the additional restructuring, in an effort to rebalance our cost structure in alignment with our strategic refocus and development of our oncology portfolio, we also announced that we would pause clinical development in our eseba-vec program for the treatment of HPV16+ head and neck cancers, including an early termination of our Phase 1/2 clinical trial for the treatment of HPV16+ cancers. While we will continue to seek partnering opportunities for the eseba-vec program, we will focus primarily on progressing the Phase 1-ready HB-700 program for the treatment of KRAS mutant cancers. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our operating structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring, our results of operation and financial condition would be adversely affected. Furthermore, our strategic restructuring plan may be disruptive to our operations. For example, our workforce reductions could yield unanticipated consequences, such as attrition beyond planned staff reductions, increased difficulties in our day-to-day operations and reduced employee morale. If employees who were not affected by the reduction in force seek alternate employment, this could result in us seeking contract support which may result in unplanned additional expense or harm our productivity. Our workforce reductions could also harm our ability to attract and retain qualified management, scientific, and clinical personnel who are critical to our business. Any failure to attract or retain qualified personnel could prevent us from successfully developing our product candidates in the future.

We may need to grow or contract our organization, and we may experience difficulties in managing this growth or contraction, which could disrupt our operations.

In addition to the risks associated with a reduction in force, as our finances, development and commercialization plans and strategies evolve, we may choose to expand or contract our employee base for managerial, operational, manufacturing, financial and other resources. Future growth or additional contraction would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. Also, our management may need to divert a disproportionate amount of their attention away from our day-to-day activities and devote a substantial amount of time to managing either growth or

contraction activities. We may not be able to effectively manage our operations which may result in weaknesses in our infrastructure, give rise to operational errors, loss of business opportunities, loss of employees and reduced productivity among remaining employees.

Growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of existing and additional product candidates. If our management is unable to effectively manage such growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates and compete effectively with others in our industry will depend, in part, on our ability to effectively manage any such growth.

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

Although we recently implemented a series of workforce reductions and discontinued our GMP manufacturing facility project as part of our recent strategic refocus, as our research, development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial and other personnel, as well as additional facilities to expand our operations. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert 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. Due to our limited financial resources and the limited experience of some members of our management team in managing a public company, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may also lead to significant costs. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, or we are not able to effectively build out new facilities to accommodate this expansion, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including substantially all aspects of regulatory approval, clinical trial management and manufacturing. Our independent organizations, advisors and consultants may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

Risks Related to Ownership of Our Common Stock

An active trading market for our common stock may not be sustainable, and you may not be able to resell your shares of our common stock at or above the purchase price.

An active trading market for our shares may not be sustained. You may not be able to sell your shares quickly or at the market price if trading in shares of our common stock is not active. As a result of these and other factors, it may be difficult for our stockholders to resell their shares of our common stock at or above the prices at which they acquired their shares or sell their shares at the time they would like to sell. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration.

The price of our stock may be volatile.

The trading price of our common stock could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. The market price for our common stock may be influenced by many factors, including:

- the commencement, enrollment or results of the clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- adverse results or delays in clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- our inability to establish collaborations if needed;
- our failure to commercialize our product candidates;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth or concentration;

- the size and growth of our initial cancer target markets;
- our ability to successfully treat additional types of cancers or at different stages;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or immunotherapy in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and Nasdaq and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition.

Our principal stockholders and management own a significant percentage of our stock and exert significant influence over matters subject to stockholder approval.

Our executive officers, directors, and 5% stockholders beneficially own approximately 40% of our outstanding voting stock. These stockholders may be able to determine many matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into license or collaboration agreements with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. Accordingly, our revenue may depend on development funding and the achievement of development and clinical milestones under current and any potential future license and collaboration agreements and, if approved, sales of our product candidates. These upfront and milestone payments may vary significantly from period to period and any variance could cause a significant fluctuation in our operating results from one period to the next.

Further, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and cost of, and level of investment in, research and development activities relating to our current and any future product candidates, which will change from time to time;
- the timing and outcomes of clinical trials for our current and any other future product candidates;
- the cost of manufacturing our current and any future product candidates, which may vary depending on FDA guidelines and requirements, the quantity of production and the terms of our agreements with manufacturers;
- our ability to adequately support our future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic environment.

The cumulative effect 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. Investors should not rely on our past results as an indication of our future performance. 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. The price of our common stock could decline even when we have met any previously publicly stated revenue and/or earnings guidance we may provide.

We expect to continue to incur significant increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives.

As a public company, and particularly now that we are no longer an emerging growth company, as defined in the JOBS Act, we incur significant legal, accounting and other expenses that we did not incur as a private company. Our status as an “emerging growth company” ended on December 31, 2024. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We expect that we will continue to need to hire additional accounting, finance, and other personnel in connection with our efforts to comply with the requirements of being, a public company and our management and other personnel will need to devote a substantial amount of time towards maintaining compliance with these requirements. These requirements will continue to increase our legal and

financial compliance costs and will make some activities more time-consuming and costly. We are continuously evaluating these rules and regulations which are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of the Sarbanes-Oxley Act (SOX Section 404) we are required to furnish a report by our management on our internal control over financial reporting with our Annual Report on Form 10-K with the SEC and to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, we may, under certain conditions, still qualify as a "smaller reporting company" and benefit from similar exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. To achieve compliance with SOX Section 404 within the prescribed period, we engage in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by SOX Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock, which may never occur.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by our board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;

- a requirement of approval of (i) not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action and (ii) the majority of the outstanding shares of our voting stock to amend specific provisions of our certificate of incorporation; and

- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Our amended and restated bylaws designate the Court of Chancery of the State of Delaware as 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.

Our amended and restated bylaws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers and employees to us or our stockholders, (iii) any action asserting a claim against us or any of our current or former directors, officers, or other employees or stockholders arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws, (iv) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws, or (v) any action asserting a claim against us or any of our current or former directors or officers or other employees that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. Stockholders who do bring a claim in the Court of Chancery could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near the jurisdiction. The Court of Chancery may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our stockholders. Alternatively, if a court were to find this provision of our amended and restated certificate of incorporation or amended and restated bylaws inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs, which could have a material adverse effect on our business, financial condition or results of operation.

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

Upon the closing of our initial public offering in April 2019, we became subject to the periodic reporting requirements of the Exchange Act. We are continuing to refine our disclosure controls and procedures to provide reasonable assurance that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

Pursuant to Section 404 of Sarbanes-Oxley, our management is required to report upon the effectiveness of our internal control over financial reporting. In addition, if we do not qualify as a "smaller reporting company" at the time we file an Annual Report on Form 10-K, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we will need to implement additional financial and management controls, reporting systems and procedures and hire additional accounting and finance staff.

Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

General Risks

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

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, such as the failure of Silicon Valley Bank and various regional banks in 2023, have in the past and may in the future lead to market-wide liquidity problems. If any of our lenders or counterparties to any such instruments were to be placed into receivership, we may be unable to access such funds. In addition, if any of our customers, suppliers or other parties with whom we conduct business are unable to access funds pursuant to such instruments or lending arrangements with such a financial institution, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected.

Heightened inflation and increases in interest rates may increase our labor costs, costs to conduct clinical trials and other operational costs, or adversely affect our ability to obtain additional funding on attractive terms.

Although inflation has not had a material impact on our business or operating results historically, inflation, has had, and may continue to have, an impact on the labor costs we incur to attract and retain qualified personnel, costs to conduct clinical trials and other operational costs. Inflationary costs could adversely affect our business, financial condition and results of operations. Increased interest rates may adversely affect our borrowing rate and our ability to obtain, or the terms under which we can obtain, any potential additional funding.

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

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to: comply with the regulations of the FDA and other comparable foreign regulatory bodies, provide true, complete and accurate information to the FDA and other comparable foreign regulatory bodies, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws and regulations will increase significantly, and our costs associated with compliance with such laws and regulations are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally.

We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee and other third-party misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. 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 civil, criminal and administrative penalties, damages, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business, financial condition and results of operations.

Violations of or liabilities under environmental, health and safety laws and regulations could subject us to fines, penalties or other costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures, the handling, use, storage, treatment and disposal of hazardous materials and wastes and the cleanup of contaminated sites. Our operations involve the use of potentially hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We could incur substantial costs as a result of violations of or liabilities under environmental requirements in connection with our operations or property, including fines, penalties and other sanctions, investigation and cleanup costs and third-party claims. Although we generally contract with third parties for the disposal of hazardous materials and wastes from our operations, we cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of changes to applicable laws and regulations and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts.

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.

We are subject to stringent and evolving U.S. and foreign laws, regulations and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, sensitive third-party data, business plans, transactions, clinical trial data and financial information (collectively, sensitive data).

Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, HIPAA imposes specific requirements relating to the privacy, security, and transmission of individually identifiable protected health information. For more information regarding risks associated with HIPAA, please refer to the section above that discusses risks associated with U.S. healthcare laws.

In the past few years, numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 (“CPRA”) (collectively, “CCPA”), applies to personal data of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines of up to $7,500 per intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Although there are limited exemptions for clinical trial data under the CCPA, the CCPA and other similar laws may impact (possibly significantly) our business activities depending on how it is interpreted, should we become subject to the CCPA in the future. 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. These developments may further complicate compliance efforts and increase legal risk and compliance costs for us and the third parties with whom we work.

Outside the United States, an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, EU GDPR and the UK GDPR impose strict requirements for processing personal data. For example, under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

We may be subject to new laws governing the privacy of consumer health data, including reproductive, sexual orientation, and gender identity privacy rights. For example, Washington’s My Health My Data Act (“MHMD”) broadly defines consumer health data, places restrictions on processing consumer health data (including imposing stringent requirements for consents), 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.

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

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

In addition to data privacy and security laws, we are bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. We also publish privacy policies, marketing materials, whitepapers and other statements concerning data privacy and security, Regulators in the United States are increasingly scrutinizing these statements, and if these policies, materials, or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading 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 and may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties with whom we work.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties with whom we work may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties with whom we work fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal data (including clinical trial data); and orders to destroy or not use personal data. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for 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; 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

Cybersecurity risks and the failure to maintain the security, confidentiality, integrity, and availability of our information technology systems or data, and those maintained on our behalf, could result in adverse consequences that materially affect our business, including without limitation regulatory investigations or actions, a material disruption of the development programs of our product candidates, damage to our reputation and/or subject us to costs, loss of customers or sales, fines and penalties or lawsuits.

In the ordinary course of our business, we collect and store sensitive data, and, as a result, we and the third parties with whom we work face a variety of evolving threats that could cause security incidents. We manage and maintain our applications and data utilizing on-site systems and outsourced vendors. These applications and data encompass a wide variety of business critical information, including research and development information, commercial information and business and financial information. Because information systems, networks and other technologies are critical to many of our operating activities, shutdowns or service disruptions at our company or vendors that provide information systems, networks or other services to us pose increasing risks. Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive data and information technology systems, and those of the third parties with whom we work. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties with whom we work may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our services.

We and the third parties with whom we work are subject to a variety of evolving threats, including but not limited to computer hacking, phishing attacks and social engineering (including through deep fakes, which may be increasingly more difficult to identify as fake), supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by AI, ransomware, dissemination of malware, computer viruses, worms and other destructive or disruptive software, denial of service attacks and other malicious activity, credential stuffing, credential harvesting, personnel misconduct or error as well as power outages, telecommunications failures, natural disasters (including extreme weather), terrorist attacks or other similar events. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of sensitive data and income, reputational harm, and diversion of funds. 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. Such events could have an adverse impact on us and our business, including loss of data and damage to equipment and data. In addition, system redundancy may be ineffective or inadequate, and our disaster recovery planning may not be sufficient to cover all eventualities. If such events were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, such as the loss of clinical trial data from completed or future clinical trials. Such loss could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, we may not have adequate insurance coverage to compensate for any losses associated with such events.

Remote work has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit and in public locations. Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. We may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We rely on third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation the manufacture of our product candidates and to conduct clinical trials. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences, including the unauthorized access, disclosure and use of sensitive data, including information from our patient registry or other patient information, which is protected by HIPAA, and other laws. Any such access, disclosure, or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, damage to our reputation and the further development and commercialization of our product candidates could be delayed.

In addition, our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of our suppliers are affected by a man-made or natural disaster or other business interruption. Damage or extended periods of interruption to our third-party collaborators', including Gilead's, corporate, development or research facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause them to cease or delay development.

As we outsource more of our information systems to vendors, engage in more electronic transactions with payors and patients, and rely more on cloud-based information systems, the related security risks will increase, and we will need to expend additional resources to protect our technology and information systems. In addition, there can be no assurance that our internal information technology systems or those of our third-party contractors, or our consultants' efforts to implement adequate security and control measures, will be sufficient to protect us against breakdowns, service disruption, data deterioration or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a cyber-attack, security breach, industrial espionage attacks or insider threat attacks which could result in financial, legal, business or reputational harm.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We also take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties with whom we work). We may not, however, detect and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties with whom we work. For example, we have been the target of unsuccessful phishing attempts in the past and we expect such attempts will continue in the future. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to provide our products and services.

We may expend significant resources or modify our business activities to try to protect against security incidents. Additionally, certain data privacy and security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive data. Applicable data privacy and security obligations may require us, or we may voluntarily choose, to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents, or to take other actions, such as providing credit monitoring and identity theft services. Such disclosures and related actions can be costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences.

If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant

consequences may prevent or cause customers to stop using our services, deter new customers from using our services, and negatively impact our ability to grow and operate our business.

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

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

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Cybersecurity Risk Management and Strategy

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

Our cybersecurity function, led by our head of IT and supported by third-party service providers, identifies and assesses risks from cybersecurity threats by monitoring and evaluating our threat environment using various methods including, for example: maintaining manual and automated tools, subscribing to reports and services that identify cybersecurity threats, conducting scans of our threat environment, evaluating our and our industry's cybersecurity risk profile, evaluating threats reported to us, completing internal and external cybersecurity audits, completing third-party cybersecurity threat assessments, conducting vulnerability assessments, leveraging external intelligence feeds, and tabletop incident response exercises.

Depending on the environment, we implement and maintain technical, physical, and organizational measures, processes, standards, practices, and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data. These measures, processes, standards, practices, and policies address, for example: incident detection and response, risk assessments, security certifications, encryption, network security controls, data segregation, access controls, physical security, asset management (such as tracking and disposal), systems monitoring, employee cybersecurity awareness training, and systems monitoring. We also have cybersecurity insurance.

Our process for identifying and assessing material risks from cybersecurity threats operates alongside our broader overall enterprise risk assessment process. We have a cybersecurity-specific risk assessment process designed to assess identified material risks from cybersecurity threats. This process is designed to help us manage our material risks from cybersecurity threats and protect against, detect, and respond to cybersecurity incidents.

We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including for example cybersecurity software providers and cybersecurity consultants that provide threat intelligence, managed cybersecurity, forensic, and penetration testing services.

Further, we use third-party service providers to perform a variety of functions throughout our business, such as software-as-a-service providers, data hosting companies, contract research organizations, and contract manufacturing organizations. We have certain vendor management processes designed to help manage cybersecurity risks associated with our use of these providers. Depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, our vendor management processes may involve different levels of assessment designed to help identify cybersecurity risks associated with a provider, including, for example, security questionnaires and the imposition of contractual obligations related to cybersecurity on the provider.

For a description of the cybersecurity risks and related impacts that may materially affect the Company and how they may do so, see our risk factors in Part I, Item 1A of this Annual Report on Form 10-K, including "Cybersecurity risks and the failure to maintain the security, confidentiality, integrity, and availability of our information technology systems or data, and those maintained on our behalf, could result in adverse consequences that materially affect our business, including without limitation regulatory investigations or actions, a material disruption of the development programs of our product candidates, damage to our reputation and/or subject us to costs, loss of customers or sales, fines and penalties or lawsuits."

Cybersecurity Governance

Our Board of Directors addresses the Company's cybersecurity risk management as part of its general oversight function. Our Audit Committee is responsible for the oversight of risks from cybersecurity threats and data breaches. On a quarterly basis, the Audit Committee receives an overview from our head of IT regarding our cybersecurity threat risk management and strategy processes, which may include, for example, covering topics such as data security posture, results from third-party assessments, our incident response plan, and material cybersecurity threat risks or incidents and developments, as well as the steps management has taken to respond to such risks. The Chair of the Audit Committee periodically updates our Board of Directors on its oversight of cybersecurity and data breach risk management and strategies.

Our executive management team, with regulatory and governance oversight from our Audit Committee, are responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into the Company's overall risk management strategy, and communicating key priorities to relevant personnel.

Our cybersecurity function, led by our head of IT and supported by our third-party service providers, is responsible for our cybersecurity risk management and strategy processes. These functions have significant prior work experience in various roles involving managing information security, developing cybersecurity strategy and implementing effective information and cybersecurity programs.

Our cybersecurity incident response plan provides for escalation of certain cybersecurity incidents to members of management depending on the circumstances, including our CFO, CDO, and CEO. Management works with the Company's incident response team to help the Company mitigate and remediate cybersecurity incidents of which they are notified. Our incident response team also reports material cybersecurity incidents to the Chair of the Audit Committee.

Item 2. Properties

Our principal executive offices are located in New York, New York, pursuant to a lease that expires in August 2026. Our European research and preclinical development operations are located in Vienna, Austria, where we lease and occupy approximately 30,681 square feet of office and laboratory space. Our first Austrian facility is leased pursuant to two operating leases, comprised of (i) a lease of unlimited duration for approximately 15,239 square feet of office and laboratory space which will be terminated effective March 31, 2025 and (ii) a lease initially set to expire in September 2028 and with no option to extend for approximately 2,367 square feet of storage space which will be terminated effective June 30, 2025. In 2019, we entered into a lease for a second facility located in Vienna, Austria that was initially set to expire in February 2029, where we occupy approximately 15,440 square feet of office and laboratory space, which will be terminated effective February 28, 2025. In May 2021 we purchased a parcel of land in the north of Vienna and have received building permission to build a GMP manufacturing plant of approximately 48,440 square feet.

In January 2024 our Board decided to implement a Restructuring Plan, which included the discontinuation of the GMP manufacturing project and the divestment of all associated assets, including the parcel of land. Strategic considerations preceding the adoption of the Restructuring Plan resulted in the impairment of the full carrying value of the GMP manufacturing facility project in the year ended December 31, 2023 and the land is currently held for sale. We are currently evaluating the required space needed to meet our future need following our strategic refocus. We believe if we require new or additional space, we will be able to obtain additional facilities on commercially reasonable terms.

PART II—OTHER INFORMATION

Item 3. Legal Proceedings.

We are not currently a party to any material legal proceedings. From time to time, we may become involved in other litigation or legal proceedings relating to claims arising from the ordinary course of business.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Certain Information Regarding the Trading of Our Common Stock

Our common stock trades under the symbol “HOOK” on The Nasdaq Capital Market and has been publicly traded since April 18, 2019. Prior to this time, there was no public market for our common stock.

Holders of Our Common Stock

As of February 24, 2025, there was one holder of record of shares of our common stock, which does not include stockholders for whom shares are held in “nominee” or “street” name, and two holders of record of shares of our Class A common stock.

Dividends

We have not paid any cash dividends on our common stock since inception and do not anticipate paying cash dividends in the foreseeable future.

Securities Authorized for Issuance Under Equity Compensation Plans

The information required by Item 5 of Form 10-K regarding equity compensation plans is incorporated herein by reference to Item 12 of Part II of this Annual Report.

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. [Reserved]

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

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

Overview

We are a clinical-stage biopharmaceutical company developing a new class of immunotherapeutics based on our proprietary arenavirus platform that is designed to target and amplify T cell and immune responses to fight diseases. Our replicating and non-replicating technologies are engineered to induce robust and durable antigen-specific CD8+ T cell responses and pathogen-neutralizing antibodies. We believe that our technologies can meaningfully leverage the human immune system for therapeutic purposes by inducing CD8+ T cell response levels previously not achieved by other immune therapy approaches.

We are building a proprietary immuno-oncology pipeline utilizing our replicating technology. Our oncology portfolio targets oncoviral cancer antigens and next-generation antigens and includes two primary programs in development: eseba-vec (formerly HB-200) and HB-700. Eseba-vec is in clinical development for the treatment of Human Papillomavirus 16-positive ("HPV16+") head and neck cancers. Eseba-vec in combination with pembrolizumab received Fast Track Designation from the U.S. Food and Drug Administration ("FDA") in January 2022 and PRIME designation from the European Medicines Agency in April 2024 for the treatment of first-line HPV16+ recurrent/metastatic oropharyngeal squamous cell carcinoma. In April 2024, we received Investigational New Drug ("IND") clearance from the FDA for HB-700 for the treatment of KRAS mutated cancers, including, lung, colorectal and pancreatic cancers.

Our strategic priority in 2024 has been the development of our oncology portfolio, most importantly the advancement of our eseba-vec program, and the initiation of the AVALON-1 trial, a randomized Phase 2/3 trial of eseba-vec. Additionally, we are developing infectious disease therapies in partnership with other companies. Our Hepatitis B ("HBV") program, HB-400, and our Human Immunodeficiency Virus ("HIV") program, HB-500, are developed in a partnership with Gilead Sciences Inc. ("Gilead").

In November 2024, in connection with our Restructuring Plan, in alignment with our strategic refocus and development of our oncology portfolio, we announced that we will pause clinical development in our eseba-vec program for the treatment of HPV16+ head and neck cancers, including an early termination of our ongoing Phase 1/2 clinical trial for the treatment of HPV16+ cancers. The early termination of our ongoing Phase 1/2 clinical trial for the treatment of HPV16+ is not due to lack of efficacy or adverse safety profiles. While we will continue to seek partnering opportunities for the eseba-vec program, we expect to focus primarily on progressing the phase 1-ready HB-700 program for the treatment of KRAS mutant cancers.

Eseba-vec, our first program in oncology, was evaluated in a early terminated Phase 1/2 clinical trial for the treatment of HPV16+ cancers. This trial has completed enrollment in Phase 2 and was evaluating eseba-vec therapy in combination with pembrolizumab in the first line setting of HPV16+ PD-L1+ oropharynx cancer.

HB-700 was designed for treatment of cancers encoding mutated KRAS, especially KRAS-mutated pancreatic, colorectal, and lung cancers. By simultaneously targeting the five most common mutations, we believe HB-700 has the potential to benefit more patients than single mutation inhibitors.

In October 2022, we entered into a Research Collaboration and License Agreement (the "Roche Collaboration Agreement"), with Roche to (i) grant Roche an exclusive license to research, develop, manufacture and commercialize our pre-clinical HB-700 cancer program, an arenaviral immunotherapeutic for KRAS-mutated cancers, and (ii) grant Roche an option right to exclusively license for research, development manufacturing and commercialization, a second, novel arenaviral immunotherapeutic program targeting undisclosed cancer antigens. We announced in January 2024 that we received notification from Roche of their decision to terminate the collaboration and licensing agreement for our HB-700 program in KRAS mutated cancers. Effective April 25, 2024, we regained full control of the associated intellectual property portfolio and have full collaboration and licensing rights for this program. Pursuant to the Roche Collaboration Agreement, we previously received a non-refundable upfront payment of $25.0 million, a milestone payment of $10.0 million and in 2024 we received a $10.0 million milestone payment associated with the submission of the IND to the FDA.

Nonclinical development and clinical trial material manufacturing for HB-700 has been completed. In April 2024, we received FDA clearance of our IND application for HB-700. HB-700 is derisked by clinical proof of concept with platform asset eseba-vec (HB-200), and we are planning a Phase 1/2 in mutated KRAS metastatic NSCLC with the first person to be dosed in the Phase 1 part mid-2025.

We are collaborating with Gilead to research arenavirus functional cures for chronic Hepatitis B and HIV infections under a Collaboration and License Agreement signed in 2018 (the "Gilead Collaboration Agreement"). Both programs have completed preclinical research, and in April 2023 the first participant in a Phase 1 clinical trial of the Hepatitis B product candidate being conducted by Gilead was dosed. Gilead is solely responsible for further development and commercialization of the Hepatitis B product candidate and we are eligible for up to a further $185.0 million in development and commercialization milestone payments, plus tiered royalties. According to the amendment to the Gilead Collaboration Agreement, signed in February 2022, we have taken on development responsibilities for the HIV program candidate through a Phase 1b clinical trial and Gilead will provide funding through a combination of an initiation payment of $15.0 million, a milestone payment of $5.0 million and equity contributions of up to $35.0 million. In November 2023, we received FDA clearance of our IND application for HB-500 and started the Phase 1b trial in the second quarter of 2024. The first person was dosed on July 1, 2024, resulting in the achievement of a $5.0 million milestone payment. Gilead retains the exclusive option, to further develop and commercialize the HIV program, in which case we are eligible for up to a further $227.5 million in developmental and commercialization milestone payments, inclusive of a $10.0 million option exercise payment, plus tiered royalties.

On January 29, 2024, we announced our decision to prioritize the clinical development of our eseba-vec program for the treatment of HPV16+ head and neck cancers and our two Gilead-partnered infectious disease programs and to pause development activities related to HB-300, targeting self-antigens for the treatment of prostate cancer, and most of our preclinical research activities. In connection with this strategic refocus, our Board of Directors approved a plan to reduce our workforce by 55 full-time employees, or approximately 30% of the then-current employee base, and to rebalance our cost structure in alignment with the new prioritization of research and development programs. The prioritization of our eseba-vec program and our two Gilead-partnered programs also included the discontinuation of our GMP manufacturing facility project. This part of the restructuring plan was completed by the end of the second quarter of 2024.

In September 2024, our Board of Directors approved a plan to reduce our workforce by another 28 employees, or approximately 20% of the then-current employe base, and to further rebalance our cost structure in alignment with the prioritization of clinical development programs. We announced and began the implementation of this additional restructuring plan in the third quarter of 2024 and we expect the restructuring to be substantially completed by the end of the first quarter of 2025.

On November 18, 2024 our Board of Directors approved a plan to continue to improve our cost structure and operating efficiency, which includes a reduction in our workforce by approximately 80% of the then-current employee base and the closing and consolidation of offices and laboratories in Vienna, Austria. We began the implementation of this restructuring plan in the fourth quarter of 2024 and expect these continued restructuring actions to be substantially completed by the end of the first half of 2025. In connection with the continued restructuring plan, in an effort to rebalance our cost structure in alignment with our strategic refocus and development of our oncology portfolio, we also

announced that we will pause clinical development in our eseba-vec program, including an early termination of our ongoing Phase 1/2 clinical trial for the treatment of HPV16+ cancers. Going forward, we may implement further cost-saving initiatives that could result in additional restructuring charges including severance and other employee charges.

We have funded our operations to date primarily from public offerings of common stock and convertible preferred stock, including our initial public offering, as well as private placements of our redeemable convertible preferred stock, grant funding and loans from an Austrian government agency, and upfront, milestone and initiation payments from Gilead and Roche in connection with our respective collaboration and license agreements. As of December 31, 2024 we had cash, cash equivalents and restricted cash of $39.9 million.

We do not expect to generate revenue from any product candidates that we develop until we obtain regulatory approval for one or more of such product candidates, if at all, and commercialize our products or enter into additional collaboration agreements with third parties. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

All of our product candidates will require substantial additional development time and resources before we would be able to apply for and receive regulatory approvals and begin generating revenue from product sales. We currently have no marketing and sales organization and have no experience in marketing products; accordingly, we will incur significant expenses to develop a marketing organization and sales force in advance of generating any commercial product sales. As a result, we will need substantial additional capital to support our operating activities. In addition, we expect to continue to incur legal, accounting and other expenses in operating our business, including the costs associated with operating as a public company.

We currently anticipate that we will seek to fund our operations through equity or debt financings or other sources, such as government grants and additional collaboration agreements with third parties. Adequate funding may not be available to us on acceptable terms, or at all. If sufficient funds on acceptable terms are not available when needed, we will be required to significantly reduce our operating expenses and delay, reduce the scope of, or eliminate one or more of our development programs.

We have incurred recurring losses, including net losses of $43.5 million for the year ended December 31, 2024 and $81.6 million for the year ended December 31, 2023. As of December 31, 2024, we had an accumulated deficit of $412.8 million and we do not expect positive cash flows from operations in the foreseeable future, if ever. We expect to continue to incur net operating losses for at least the next several years as we advance our product candidates through clinical development, seek regulatory approval, prepare for and, if approved, proceed to commercialization, continue our research and development efforts and invest to establish further commercial manufacturing capacity.

Impacts of Market Conditions on Our Business

Unfavorable conditions in the economy in the United States, Austria and elsewhere may negatively affect the growth of our business and our results of operations. Macroeconomic events and conditions such as heightened inflation, increased interest rates, disruptions to global financial markets or a recession or other market correction, including as a result of the ongoing military conflict between Russia and Ukraine and the related sanctions imposed against Russia, any escalation of the conflict in the Middle East, and other global macroeconomic factors, could reduce our ability to access capital, which could materially impact our business and the value of our common stock.

Components of Our Results of Operations

Revenue from collaboration and licensing

To date, we have not generated any revenue from product sales and do not expect to do so in the near future, if at all. All of our revenue to date has been derived from research collaboration and license agreements with Gilead and Roche.

Gilead Collaboration Agreement

On June 4, 2018, we entered into the Gilead Collaboration Agreement to evaluate potential vaccine products using or incorporating our replicating technology and non-replicating technology for the treatment, cure, diagnosis or prevention of HBV and HIV.

Under the Gilead Collaboration Agreement, we granted Gilead an exclusive, royalty-bearing license to our technology platform for researching, developing, manufacturing and commercializing products for HIV and HBV. We received a non-refundable $10.0 million upfront payment upon entering the Gilead Collaboration Agreement. In February 2022, we signed an amended and restated collaboration agreement (the "Restated Gilead Collaboration Agreement") which revised the terms only for the HIV program, whereby we took on development responsibilities for the HIV program candidate through a Phase 1b clinical trial. Pursuant to the Restated Gilead Collaboration Agreement, Gilead retains an exclusive right (the "Option") to take back the development responsibilities, thus keeping the rights for the HIV program, including further development and commercialization in return for an option exercise payment of $10.0 million. Pursuant to the Restated Gilead Collaboration Agreement, we are eligible for up to $140.0 million in developmental milestone payments for the HBV program and $50.0 million in commercialization milestone payments. If Gilead exercises the Option, we are eligible for up to $172.5 million in developmental milestone payments for the HIV program, inclusive of the $10.0 million Option exercise payment, and $65.0 million in commercialization milestone payments for the HIV program. Upon the commercialization of a product, we are eligible to receive tiered royalties of a high single-digit to mid-teens percentage on the worldwide net sales of each HBV product, and royalties of a mid-single-digit to 10% of worldwide net sales of each HIV product. Gilead is obligated to reimburse us for our costs, including all benefits, travel, overhead, and any other expenses, relating to performing research and development activities under the Restated Gilead Collaboration Agreement with respect to the HBV program, and if the Option is exercised, any manufacturing costs related to the HIV program. Through December 31, 2024, we have received a non-refundable upfront payment of $10.0 million, a program initiation fee of $15.0 million, a $5.0 million milestone payment for the completion and delivery of a regulatory support package for HB-400, a $5.0 million milestone payment for the first person dosed in a Phase 1b clinical trial of HB-500 and $16.2 million in milestone payments for the achievement of pre-clinical research milestones from Gilead. In addition, we have recognized $43.0 million of cost reimbursements for research and development services performed under the Restated Gilead Collaboration Agreement.

We determined that our performance obligations under the terms of the original Gilead Collaboration Agreement included one combined performance obligation for each of the HBV and HIV research programs, comprised of the transfer of intellectual property rights and providing research and development services. Accordingly, we recognized these amounts as revenue over the performance period of the respective services on a percent of completion basis using total estimated research and development labor hours for each of the performance obligations. The terms of the Restated Gilead Collaboration Agreement added an additional performance obligation to us to perform research and development work for the HIV program. We recognize the amounts of revenue allocated to the performance obligation resulting from the Restated Gilead Collaboration Agreement on a percent of completion basis over the performance period, using total estimated research and development costs as the measure of progress.

Roche Collaboration Agreement

On October 18, 2022, we entered into the Roche Collaboration Agreement to (i) grant Roche an exclusive license to research, develop, manufacture and commercialize our pre-clinical HB-700 cancer program, an arenaviral immunotherapeutic for KRAS-mutated cancers, and (ii) grant Roche an exclusive option right to exclusively license for research, development manufacturing and commercialization, a second, novel arenaviral immunotherapeutic program targeting undisclosed cancer antigens. In January 2024, Roche provided us with written notice of the termination of the collaboration and licensing agreement.

Under the terms of the terminated Roche Collaboration Agreement, we granted Roche an exclusive, royalty-bearing license to our technology platforms for KRAS-mutated cancers, and an option right to exclusively license a second, novel arenaviral immunotherapeutic program targeting undisclosed cancer antigens. Pursuant to the terms of the Roche Collaboration Agreement, following the termination notice, the Roche Collaboration Agreement was terminated

on April 25, 2024. Effective April 25, 2024, we regained full control of the associated intellectual property portfolio and will have full collaboration and licensing rights for the KRAS program.

Through December 31, 2024, we received from Roche the non-refundable upfront payment of $25.0 million, $10.0 million in milestone payments for the achievement of a GMP manufacturing milestone under the HB-700 program and $10.0 million in milestone payments associated with an IND submission for the HB-700 program. In addition, we have recognized $0.6 million of cost reimbursements for research and development activities related to a first in human trial.

We determined that our performance obligations under the terms of the Roche Collaboration Agreement included one combined performance obligation for the transfer of intellectual property rights (licenses) and providing research and development services for the HB-700 program, and a second, separate performance obligation during the UCA Option period to perform research and development services with respect to the UCA Program. Accordingly, we allocated the non-refundable upfront payment of $25.0 million between the two performance obligations. Milestone payments that were contingent on future events were added to the transaction price when the triggering event has become probable. The consideration allocated to a performance obligation has been recognized as revenue over the performance period of the respective services on a percent of completion basis using total estimated research and development costs for each of the performance obligations. Milestone payments, or parts thereof, that related to completed services were reflected via a cumulative catch up for past performance.

Operating Expenses

Our operating expenses since inception have only consisted of research and development costs, general and administrative costs, impairment and restructuring expenses.

Research and Development Expenses

Since our inception, we have focused significant resources on our research and development activities, including establishing our arenavirus platform, conducting preclinical studies, developing a manufacturing process, conducting Phase 1 and Phase 2 clinical trials, including the paused eseba-vec (formerly HB-200) clinical trials, and progressing IND applications, including for HB-700. Research and development activities account for a significant portion of our operating expenses. Research and development costs are expensed as incurred. These costs include:

- salaries, benefits and other related costs, including stock-based compensation, for personnel engaged in research and development functions;
- expenses incurred in connection with the preclinical development of our programs and clinical trials of our product candidates, including under agreements with third parties, such as consultants, contractors, academic institutions and contract research organizations (“CROs”);
- the cost of manufacturing drug products for use in clinical trials, including under agreements with third parties, such as CMOs, consultants and contractors;
- laboratory costs;
- leased facility costs, equipment depreciation and other expenses, which include direct and allocated expenses; and
- third-party license fees.

The majority of our research and development costs are external costs, which we track on a program-by-program basis. We do not track our internal research and development expenses on a program-by-program basis as they primarily relate to shared costs deployed across multiple projects under development.

We expect our research and development expenses to increase substantially in the future as we advance our existing and future product candidates into and through clinical trials and pursue regulatory approval. The process of conducting the necessary clinical studies to obtain regulatory approval is costly and time-consuming. Clinical trials generally become larger and more costly to conduct as they advance into later stages and, in the future, we will be required to make estimates for expense accruals related to clinical trial expenses.

At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the development of any product candidates that we develop from our programs. We are also unable to predict when, if ever, material net cash inflows will commence from sales of product candidates we develop, if at all. This is due to the numerous risks and uncertainties associated with developing product candidates, including the uncertainty of:

- successful completion of preclinical studies and clinical trials;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- substantial doubt regarding our ability to continue as a going concern;
- acceptance of INDs for our planned clinical trials or future clinical trials;
- successful enrollment and completion of clinical trials;
- successful data from our clinical program that support an acceptable risk-benefit profile of our product candidates in the intended populations;
- receipt and maintenance of regulatory and marketing approvals from applicable regulatory authorities;
- scaleup of our manufacturing processes and formulation of our product candidates for later stages of development and commercialization;
- establishing our own manufacturing capabilities or agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if our product candidate is approved;
- entry into collaborations to further the development of our product candidates;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates;
- successfully launching commercial sales of our product candidates, if approved;
- acceptance of the product candidates benefits and uses, if approved, by patients, the medical community and third-party payors;
- the prevalence and severity of adverse events experienced with our product candidates;
- maintaining a continued acceptable safety profile of the product candidates following approval;
- effectively competing with other therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors; and

- qualifying for, maintaining, enforcing and defending intellectual property rights and claims.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in our clinical trials due to patient enrollment or other reasons, we would be required to expend significant additional financial resources and time on the completion of clinical development.

The following table summarizes our research and development expenses by product candidate or program (in thousands):

	Year ended December 31,	
	2024	2023
Eseba-vec (formerly HB-200) program	$ 51,318	$ 41,301
HB-300 program	3,221	11,654
Gilead partnered programs	6,730	13,020
HB-700 & UCA programs (formerly Roche partnered programs)	5,942	14,187
Other and earlier-stage programs	566	4,946
Other unallocated research and development expenses	730	1,316
Total research and development expenses	$ 68,507	$ 86,424

Other unallocated research and development expenses include stock-based compensation expense, certain lease expenses and other operating expenses that we do not track on a program-by-program basis, since our research and development employees and infrastructure resources are utilized across our programs.

General and Administrative Expenses

Our general and administrative expenses consist primarily of personnel costs in our executive, finance and investor relations, business development and administrative functions. Other general and administrative expenses include consulting fees and professional service fees for auditing, tax and legal services, transaction costs related to a potential merger or acquisition, lease expenses related to our offices, premiums for directors and officers liability insurance, intellectual property costs incurred in connection with filing and prosecuting patent applications, depreciation and other costs. We expect our general and administrative expenses to continue to increase in the future as we expand our operating activities and prepare for potential commercialization of our current and future product candidates, increase our headcount and investor relations activities and maintain compliance with requirements of the Nasdaq Capital Market and the Securities and Exchange Commission.

Impairment Expenses

Impairment expenses consist of non-cash impairment charges relating to long-lived assets. Impairments are determined using management’s judgment about the anticipated performance of our business in relation to expectations, significant negative technological, scientific or economic trends and significant changes or planned changes in the use of the assets and their effects based on information available as of the date of these consolidated financial statements appearing elsewhere in this Annual Report. Management makes decisions to dispose of fixed assets during the regular course of business due to damage, obsolescence, strategic shifts, and loss.

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset group may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset group to future undiscounted net cash flows expected to be generated by the assets. If the carrying amount of an asset group exceeds its estimated undiscounted net future cash flows, an impairment charge is recognized for the amount by which the carrying amount of the asset group exceeds its fair value.

Impairment expenses also include write-downs of the carrying values of assets reclassified to assets held for sale.

Restructuring Expenses

Restructuring expenses consist of severance and other personnel costs and professional services and consulting costs associated with exit and disposal activities.

Grant Income

Since inception, we have received grants from the Austrian Research Promotions Agency, either under funding agreements or under research incentive programs. In addition, we have received loans under funding agreements that bear interest at below market interest rate. We account for the grants received as other income and for the imputed benefits arising from the difference between a market rate of interest and the rate of interest as additional grant income, and record interest expense for the loans at a market rate of interest.

We participate in a research incentive program provided by the Austrian government under which we are entitled to reimbursement of a percentage of qualifying research and development expenses and capital expenditures incurred in Austria. Submissions for reimbursement under the program are submitted annually. Incentive amounts are generally paid out during the calendar year that follows the year of the expenses but remain subject to subsequent examinations by the responsible authority.

Furthermore, we participated in the life sciences research and development program provided by the New York State government under which we were entitled to reimbursement of a percentage of qualifying research and development expenses in New York State up to $0.5 million per year for the years 2019 to 2021. Submissions for reimbursement under the program were submitted in the fourth quarter of 2023 and certificates of tax credits were received. Incentive amounts are generally paid out six to nine months after amended tax returns including a certificate of tax credit issued by Empire State Development are filed. We account for the grants received as other income.

We also participate in the New York City biotechnology tax credit program, according to which certain expenses for business in the biotechnology field in New York City limited to $0.25 million per year for three consecutive years from January 1, 2023 to December 31, 2025 are incentivized. Submission for reimbursement under the program for the year 2024 was submitted in January of 2025. We account for the grants received as other income.

Interest Income

Interest income results from interest earned on our cash, cash equivalents, and restricted cash.

Interest Expense

Interest expense results primarily from loans under funding agreements with the Austrian Research Promotion Agency, recorded at a market rate of interest. The difference between interest payments payable pursuant to the loans, which rates are at below market interest rates, and the market interest rate, is accounted for as grant income.

Income Tax Benefit (Expense)

Income tax benefit (expense) results from U.S. federal and state income tax as well as foreign minimum income tax and profit on a legal entity basis. The losses that we have incurred since inception result primary from the losses of our Austrian subsidiary. As of December 31, 2024, we had a deferred tax asset of $97.9 million primarily resulting from foreign net operating loss carryforwards of $400.9 million with no expiry date. We have considered that, at this point in time, it is uncertain whether we will ever be able to realize the benefits of the deferred tax asset, and accordingly, have established a full valuation allowance as of December 31, 2024.

Results of Operations

Comparison of Years Ended December 31, 2024 and 2023

The following table summarizes our results of operations for the years ended December 31, 2024 and 2023 (in thousands). Discussions of 2022 items and year-to-year comparisons between 2023 and 2022 that are not included in this Annual Report on Form 10-K can be found in "Management's Discussion and Analysis of Financial Condition and Results of Operations" Part II, Item 7 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 filed with the SEC on March 22, 2024.

	Year ended December 31,		
	2024	2023	Change
Revenue from collaboration and licensing	$ 43,946	$ 20,129	$ 23,817
Operating expenses:			
Research and development	(68,507)	(86,424)	17,917
General and administrative	(20,226)	(18,633)	(1,593)
Restructuring	(2,664)	—	(2,664)
Impairment	(4,004)	(12,766)	8,762
Total operating expenses	(95,401)	(117,823)	22,422
Loss from operations	(51,455)	(97,694)	46,239
Other income (expense):			
Grant income	7,396	11,193	(3,797)
Interest income	3,701	5,293	(1,592)
Interest expense	(2)	(317)	315
Other (expense) income, net	(3,249)	313	(3,562)
Total other income, net	7,846	16,482	(8,636)
Net loss before tax	(43,609)	(81,212)	37,603
Income tax benefit (expense)	106	(368)	474
Net loss	$ (43,503)	$ (81,580)	$ 38,077

Revenue from Collaboration and Licensing

Revenue was $43.9 million for the year ended December 31, 2024, compared to $20.1 million for the year ended December 31, 2023.

The increase of $23.8 million for the year ended December 31, 2024 compared to the year ended December 31, 2023 was primarily due to higher partial recognition of the upfront and milestone payments under the Roche Collaboration as a result of the termination of the Roche Collaboration Agreement leading to accelerated recognition of the upfront and milestone payments that were initially recorded as deferred revenue, including the partial recognition of revenue from a $10.0 million milestone achieved in March 2024 and revenue recognized for a $5.0 million milestone payment for the first person dosed in a Phase 1b clinical trial of HB-500 received in July 2024 under the Restated Gilead Collaboration Agreement.

For the years ended December 31, 2024 and 2023, revenue included $0.9 million and $1.9 million, respectively, from reimbursement of research and development expenses, and $43.0 million and $18.2 million, respectively, from partial recognition of upfront, milestone and initiation payments that were initially recorded as deferred revenue.

For the year ended December 31, 2024, revenue included $7.5 million related to the Restated Gilead Collaboration Agreement, of which $0.8 million resulted from reimbursement of research and development expenses, and $6.7 million from partial recognition of upfront, milestone and initiation payments that were initially recorded as deferred revenue. In addition, revenue included $36.4 million related to the terminated Roche Collaboration Agreement, of which $0.1 million resulted from reimbursement of expenses and $36.3 million resulted from revenue recognized. Revenue recognized includes $26.3 million of the upfront and milestone payments that were originally recorded as

deferred revenue and $10.0 million related to a milestone payment achieved in March 2024 and received in April 2024 associated with an IND submission for the HB-700 program.

For the year ended December 31, 2023, revenue included $8.5 million related to the Restated Gilead Collaboration Agreement, of which $1.4 million resulted from reimbursement of research and development expenses, and $7.1 million from partial recognition of milestone and initiation payments that were initially recorded as deferred revenue. In addition, revenue included $11.6 million related to the Roche Collaboration Agreement, of which $11.1 million resulted from partial recognition of milestone and initiation payments that were initially recorded as deferred revenue, and $0.5 million from reimbursement of expenses.

Research and Development Expenses

For the year ended December 31, 2024, our research and development expenses were $68.5 million, compared to $86.4 million, for the year ended December 31, 2023.

The decrease of $17.9 million for the year ended December 31, 2024 compared to the year ended December 31, 2023 was affected by the implementation of the Restructuring Plan, including the pause of eseba-vec and HB-300, and was attributable to a decrease in direct research and development expenses of $8.5 million, and a decrease in indirect research and development expenses of $9.4 million. Indirect research and development expenses decreased mainly because of lower personnel-related expenses including stock-based compensation of $5.1 million, lower expenses for laboratory consumables of $1.4 million and lower expenses for travel, training and recruitment of $1.1 million. The decrease in personnel-related expenses including stock-based compensation mainly resulted from the effects of our workforce reduction, including the effects of stock option forfeitures. The decrease in direct research and development expenses was primarily driven by lower manufacturing expenses of $13.4 million, lower expenses for research and development services of $3.9 million, primarily for our eseba-vec program and Gilead partnered programs, and decreased spending for our other programs, partially offset by higher clinical study expenses of $6.8 million, primarily for our since paused eseba-vec program, as well as amortization expenses related to capitalized sublicense payments following the termination of the Roche Collaboration of $2.0 million.

General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2024 were $20.2 million, compared to $18.6 million for the year ended December 31, 2023.

The increase of $1.6 million for the year ended December 31, 2024 compared to the year ended December 31, 2023 was primarily due to an increase in professional and consulting fees of $1.9 million and an increase in personnel-related expenses including stock-based compensation of $0.3 million, partially offset by a decrease in other expenses of $0.3 million and lower expenses for travel, training and recruitment of $0.3 million. The increase in professional and consulting fees was primarily attributable to specialized organizational programs including related legal fees. Professional and consulting fees for the year ended December 31, 2024 include $1.3 million for services related to a potential merger or acquisition. The increase in personnel-related expenses resulted primarily from severance arrangements not related to the restructuring programs.

Restructuring Expenses

Restructuring expenses for the year ended December 31, 2024 were $2.7 million.

Restructuring expenses for the year ended December 31, 2024 resulted from the cost-savings and restructuring actions from the adoption of the Restructuring Plan announced in January, September and November 2024, and consisted of $2.1 million of severance and other personnel costs and $0.6 million of disposal costs, professional fees and consulting costs associated with exit and disposal activities. Severance and other personnel costs are primarily related to the restructuring actions announced in January and September which included a social plan and severance payments. There were no restructuring expenses for the year ended December 31, 2023.

Impairment Expenses

Impairment expenses for the year ended December 31, 2024 were $4.0 million, compared to $12.8 million for the year ended December 31, 2023.

Impairment expenses for the year ended December 31, 2024 resulted from the cost-savings and restructuring actions from the adoption of the Restructuring Plan, which included the termination of a part of our rented office and laboratory space in Vienna, Austria. We assessed the recoverability of the long-lived assets relating to the leasehold improvements, laboratory equipment, furniture and fixtures, and computer equipment and software at December 31, 2024, and the carrying values of the assets were written down to their estimated fair value. Impairment expenses for the year ended December 31, 2024 also include write-downs of the carrying values of laboratory equipment reclassified to assets held for sale. Impairment expenses for the year ended December 31, 2023 was comprised of $12.8 million of asset write-downs related to our GMP manufacturing facility project. As a result of the strategic considerations preceding the decision to implement a Restructuring Plan, we assessed the recoverability of the long-lived assets related to the GMP manufacturing project at December 31, 2023, and concluded it was more likely than not, that the GMP manufacturing facility project will be discontinued leading to a trigger for the impairment test that ultimately resulted in the write-offs.

Grant Income

In the year ended December 31, 2024 we recorded grant income of $7.4 million, compared to $11.2 million in the year ended December 31, 2023 from grants, research incentives and imputed benefits from below market interest rates on loans from governmental agencies. The decrease of $3.8 million was primarily due to the lower income of $2.0 million from Austrian research and development incentives as a result of lower eligible research and development expenses, the $1.4 million related to the New York State life sciences research and development program for the years 2019 to 2021 which was recognized in the year ended December 31, 2023, lower imputed benefits from below market interest rates on loans from governmental agencies of $0.3 million, as well as $0.1 million related to the New York City biotechnology tax credit program which was recognized in the year ended December 31, 2023.

Interest Income and Expense

Interest income was $3.7 million for the year ended December 31, 2024, compared to $5.3 million for the year ended December 31, 2023. The decrease in interest income for the year ended December 31, 2024 was a result of a lower cash position and by decreasing U.S. dollar and euro interest rates. Interest income represents interest from cash and cash equivalents held in U.S. dollars and euros resulting from the proceeds from the issuance of common stock and convertible preferred stock as well as payments received under our Gilead and Roche collaborations. During the year ended December 31, 2024 our cash, cash equivalents and restricted cash were mainly held in dollars at U.S. investment grade financial institutions or in money market funds. In addition, smaller amounts were held in euros and dollars at our Austrian subsidiary.

Interest expenses for loans from government agencies were less than $0.1 million for the year ended December 31, 2024, compared to $0.3 million for the year ended December 31, 2023. Interest expense was recorded at the market rate of interest, which exceeded the contractual interest rate. The decrease of interest expenses was primarily due to the final principal repayment related to the FFG Loans in the second quarter of 2024.

Other Income and Expenses

Other expenses were $3.2 million for the year ended December 31, 2024, compared to other income of $0.3 million for the year ended December 31, 2023. The change in the year ended December 31, 2024 resulted primarily from exchange rate differences and foreign currency remeasurements.

Liquidity and Capital Resources

Since our inception in 2011, we have funded our operations primarily from public offerings and private placements of common stock and convertible preferred stock, including our initial public offering, as well as private placements of our redeemable convertible preferred stock, grant funding and loans from an Austrian government agency, and upfront, milestone and initiation payments from Gilead and Roche in connection with research collaboration agreements.

Prior to our IPO, we raised gross proceeds of approximately $142.5 million from the issuance of our redeemable convertible preferred stock. In April 2019, we completed our IPO in which we issued and sold 600,000 (6,000,000 before the Reverse Stock Split) shares of our common stock, at $140.00 per share, for gross proceeds of $84.0 million, or net proceeds of $74.6 million. In December 2020, we completed a follow-on public offering in which we issued 391,000 (3,910,000 before the Reverse Stock Split) shares of our common stock, at $117.50 per share, and 2,978 shares of our Series A convertible preferred stock, at $11,750.00 per share, for net proceeds of $75.0 million after deducting underwriting discounts and commissions and offering expenses. In March 2022, we completed a follow-on public offering in which we issued 2,170,000 (21,700,000 before the Reverse Stock Split) shares of our common stock, at $20.00 per share, and 15,800 shares of our Series A-1 convertible preferred stock, at $2,000.00 per share, for net proceeds of $70.2 million after deducting underwriting discounts and commissions and offering expenses. In June 2023, we completed a follow-on public offering in which we issued 2,290,077 (22,900,768 before the Reverse Stock Split) shares of our common stock, at $13.10 per share, and 15,268 shares of our Series A-2 convertible preferred stock, at $1,310.00 per share, for net proceeds of $46.2 million after deducting underwriting discounts and commissions and offering expenses. In addition, in February 2022, Gilead purchased 166,666 (1,666,666 before the Reverse Stock Split) shares of our common stock for $5.0 million, at a purchase price of $30.00 per share, and in December 2023, Gilead purchased 1,500,000 (15,000,000 before the Reverse Stock Split) shares of our common stock, at $14.167 per share, for net proceeds of approximately $21.1 million after deducting offering expenses. Pursuant to the terms of the Amended Stock Purchase Agreement, we may require Gilead to purchase the balance of $8.75 million of common stock as participation in potential future equity raises (see "Note 12. Common stock, Class A common stock and convertible preferred stock" to our consolidated financial statements appearing elsewhere in this Annual Report). We also received $51.2 million from non-refundable upfront, milestone and initiation payments pursuant to the Restated Gilead Collaboration Agreement and $45.0 million from non-refundable upfront and milestone payments related to the Roche Collaboration Agreement. As of December 31, 2024, we had cash, cash equivalents and restricted cash of $39.9 million.

On July 12, 2022, we filed a registration statement on Form S-3 (the "Registration Statement") with the SEC, which was declared effective on July 21, 2022. The Registration Statement registers the offering, issuance and sale of an unspecified amount of common stock, preferred stock, debt securities, warrants and/or units of any combination thereof. We simultaneously entered into a Sales Agreement with Leerink Partners LLC ("Leerink"), as sales agent, to provide for the issuance and sale by us of up to $50.0 million of common stock from time to time in "at-the-market" offerings under the Registration Statement and related prospectus filed with the Registration Statement ("Leerink ATM Program"). As of June 30, 2024, no sales had been made pursuant to the Leerink ATM Program. On August 5, 2024, we delivered a termination notice to Leerink to terminate the Sales Agreement, effective as of August 8, 2024. At the time of termination, $50.0 million remained available for issuance pursuant to the Sales Agreement. On August 8, 2024, we entered into an Open Market Sale Agreement℠ with Jefferies LLC, as sales agent, to provide for the issuance and sale by us of up to $50.0 million of common stock from time to time in "at-the-market" offerings under the Registration Statement and related prospectus filed with the Registration Statement or the ATM Program. As of December 31, 2024, no sales had been made pursuant to the Jefferies ATM Program.

We entered into various funding agreements with the Austrian Research Promotion Agency (Österreichische Forschungsförderungsgesellschaft, or "FFG"). The loans by FFG (the "FFG Loans") were made on a project-by-project basis and bear interest at a rate of 0.75% per annum. In the event that the underlying program research results in a scientific or technical failure, the principal then outstanding under any loan may be forgiven by FFG and converted to non-repayable grant funding on a project-by-project basis. The FFG Loans contained no financial covenants and were not secured by any of our assets. As of December 31, 2024 there is no remaining debt obligation under the FFG loans following the final principal repayment in April 2024.

Because the FFG Loans bear interest at below market rates we account for the imputed benefit arising from the difference between an estimated market rate of interest and the contractual interest rate as grant funding from FFG, which is included in grant income. On the date that FFG Loan proceeds are received, we recognize the portion of the loan proceeds allocated to grant funding as a discount to the carrying value of the loan and as unearned income. As of December 31, 2024, the unamortized debt discount related to FFG Loans was zero due to the final maturity on March 31, 2024 and the final repayment on April 2, 2024.

We have entered into arrangements with contract manufacturing organizations. As of December 31, 2024, we had total non-cancellable obligations under such contracts of $4.7 million.

We do not expect positive cash flows from operations in the foreseeable future, if at all. Historically, we have incurred operating losses as a result of ongoing efforts to develop our arenavirus technology platform and our product candidates, including conducting ongoing research and development, preclinical studies, clinical trials, providing general and administrative support for these operations and developing our intellectual property portfolio. We expect to continue to incur net operating losses for at least the next several years as we progress clinical development, seek regulatory approval, prepare for commercialization, and continue our research and development efforts relating to our other and future product candidates.

Going Concern

We evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that the consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K are issued. This evaluation initially does not take into consideration the potential mitigating effect of management's plans that have not been fully implemented as of the date the financial statements are issued. When substantial doubt exists under this methodology, management evaluates whether the mitigating effect of its plans sufficiently alleviates substantial doubt about our ability to continue as a going concern. The mitigating effect of management's plans, however, is only considered if both (1) it is probable that the plans will be effectively implemented within one year after the date that the consolidated financial statements are issued, and (2) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about our ability to continue as a going concern within one year after the date that the accompanying consolidated financial statements are issued. In performing its analysis, management excluded certain elements of its operating plan that cannot be considered probable. Under ASC 205-40, the future receipt of potential funding from future partnerships, equity or debt issuances, the potential milestones from the Gilead Collaboration Agreement and potential reductions in force cannot be considered probable at this time because these plans are not entirely within our control and/or have not been approved by the Board of Directors as of the date of the accompanying consolidated financial statements.

Our expectation to generate operating losses and negative operating cash flows in the future and the need for additional funding to support our planned operations raise substantial doubt regarding our ability to continue as a going concern for a period of one year after the date that consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K are issued. Management's plans to alleviate the conditions that raise substantial doubt include reduced spending and the pursuit of additional capital. Management has concluded that the likelihood that its plan to successfully obtain sufficient funding, or adequately reduce expenditures, while reasonably possible, is less than probable. Accordingly, we have concluded that substantial doubt exists about our ability to continue as a going concern for a period of at least 12 months from the date of issuance of the accompanying consolidated financial statements.

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of the uncertainties described above.

Reverse Stock Split

On July 9, 2024, we effected a reverse stock split of the outstanding shares of our common stock on a one-for-ten (1:10) basis (the "Reverse Stock Split"). The Reverse Stock Split became effective at 5:00 p.m. Eastern Time on July 9, 2024 (the "Effective Time") via a certificate of amendment to our Certificate of Incorporation filed with the Secretary of State of the State of Delaware. At the Effective Time of the Reverse Stock Split, every 10 issued and outstanding shares of our common stock were automatically combined into one issued and outstanding share of common stock. The par value per share of the common stock remained unchanged at $0.0001. Fractional shares were not issued in connection with the Reverse Stock Split. Stockholders who were otherwise entitled to receive a fractional share received a proportional cash payment. The Reverse Stock Split affected all stockholders uniformly and did not alter any stockholder's relative interest in our equity securities, except for any adjustments for fractional shares. As a result of the Reverse Stock Split, proportionate adjustments were made to the conversion ratio for our Class A Common Stock and the conversion prices of our Series A Convertible Preferred Stock, Series A-1 Convertible Preferred Stock and Series A-2 Convertible Preferred Stock. All share, per share and option numbers and exercise prices appearing elsewhere in this Annual Report on Form 10-K and the accompanying financial statements have been adjusted to give effect to the Reverse Stock Split for all prior periods presented. However, our annual, other periodic, and current reports, and all other information and documents incorporated by reference into this Annual Report on Form 10-K that were filed prior to July 9, 2024, do not give effect to the Reverse Stock Split.

Future Funding Requirements

We have no products approved for commercial sale. To date, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, and undertaking preclinical studies and clinical trials of our product candidates. As a result, we are not profitable and have incurred losses in each period since our inception in 2011, except for the first quarter of 2024. As of December 31, 2024, we had an accumulated deficit of $412.8 million. We expect to continue to incur significant losses for the foreseeable future. Based on our cash and cash equivalents as of December 31, 2024 and our planned operating expenses and capital expenditure requirements, there is substantial doubt regarding our ability to continue as a going concern for a period of one year after the issuance date of the consolidated financial statements accompanying this Annual Report on Form 10-K. We anticipate that we will require additional funding to:

- pursue the clinical and preclinical development of our current and future product candidates;
- leverage our technologies to advance product candidates into preclinical and clinical development;
- seek regulatory approvals for product candidates that successfully complete clinical trials, if any;
- attract, hire and retain additional clinical, quality control and scientific personnel;
- establish our manufacturing capabilities through third parties or by ourselves and scale-up manufacturing to provide adequate supply for clinical trials and commercialization;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company;
- expand and protect our intellectual property portfolio;
- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly;
- acquire or in-license other product candidates and technologies;

- consider a merger with another company or the acquisition of another company including an integration of such a company; and

- incur additional legal, accounting and other expenses in operating our business, including ongoing costs associated with operating as a public company.

Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We will require substantial additional financing and a failure to obtain this necessary capital could force us to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations.

Since our inception, we have invested a significant portion of our efforts and financial resources in research and development activities for our non-replicating and replicating technologies and our product candidates derived from these technologies. Preclinical studies and clinical trials and additional research and development activities will require substantial funds to complete. We believe that we will continue to expend substantial resources for the foreseeable future in connection with the development of our current product candidates and programs as well as any future product candidates we may choose to pursue, as well as the gradual gaining of control over our required manufacturing capabilities and other corporate uses. These expenditures will include costs associated with conducting preclinical studies and clinical trials, obtaining regulatory approvals, and manufacturing and supply, as well as marketing and selling any products approved for sale. In addition, other unanticipated costs may arise. Because the outcome of any preclinical study or clinical trial is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our current or future product candidates.

Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing our current and future product candidates and programs, and of conducting preclinical studies and clinical trials;

- the number and development requirements of other product candidates that we may pursue, and other indications for our current product candidates that we may pursue;

- the stability, scale and yields of our future manufacturing process as we scale-up production and formulation of our product candidates for later stages of development and commercialization;

- the timing of, and the costs involved in, obtaining regulatory and marketing approvals and developing our ability to establish sales and marketing capabilities, if any, for our current and future product candidates we develop if clinical trials are successful;

- the success of our collaboration with Gilead;

- our ability to establish and maintain collaborations, strategic licensing or other arrangements and the financial terms of such agreements;

- the cost of commercialization activities for our current and future product candidates that we may develop, whether alone or with a collaborator;

- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;

- the timing, receipt and amount of sales of, or royalties on, our future products, if any; and
- the emergence of competing oncology and infectious disease therapies and other adverse market developments.

A change in the outcome of any of these or other variables with respect to the development of any of our current and future product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plans may change in the future, and we will need additional funds to meet operational needs and capital requirements associated with such operating plans.

We do not have any committed external source of funds or other support for our development efforts. Until we can generate sufficient product and royalty revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements as well as grant funding. Based on our research and development plans, we have concluded that substantial doubt exists that our cash and cash equivalents, including the funds received under the Restated Gilead Collaboration Agreement, will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months from the issuance date of the consolidated financial statements appearing elsewhere in this Annual Report. These estimates are based on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect.

If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, the ownership interest of our shareholders will be diluted. If we raise additional capital through debt financing, we would be subject to fixed payment obligations and may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to obtain additional funding on favorable terms when needed, we may have to delay, reduce the scope of or terminate one or more of our research and development programs or clinical trials or our other operations.

Cash Flows

The following table sets forth a summary of the primary sources and uses of cash (in thousands):

	Year ended December 31,	
	2024	2023
Net cash used in operating activities	$ (76,978)	$ (57,524)
Net cash used in investing activities	(194)	(4,159)
Net cash (used in) provided by financing activities	(1,276)	65,670
Net (decrease) increase in cash and cash equivalents	(78,448)	3,987

Cash Used in Operating Activities

During the year ended December 31, 2024, cash used in operating activities was $77.0 million, which consisted of a net loss of $43.5 million, adjusted by non-cash charges of $8.8 million and cash used due to changes in our operating assets and liabilities of $42.2 million. The non-cash charges consisted primarily of impairment expenses of $4.0 million, resulting from write-offs of leasehold improvements, laboratory equipment, furniture and fixtures, and computer equipment and software, depreciation and amortization expense of $2.8 million, stock-based compensation of $2.0 million and other non-cash items of less than $0.1 million. The change in our operating assets and liabilities was primarily due to a decrease in deferred revenues of $27.5 million, primarily resulting from the early-recognition of deferred revenues related to the terminated Roche Collaboration Agreement, partially offset by a $5.0 million milestone payment received under the Gilead Collaboration Agreement, an increase in receivable research incentives of

$6.0 million, primarily resulting from eligible research and development expenses related to the Austrian research and development incentives, an increase in prepaid expenses and other current assets of $3.8 million, primarily related to prepayments for clinical trial agreements and transaction-related services, a decrease in operating lease liabilities of $1.6 million, a decrease in accounts payable of $1.6 million, an increase in prepaid expenses and other non-current assets of $1.4 million, and a decrease in accrued expenses and other current liabilities of $0.8 million, partially offset by a decrease in accounts receivable of $0.5 million.

During the year ended December 31, 2023, cash used in operating activities was $57.5 million, which consisted of a net loss of $81.6 million, adjusted by non-cash charges of $18.8 million and cash provided due to changes in our operating assets and liabilities of $5.3 million. The non-cash charges consisted primarily of restructuring expenses of $12.8 million, resulting from a write-off of our GMP manufacturing facility project, depreciation and amortization expense of $3.6 million, stock-based compensation of $2.3 million and other non-cash items of $0.1 million. The change in our operating assets and liabilities was primarily due to an increase in accounts payable of $6.5 million, a decrease in accounts receivable of $6.2 million, primarily resulting from the collection of a $5.0 million milestone payment and cost reimbursements from Gilead, an increase in other non-current liabilities of $2.7 million, a decrease in prepaid expenses and other current assets of $1.7 million, an increase in accrued expenses and other current liabilities of $0.5 million, and a decrease in other non-current assets of $0.3 million, partially offset by a decrease in deferred revenues of $8.3 million, an increase in receivable research incentives of $2.7 million, and a decrease in operating lease liabilities of $1.6 million.

Cash Used in Investing Activities

During the years ended December 31, 2024 and 2023, cash used in investing activities was $0.2 million and $4.2 million, respectively. The decrease of $4.0 million compared to the year ended December 31, 2023 resulted from decreased capital expenditures in connection with our GMP manufacturing facility project and lower expenditures for purchase of equipment. Cash used in investing activities in the year ended December 31, 2024 resulted from capital expenditures for purchase of property and equipment.

During the year ended December 31, 2023, cash used in investing activities resulted from capital expenditures in connection with our GMP manufacturing facility project and for purchase of property and equipment.

Cash (Used in) Provided by Financing Activities

During the year ended December 31, 2024, cash used in financing activities was $1.3 million and consisted mainly of a principal repayment of FFG loans of $1.1 million and costs related to Gilead's purchase of common stock in December 2023.

During the year ended December 31, 2023, cash provided by financing activities was $65.7 million, which consisted mainly of net proceeds of $46.3 million from our follow-on public offering in June 2023 and of net proceeds of $21.2 million from Gilead's purchase of 1,500,000 shares of our common stock in December 2023, partially offset by principal repayments of FFG loans of $1.8 million.

Intellectual Property Licenses

In October 2011, we entered into a license agreement with University of Zurich for an exclusive, worldwide, royalty-bearing license for a propagation-deficient arenavirus vector. Pursuant to the license agreement, we are obligated to pay the University of Zurich low single-digit royalties on aggregate net sales of products licensed under the agreement, and to pay percentages ranging from the mid-single digits to 20% of the sublicense fees that we may receive from sublicensing, depending on the amount of fees received from sublicensees.

In January 2017, we entered into a license agreement with University of Basel for an exclusive, worldwide, royalty-bearing license for a tri-segmented Pichinde virus vector. We are required to use reasonable efforts to make commercially available licensed products. Pursuant to the license agreement, we are obligated to pay nominal milestone payments for each licensed product upon the achievement of certain development and regulatory milestones and to pay

royalties of low single digits of net sales of licensed products. We are also obligated to pay a low- to high-single digit percentage of the sublicense fees that we may receive from sublicensing.

In February 2017, we entered into a license agreement with the University of Geneva for an exclusive, worldwide, royalty-bearing license for a tri-segmented arenavirus vector. Pursuant to the license agreement, we are obligated to pay the University of Geneva an annual fee which is fully deductible from any milestone, royalty or sublicense payments. We are also obligated to pay milestone nominal payments for each licensed product upon the achievement of certain development and regulatory milestones and to pay low single-digit royalties on aggregate net sales of products licensed under the agreement, and to pay percentages ranging from the low-single digits to 10% of the sublicense fees that we may receive from sublicensing.

In September 2013, we entered into a Biological Materials License Agreement with NIH for a worldwide, nonexclusive license to make, have made, import and use certain cells and cell clones developed at the Vaccine Research Center of the NIH, i.e., the NIH Licensed Products, to manufacture viral vectors based on our proprietary arenavirus-based vectors. Pursuant to the terms of the NIH Agreement, we are obligated to pay the NIH low to mid six figure annual royalty payments, increasing as our most developed product candidate manufactured from NIH Licensed Products proceeds through development stages. We must also pay the NIH 10% of any consideration we receive from sublicensees.

In October 2020, we entered into a license agreement with the University of Basel for an exclusive, worldwide, royalty-bearing license for a tri-segmented arenavirus Split vector technology. We terminated the respective license agreement, effective as of October 1, 2024.

In October 2022, we entered into a non-exclusive license agreement with the Regents of the University of Minnesota for a worldwide, non-exclusive license to patent rights related to our replicating technology patent which is exclusively licensed to us by the University of Geneva. We paid the University of Minnesota a low six figure amount upon entering into the agreement and are required to pay a non-material annual maintenance fee, and, upon commercialization of the first Minnesota Licensed Product, an annual minimum royalty which is creditable against royalties payable in the same year. While the Minnesota Agreement remains in effect, we are required to pay the University of Minnesota royalties on aggregate net sales of Minnesota Licensed Products, of a generally below single digit percentage. We must also pay the University of Minnesota low single digit percentages of certain considerations we receive from sublicensees, subject to pre-defined minimum and maximum payments. We further have to pay the University of Minnesota a nominal amount if we assign the Minnesota Agreement as part of a change of control.

In the year ended December 31, 2024, we recorded $3.6 million in licensing fees from intellectual property licenses as research and development expenses. At December 31, 2024, no payable from sublicensing fees was included in accrued expenses and other current liabilities. In the year ended December 31, 2023, we recorded $1.6 million in licensing fees from intellectual property licenses as research and development expenses. At December 31, 2023, no payable from sublicensing fees was included in accrued expenses and other current liabilities.

For additional information on these license agreements, please see “Business—Intellectual Property—License Agreements.”

Critical Accounting Policies and Estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which we have prepared in accordance with the rules and regulations of the SEC, and generally accepted accounting principles in the United States (“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 financial statements, as well as the reported expenses during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on 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. Our actual results may differ from these estimates under different assumptions or conditions.

Our critical accounting policies and the methodologies and assumptions we apply under them have not materially changed as compared to those disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations - Critical Accounting Policies" in our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the Securities and Exchange Commission ("SEC") on March 22, 2024.

Recognition of revenue from contracts with customers

We have entered into the Restated Gilead Collaboration Agreement for the development and commercialization of certain of our product candidates. Our performance obligations under the terms of this agreement include one combined performance obligation for each research program comprised of the transfer of intellectual property rights (licenses) and providing research and development services. Payments by Gilead to us under this agreement included a non-refundable up-front payment, payments for research and development activities, and may include payments based upon the achievement of defined clinical development and commercial milestones and royalties on product sales if certain future conditions are met.

We have entered into the Roche Collaboration Agreement for the development and commercialization of certain of our product candidates. Our performance obligations under the terms of this agreement included one combined performance obligation for the transfer of intellectual property rights (licenses) and providing research and development services for the HB-700 program, and a second, separate performance obligation to perform research and development services and to deliver a specified package of preclinical data and results with respect to targeting undisclosed cancer antigens ("UCA program"). Payments by Roche under the Roche Collaboration Agreement included a non-refundable up-front payment, payments based upon the achievement of defined milestones, an additional payment if the option for the UCA program was exercised and royalties on product sales. In January 2024, Roche provided us with written notice of the termination of the Roche Collaboration Agreement resulting in early recognition of revenue previously recorded as deferred revenue. The termination was made according to Roche's right to terminate without cause, acknowledging that we had met all go-forward criteria under the agreement. Upon the Roche Collaboration Agreement termination effective date of April 25, 2024, we regained full control of the associated intellectual property portfolio and have full collaboration and licensing rights for the HB-700 program.

We evaluate our collaboration and licensing arrangements pursuant to Accounting Standards Codification 606 (ASC 606). To determine the recognition of revenue from arrangements that fall within the scope of ASC 606, 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 a performance obligation. We present revenues from collaboration and licensing arrangements separately from other sources of revenue.

Amounts received by us as non-refundable upfront payment under the Restated Gilead Collaboration Agreement and the terminated Roche Collaboration Agreement as well as success-based milestone payments under the terminated Roche Collaboration Agreement prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in our consolidated balance sheets. Contingent milestone payments related to specified preclinical and clinical development milestones are not initially recognized within the transaction price as they are fully constrained under the guidance in ASC 606. Such amounts are recognized as revenue over the performance period of the respective services on a percent of completion basis for each of the obligations. We measure the progress toward complete satisfaction of the performance obligations based on the total cost of each collaboration program. This method of measuring progress results in recognizing revenue in proportion to the cost incurred during the quarter in relation to total expected cost for the respective program, according to the respective collaboration budget. Reimbursement of costs for our services under the Restated Gilead Collaboration Agreement and the terminated Roche Collaboration Agreement are presented as revenue and not deducted from expenses. The Restated Gilead Collaboration Agreement also includes certain sales-based milestone and royalty payments upon successful commercialization of a licensed product which we anticipate recognizing if and when sales from a licensed product are generated.

Leasing

The determination of whether an arrangement is qualified as a lease is made at contract inception. Operating lease assets and liabilities are recognized at the commencement date of the lease based upon the present value of lease payments over the lease term. When determining the lease term, we include options to extend or terminate the lease when it is reasonably certain that the option will be exercised. We use the implicit rate when readily determinable and our incremental borrowing rate when the implicit rate is not readily determinable based upon the information available at the commencement date in determining the present value of the lease payments. The incremental borrowing rate is determined using a secured borrowing rate for the same currency and term as the associated lease. The lease payments used to determine operating lease assets may include lease incentives, stated rent increases and escalation clauses linked to rates of inflation when determinable and are recognized as operating lease assets on the consolidated balance sheets. Certain of our arrangements contain lease and non-lease components. We applied an accounting policy choice to separate or not to separate lease payments for the identified assets from any non-lease payments included in the contract by asset class. Operating leases are reflected in operating lease assets, in accrued expenses and other current liabilities and in non-current operating lease liabilities in our consolidated balance sheets. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including salaries and bonuses, stock-based compensation, employee benefits, facilities costs, laboratory supplies, depreciation, manufacturing expenses and external costs of vendors engaged to conduct preclinical development activities and clinical trials as well as the cost of licensing technology. Advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed.

Upfront payments, milestone payments and annual payments made for the licensing of technology are generally expensed as research and development in the period in which they are incurred. Incremental sublicense fees triggered by contracts with customers are capitalized and expensed as research and development expenses over the period in which the relating revenue is recognized.

Stock-Based Compensation

We measure all stock options and other stock-based awards granted to employees and directors based on the fair value on the date of the grant and recognize compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award. We classify stock-based compensation expense in our consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified. Generally, we issue stock options, with service-only vesting conditions and record expense using the graded-vesting method.

We estimate the fair value of each stock option award using the Black-Scholes option-pricing model, which uses as inputs the fair value of our common stock and assumptions we make. As we have only been a public company since 2019, we estimate the expected stock volatility based on the volatility of our own stock as well as the historical volatility of a publicly traded set of peer companies until such time that we have adequate historical data regarding the volatility of our own traded stock price. For options with service-based vesting conditions, the expected term of our stock options has been determined utilizing the “simplified” method for awards that qualify as “plain-vanilla” options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that we have never paid cash dividends and do not expect to pay any cash dividends in the foreseeable future. We do not estimate and apply a forfeiture rate as we have elected to account for forfeitures as they occur.

Recognition of other income under government grant agreements and research incentives

We recognize income from grants, research incentives and the imputed benefit arising from the difference between an estimated market rate of interest and the contractual interest rate on loans received from Austrian government agencies as well as from New York State and New York City government agencies in the United States. Income from grants and incentives is recognized in the period during which the related qualifying expenses are incurred, provided that the conditions under which the grants or incentives were provided have been met. For grants under funding agreements and for proceeds under research incentive programs, we recognize grant and incentive income in an amount equal to the qualifying expenses incurred in each period multiplied by the applicable reimbursement percentage.

Grant income that we have received in advance of incurring qualifying expenses is recorded in the consolidated balance sheets as deferred income. Grant and incentive income recognized upon incurring qualifying expenses in advance of receipt of grant funding or proceeds from research and development incentives is recorded in the consolidated balance sheets as prepaid expenses and other current assets.

We have received loans under funding agreements that bear interest below market rates. We account for the imputed benefit arising from the difference between an estimated market interest rate and the actual interest rate charged on such loans as additional grant income, and record interest expense for the loans at a market interest. On the date that loan proceeds are received, we recognize the portion of the loan proceeds allocated to grant funding as a discount to the carrying value of the loan and as unearned income, which is subsequently recognized as additional grant income over the term of the funding agreement.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our consolidated financial statements appearing in this Annual Report on Form 10-K.

Smaller Reporting Company

We are a “smaller reporting company” meaning that the market value of our stock held by non-affiliates is less than $700 million and our annual revenue was less than $100 million during our most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million. For so long as we remain a smaller reporting company, we are permitted and intend to rely on exemptions from certain disclosure and other requirements that are applicable to other public companies that are not smaller reporting companies.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk from changes in interest rates, foreign exchange rates and inflation. All of these market risks arise in the ordinary course of business, as we do not engage in speculative trading activities. The following analysis provides additional information regarding these risks.

Foreign Currency and Exchange Risk

We are subject to the risk of fluctuations in foreign currency exchange rates, specifically with respect to the euro. Our functional currency is the U.S. dollar and the functional currency of our wholly owned foreign subsidiary, HOOKIPA Biotech GmbH, is the euro. Our cash, cash equivalents and restricted cash as of December 31, 2024 included small amounts of cash balances held by HOOKIPA Biotech GmbH in euro. Assets and liabilities of Hookipa Biotech GmbH are translated into U.S. dollars at the exchange rate in effect on the balance sheet date. Income items and expenses are translated at the average exchange rate in effect during the period. Unrealized translation gains and losses are recorded as a cumulative translation adjustment, which is included in the consolidated Statements of Convertible Preferred Stock and Stockholders’ Equity as a component of accumulated other comprehensive loss. Adjustments that

arise from exchange rate changes on transactions denominated in a currency other than the local currency are included in other income and expenses, net in the consolidated statements of operations and comprehensive loss as incurred. A significant portion of our operating costs are in Austria, which are denominated in the euro. This foreign currency exposure gives rise to market risk associated with exchange rate movements of the U.S. dollar against the euro. Furthermore, we anticipate that a significant portion of our expenses will continue to be denominated in the euro. A hypothetical 10% weakening of the U.S. dollar compared to the euro would have increased our net loss for the year ended December 31, 2024, by approximately $2.5 million and decreased our currency translation adjustment by approximately $0.2 million. A hypothetical 10% strengthening of the U.S. dollar compared to the euro would have an equal and opposite effect on our financial statements.

Interest Rate Risk

We are exposed to market risk related to changes in interest rates. We had cash, cash equivalents and restricted cash of $39.9 million as of December 31, 2024, which included account balances with foreign banks. Interest income is sensitive to changes in the general level of interest rates; however, due to the nature of these investments, we do not believe that we have any material exposure to changes in the fair value of our investment portfolio as a result of changes in interest rates.

Impacts of Inflation

While it is difficult to accurately measure the impact of inflation due to the imprecise nature of the estimates required, we do not believe inflation has had a material effect on our historical results of operations and financial condition. However, inflation, has had, and may continue to have, an impact on the labor costs we incur to attract and retain qualified personnel, costs to conduct clinical trials and other operational costs. If our costs were to become subject to significant inflationary pressures, we may not be able to fully offset higher costs through raising funds or other corrective measures, and our inability or failure to do so could adversely affect our business, financial condition, and results of operations. In addition, increased inflation has had, and may continue to have, an effect on interest rates. Increased interest rates may adversely affect our borrowing rate and our ability to obtain, or the terms under which we can obtain, any potential additional funding.

Item 8. Financial Statements and Supplementary Data

The financial statements required to be filed pursuant to this Item 8 are appended to this report. An index of those financial statements is found in Item 15 of Part IV of this Annual Report on Form 10-K.

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

None.

Item 9A. Controls and Procedures

The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there

are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of Disclosure Controls and Procedures

As of December 31, 2024, management, with the participation of our Principal Executive Officer and Principal Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including the Principal Executive Officer and the Principal Financial Officer, to allow timely decisions regarding required disclosures.

Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on that evaluation, our Principal Executive Officer and Principal Financial Officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of December 31, 2024.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act). Under the supervision of and with the participation of our Principal Executive Officer and Principal Financial Officer, our management assessed the effectiveness of our internal control over financial report as of December 31, 2024 based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in "Internal Control-Integrated Framework" (2013). Based on this assessment, management concluded that our internal control over financial reporting was effective as of December 31, 2024.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a 15(f) and 15d 15(f) under the Exchange Act) identified that occurred during the quarter ended December 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Rule 10b5-1 Trading Plans

During the quarter ended December 31, 2024, none of the Company's directors or officers (as defined in Rule 16a-1(f) of the Securities Exchange Act of 1934) adopted, terminated or modified a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (as such terms are defined in Item 408 of Regulation S-K).

Certificate of Incorporation

At our 2022 Annual Meeting of Stockholders held on June 30, 2022 (the "2022 Annual Meeting"), our stockholders approved, among other things, proposals to (i) elect two Class III directors for three-year terms, (ii) amend our certificate of incorporation to increase the total number of authorized shares of common stock from 100,000,000 shares to 200,000,000 shares, and (iii) amend our 2019 Stock Option and Incentive Plan (collectively, the "2022 Stockholder Actions"). The 2022 Stockholder Actions are described more fully in our definitive proxy statement for the 2022 Annual Meeting, filed with the SEC on May 16, 2022, and the voting results from the 2022 Annual Meeting are set forth in our Current Report on Form 8-K filed with the SEC on July 1, 2022. The record date established for the 2022 Annual Meeting was April 13, 2022, which was 78 days before the date of the 2022 Annual Meeting, which was held on

June 30, 2022. Under the Delaware General Corporation Law (the "DGCL"), the record date should have been set for no sooner than Sunday, May 1, 2022, which was the 60th day before the 2022 Annual Meeting.

At our 2023 Annual Meeting of Stockholders held on June 9, 2023 (the "2023 Annual Meeting"), our stockholders approved, among other things, a proposal to elect three Class I directors for three-year terms (the "2023 Stockholder Action"). The 2023 Stockholder Action is described more fully in our definitive proxy statement for the 2023 Annual Meeting, filed with the SEC on April 13, 2023, and the voting results from the meeting are set forth in our Current Report on Form 8-K filed with the SEC on June 9, 2023. The record date established for the 2023 Annual Meeting was April 4, 2023, which was 66 days before the date of the 2023 Annual Meeting, which was held on June 9, 2023. Under the DGCL, the record date should have been set for no sooner than Monday, April 10, 2023, which was the 60th day before the 2023 Annual Meeting.

In December 2024, we filed a petition in the Delaware Court of Chancery pursuant to Section 205 of the DGCL seeking an order validating and declaring effective the 2022 Stockholder Actions and the 2023 Stockholder Action. On February 14, 2025, the Court of Chancery issued an order approving our petition in full.

Item 9C. Disclosure regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

We intend to file a definitive Proxy Statement for our 2025 Annual Meeting of Stockholders ("2025 Proxy Statement") with the SEC, pursuant to Regulation 14A, not later than 120 days after the end of our fiscal year. Accordingly, certain information required by Part III has been omitted under General Instruction G(3) to Form 10-K. Only those sections of the 2025 Proxy Statement that specifically address the items set forth herein are incorporated by reference.

Item 10. Directors, Executive Officers, and Corporate Governance

The information required by this Item 10 is incorporated by reference to the sections of the 2025 Proxy Statement under the captions "Director Biographies," "Executive Officers," "The Board of Directors and its Committees," "Corporate Governance" and "Delinquent Section 16(a) Reports".

Item 11. Executive Compensation

The information required by this Item 11 is incorporated by reference to the sections of the 2025 Proxy Statement under the captions "Executive Compensation" and "Director Compensation."

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

The information required by this Item 12 is incorporated by reference to the sections of the 2025 Proxy Statement under the captions "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" and "Equity Compensation Plan Information."

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

The information required by this Item 13 is incorporated by reference to the sections of the 2025 Proxy Statement under the captions "Certain Relationships and Related Person Transactions" and "The Board of Directors and Its Committees – Board Independence."

Item 14. Principal Accountant's Fees and Services

The information required by this Item 14 is incorporated by reference to the sections of the 2025 Proxy Statement under the caption "Ratification of the Selection of Independent Registered Public Accounting Firm."

Part IV

Item 15. Exhibits.

(1) Financial Statements and Financial Statement Schedules

The following documents are included on pages F-1 through F-7 attached hereto and are filed as part of this Annual Report on Form 10-K.

(2) Financial Statement Schedules:

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

(3) Exhibits.

The following is a list of exhibits filed as part of this Annual Report on Form 10-K.

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of the Company (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed on July 1, 2022 (File No. 001- 38869) and incorporated herein by reference)
3.2	Amended and Restated Bylaws of the Company (filed as Exhibit 3.2 to the Company's Current Report on Form 8-K filed on April 23, 2019 (File No. 001-38869) and incorporated herein by reference)
4.1	Specimen Common Stock Certificate (filed as Exhibit 4.1 to the Company's Registration Statement on Form S-1 filed on April 8, 2019 (File No. 333-230451) and incorporated herein by reference)
4.2	Shareholders Agreement among HOOKIPA Pharma Inc. and certain of its shareholders, dated February 15, 2019 (filed as Exhibit 4.1. to the Company's Current Report on Form 8-K filed on April 23, 2019 (File No. 001-38869) and incorporated herein by reference)
4.3	Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 (filed as Exhibit 4.3 to the Company's Annual Report on Form 10-K filed on March 22, 2024 (File No. 001-38869) and incorporated herein by reference)
4.4	Registration Rights Agreement, dated June 17, 2022, by and between the Company and Gilead Sciences, Inc. (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 22, 2022 (File No. 001-38869) and incorporated herein by reference)
10.1#	HOOKIPA Pharma Inc. 2018 Stock Option and Grant Plan and forms of awards thereunder (filed as Exhibit 10.1 to the Company's Registration Statement on Form S-1 filed on March 22, 2019 (File No. 333-230451) and incorporated herein by reference)
10.2#	Amended and Restated 2019 Stock Option and Incentive Plan (filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on May 11, 2023 (File No.001-38869) and incorporated herein by reference)
10.3#	Incentive Stock Option Agreement under the Company's 2019 Stock Option and Incentive Plan (filed as Exhibit 10.3 to the Company's Registration Statement on Form S-1 filed on April 8, 2019 (File No. 333-230451) and incorporated herein by reference)
10.4#	Non-Qualified Stock Option Agreement for Company Employees under the Registrant's 2019 Stock Option and Incentive Plan (filed as Exhibit 10.4 to the Company's Registration Statement on Form S-1 filed on April 8, 2019 (File No. 333-230451) and incorporated herein by reference)
10.5#	Non-Qualified Stock Option Agreement for Non-Employee Directors under the Registrant's 2019 Stock Option and Incentive Plan (filed as Exhibit 10.5 to the Company's Registration Statement on Form S-1 filed on April 8, 2019 (File No. 333-230451) and incorporated herein by reference)
10.6#	Restricted Stock Award Agreement under the Registrant's 2019 Stock Option and Incentive Plan (filed as Exhibit 10.6 to the Company's Registration Statement on Form S-1 filed on April 8, 2019 (File No. 333-230451) and incorporated herein by reference)

10.7#	Restricted Stock Award Agreement for Company Employees under the Registrant's 2019 Stock Option and Incentive Plan (filed as Exhibit 10.7 to the Company's Registration Statement on Form S-1 filed on April 8, 2019 (File No. 333-230451) and incorporated herein by reference)
10.8#	Restricted Stock Award Agreement for Non-Employee Directors under the Registrant's 2019 Stock Option and Incentive Plan (filed as Exhibit 10.8 to the Company's Registration Statement on Form S-1 filed on April 8, 2019 (File No. 333-230451) and incorporated herein by reference)
10.9#	2019 Employee Stock Purchase Plan (filed as Exhibit 10.9 to the Company's Registration Statement on Form S-1 filed on April 8, 2019 (File No. 333-230451) and incorporated herein by reference)
10.10#	HOOKIPA Pharma Inc. 2023 Inducement Plan and form of award agreements thereunder (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 13, 2023 (File No. 001-38869) and incorporated herein by reference)
10.11#	Form of Director Indemnification Agreement (filed as Exhibit 10.10 to the Company's Registration Statement on Form S-1 filed on March 22, 2019 (File No. 333-230451) and incorporated herein by reference)
10.12#	Form of Officer Indemnification Agreement (filed as Exhibit 10.11 to the Company's Registration Statement on Form S-1 filed on March 22, 2019 (File No. 333-230451) and incorporated herein by reference)
10.13#	Employment Agreement between Joern Aldag and HOOKIPA Biotech GmbH (filed as Exhibit 10.12 to the Company's Registration Statement on Form S-1 filed on April 8, 2019 (File No. 333-230451) and incorporated herein by reference)
10.14#*	Termination Agreement between Joern Aldag and HOOKIPA Biotech GmbH dated August 30, 2024
10.15#	Employment Agreement between Dr. Malte Peters and HOOKIPA Biotech GmbH, dated July 22, 2024 (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 26, 2024 (File No. 001-38869) and incorporated herein by reference)
10.16#	Employment Agreement between Terry Coelho and the Company, dated July 22, 2024 (filed as Exhibit 10.2 to the Company's Current Report on Form 8-K filed on July 26, 2024 (File No. 001-38869) and incorporated herein by reference)
10.17#	Consultancy Service Agreement between Hookipa Biotech GmbH and Malte Peters, effective September 15, 2023 (filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on November 9, 2023 (File No. 001-38869) and incorporated herein by reference)
10.18	Lease by and between HOOKIPA Biotech GmbH and Marxbox Bauprojekt GmbH & Co OG, dated February 3, 2012, as supplemented by the Lease Agreement, dated April 2, 2014 (filed as Exhibit 10.16 to the Company's Registration Statement on Form S-1 filed on March 22, 2019 (File No. 333-230451) and incorporated herein by reference)
10.19	Lease by and between HOOKIPA Biotech GmbH and Wüstenrot Marxbox GmbH & Co KG, dated May 15, 2018 (filed as Exhibit 10.17 to the Company's Registration Statement on Form S-1 filed on March 22, 2019 (File No. 333-230451) and incorporated herein by reference)
10.20†	Amended and Restated Collaboration and License Agreement, by and between Hookipa Biotech GmbH and Gilead Sciences, Inc., dated as of February 15, 2022 (filed as Exhibit 10.1. to the Company's Current Report on Form 8-K/A filed on March 1, 2022 (File No. 001-38869) and incorporated herein by reference)

10.21†	Patent License Agreement, by and between Hookipa Biotech GmbH and the University of Zurich, dated as of October 6, 2011 (filed as Exhibit 10.19 to the Company's Registration Statement on Form S-1 filed on March 22, 2019 (File No. 333-230451) and incorporated herein by reference)
10.22†	Patent License Agreement, by and between Hookipa Biotech AG and the University of Basel, dated as of January 16, 2017 (filed as Exhibit 10.20 to the Company's Registration Statement on Form S-1 filed on March 22, 2019 (File No. 333-230451) and incorporated herein by reference)
10.23†	Patent License Agreement, by and between Hookipa Biotech AG and the University of Geneva, dated as of February 8, 2017 (filed as Exhibit 10.21 to the Company's Registration Statement on Form S-1 filed on March 22, 2019 (File No. 333-230451) and incorporated herein by reference)
10.24†	The National Institutes of Health Biological Materials License Agreement, by and between the National Institutes of Health within the Department of Health and Human Services through the Office of Technology Transfer and Hookipa Biotech AG, dated as of September 25, 2013, as amended by the First Amendment, dated April 12, 2017, and the Second Amendment, dated July 11, 2018 (filed as Exhibit 10.22 to the Company's Registration Statement on Form S-1 filed on March 22, 2019 (File No. 333-230451) and incorporated herein by reference)
10.25	Funding Contract, by and between Hookipa Biotech AG and The Austrian Research Promotion Agency, dated August 8, 2012, as extended by the Funding Contract, dated December 17, 2013, and the Funding Contract, dated May 22, 2015 (filed as Exhibit 10.23 to the Company's Registration Statement on Form S-1 filed on March 22, 2019 (File No. 333-230451) and incorporated herein by reference)
10.26	Funding Contract, by and between Hookipa Biotech AG and The Austrian Research Promotion Agency, dated December 16, 2014, as extended by the Funding Contract, dated October 4, 2016, the Funding Contract, dated February 27, 2018, and the Funded Contract dated October 25, 2019 (filed as Exhibit 10.23 to the Company's Annual Report on Form 10-K filed on March 18, 2021 (File No. 001- 38869) and incorporated herein by reference)
10.27	Lease by and between the Registrant and Wüstenrot Marxbox GmbH & Co. KG, dated February 26, 2019 (filed as Exhibit 10.25 to the Company's Registration Statement on Form S-1 filed on March 22, 2019 (File No. 333-230451) and incorporated herein by reference)
10.28	Amended and Restated Stock Purchase Agreement, by and between the Registrant and Gilead Sciences, Inc., dated as of December 20, 2023 (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 21, 2023 (File No. 001-38869) and incorporated herein by reference)
10.29††	Research Collaboration and License Agreement, dated October 19, 2022, by and among Hookipa Biotech GmbH, F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 20, 2022 (File No. 001-38869) and incorporated herein by reference)
10.30	Amendment No. 1 to License Agreement, by and between University of Basel and Hookipa Biotech GmbH, dated July 11, 2022 (filed as Exhibit 10.28 to the Company's Annual Report on Form 10-K filed on March 15, 2023 (File No. 001-38869) and incorporated herein by reference).
10.31	Amendment No. 2 to License Agreement, by and between University of Basel and Hookipa Biotech GmbH, dated September 15, 2022 (filed as Exhibit 10.29 to the Company's Annual Report on Form 10-K filed on March 15, 2023 (File No. 001-38869) and incorporated herein by reference).
19.1*	Insider Trading Policy
21.1	List of Subsidiaries of the Company (filed as Exhibit 21.1 to the Company's Registration Statement on Form S-1 filed on March 22, 2019 (File No. 333-230451) and incorporated herein by reference)

23.1*	Consent of PwC Wirtschaftsprüfung GmbH, Independent Registered Public Accounting Firm
31.1*	Certificate of Principal Executive Officer pursuant to Exchange Act 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*	Certificate of Principal Financial Officer pursuant to Exchange Act 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+	Certificate of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes Oxley Act of 2002
97.1	Clawback Policy (filed as Exhibit 97.1 to the Company's Annual Report on Form 10-K filed on March 22, 2024 (File No. 001-38869) and incorporated herein by reference)
101.INS	Inline XBRL Instance 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)

† Confidential treatment granted as to certain portions, which portions have been omitted and filed separately with the Securities and Exchange Commission.
†† Portions of this document (indicated by "[***]" have been omitted because they are not material and are the type that the Company treats as private and confidential.
# Indicates a management contract or any compensatory plan, contract or arrangement required to be filed as an exhibit pursuant to Item 15(a)(3) of Form 10-K.
* Filed herewith.
+ Furnished herewith.

Item 16. Form 10-K Summary

Not applicable

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.

HOOKIPA Pharma Inc.

Date: February 27, 2025

By: /s/ Malte Peters
Malte Peters
Chief Executive Officer (Principal Executive Officer)

POWER OF ATTORNEY AND SIGNATURES

We, the undersigned directors and officers of HOOKIPA Pharma Inc. (the "Company"), hereby severally constitute and appoint Joern Aldag and Reinhard Kandera, and each of them singly, our true and lawful attorneys, with full power to them, and to each of them singly, to sign for us and in our names in the capacities indicated below, any and all amendments to this Annual Report on Form 10-K, and to file or cause to be filed the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as each of us might or could do in person, and hereby ratifying and confirming all that said attorneys, and each of them, or their substitute or substitutes, shall do or cause to be done by virtue of this Power of Attorney.

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

Signature	Title(s)	Date
/s/ Malte Peters Malte Peters	Chief Executive Officer and Director (Principal Executive Officer)	February 27, 2025
/s/ Terry Coelho Terry Coelho	Executive Vice President, Chief Financial Officer and Director (Principal Financial and Accounting Officer)	February 27, 2025
/s/ Julie O'Neill Julie O'Neill	Chairwoman of the Board	February 27, 2025
/s/ David Kaufman David Kaufman	Director	February 27, 2025
/s/ Sean Cassidy Sean Cassidy	Director	February 27, 2025

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of HOOKIPA Pharma Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of HOOKIPA Pharma Inc. and its subsidiary (the "Company") as of December 31, 2024 and 2023, and the related consolidated statements of operations and comprehensive loss, of convertible preferred stock and stockholders' equity and of cash flows for each of the three years in the period ended December 31, 2024, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 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 accounting principles generally accepted in the United States of America.

Substantial Doubt about the Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company is still in the development phase and has not been marketing its technologies to date. Through December 31, 2024, the Company has funded its operations with proceeds from sales of common stock, sales of convertible preferred stock, sales of redeemable convertible preferred stock, collaboration and licensing agreements, grants and borrowings under various agreements with foreign public funding agencies. Since inception, the Company has incurred recurring losses and expects to continue to generate negative operating cash flows and the need for additional funding to support its planned operations in the foreseeable future raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the Audit Committee and that (i) relate to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgements. The communication of critical audit matters does not alter in any way

our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which they relate.

Revenue recognition - Collaboration and License Agreements

As described in Note 3 to the consolidated financial statements, the Company´s revenues of $44 million for the year ended December 31, 2024 are from Collaboration and License Agreements. Under the terms of the Collaboration and License Agreements the Company provided to its partners exclusive, royalty-bearing licenses to the Company's technology platforms, received non-refundable upfront payments, a program initiation fee and agreed on various additional payments which are due upon the achievement of defined milestones. Non-refundable upfront-payments and the non-refundable program initiation payment received by the Company upon signing and milestone payments that are linked to future performance obligations, are initially recorded as deferred revenue. Such amounts are recognized as revenue over the performance period of the respective services on a percent of completion basis using total estimated internal research and development costs and external costs for research, manufacturing and clinical trial activities (input method) for each of the obligations. Contingent milestone payments related to specified preclinical and clinical development milestones represent variable consideration that are not initially recognized within the transaction price due to the scientific uncertainties and the required commitment of Collaboration Partners. Such amounts that become likely to be realized are included in the variable consideration associated with these payments within the transaction price.

Due to the nature of the work required to be performed on the Company's performance obligations recognized over time, the estimation of total research and development labor cost, costs for research, manufacturing and clinical trial activities at completion is complex, subject to many variables and requires significant judgment by management. Management's significant judgments relate to key contract terms, progress towards completion and the related program schedule, identified risks and opportunities and related changes in estimates of costs. The risks and opportunities for the contracts relate to management's ability and cost to perform against the requirements of the schedule, consideration of delays, technical requirements and related variable consideration. Management also makes judgments about assumptions related to the availability and cost of materials, the length of time to complete the performance obligation and execution by the Company's subcontractors. Management reviews contract estimates on a periodic basis or when a change in circumstances warrants a modification to a previous estimate.

The principal considerations for our determination that performing procedures relating to the collaboration and license agreement assessments is a critical audit matter are (i) the significant judgments made by management when recognizing revenue over the period in which services were performed and (ii) a high degree of auditor judgment, subjectivity, and effort in performing procedures and evaluating audit evidence related to management's significant assumptions. Furthermore, we also considered the audit effort involved in the use of professionals with specialized skills and knowledge to assess the appropriateness of revenue recognition.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included an understanding of the cost accounting and revenue recognition process including the design assessment of key controls within these processes. Our audit procedures related to the recognition of revenue over time and deferred revenue included the following procedures, among others (i) testing the Company's estimates of project progress by evaluating the costs associated with the development activities (ii) testing the significant assumptions used to develop the estimates of project progress and the timely identification of circumstances which may require a modification to a previous estimate; (iii) the consistent application of accounting policies and (iv) testing completeness and accuracy of the underlying data.

Vienna, Austria
February 27, 2025

PwC Wirtschaftsprüfung GmbH
/s/ Gabor Kruepl
Austrian Certified Public Accountant

We have served as the Company's, or its predecessors, auditor since 2012, which includes periods before the Company became subject to SEC reporting requirements.

PART I—FINANCIAL INFORMATION

HOOKIPA PHARMA INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except share amounts)

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 39,684	$ 117,096
Restricted cash	98	—
Accounts receivable	290	511
Receivable research incentives	23,380	18,760
Assets held for sale	2,216	—
Prepaid expenses and other current assets	14,997	10,749
Total current assets	80,665	147,116
Non-current assets:		
Restricted cash	104	425
Property, plant and equipment, net	179	7,742
Operating lease right of use assets	885	5,473
Prepaid expenses and other non-current assets	712	581
Total non-current assets	1,880	14,221
Total assets	$ 82,545	$ 161,337
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 8,687	$ 12,498
Deferred revenues	4,762	14,631
Operating lease liabilities, current	552	1,638
Accrued expenses and other current liabilities	10,652	12,101
Loans payable, current	—	1,120
Total current liabilities	24,653	41,988
Non-current liabilities		
Operating lease liabilities, non-current	323	3,801
Deferred revenues, non-current	725	19,674
Other non-current liabilities	5,630	6,017
Total non-current liabilities	6,678	29,492
Total liabilities	31,331	71,480
Commitments and contingencies (Note 15)		
Stockholders' equity(1):		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at December 31, 2024 and December 31, 2023, respectively; Series A convertible preferred stock, 2,978 shares designated, 370 shares outstanding at December 31, 2024 and December 31, 2023, respectively; Series A-1 convertible preferred stock, 15,800 shares designated, 10,800 shares outstanding at December 31, 2024 and December 31, 2023, respectively; Series A-2 convertible preferred stock, 15,268 shares designated, and 15,268 shares outstanding at December 31, 2024 and December 31, 2023, respectively	0	0
Common stock, $0.0001 par value; 40,000,000 shares and 20,000,000 shares authorized at December 31, 2024 and December 31, 2023, respectively; 9,655,022 shares and 9,655,059 shares issued and outstanding at December 31, 2024 and December 31, 2023, respectively	1	1
Class A common stock, $0.0001 par value; 3,900,000 shares authorized at December 31, 2024 and December 31, 2023, respectively; 2,399,517 shares issued and outstanding at December 31, 2024 and December 31, 2023, respectively	0	0
Additional paid-in capital	469,064	467,050
Accumulated other comprehensive loss	(5,087)	(7,933)
Accumulated deficit	(412,764)	(369,261)
Total stockholders' equity	51,214	89,857
Total liabilities and stockholders' equity	$ 82,545	$ 161,337

(1) Share and per share amounts have been restated to reflect the one-for-ten reverse stock split effected in July 2024 on a retroactive basis for all periods presented.

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

HOOKIPA PHARMA INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share amounts)

	Year ended December 31,		
	2024	2023	2022
Revenue from collaboration and licensing	$ 43,946	$ 20,129	$ 14,249
Operating expenses:			
Research and development	(68,507)	(86,424)	(68,645)
General and administrative	(20,226)	(18,633)	(18,759)
Restructuring	(2,664)	—	—
Impairment	(4,004)	(12,766)	—
Total operating expenses	(95,401)	(117,823)	(87,404)
Loss from operations	(51,455)	(97,694)	(73,155)
Other income (expense):			
Grant income	$ 7,396	$ 11,193	$ 7,916
Interest income	3,701	5,293	1,633
Interest expense	(2)	(317)	(687)
Other (expense) income, net	(3,249)	313	(392)
Total other income, net	7,846	16,482	8,470
Net loss before tax	(43,609)	(81,212)	(64,685)
Income tax benefit (expense)	106	(368)	(230)
Net loss	(43,503)	(81,580)	(64,915)
Other comprehensive loss:			
Foreign currency translation (loss) gain, net of tax	2,846	(777)	(2,376)
Comprehensive loss	$ (40,657)	$ (82,357)	$ (67,291)
Net loss per share — basic and diluted[1]	$ (3.47)	$ (8.63)	$ (9.91)

[1] Share and per share amounts have been restated to reflect the one-for-ten reverse stock split effected in July 2024 on a retroactive basis for all periods presented.

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

HOOKIPA PHARMA INC.

CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY

(In thousands, except share amounts)

	Convertible Preferred Stock		Common Stock				Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
			Common Stock[1]		Class A Common Stock					
	Shares	Amount	Shares	Amount	Shares	Amount				
Balances as of January 1, 2022	**1,697**	**0**	**2,738,348**	**0**	**3,819,732**	**0**	**317,138**	**(4,780)**	**(222,766)**	**89,592**
Issuance of Series A-1 convertible preferred stock upon public offering at $2,000 per share for cash, net of issuance costs of $1,975	15,800	0	—	—	—	—	29,625	—	—	29,625
Issuance of common stock upon public offering at $20.00 per share for cash, net of issuance costs of $2,713	—	—	2,170,000	0	—	—	40,687	—	—	40,687
Issuance of common stock upon stock purchase agreement with Gilead at $30.00 per share for cash, no issuance costs	—	—	166,666	0	—	—	5,000	—	—	5,000
Conversion of Class A common stock to common stock	—	—	142,022	0	(1,420,215)	(0)	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	3,422	0	—	—	3	—	—	3
Vesting of equity grants	—	—	11,255	0	—	—	(0)	—	—	—
ATM costs	—	—	—	—	—	—	(142)	—	—	(142)
Foreign currency translation adjustment, net of tax	—	—	—	—	—	—	—	(2,376)	—	(2,376)
Stock-based compensation expense	—	—	—	—	—	—	5,043	—	—	5,043
Net loss	—	—	—	—	—	—	—	—	(64,915)	(64,915)
Balances as of December 31, 2022	**17,497**	**$ 0**	**5,231,713**	**$ 1**	**2,399,517**	**$ 0**	**$ 397,353**	**$ (7,156)**	**$ (287,681)**	**$ 102,517**
Issuance of Series A-2 convertible preferred stock upon public offering at $1,310 per share for cash, net of issuance costs of $1,471	15,268	0	—	—	—	—	18,530	—	—	18,530
Issuance of common stock upon public offering at $13.10 per share for cash, net of issuance costs of $2,207	—	—	2,290,077	0	—	—	27,793	—	—	27,793
Issuance of common stock upon stock purchase agreement with Gilead at $14.167 per share for cash, net of issuance costs of $136	—	—	1,500,000	0	—	—	21,114	—	—	21,114
Conversion of Series A convertible preferred stock to common stock	(1,327)	(0)	132,700	0	—	—	(0)	—	—	—
Conversion of Series A-1 convertible preferred stock to common stock	(5,000)	(0)	500,000	0	—	—	(0)	—	—	—
Issuance of common stock upon exercise of stock options	—	—	569	0	—	—	1	—	—	1
ATM costs	—	—	—	—	—	—	(86)	—	—	(86)
Foreign currency translation adjustment, net of tax	—	—	—	—	—	—	—	(777)	—	(777)
Stock-based compensation expense	—	—	—	—	—	—	2,345	—	—	2,345
Net loss	—	—	—	—	—	—	—	—	(81,580)	(81,580)
Balances as of December 31, 2023	**26,438**	**$ 0**	**9,655,059**	**$ 1**	**2,399,517**	**$ 0**	**$ 467,050**	**$ (7,933)**	**$ (369,261)**	**$ 89,857**
Fractional shares retired as a result of reverse split	—	—	(37)	(0)	—	—	(0)	—	—	(0)
Foreign currency translation adjustment, net of tax	—	—	—	—	—	—	—	2,846	—	2,846
Stock-based compensation expense	—	—	—	—	—	—	2,014	—	—	2,014
Net loss	—	—	—	—	—	—	—	—	(43,503)	(43,503)
Balances as of December 31, 2024	**26,438**	**$ 0**	**9,655,022**	**$ 1**	**2,399,517**	**$ 0**	**$ 469,064**	**$ (5,087)**	**$ (412,764)**	**$ 51,214**

[1] All share amounts in this column, including appropriate reclassifications between common stock and additional paid-in capital, have been restated to reflect the one-for-ten reverse stock split effected in July 2024 on a retroactive basis for all periods presented.

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

HOOKIPA PHARMA INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year ended December 31,		
	2024	**2023**	**2022**
Operating activities:			
Net loss	$ (43,503)	$ (81,580)	$ (64,915)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	2,014	2,345	5,043
Depreciation and amortization expense	2,753	3,552	3,602
Impairment expense	4,004	12,766	—
Other non-cash items	0	64	160
Changes in operating assets and liabilities:			
Accounts receivable	524	6,180	(341)
Receivable research incentives	(5,988)	(2,726)	(1,958)
Prepaid expenses and other current assets	(3,815)	1,735	2,007
Prepaid expenses and other non-current assets	(1,440)	304	424
Accounts payable	(1,570)	6,499	(1,999)
Deferred revenues	(27,538)	(8,258)	35,508
Operating lease liabilities	(1,591)	(1,622)	(1,584)
Accrued expenses and other liabilities	(828)	490	2,510
Other non-current liabilities	—	2,727	1,546
Net cash used in operating activities	(76,978)	(57,524)	(19,997)
Investing activities:			
Purchases of property and equipment	(194)	(4,159)	(5,017)
Net cash used in investing activities	(194)	(4,159)	(5,017)
Financing activities:			
Payments related to finance leases	—	—	(25)
Proceeds from issuance of convertible preferred stock, net of issuance costs	—	18,530	29,625
Proceeds from issuance of common stock, net of issuance costs	—	49,043	45,691
Payments for deferred offering costs	(135)	(149)	(195)
Repayments of borrowings	(1,141)	(1,754)	(2,825)
Net cash (used in) provided by financing activities	(1,276)	65,670	72,271
Net (decrease) increase in cash, cash equivalents and restricted cash	(78,448)	3,987	47,257
Cash, cash equivalents and restricted cash at beginning of period	117,521	113,444	66,912
Effect of exchange rate changes on cash, cash equivalents and restricted cash	813	90	(725)
Cash, cash equivalents and restricted cash at end of period	$ 39,886	$ 117,521	$ 113,444
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ (2)	$ (14)	$ (32)
Cash paid for income taxes	$ (1)	$ (403)	$ (1)
Supplemental disclosure of non-cash financing activities:			
Property and equipment additions in accounts payable and accrued expenses	$ —	$ (34)	$ (56)
Lease assets obtained in exchange for new operating lease liabilities	$ 433	$ 2,874	$ 225
Lease assets derecognized upon lease modification	$ (3,219)	$ —	$ —

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

HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of the business and organization

HOOKIPA Pharma Inc. ("HOOKIPA" or the "Company") is a clinical stage biopharmaceutical company developing a new class of immunotherapeutics based on its proprietary arenavirus platform that is designed to reprogram the body's immune system.

The Company was incorporated under the name of HOOKIPA Biotech, Inc. under the laws of the State of Delaware in February 2017 as a fully-owned subsidiary of Hookipa Biotech AG. In June 2018, the Company changed its name from Hookipa Biotech, Inc. to HOOKIPA Pharma Inc. and in order to effectuate the change of the jurisdiction of incorporation, the Company acquired all of the shares of Hookipa Biotech AG, now Hookipa Biotech GmbH. HOOKIPA is headquartered in New York, with European research and preclinical development operations headquartered in Vienna, Austria. In April 2019, the Company closed its initial public offering ("IPO") and its common stock is currently trading on the Nasdaq Capital Market under the ticker symbol "HOOK".

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, the ability to establish clinical- and commercial-scale manufacturing processes and the ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities and may not ultimately lead to a marketing approval and commercialization of a product. Even if the Company's drug development efforts are successful, it is uncertain if and when the Company will realize significant revenue from product sales.

2. Summary of significant accounting policies

Basis of presentation

The Company's consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiary. All intercompany accounts and transactions have been eliminated in consolidation.

Going concern

At each reporting period, in accordance with Accounting Standards Codification ("ASC") 205-40, Going Concern, the Company evaluates whether there are conditions or events that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. The Company's evaluation entails analyzing prospective operating budgets and forecasts for expectations of the Company's cash needs and comparing those needs to the current cash and cash equivalent balances. The Company is required to make certain additional disclosures if it concludes substantial doubt exists and it is not alleviated by the Company's plans or when its plans alleviate substantial doubt about the Company's ability to continue as a going concern.

This evaluation initially does not take into consideration the potential mitigating effect of management's plans that have not been fully implemented as of the date the consolidated financial statements are issued. When substantial doubt exists under this methodology, management evaluates whether the mitigating effect of its plans sufficiently alleviates substantial doubt about the Company's ability to continue as a going concern. The mitigating effect of management's plans, however, is only considered if both (1) it is probable that the plans will be effectively implemented within one year after the date that the consolidated financial statements are issued, and (2) it is probable that the plans,

when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that these consolidated financial statements are issued. In performing its analysis, management excluded certain elements of its operating plan that cannot be considered probable. Under ASC 205-40, the future receipt of potential funding from future partnerships, equity or debt issuances, the potential milestones from the Gilead Collaboration Agreement and potential reductions in force cannot be considered probable at this time because these plans are not entirely within the Company's control and/or have not been approved by the Board of Directors as of the date of these consolidated financial statements.

Since inception, the Company's activities have consisted primarily of performing research and development to advance its technologies. The Company is still in the development phase and has not been marketing its technologies to date. Through December 31, 2024, the Company has funded its operations with proceeds from sales of common stock, sales of convertible preferred stock, sales of redeemable convertible preferred stock, collaboration and licensing agreements, grants and borrowings under various agreements with foreign public funding agencies. Since inception, the Company has incurred recurring losses, including net losses of $43.5 million, $81.6 million and $64.9 million for the years ended December 31, 2024, 2023 and 2022, respectively. As of December 31, 2024, the Company had an accumulated deficit of $412.8 million. The Company expects to continue to generate operating losses in the foreseeable future. As of the filing date of this Annual Report on Form 10-K, the Company's expectation to generate negative operating cash flows in the future and the need for additional funding to support its planned operations raise substantial doubt regarding the Company's ability to continue as a going concern for a period of one year after the date that these consolidated financial statements are issued. Management's plans to alleviate the conditions that raise substantial doubt include reduced spending and the pursuit of additional capital. Management has concluded that the likelihood that its plan to successfully obtain sufficient funding, or adequately reduce expenditures, while reasonably possible, is less than probable. Accordingly, the Company has concluded that substantial doubt exists about the Company's ability to continue as a going concern for a period of at least 12 months from the date of issuance of these consolidated financial statements.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The consolidated financial statements do not reflect any adjustments relating to the recoverability and classification of assets or the amounts and classification of liabilities that might result from the outcome of the uncertainties described above.

Reverse stock split

On July 9, 2024, the Company effected a reverse stock split of the outstanding shares of its common stock on a one-for-ten (1:10) basis (the "Reverse Stock Split"). The Reverse Stock Split became effective at 5:00 p.m. Eastern Time on July 9, 2024 (the "Effective Time") via a certificate of amendment to the Company's Certificate of Incorporation filed with the Secretary of State of the State of Delaware. At the Effective Time of the Reverse Stock Split, every 10 issued and outstanding shares of the Company's common stock were automatically combined into one issued and outstanding share of common stock. The par value per share of the common stock remained unchanged at $0.0001. Fractional shares were not issued in connection with the Reverse Stock Split. Stockholders who were otherwise entitled to receive a fractional share received a proportional cash payment. The Reverse Stock Split affected all stockholders uniformly and did not alter any stockholder's relative interest in the Company's equity securities, except for any adjustments for fractional shares. As a result of the Reverse Stock Split, proportionate adjustments were made to the conversion ratio for the Company's Class A Common Stock and the conversion prices of the Company's Series A Convertible Preferred Stock, Series A-1 Convertible Preferred Stock and Series A-2 Convertible Preferred Stock. All share, per share and option numbers and exercise prices appearing in this Annual Report on Form 10-K and the financial statements have been adjusted to give effect to the Reverse Stock Split for all prior periods presented. However, the Company's annual, other periodic, and current reports, and all other information and documents incorporated by reference into this Annual Report on Form 10-K that were filed prior to July 9, 2024, do not give effect to the Reverse Stock Split.

HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

Use of estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue, income and expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the recognition of revenue and income, the accrual of research and development expenses and general and administrative expenses, the present value of lease right of use assets and corresponding liabilities, the valuation of stock-based awards, the valuation of current loans payable, the impairment of long-lived assets, the fair value of assets held for sale and going concern. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates as there are changes in circumstances, facts and experience.

As of the date of issuance of these consolidated financial statements, the Company is not aware of any specific event or circumstance that would require the Company to update estimates, judgments or revise the carrying value of any assets or liabilities. Actual results may differ from those estimates or assumptions.

Foreign currency and currency translation

The functional currency for the Company is the United States dollar and the functional currency for the Company's wholly owned foreign subsidiary, HOOKIPA Biotech GmbH, is the euro.

Assets and liabilities of HOOKIPA Biotech GmbH are translated into United States dollars at the exchange rate in effect on the balance sheet date. Income items and expenses are translated at the average exchange rate in effect during the period. Unrealized translation gains and losses are recorded as a cumulative translation adjustment, which is included in the Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity as a component of Accumulated other comprehensive loss. Adjustments that arise from exchange rate changes on transactions denominated in a currency other than the local currency are included in other income and expenses, net in the consolidated statements of operations and comprehensive loss as incurred.

Concentrations of credit risk and of significant suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents and short-term bank deposits held with banks in excess of publicly insured limits. For the years ended December 31, 2024 and December 31, 2023 the net proceeds from the Company’s offerings have been deposited in interest-bearing bank accounts with two of the largest investment grade U.S. financial institutions and have been partially invested in money market funds. The money market funds, held in U.S. dollars, are primarily invested in U.S. and foreign short-term debt obligations. As of December 31, 2024 and December 31, 2023, the Company’s cash and cash equivalents included smaller amounts of cash balances held in accounts with regional European banks at the Company’s Austrian subsidiary, partially in euros. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

The Company relies, and expects to continue to rely, on a small number of vendors to manufacture supplies and raw materials for its development programs. These programs could be adversely affected by a significant interruption in these manufacturing services or the availability of raw materials.

As of December 31, 2024 Gilead Sciences, Inc. (“Gilead”) accounted for the majority of the accounts receivable balance. As of December 31, 2023 Gilead and F. Hoffmann-La Roche Ltd. and Hoffmann-La Roche Inc. (together “Roche”) accounted for the majority of the accounts receivable balance. For the years ended December 31, 2024, December 31, 2023 and December 31, 2022 Gilead and Roche accounted for the majority of the

HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

Company's revenues. For the year ended December 31, 2024 Roche accounted for a large portion of the Company's revenues as a result of a contract modification and the recognition of upfront and milestone payments previously recorded as deferred revenues. Other customers accounted for less than 10.0% of accounts receivable or net revenues. The Company monitors the financial performance of its customers so that it can appropriately respond to changes in their credit worthiness. To date, the Company has not experienced any significant losses with respect to collection of its accounts receivable.

Deferred offering costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of an equity financing, these costs are recorded in stockholders' equity as a reduction of the additional paid-in capital on a pro-rata basis generated as a result of the offering. Should the in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the consolidated statements of operations and comprehensive loss.

Fair value measurements

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1 - Quoted prices in active markets for identical assets or liabilities.
- Level 2 - Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's cash equivalents are carried at fair value, determined according to the fair value hierarchy described above (see Note 6).

Cash equivalents

The Company considers all highly liquid investments with maturities of three months or less at the date of purchase to be cash equivalents. As of December 31, 2024 and December 31, 2023 cash equivalents consisted of money market funds and short-term deposits. The Company classifies investments in money market funds within Level 1 of the fair value hierarchy as the prices are available from quoted prices in active markets.

HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

Assets held for sale

The fair values of property, plant, and equipment held for sale is classified as Level 3 in the fair value hierarchy due to a mix of unobservable inputs utilized such as independent research in the market as well as actual quotes from market participants.

Property and equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation and amortization expense is recognized using the straight-line method over the estimated useful life of each asset as follows:

	Estimated useful life
Leasehold improvements	shorter of useful life or term of lease
Laboratory equipment	2 - 10 years
Furniture and fixtures	2 - 10 years
Computer equipment and software	2 - 4 years

Costs for capital assets not yet placed into service are capitalized as construction-in-progress and depreciated once placed into service. Expenditures for repairs and maintenance are charged to expense as incurred. When property and equipment is sold or otherwise disposed of, the cost and related accumulated depreciation are eliminated from the accounts and any resulting gain or loss is reflected in the consolidated statements of operations.

Leases

The determination whether an arrangement qualifies as a lease is made at contract inception. A lease qualifies as a finance lease if any of the following criteria are met at the inception of the lease: (i) there is a transfer of ownership of the leased asset to the Company by the end of the lease term, (ii) the Company holds an option to purchase the leased asset that it is reasonably certain to exercise, (iii) the lease term is for a major part of the remaining economic life of the leased asset, (iv) the present value of the sum of lease payments equals or exceeds substantially all of the fair value of the leased asset, or (v) the nature of the leased asset is specialized to the point that it is expected to provide the lessor no alternative use at the end of the lease term. All other leases are recorded as operating leases and are included in right of use ("ROU") assets and lease liabilities in the consolidated balance sheets. For leases with an initial term of 12 months or less, the Company does not recognize a right of use asset or lease liability. These short-term leases are expensed on a straight-line basis over the lease term.

ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent its obligation to make lease payments arising from the lease. ROU assets and lease liabilities are recognized at the commencement date of the lease based upon the present value of lease payments over the lease term. When determining the lease term, the Company includes options to extend or terminate the lease when it is reasonably certain that the option will be exercised. The Company uses the implicit rate when readily determinable and uses its incremental borrowing rate when the implicit rate is not readily determinable based upon the information available at the commencement date in determining the present value of the lease payments. The incremental borrowing rate is determined using a secured borrowing rate for the same currency and term as the associated lease. The lease payments used to determine ROU assets may include lease incentives, stated rent increases and escalation clauses linked to rates of inflation when determinable and are recognized as ROU asset on the consolidated balance sheet. In addition, certain of the Company's arrangements contain lease and non-lease components. The Company generally separates lease payments from non-lease payments. Operating leases are reflected in operating lease assets, in current operating lease liabilities and non-current operating lease liabilities in the consolidated balance sheets. Finance leases are reflected in finance lease

assets, in accrued expenses and other current liabilities and in other non-current operating lease liabilities in the consolidated balance sheets. The ROU asset is tested for impairment in accordance with ASC 360.

Capitalized Software Development Cost

The Company capitalizes certain implementation costs for internal-use software incurred in a cloud computing agreement that is a service contract. Eligible costs associated with cloud computing arrangements, such as software business applications used in the normal course of business, are capitalized in accordance with ASC 350. These costs are recognized on a straight-line basis in the same line item in the statement of operations and comprehensive loss as the expense for fees for the associated cloud computing arrangement, over the term of the arrangement, plus reasonably certain renewals. Amortization expense of $0.1 million associated with the Company's cloud computing arrangements has been recognized during each of the fiscal years ended December 31, 2024, December 31, 2023 and December 31, 2022. The Company tests for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. In the year ended December 31, 2024 the Company recognized an impairment loss of less than $0.1 million associated with the Company's cloud computing arrangements (see Note 7).

Impairment of long-lived assets

Long-lived assets, including operating and finance lease right of use assets, consist of property and equipment. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative technological, scientific or economic trends and significant changes or planned changes in the use of the assets.

If an impairment review is performed to evaluate a long-lived asset group for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset group to its carrying value. An impairment loss would be recognized in loss from operations when estimated undiscounted future cash flows expected to result from the use of an asset group are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset group over its fair value (see Note 5 and Note 7).

Restructuring

Costs and liabilities associated with restructuring activities are recognized when the actions are probable and estimable, which is when management approves the associated actions. Employee-related severance charges are recognized at the time of communication to employees (see Note 4).

Segment information

The Company manages its operations as a single segment at the consolidated level for the purposes of assessing performance and making operating decisions. The Company's singular focus is on developing pharmaceutical products to prevent and cure infectious diseases and cancer. The Chief Executive Officer is the chief operating decision maker, and regularly reviews the consolidated operating results to make decisions about the allocation of the Company's resources based on consolidated net loss that is reported on the consolidated statements of operations. The majority of the Company's tangible assets are held in Austria (see Note 19).

The measure of segment assets is reported on the consolidated balance sheet as total assets.

HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

Revenue recognition from collaboration and licensing

The Company recognized revenue from collaboration and license agreements with Gilead and Roche.

Under the collaboration and license agreement with Gilead (as amended and restated, the "Gilead Collaboration Agreement"), the parties agreed to collaborate with respect to two preclinical research programs to evaluate potential vaccine products for the treatment, cure, diagnosis or prevention of the hepatitis B virus ("HBV") and the human immunodeficiency virus ("HIV"). In February 2022, the parties signed an amended and restated collaboration agreement (the "Restated Gilead Collaboration Agreement"), which revised the terms only for the HIV program, whereby the Company took on development responsibilities for the HIV program candidate through a Phase 1b clinical trial. The Company's performance obligations under the terms of the original agreement include one combined performance obligation for each research program (HBV and HIV) comprised of the transfer of intellectual property rights (licenses) and providing research and development services. The terms of the Restated Gilead Collaboration Agreement added an additional performance obligation to perform research and development work for the HIV program. The licenses do not represent distinct performance obligations, because they cannot be used without the research and development services. Payments to the Company under the Restated Gilead Collaboration Agreement include a non-refundable up-front payment, payments for research and development activities, payments based upon the achievement of defined milestones, and if certain future conditions are met, payments for manufacturing services, commercial milestones and royalties on product sales.

Under the research collaboration and license agreement with Roche (the "Roche Collaboration Agreement"), the Company agreed to conduct research and early clinical development through Phase 1b for HB-700, a novel investigational arenaviral immunotherapy for the treatment of KRAS-mutated cancers. The Roche Collaboration Agreement also included an obligation of the Company to deliver a specified package of preclinical data and results with respect to a second program, targeting undisclosed cancer antigens (collectively "UCAs") and an option for Roche to license the UCA program. The Company's performance obligations under the terms of the Roche Collaboration Agreement included one combined performance obligation for the transfer of intellectual property rights (licenses) and providing research and development services for the HB-700 program, and a second, separate performance obligation to perform research and development services with respect to the UCA program. The UCA Option provided a right to license the program at the standalone selling price and therefore did not constitute a separate performance obligation. Payments to the Company under the Roche Collaboration Agreement included a non-refundable up-front payment, payments based upon the achievement of defined milestones, an additional payment if the option for the UCA program was exercised and royalties on product sales. In January 2024, Roche provided written notice of the termination of the Roche Collaboration Agreement to the Company resulting in early recognition of revenue previously recorded as deferred revenue. The termination was made according to Roche's right to terminate without cause, acknowledging that, the Company had met all go-forward criteria under the agreement. Upon the Roche Collaboration Agreement termination effective date of April 25, 2024, the Company regained full control of the associated intellectual property portfolio and has full collaboration and licensing rights for the HB-700 program.

The Company evaluates its collaboration and licensing arrangements pursuant to ASC 606 Revenue from Contracts with Customers. To determine the recognition of revenue from arrangements that fall within the scope of ASC 606, the Company performs 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) the Company satisfies a performance obligation.

Under ASC 606, the Company applies significant judgement to evaluate whether the promises under the collaboration and licensing arrangements, represent separate or one or more combined performance obligations, the allocation of the transaction price to identified performance obligations, the timing of revenue recognition, whether the

HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

UCA Option constitutes a material right, and the determination of when milestone payments are probable of being received.

Upfront payment and program initiation fee

The non-refundable upfront-payment received by the Company upon signing of the Gilead Collaboration Agreement, and milestone payments that were linked to future performance obligations, were initially recorded as deferred revenue and allocated between the two research program performance obligations. Such amounts are recognized as revenue over the performance period of the respective services on a percent of completion basis using total estimated research and development labor hours (input method) for each of the obligations. The percent of completion basis using labor hours was considered the best measure of progress in which control of the combined performance obligations transfers to the customer, due to the short time intervals in which research results are shared with the collaboration partner and the nature of the work being performed.

The non-refundable program initiation payment received from Gilead upon signing of the Restated Collaboration Agreement was also initially recorded as deferred revenue and is recognized on a percent of completion basis using total estimated research and development costs (input method) for the performance of the obligations. The percent of completion basis using research and development costs was considered the best measure of progress in which control of the performance obligations transfers to the customer, due to the immediate benefit that it adds to the value of the customer's rights on the program, the short time intervals in which development results are shared and the nature of the work being performed.

The non-refundable upfront-payment received by the Company upon signing of the Roche Collaboration Agreement was initially recorded as deferred revenue and allocated between the HB-700 program and the UCA program. Such amounts were recognized as revenue over the performance period of the respective services on a percent of completion basis using total estimated research and development costs (input method) for each of the obligations during the initial term of the contract. The percent of completion basis using research and development costs was considered the best measure of progress in which control of the performance obligations transfers to the customer.

Reimbursement for services

Under the Gilead Collaboration Agreement and historically under the Roche Collaboration Agreement prior to termination, the Company incurs employee expenses as well as external costs for research, manufacturing and clinical trial activities presented as operating expenses or prepaid expenses. Based on the nature of the Company's responsibilities under the collaboration arrangements, reimbursement of those costs are presented as revenue and not deducted from expenses, as the Company controls the research activities. Amounts of consideration allocated to the performance of research or manufacturing services are recognized over the period in which services are performed. Reimbursements for external costs are recognized as revenues as progress is achieved. Unpaid reimbursement amounts are presented as Accounts Receivable.

Research and development milestones

The Gilead Collaboration Agreement includes, and the Roche Collaboration Agreement included, contingent milestone payments related to specified preclinical and clinical development milestones. These milestone payments represent variable consideration that are not initially recognized within the transaction price as they are fully constrained under the guidance in ASC 606, due to the scientific uncertainties and the required commitment from Gilead and Roche. While no further milestone payments are expected under the terminated Roche Collaboration Agreement, the Company will continue to assess the probability of significant reversals for any amounts that become likely to be realized under the Gilead Collaboration Agreement prior to including the variable consideration associated with these payments within the transaction price.

HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

Sales-based milestones and royalty payments

The Gilead Collaboration Agreement also includes, and the Roche Collaboration Agreement included, certain sales-based milestone and royalty payments upon successful commercialization of a licensed product. In accordance with ASC 606-10-55-65 Sales Based or Usage Based Royalties, the Company recognizes revenues from sales-based milestone and royalty payments at the later of (i) the occurrence of the subsequent sale; or (ii) the performance obligation to which some or all of the sales-based milestone or royalty payments has been allocated has been satisfied. The Company anticipates recognizing these milestones and royalty payments if and when subsequent sales are generated from a licensed product by the collaboration partner.

Cost to fulfill contracts

The Company incurs costs for personnel, supplies and other costs related to its laboratory operations as well as fees from third parties and license expenses in connection with its research and development obligations under the collaboration and licensing agreements. These costs are recognized as research and development expenses over the period in which services are performed. Sublicense fees triggered by the receipt of payments are capitalized as an asset when the obligation to pay the fee arises. The capitalized asset is amortized over the period in which the revenue from the triggering payment is recognized.

Research and development costs

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including salaries and bonuses, stock-based compensation, employee benefits, facilities costs, laboratory supplies, depreciation, manufacturing expenses and external costs of vendors engaged to conduct preclinical development activities and clinical trials as well as the cost of licensing technology. Advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed.

Upfront payments, milestone payments and annual payments made for the licensing of technology are generally expensed as research and development in the period in which they are incurred. Incremental sublicense fees triggered by contracts with customers are capitalized and expensed as research and development expenses over the period in which the related revenue is recognized.

Research and manufacturing contract costs and accruals

The Company has entered into various research and development and manufacturing contracts. Related payments are recorded as the corresponding expenses are incurred. The Company records accruals for estimated ongoing costs and prepaid expenses for advance payments. When evaluating the adequacy of the accrued liabilities and prepaid expenses, the Company analyzes progress of the research studies or clinical trials and manufacturing activities, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Government grant agreements and research incentives

The Company recognizes funding from grants and research incentives received from Austrian government agencies as well as from New York State and New York City government agencies in the United States as other income. Income from grants and incentives is recognized in the period during which the related qualifying expenses are incurred, provided that the conditions under which the grants or incentives were provided have been met. For grants under funding

agreements and for proceeds under research incentive programs, the Company recognizes grant and incentive income in an amount equal to the estimated qualifying expenses incurred in each period multiplied by the applicable reimbursement percentage.

Grant funding that has been received by the Company in advance of incurring qualifying expenses is recorded as deferred income. Grant and incentive income recognized upon incurring qualifying expenses in advance of receipt of grant funding or proceeds from research and development incentives is recorded in the consolidated balance sheets as prepaid expenses and other current assets.

The Company has received loans under funding agreements that bear interest at rates that are below market rates of interest. The Company accounts for the imputed benefit arising from the difference between a market rate of interest and the rate of interest charged as additional grant funding, and records interest expense for the loans at a market rate of interest. On the date that loan proceeds are received, the Company recognizes the portion of the loan proceeds allocated to grant funding as a discount to the carrying value of the loan and as other liability, which is subsequently recognized as additional grant income over the term of the funding agreement.

Stock-based compensation

The Company measures stock-based awards granted to employees and directors based on the fair value on the date of grant using the Black-Scholes option-pricing model for options or the difference between the purchase price per share of the award, if any, and the fair value of the Company's common stock for restricted common stock awards. Compensation expense for those awards is recognized over the requisite service period, which is generally the vesting period of the respective award. The Company uses the graded-vesting method to record the expense of awards with service-based vesting conditions.

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

Comprehensive loss

Comprehensive loss includes net loss and foreign currency translation adjustments. For the year ended December 31, 2024, $2.8 million of foreign currency gain adjustments. For the years ended December 31, 2023 and December 31, 2022, comprehensive loss included $0.8 million and $2.4 million, respectively, of foreign currency translation loss adjustments.

Net loss per share

Basic net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock outstanding for the period. Diluted net loss per share is computed by dividing net loss by the weighted average number of shares outstanding for the period, including potential dilutive shares assuming the dilutive effect of outstanding stock options and of convertible preferred stock. For periods in which the Company has reported net losses, diluted net loss per common share is the same as basic net loss per share, since dilutive common shares are not assumed to have been issued if their affect is anti-dilutive.

The Company reported a net loss attributable to common stockholders for the years ended December 31, 2024, 2023 and 2022.

HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

Income taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements or in the Company's tax returns. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date. Changes in deferred tax assets and liabilities are recorded in income tax expense. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

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

The 2017 Tax Cuts and Jobs Act subjects a US shareholder to tax on global intangible low-taxed income (“GILTI”) earned by certain foreign subsidiaries. The FASB Staff Q&A, Topic 740, No. 5, Accounting for Global Intangible Low-Taxed Income, states that an entity can make an accounting policy election to either recognize deferred taxes for temporary basis differences expected to reverse as GILTI in the future years or provide for tax expense related to GILTI in the year the tax is incurred. The Company has elected to recognize tax expense related to GILTI in the year the tax is incurred.

Recent accounting pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (“FASB”) or other standard setting bodies that the Company adopts as of the specified effective date.

Adopted as of current period

In November 2023, the FASB issued ASU No. 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures which requires public entities to disclose significant segment expenses regularly provided to the chief operating decision-maker. Public entities with a single reporting segment have to provide all disclosures required by ASC 280, including the significant segment expense disclosures. For public business entities, the guidance is effective for annual periods beginning after December 15, 2024. The Company adopted this standard with no impact to its consolidated financial statements.

Recently Issued Accounting Pronouncements

In November 2024, the FASB issued ASU 2024-03, Disaggregation of Income Statement Expenses, requiring entities to provide more information about an entity’s expenses. The new guidance requires disclosures about specific types of expenses included in the expense captions presented on the face of the income statement as well as disclosures

about selling expenses. The guidance is first effective for calendar year-end public business entities in their 2027 annual financial statements and 2028 interim financial statements. Companies can adopt the guidance on either a prospective or retrospective basis. The Company is currently evaluating the impact of the adoption of ASU 2024-03 on the consolidated financial statements and disclosures.

In November 2024, the FASB issued ASU 2024-04, Induced Conversions of Convertible Debt Instruments. The new guidance clarifies the assessment of whether a transaction should be accounted for as an induced conversion or extinguishment of convertible debt when changes are made to conversion features as part of an offer to settle the instrument. The guidance is effective for fiscal years beginning after December 15, 2025, with early adoption permitted, and it can be adopted either on a prospective or retrospective basis. The Company is currently evaluating the impact of the adoption of ASU 2024-04 on the consolidated financial statements and disclosures, but does not expect this ASU to have an impact on the consolidated financial statements and disclosures.

In December 2023, the FASB issued final guidance in ASU No. 2023-09, Income Taxes (ASC 740): Improvements to Income Tax Disclosures requiring entities to provide additional information in the rate reconciliation and disclosures about income taxes paid. For public business entities, the guidance is effective for annual periods beginning after December 15, 2024. The Company does not expect this ASU to have a material impact on the consolidated financial statements and disclosures.

3. Collaboration and Licensing Agreements

Gilead Collaboration and License Agreement

In June 2018, the Company entered into the Gilead Collaboration Agreement whereby the Company and Gilead agreed to collaborate with respect to two preclinical research programs to evaluate potential vaccine products for the treatment, cure, diagnosis or prevention of HBV and HIV. In February 2022, the Company signed the Amended and Restated Collaboration Agreement, which altered key aspects of the collaboration pertaining to the HIV therapeutic. Most importantly, the Amended and Restated Collaboration Agreement allocated additional research and development responsibility to the Company with respect to the Company's HIV candidate and provided for additional funding by Gilead of such research and development activities as well as increased later stage development and commercial milestone payments.

Under the Gilead Collaboration Agreement, the Company granted Gilead an exclusive, royalty-bearing license to the Company's technology platforms. Upon entering into the agreement in June 2018, the Company received a non-refundable $10.0 million upfront payment from Gilead and upon signing of the Restated Gilead Collaboration Agreement in February 2022, the Company received a program initiation fee of $15.0 million. Gilead is also obligated to make additional payments to the Company upon the achievement of pre-clinical, development and commercial milestones. The development milestones amount to $140.0 million for the HBV program, and up to $172.5 million for the HIV program, inclusive of a $10.0 million program completion fee, payable upon Gilead's exercise of the option to pursue further development activities post Phase 1b. The commercial milestones amount to a total of $50.0 million for the HBV program, and $65.0 million for the HIV program. Additionally, Gilead is obligated to pay royalties on net sales for each program. Payments from Gilead generally have a 60 day payment term.

The $10.0 million upfront payment, the $15.0 million initiation fee and $13.0 million in milestone payments were initially recorded as deferred revenue in the consolidated balance sheet and are recognized as revenue when revenue recognition criteria are met. As of December 31, 2024, $5.5 million of such payments were still recorded as a liability in deferred revenues, current and non-current. As of December 31, 2023, $7.5 million of upfront and milestone payments were included as a liability in deferred revenues, current and non-current. Approximately 87% of deferred revenue is expected to be recognized as revenue in 2025 and the remaining 13% in 2026.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

In the year ended December 31, 2024, the Company recognized $6.7 million of the milestone and initiation payments that were originally recorded as deferred revenue. Furthermore, the Company recognized $0.8 million revenue from cost reimbursements for research and development services. In the year ended December 31, 2023, the Company recognized $7.1 million of the upfront and milestone payments that were originally recorded as deferred revenue and $1.4 million revenue from cost reimbursements for research and development services. In the year ended December 31, 2022, the Company recognized $3.7 million of the upfront and milestone payments that were originally recorded as deferred revenue, $5.2 million revenue from cost reimbursements for research and development services and $5.0 million revenue from a milestone achieved in December 2022.

Sublicense fees payable to certain licensors of technologies upon the receipt of the deferred upfront and milestone payments, were capitalized as a contract asset and will be amortized over the period in which the revenue from the triggering payment is recognized. As of December 31, 2024 and 2023, the contract asset relating to the sublicense payment was $0.2 million and $0.1 million, respectively, and there was no liability relating to sublicense payment.

Roche Collaboration and License Agreement

In October 2022, the Company entered into the Roche Collaboration Agreement whereby the Company and Roche agreed to collaborate with respect to the development of novel arenaviral immunotherapies for KRAS-mutated cancers and, potentially, a second, novel arenaviral immunotherapeutic program targeting specific undisclosed cancer antigens. In January 2024, Roche provided written notice of the termination of the Roche Collaboration Agreement to the Company. The termination was made according to Roche's right to terminate without cause, acknowledging that the Company had met all go-forward criteria under the agreement. Pursuant to the terms of the Roche Collaboration Agreement, following the termination notice, the Roche Collaboration Agreement terminated on April 25, 2024.

Under the terms of the original Roche Collaboration Agreement, the Company had granted Roche an exclusive, royalty-bearing license to the Company's technology platforms for KRAS-mutated cancers, and an option right to exclusively license a second, novel arenaviral immunotherapeutic program targeting undisclosed cancer antigens. Upon the termination effective date of April 25, 2024, the Company regained full control of the associated intellectual property portfolio and full collaboration and licensing rights for this program.

Upon signing the Roche Collaboration Agreement in October 2022, the Company received a non-refundable upfront payment of $25.0 million. This upfront payment, a $10.0 million milestone payment received in the three months ended March 31, 2023, and a $10.0 million milestone payment received in the three months ended June 30, 2024 were considered as part of the transaction price and were recognized as revenue when revenue recognition criteria were met over the period in which services were performed. As of December 31, 2024, no liabilities were recorded in deferred revenues, current and non-current. As of December 31, 2023, $26.8 million of such payments were included as a liability in deferred revenues, current and non-current.

The Company considered the termination by Roche as a contract modification of the combined performance obligations and the transaction price. The modification was accounted for on a cumulative catch-up basis, applying the revised percent of completion to the revised transaction price, resulting in an immediate increase of revenue in the period of the modification. The transaction price was recognized as revenue over the remaining performance period using updated total estimated research and development costs.

In the year ended December 31, 2024, the Company recognized revenues of $36.3 million of the upfront and milestone payments that were originally recorded as deferred revenue. Furthermore, the Company recognized $0.1 million of revenue from cost reimbursements for activities related to the preparation of a first in human trial of HB-700. In the year ended December 31, 2023, the Company recognized $11.1 million of the upfront and milestone payments that were originally recorded as deferred revenue. Furthermore, the Company recognized $0.5 million of revenue from cost reimbursements for activities related to the preparation of a first in human trial. In the year ended

December 31, 2022, the Company recognized $0.3 million of the upfront payment that was originally recorded as deferred revenue.

Sublicense fees payable to certain licensors of technologies upon the receipt of the deferred upfront and milestone payments, were capitalized as a contract asset and will be amortized over the period in which the revenue from the triggering payment is recognized. As of December 31, 2024, there was no contract asset and no liability relating to sublicense payments. As of December 31, 2023 the contract asset and the liability relating to the sublicense payment was $2.0 million and there was no liability relating to sublicense payments.

4. Restructuring

On January 29, 2024, the Company announced and began implementing its decision to prioritize the clinical development of its eseba-vec (formerly HB-200) program for the treatment of HPV16+ head and neck cancers and its two Gilead-partnered infectious disease programs and to pause development activities related to HB-300 and most of its preclinical research activities. In connection with this strategic refocus, the Company's board of directors approved a Restructuring Plan to rebalance the Company's cost structure, which originally included a reduction of the Company's workforce by approximately 30% and the discontinuation of the Company's GMP manufacturing facility project. This original part of the Restructuring Plan was completed by the end of the second quarter of 2024 and the Company recorded restructuring charges of $1.3 million in the six months ended June 30, 2024.

During the third quarter of 2024, the Company started an enterprise-wide initiative intended to improve its business through specialized organizational programs that include targeted cost-savings and continued to take actions to implement further restructuring actions, which included a further reduction of the Company's workforce by another approximately 20%. These continued restructuring actions are expected to be substantially completed by the end of the first quarter of 2025. The restructuring charges recorded for the continued restructuring actions for the three months ended September 30, 2024 were $0.9 million.

On November 18, 2024 the Company approved a plan to continue to improve its cost structure and operating efficiency, which includes a reduction in the Company's workforce by approximately 80% of the Company's then-current employee base and the closing and consolidation of office and laboratories in Vienna, Austria. The Company began the implementation of this restructuring plan in the fourth quarter of 2024 and expects these continued restructuring actions to be substantially completed by the end of the first half of 2025. The restructuring charges recorded for the continued restructuring actions for the three months ended December 31, 2024 were $0.5 million. This restructuring expenses relate primarily to disposal costs for the closing and consolidation of office and laboratories in Vienna, Austria, did not include social plan or severance payments and it is planned that the affected employees will continue to work throughout their termination period. In connection with the continued Restructuring Plan, in an effort to rebalance the Company's cost structure in alignment with the Company's strategic refocus and development of its oncology portfolio, the Company also announced that it will pause clinical development in its eseba-vec program, including an early termination of the Company's ongoing Phase 1/2 clinical trial for the treatment of HPV16+ cancers. Going forward, the Company may implement further cost-saving initiatives that could result in additional restructuring charges including severance and other employee charges.

As a result of the restructuring plan and the enterprise-wide initiative, the Company incurred the following charges which were included within Restructuring expense in the consolidated statements of operations and comprehensive loss.

HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

The following table summarizes the effect of the restructuring charges (in thousands):

	Year ended December 31,		
	2024	2023	2022
Restructuring expense			
Severance and other personnel expenses	$ 2,067	$ —	$ —
Professional fees, disposal costs and other related charges	$ 597	$ —	$ —
Total	$ 2,664	$ —	$ —

The following table summarizes a roll-forward of cash restructuring-related liabilities, which are included within Accrued expenses and other current liabilities in the consolidated balance sheets (in thousands):

	Severance and other personnel costs	Disposal costs, professional fees and other related charges	Total
Balance as of December 31, 2023	$ —	$ —	$ —
Severance and other personnel costs, professional fees and other related charges	2,067	597	2,664
Total payments	(1,493)	(329)	(1,822)
Balance as of December 31, 2024	$ 574	$ 268	$ 842

5. Impairment

As a result of the targeted cost-savings, restructuring actions, and strategic considerations resulting from the adoption of the restructuring plan, which included the termination of a part of the Company's rented office and laboratory space in Vienna, Austria, the Company assessed the recoverability of the long-lived assets relating to the leasehold improvements, laboratory equipment, furniture and fixtures, and computer equipment and software at December 31, 2024, and determined that the undiscounted cash flows of certain asset groups were below the carrying values, indicating impairment. The carrying values of the assets were written down to their estimated fair value, which was determined based on the cost approach. The impairment test was performed as of December 31, 2024 and the fair values are classified as Level 3 of the fair value hierarchy due to a mix of unobservable inputs utilized such as assumptions and estimates for the current replacement costs of similar assets adjusted for estimated depreciation and deterioration of the existing equipment and economic obsolescence, independent research in the market as well as actual quotes from market participants.

For the year ended December31, 2023, as a result of strategic considerations preceding the adoption of a restructuring plan, the Company assessed the recoverability of the long-lived assets relating to the GMP manufacturing project at December 31, 2023, and determined that the undiscounted cash flows of the asset group were below the carrying values, indicating impairment. The assets were written down to their estimated fair value, which was determined based on the cost approach.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

The following table summarizes the effect of non-cash impairment charges, which are included within Impairment expense in the consolidated statements of operations and comprehensive loss (in thousands):

	Year ended December 31,		
	2024	2023	2022
Non-cash impairment charges			
Asset write-offs	$ (4,004)	$ (12,766)	$ —
Total non-cash impairment charges	$ (4,004)	$ (12,766)	$ —

6. Fair Value of Financial Assets

The following tables present information about the Company's financial assets measured at fair value on a recurring basis and indicating the level of the fair value hierarchy utilized to determine such fair values (in thousands):

	Fair Value Measurement at December 31, 2024			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 13,200	$ —	$ —	$ 13,200
Assets held for sale	—	—	2,216	2,216
Total	$ 13,200	$ —	$ 2,216	$ 15,416

	Fair Value Measurement at December 31, 2023			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 91,084	$ —	$ —	$ 91,084
Total	$ 91,084	$ —	$ —	$ 91,084

During the year ended December 31, 2024, there were no transfers between Level 1, Level 2 and Level 3.

7. Property, plant and equipment, net and assets held for sale

Property, plant and equipment, net consisted of the following (in thousands):

	December 31, 2024	December 31, 2023
Land	$ —	$ 2,025
Leasehold improvements	3,095	3,300
Construction in progress	8	212
Laboratory equipment	—	8,722
Furniture and fixtures	601	654
Computer equipment and software	2,361	2,652
Property and equipment, gross	6,065	17,565
Less: Accumulated depreciation	(5,886)	(9,823)
Property and equipment, net	$ 179	$ 7,742

The decrease in property and equipment, net is driven by the reclassification of land and laboratory equipment to assets held for sale as of December 31, 2024, as well as impairment charges resulting from the adoption of the Restructuring Plan, which included the termination of a part of the Company's rented office and laboratory space in Vienna, Austria.

HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

Depreciation expense for continuing operations for the years ended December 31, 2024, 2023 and 2022 was $0.4 million, $2.0 million and $1.9 million, respectively.

In the year ended December 31, 2024 the Company recognized an impairment loss of $4.0 million. In the year ended December 31, 2023 the Company recognized an impairment loss of $12.8 million related to the GMP manufacturing facility project, which reduced the carrying value of this asset group to zero (see Note 5). There were no impairments in the year ended December 31, 2022. Impairment charges are included within Impairment expense in the consolidated statements of operations and comprehensive loss.

As of December 31, 2024, the following assets, all located in Vienna, Austria, were classified as held for sale and are presented as held for sale in the Company's consolidated balance sheet as of December 31, 2024:

Assets	Balance as of December 31, 2023	Additions to Assets Held for Sale	Assets Sold	Balance as of December 31, 2024
Land	$ —	$ 1,895	$ —	$ 1,895
Laboratory equipment	—	321	—	321
Total	$ —			$ 2,216

In December 2024, the Company began to actively market the land in Vienna, Austria, which was intended to use for the discontinued GMP manufacturing facility project. As such, the land has been reclassified as held for sale as of December 31, 2024. This asset is recognized at the lower of net book value or fair value less costs to sell. The Company evaluated the fair value of the land and determined fair value less costs to sell exceeded net book value. Accordingly, no impairment on the land was recorded during the year ended December 31, 2024. As a result of the termination of a part of the Company's rented office and laboratory space in Vienna, Austria, the Company had $0.3 million in laboratory equipment that met the criteria for classification as held for sale. These assets are recognized at the lower of net book value or fair value less costs to sell using a market approach. The Company evaluated the fair value of its assets held for sale and determined fair value of the assets held for sale less costs to sell to be lower than net book value. Accordingly, the Company recorded an impairment of $3.6 million on laboratory equipment held for sale during the year ended December 31, 2024 to reflect the difference between net book value and the fair value less costs to sell of assets held for sale. Such impairment charges are included within Impairment expense in the consolidated statements of operations and comprehensive loss.

8. Receivable research incentive

The Company participates in a research incentive program provided by the Austrian government under which it is entitled to reimbursement of a percentage of qualifying research and development expenses and capital expenditures incurred in Austria. Submissions for reimbursement under the program are submitted annually. Incentive amounts are generally paid out during the calendar year that follows the year of the expenses but remain subject to subsequent examinations by the responsible authority. Reimbursements received in excess of the recognized receivable research incentive for a certain period are recorded within other long term liabilities for potential repayment until such time that an audit has taken place, upon expiration of the potential reclaim period, or when it is no longer probable that a reclaim will happen. The years 2018 to present remain open to examination by the authorities.

Furthermore, the Company participated in the life sciences research and development program provided by the New York State government under which it was entitled to reimbursement of a percentage of qualifying research and development expenses in New York State up to $0.5 million per year for the years 2019 to 2021. Incentive amounts are generally paid out six to nine months after amended tax returns including a certificate of tax credit issued by Empire State Development are filed.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

The Company also participates in the New York City biotechnology tax credit program, according to which certain expenses for business in the biotechnology field in New York City limited to $0.25 million per year for three consecutive years from January 1, 2023 to December 31, 2025 are incentivized. The biotechnology tax credit can be refunded or applied against the next year's tax if it exceeds the current year's tax liability. A submission for reimbursement under the program for the year 2024 was submitted in January of 2025, and no receivable was recognized in the year ended December 31, 2024.

As of December 31, 2024, the Company recognized receivables of $23.4 million from the research incentive programs, which are reported in receivable research incentive in the Company's consolidated balance sheet. $23.2 million relate to the Austrian research incentive program, $0.1 million relate to the New York State life sciences research and development program and $0.1 million relate to the New York City biotechnology tax credit program. In February 2025, the Company received the payment related to the $17.3 million receivable from Austrian research incentive program for the years 2022 and 2023. As of December 31, 2023, the Company recognized receivables of $18.8 million from the research incentive programs with $17.3 million related to the Austrian research incentive program, $1.4 million relate to the New York State life sciences research and development program and $0.1 million relate to the New York City biotechnology tax credit program.

During the years ended December 31, 2024, 2023 and 2022, the Company recorded $7.4 million, $10.9 million and $7.3 million, respectively, of income related to the incentive programs within the Company's consolidated statements of operations and comprehensive loss as part of the grant income. Income for the year ended December 31, 2024 relate to the Austrian incentive program. Income for the year ended December 31, 2023 included $9.4 million related to the Austrian research incentive program, $1.4 million related to the New York State life sciences research and development program and $0.1 million related to the New York City biotechnology tax credit program. Income for the year ended December 31, 2022 related to the Austrian research incentive program. Research incentives depend on the eligible research and development expenses of the respective period.

9. Leases

The Company leases real estate, including office and laboratory space and has entered into various other agreements with respect to assets used in conducting its business. The Company's leases have remaining lease terms ranging from less than 1 year to 4.3 years. Some of the lease agreements contain rent holidays and rent escalation clauses that were included in the calculation of the right of use assets and lease liabilities. The Company's current leases qualify as operating leases. The Company is required to maintain a cash balance of $0.2 million to secure letters of credit associated with real estate leases. $0.1 million of this amount were classified as non-current restricted cash and $0.1 million were classified as current restricted cash in the consolidated balance sheet as of December 31, 2024.

HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

The following table summarizes the effect of lease costs in the Company's consolidated statements of operations and comprehensive loss (in thousands):

	Income statement location	Year ended December 31, 2024	Year ended December 31, 2023	Year ended December 31, 2022
Operating lease expenses	Research and development expenses	$ 1,374	$ 1,347	1,430
	General and administrative expenses	321	242	219
Finance lease amortization expenses	Research and development expenses	—	—	89
	General and administrative expenses	—	—	—
Interest on finance lease liabilities	Interest expenses	—	—	0
Sublease income	Other income (expense)	—	—	—
Net lease expense		$ 1,695	$ 1,589	1,738

The minimum lease payments for the next five years and thereafter are expected to be as follows (in thousands):

	December 31, 2024 Operating lease
2025	558
2026	208
2027	73
2028	73
2029	—
Thereafter	—
Total lease payments	912
Less: interest	37
Present value of lease liabilities	$ 875

The weighted average remaining lease term and weighted average discount rate of operating leases are as follows:

	December 31, 2024	December 31, 2023
Weighted average remaining lease term in years	2.0	3.7
Weighted average discount rate [1]	4.8 %	4.1 %

[1] The majority of the contracts are denominated in euros. The discount rate was determined on a currency-equivalent basis.

During the year ended December 31, 2024, the Company initiated the closing and consolidation of its office and laboratories in Vienna, Austria, which reduced the term of the related leases by approximately 2.5 years ending between the end of February 2025 and the end of June 2025. These lease terminations did not include additional right-of-use or lease liability other than the reduced lease term. The respective lease liabilities were remeasured and the amounts resulting from the remeasurement of the lease liabilities were recognized as an adjustment to the corresponding right of use assets.

HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

10. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	December 31, 2024	December 31, 2023
Salaries and bonuses	4,193	5,665
Social security contributions	259	340
Unearned grant income	—	52
Accrued external research and development expenses	1,845	4,594
Accrued external general and administration expenses	2,921	292
Accrued for property and equipment acquisitions	—	14
Accrued for restructuring expenses	842	—
Income taxes	—	367
Other accruals and liabilities	592	777
	$ 10,652	$ 12,101

11. Loans payable

As of December 31, 2024 and December 31, 2023, loans payable consisted of the following (in thousands):

	December 31, 2024	December 31, 2023
Loans from FFG	$ —	$ 1,172
Unamortized debt discount	—	(52)
Total loans payable, net	$ —	$ 1,120

In connection with the funding agreements with the Austrian Research Promotion Agency, (*Österreichische Forschungsförderungsgesellschaft,* or "FFG"), the Company has received various loans ("FFG Loans"). The FFG Loans were made on a project-by-project basis.

The FFG Loans bear interest at rates that were below market rates of interest. The Company accounted for the imputed benefit arising from the difference between an estimated market rate of interest and the rate of interest charged by FFG as grant income from FFG. On the date that FFG loan proceeds are received, the Company recognized the portion of the loan proceeds allocated to grant funding as a discount to the carrying value of the loan and as unearned income, which was recognized as grant income over the term of the funding agreement.

The Company recognized no grant income during the year ended December 31, 2024, and grant income of $0.3 million and $0.6 million during the years ended December 31, 2023 and 2022, respectively, related to the recognition of the unearned income recorded for the imputed benefit of FFG Loans at below-market interest rates. No current unearned income related to the imputed benefit of FFG Loans at below-market interest rates as of December 31, 2024 and current unearned income of less than $0.1 million as of December 31, 2023.

In addition, the Company had recorded a discount to the carrying value of each FFG Loan for the portion of the loan proceeds allocated to grant funding, which was being amortized to interest expense over the term of the loan using the effective interest method. As of December 31, 2024 there was no unamortized debt discount related to FFG Loans and as of December 31, 2023, the unamortized debt discount related to FFG Loans was $0.1 million.

The Company recognized interest expense of less than $0.1 million, $0.3 million and $0.7 million during the years ended December 31, 2024, 2023 and 2022, respectively, related to the FFG Loans, which included interest expense

related to the amortization of debt discount of less than $0.1 million, $0.3 million and $0.7 million during the years ended December 31, 2024, 2023 and 2022, respectively. As of December 31, 2024, the Company has no outstanding loans payable. A final principal repayment of $1.1 million was made in the year ended December 31, 2024. A principal repayment of $1.8 million was made in the year ended December 31, 2023.

The Company used an estimated market rate of 20%, which was determined based on an average of the available interest rates on unsecured loans to comparable companies. A 10% increase or decrease in the estimated market rate of interest would have had no material impact on grant income or liabilities.

In the event that the underlying program research resulted in a scientific or technical failure, the principal then outstanding under any loan may be forgiven by FFG on a project-by-project basis. The FFG Loans contained no financial covenants and were not secured by any of the Company's assets.

12. Common stock, Class A common stock and convertible preferred stock

The Company’s capital structure consists of common stock, Class A common stock and preferred stock. On July 9, 2024, the Company effected a reverse stock split of the outstanding shares of its common stock on a one-for-ten basis (see Note 2). As of December 31, 2024, the Company was authorized to issue 40,000,000 shares of common stock, 3,900,000 shares of Class A common stock and 10,000,000 shares of preferred stock. The Company has designated 2,978 of the 10,000,000 authorized shares of preferred stock as non-voting Series A convertible preferred stock, 15,800 of the 10,000,000 authorized shares of preferred stock as non-voting Series A-1 convertible preferred stock and 15,268 of the 10,000,000 authorized shares of preferred stock as non-voting Series A-2 convertible preferred stock. As of December 31, 2024, the Company had 9,655,022 shares of common stock, 2,399,517 shares of Class A common stock, 370 shares of Series A convertible preferred stock, 10,800 shares of Series A-1 convertible preferred stock and 15,268 shares of Series A-2 convertible preferred stock outstanding and issued. As a result of the Reverse Stock Split, 37 shares of common stock were retired due to round-down effects and redeemed in cash.

On June 5, 2023, the Company closed a public offering of 2,290,077 (22,900,768 before the Reverse Stock Split) shares of its common stock and 15,268 shares of Series A-2 convertible preferred stock at a public offering price of $13.10 and $1,310.00 per share, respectively, for net proceeds of $46.2 million after deducting underwriting discounts and commissions and offering expenses.

On February 15, 2022, the Company entered into a stock purchase agreement with Gilead (“Stock Purchase Agreement”), that requires Gilead, at the Company’s option, to purchase up to $35.0 million of the Company’s common stock. On February 15, 2022, Gilead purchased an initial amount of 166,666 (1,666,666 before the Reverse Stock Split) shares of the Company’s common stock in exchange for $5.0 million in cash at a purchase price per share equal to $30.00. On December 20, 2023, the parties amended and restated the Stock Purchase Agreement (the “Amended Stock Purchase Agreement”) and Gilead purchased 1,500,000 (15,000,000 before the Reverse Stock Split) shares of the Company’s common stock in exchange for approximately $21.25 million in cash at a purchase price per share equal to $14.167. Pursuant to the terms of the Amended Stock Purchase Agreement, the Company may require Gilead to purchase the balance of the $8.75 million of common stock as participation in potential future equity raises. The Company’s right to sell shares of its common stock to Gilead is subject to specified limitations, including a limitation that prevents the Company from requesting purchases of shares of common stock by Gilead that would result in a beneficial ownership of more than 19.9% of the total number of outstanding shares of common stock by Gilead.

The Company has three series of preferred stock authorized, issued and outstanding as of December 31, 2024: Series A convertible preferred stock, Series A-1 convertible preferred stock, and Series A-2 convertible preferred stock. Shares of Series A, Series A-1 and Series A-2 convertible preferred stock may be independently converted into common stock. Holders of Series A, Series A-1 and Series A-2 convertible preferred stock have equal rights, powers and privileges.

Holders of common stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. The holders of Class A common stock and Series A, Series A-1 and Series A-2 convertible preferred stock are not entitled to vote, except as required by law. The holders of common stock and Class A common stock do not have any cumulative voting rights.

Each holder of Class A common stock has the right to convert each share of Class A common stock into ten shares of common stock at such holder's election. Each holder of Series A, Series A-1 and Series A-2 convertible preferred stock has the right to convert each share of Series A, Series A-1 and Series A-2 convertible preferred stock into 100 shares of common stock at any time at the holder's option, provided that the holder will be prohibited, subject to certain exceptions, from converting Series A, Series A-1 and Series A-2 convertible preferred stock into shares of the Company's common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 9.99% of the total number of shares of the Company's common stock then issued and outstanding.

Holders of common stock and Class A common stock are entitled to receive ratably any dividends declared by the board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Holders of Series A. Series A-1 and Series A-2 preferred stock will be entitled to receive dividends at a rate equal to (on an as-if-converted-to-common stock basis), and in the same form and manner as, dividends actually paid on shares of the Company's common stock. Holders of common stock and Class A common stock have no preemptive rights, conversion rights, or other subscription rights or redemption or sinking fund provisions.

In the event of a liquidation, dissolution, or winding up of the Company, holders of the Company's Series A, Series A-1 and Series A-2 convertible preferred stock will receive a payment equal to $0.001 per share of Series A, Series A-1 and Series A-2 convertible preferred stock before any proceeds are distributed to the holders of common stock. Then, holders of common stock and Class A common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities.

There were 370 shares of Series A convertible preferred stock, 10,800 shares of Series A-1 convertible preferred stock and 15,268 shares of Series A-2 convertible preferred stock outstanding as of December 31, 2024 and December 31, 2023, respectively. In May 2023 certain of the Company's stockholders elected to convert an aggregate of 1,327 shares of Series A convertible preferred stock and an aggregate of 5,000 shares of Series A-1 convertible preferred stock owned by such holders into an aggregate of 632,700 (6,327,000 before the Reverse Stock Split) shares of the Company's common stock.

13. Stock-based compensation

2018 Stock Option and Grant Plan

In June 2018, the Company's board of directors approved the 2018 Stock Option and Grant Plan. Options granted under the 2018 Stock Option and Grant Plan generally vest over four years, with 25% of the options vesting upon the first anniversary of the grant date and the remaining 75% of the options vesting in 12 equal quarterly installments following the first anniversary of the grant date, provided the option holder continues to have an employment or service relationship with the Company on each vesting date. The options expire on the 10th anniversary of the grant date. As of December 31, 2024, 73,935 options granted under the 2018 Stock Option and Grant Plan remained outstanding. Any authorization to issue new options under the 2018 Stock Option and Grant Plan was cancelled upon the effectiveness of the 2019 Stock Option and Incentive Plan and no further awards will be granted under the 2018 Plan.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

2019 Stock Option and Incentive Plan

On April 1, 2019, the Company's stockholders approved the 2019 Stock Option and Incentive Plan, which became effective as of the effective date of the registration statement in connection with the Company's IPO. The plan provides for the grant of shares of restricted stock, long term incentive awards, stock options or other equity-based awards. As of December 31, 2024, the maximum number of shares of the Company's common stock that may be issued under the Company's 2019 Stock Option and Incentive Plan was 1,202,548 shares which shall be cumulatively increased on January 1 of each year by up to 4.0% of the then outstanding number of shares of common stock and Class A common stock. Options granted under the 2019 Stock Option and Incentive Plan generally vest over four years, with 25% of the options vesting upon the first anniversary of the grant date and the remaining 75% of the options vesting in 12 equal quarterly installments following the first anniversary of the grant date, provided the option holder continues to have an employment or service relationship with the Company on each vesting date. Initial options granted to non-executive directors upon their election generally vest over a three-year term with 33% of the options vesting upon the first anniversary of the grant date and the remaining 67% of the options vesting in eight equal quarterly installments following the first anniversary of the grant date and the next annual meeting of stockholders. Annual option re-grants to non-executive directors generally vest on the earlier of the first anniversary of the grant date. The options expire on the 10th anniversary of the grant date. For each option the beneficiary is entitled to receive one share of common stock upon the exercise of the option.

On August 7, 2023, the Company's board of directors approved a one-time offer to eligible non-executive, non-director employees to exchange certain outstanding stock options for new stock options with modified terms. Under the stock option exchange program (the "Offer"), the Company offered to exchange certain out-of-the-money stock options for new stock options at an exchange ratio of between 1.75 and 2.50 surrendered options for one new option exercisable for shares of common stock with a lower exercise price and extended vesting terms. Pursuant to the Offer, a total of 82 eligible participants tendered, and the Company accepted for cancellation, stock options to purchase an aggregate of 54,323 shares of the Company's common stock with exercise prices between $69.00 and $140.00. The eligible options that were accepted for cancellation represented approximately 86.6% of the total shares of common stock underlying all of the eligible options. In accordance with the terms and conditions of the Offer, on September 12, 2023, the Company issued new options to purchase an aggregate of 27,376 shares of common stock in exchange for the cancellation of the tendered eligible options. The exercise price per share of each new option granted in the Offer is $10.00. New options issued for previously vested stock options vest on the first anniversary of the grant date and new options issued for previously unvested stock options vest over a three-year term in twelve equal quarterly installments. The stock option exchange offer resulted in incremental stock-based compensation expense of $0.1 million, recognized using the graded-vesting method over the remaining requisite service period of the new stock options.

2023 Inducement Plan

On April 7, 2023, the Company's board of directors adopted the Company's 2023 Inducement Plan (the "2023 Inducement Plan") pursuant to which the Company reserved 50,000 shares of common stock for issuance under the 2023 Inducement Plan. The 2023 Inducement Plan provides for the grant of non-statutory stock options to eligible individuals. In accordance with Nasdaq Marketplace Rule 5635(c)(4), awards under the 2023 Inducement Plan may only be made to individuals not previously employees or directors of the Company (or following such individuals' bona fide period of non-employment with the Company), as an inducement material to the individuals' entry into employment with the Company. Awards granted under the 2023 Inducement Plan must be approved by either a majority of the Company's independent directors or the compensation committee of the Company's board of directors. As of December 31, 2024, the Company had 10,000 shares of its common stock available for future issuance under the 2023 Inducement Plan.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

The following table presents a summary of awards outstanding:

	As of December 31, 2024			
	2018 Plan	2019 Plan	Inducement Awards	Total
Granted and outstanding awards:				
Stock options	73,935	975,492	40,000	1,089,427
Total	73,935	975,492	40,000	1,089,427

Stock option valuation

The Company estimates the option's fair value on the date of grant using the Black-Scholes option-pricing model. Black-Scholes utilizes assumptions related to expected term, volatility, the risk-free interest rate, the dividend and employee exercise behavior. Forfeitures are accounted for when they occur. Expected volatilities utilized in the Black-Scholes model are based on historical volatilities of a group of comparable companies. The group of representative companies have characteristics similar to the Company, including the stage of product development and focus on the life science industry. Management believes that this represents the most accurate basis for estimating expected future volatilities under the current conditions. The risk-free interest rate is derived from the yields for U.S. Treasuries with a remaining term approximating the expected life of the options. The expected term represents the period of time that the options granted are expected to be outstanding.

The following table summarizes the assumptions used in the Black-Scholes option-pricing model for estimating the fair value of stock options granted during:

	Year ended December 31,		
	2024	2023	2022
Risk-free interest rate	4.48 %	3.70 %	3.09 %
Expected term (in years)	6.1	5.7	6.0
Expected volatility	101.7 %	93.6 %	85.4 %
Expected dividends	— %	— %	— %

For the 2024, 2023 and 2022 grants, the Company used the simplified method in developing an estimate of the expected term due to a lack of historical exercise data.

HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

Stock option activity

The following table summarizes the Company's stock option activity since January 1, 2024 (in thousands, except share and per share amounts):

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2023	810,942	$ 42.76	7.4	$ 486
Granted	465,902	7.14		
Exercised	—	—		
Forfeited	(187,417)	27.28		
Outstanding as of December 31, 2024	1,089,427	$ 30.19	5.5	$ 69
Options exercisable as of December 31, 2024	520,033	$ 53.55	3.8	$ 69
Options unvested as of December 31, 2024	569,394	$ 8.85	7.1	$ —

The aggregate intrinsic value of stock options was calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock. The fair value per common stock used for calculating the intrinsic values as of December 31, 2024, December 31, 2023 and December 31, 2022, was $2.01, $8.10 and $8.10, respectively.

No options were exercised during the year ended December 31, 2024. The aggregate intrinsic value of options exercised during the years ended December 31, 2023 and 2022 was less than $0.1 million and $0.1 million, respectively.

The weighted average grant-date fair value per share of stock options granted during the years ended December 31, 2024, 2023 and 2022 was $5.83, $5.52 and $15.50, respectively.

The total fair value of stock options vested during the years ended December 31, 2024 and 2023 was $2.3 million and $5.1 million, respectively.

No cash was received from stock option exercises under share-based payment arrangements for the year ended December 31, 2024. Cash received from stock option exercises under share-based payment arrangements for the years ended December 31, 2023 and 2022 was $1 thousand and $3 thousand, respectively.

Restricted Stock Units

In July 2024, the Company granted restricted stock units with time-based vesting conditions to officers. The restricted stock units vest in two equal installments in July 2025 and in July 2026. In December 2024, the Company granted restricted stock units with time-based vesting conditions to employees. The restricted stock units vest in two equal installments in March 2025 and in December 2025. The Company measures the fair value of restricted stock units on the date of grant using the underlying common stock fair value. Expenses are recorded using the graded-vesting method.

HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

The table below summarizes the Company's restricted stock unit activity since December 31, 2023:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding as of December 31, 2023	—	$ —
Granted	369,070	4.37
Vested	—	—
Forfeited	—	—
Outstanding as of December 31, 2024	369,070	$ 4.37

Stock-based compensation

Stock-based compensation expense was classified in the consolidated statements of operations and comprehensive loss as follows (in thousands):

	Year ended December 31,		
	2024	2023	2022
Research and development expenses[(1)]	$ 523	$ 861	$ 2,074
General and administrative expenses[(1)]	1,491	1,484	2,969
	$ 2,014	$ 2,345	$ 5,043

As of December 31, 2024 total unrecognized compensation costs related to the unvested stock-based awards were $1.5 million, which are expected to be recognized over a weighted average period of 1.6 years.

14. Income taxes

Income tax benefits during the year ended December 31, 2024 resulted from US federal income tax, partially offset by minimum tax obligations in Austria. Income tax expense during the years ended December 31, 2023 and December 31, 2022 resulted from US federal and state income tax as well as minimum tax obligations in Austria. During the years ended December 31, 2024, 2023 and 2022, the Company recorded no income tax benefits for the net operating losses incurred in each year, due to its uncertainty of realizing a benefit from those items. The Company's losses before income taxes were generated in the United States and Austria.

For financial reporting purposes, losses before income taxes for the years ended December 31, 2024, 2023 and 2022 consisted of the following (in thousands):

	Year ended December 31,		
	2024	2023	2022
United States	$ (1,341)	$ 1,710	$ (7,222)
Foreign (Austria)	(42,268)	(82,922)	(57,463)
Net loss before tax	$ (43,609)	$ (81,212)	$ (64,685)

HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

The components of the consolidated income tax provision for the years ended December 31, 2024, 2023 and 2022 were as follows (in thousands):

	Year ended December 31,		
	2024	2023	2022
Current			
Federal	$ (107)	$ 145	$ 217
State	—	222	12
Foreign (Austria)	1	1	1
Total current tax (benefit) expense	(106)	368	230
Deferred			
Federal	—	—	—
State	—	—	—
Foreign (Austria)	—	—	—
Total deferred tax expense	—	—	—
Total income tax (benefit) expense	$ (106)	$ 368	$ 230

The Company's worldwide effective tax rate for the years ended December 31, 2024, 2023 and 2022 was (0.2)%, 0.5% and 0.3%, respectively. The tax rate is affected by recurring items, such as tax rates in foreign jurisdictions and the relative amounts of income earned in those jurisdictions, which is expected to be fairly consistent in the near term. It is also affected by discrete items that may occur in any given year, but are not consistent from year to year. The following items had the most significant impact on the difference between the statutory U.S. federal income tax rate of 21% for the years ended December 31, 2024, 2023 and 2022 and the effective tax rate:

	Year ended December 31,		
	2024	2023	2022
U.S. federal statutory income tax rate	(21.0)%	(21.0)%	(21.0)%
State income taxes, net of federal benefit	—	(0.3)	—
Foreign tax rate differential[(1)]	(2.0)	(2.7)	(4.0)
Not taxable government grants[(2)]	(4.9)	(6.8)	(3.8)
Stock-based compensation	0.8	0.6	0.5
Global intangible low-taxed income	—	2.3	1.4
Other	2.2	0.2	0.1
Change in deferred tax asset valuation allowance[(3)]	24.7	28.2	27.1
Effective income tax rate	(0.2)%	0.5 %	0.3 %

[(1)] The 2.0% increase for the year ended December 31, 2024, the 2.7% increase for the year ended December 31, 2023, and the 4.0% increase for the year ended December 31, 2022, resulted from tax rate differences between U.S. and non-U.S. jurisdictions. Net loss before tax was principally generated in Austria, where the statutory tax rate is 23% for the year ended December 31, 2024, 24% for the year ended December 31, 2023 and 25% for the year ended December 31, 2022.

[(2)] For the years ended December 31, 2024, 2023 and 2022, 4.9%, 6.8% and 3.8% increase, respectively, resulted from non-taxable research subsidies received from Austrian government agencies.

[(3)] For the years ended December 31, 2024, 2023 and 2022, 24.7% reduction, 28.2% reduction and 27.1% reduction, respectively, resulted from changes in valuation allowance on deferred tax assets. Deferred tax assets will only be recovered when the generation of future taxable income is more likely than not. Due to the nature of the Company's research activities and the inherent uncertainties the deferred tax assets are fully offset by a valuation allowance.

HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

Components of the net deferred tax assets or liabilities as of the years ended December 31, 2024 and 2023 consisted of the following (in thousands):

	Year ended December 31,	
	2024	2023
Deferred tax assets:		
Net operating loss carryforwards	$ 94,272	$ 87,445
Capitalized R&D expenses	(0)	2,657
Credit carryforwards	1,787	1,265
Accrued expenses and other	182	317
Stock-based compensation	1,426	1,421
Operating lease liabilities	203	1,254
Total deferred tax assets	97,870	94,359
Valuation allowance	(93,382)	(89,309)
Total deferred tax assets	4,488	5,050
Deferred tax liabilities:		
Accrued expenses and other	(4,281)	(3,774)
Fixed assets	(2)	(14)
Operating lease right of use asset	(205)	(1,262)
Total deferred tax liabilities	(4,488)	(5,050)
Net deferred tax assets	$ —	$ —

As of December 31, 2024, 2023 and 2022, the Company had Austrian net operating loss carryforwards of $400.9 million, $378.1 million and $275.3 million, respectively, that do not expire, however these carryforwards are limited to 75% of the taxable income in any one tax period. As of December 31, 2024, 2023 and 2022, the Company had federal net operating loss carryforwards that were generated after December 31, 2017 of $9.5 million, $2.2 million and $13.8 million, respectively, that do not expire, however these carryforwards are limited to 80% of the taxable income in any one tax period. In the year ended December 31, 2024 the Company filed for a method change which changed the net operating loss carry forwards for the year ended December 31, 2023 from $2.2 million to $10.5 million. The Company generated US taxable income in the current year and was able to offset 80% the taxable income utilizing net operating loss carryforwards which gave rise to current taxes during 2023. The federal net operating loss carryforward as of December 31, 2024 was $9.5 million, and US Federal net operating loss carryforward as of December 31, 2023 was $2.2 million. The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets resulting from its net operating loss carryforwards. Management has considered the Company's history of cumulative net losses incurred since inception and the uncertainties related to the long period necessary to achieve profits from commercialization of any products and has concluded that it is more likely than not that the Company will not realize the benefits of its deferred tax assets. Accordingly, a full valuation allowance has been established against the deferred tax assets as of December 31, 2024, 2023 and 2022. According to a tax reform in Austria in 2022, the corporate income tax rate was reduced from 24.0% to 23.0% in 2024. The tax rate of 23.0% was used to determine deferred taxes and the valuation allowance for the Austrian business. Management reevaluates the positive and negative evidence at each reporting period.

The amount of the deferred tax asset considered realizable, however, could be adjusted if estimates of future taxable income during the carryforward period are reduced or increased or if objective negative evidence in the form of

losses is no longer present and additional weight may be given to subjective evidence. The tax years in which the tax carryforwards were generated may still be adjusted upon examination by the tax authorities.

Changes in the valuation allowance for deferred tax assets during the years ended December 31, 2024, 2023 and 2022 related primarily to the increases in net operating loss carryforwards as follows (in thousands):

	Year ended December 31,		
	2024	2023	2022
Valuation allowance at beginning of period	$ (89,309)	$ (65,774)	$ (53,728)
Increases	(4,073)	(23,535)	(12,046)
Valuation allowance at end of period	$ (93,382)	$ (89,309)	$ (65,774)

On December 22, 2017, the United States enacted the Tax Cuts and Jobs Act (“Tax Reform Legislation” or “TCJA”). The Tax Reform Legislation introduced section 951A, a new tax on so-called “global intangible low-taxed income”. GILTI applies to income of a controlled foreign corporation (“CFC”) that is not otherwise subpart F income, and consists of the excess "tested income" over a 10% return on the CFC's “qualified business asset investment,” or “QBAI”. QBAI is the total tax basis of the CFC's depreciable, tangible property used in the production of tested income. The full amount of GILTI is included in taxable income. The GILTI inclusion is then reduced by 50% (reduced to 37.5% after 2025). However, that reduction in GILTI may be limited based on the level of U.S. taxable income. A limited allowance for foreign tax credits is allowed that would reduce the U.S. tax cost. GILTI foreign tax credits can only reduce U.S. taxes owed on GILTI and are not eligible for carryforward. The Company's Austrian subsidiary falls under the category of a CFC and due to the nature of its business model as a technology company, there may not be a material amount of tangible assets if this subsidiary starts to generate profits. GILTI taxation therefore may be applicable. The Company considered no GILTI inclusion for the year ended December 31, 2024, and previously estimated $8.8 million of GILTI inclusion for the tax year ended December 31, 2023. No U.S. tax on GILTI, net of research credits, for the year ended December 31, 2024, and U.S. tax on GILTI, net of research credits, of $0.4 million for the year ended December 31, 2023.

The Company files income tax returns in the U.S. federal jurisdiction as well as in New York. The tax years from 2018 to present remain open to examination by the jurisdictions in which the Company is subject to tax. There are currently no pending income tax examinations in the U.S. Furthermore, the Company files income tax returns in Austria. The tax years 2018 to present remain open to examination by the jurisdiction. There are currently no pending income tax examinations in Austria.

The Company evaluates tax positions for recognition using a more likely than not recognition threshold, and those tax positions eligible for recognition are measured as the largest amount of tax benefit that is greater than 50% likely of being realized upon the effective settlement with a taxing authority that has full knowledge of all relevant information. As of December 31, 2024 and 2023, the Company had no unrecognized income tax benefits that would affect the Company’s effective tax rate if recognized.

15. Commitments and contingencies

Contract manufacturing arrangements

The Company has entered into arrangements with contract manufacturing organizations (“CMOs”) for manufacturing of materials for research and development purposes, including manufacturing of clinical trial materials. These contracts generally provide for non-cancellable obligations or cancellation penalties depending on the time of cancellation. As of December 31, 2024, the Company’s total non-cancellable obligations under contracts with CMOs were $4.7 million, which relates to 2025 deliverables.

HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

Intellectual property licenses

The Company has entered into certain license agreements under which it is obligated to make milestone payments upon the achievement of certain development and regulatory milestones, to pay royalties on net sales of licensed products, and to pay a percentage of the sublicense fees which the Company receives from its sublicensees.

In the years ended December 31, 2024, 2023 and 2022, the Company recorded $3.6 million, $1.6 million and $1.0 million, respectively, in licensing fees related to intellectual property licenses as research and development expenses. The amount is mainly related to the upfront payment and milestone payments received by the Company under the Gilead Collaboration Agreement and the Roche Collaboration Agreement. The amount recognized as expenses has been agreed to by the licensors but calculation of sublicensing fees on future payments may be subject to interpretation and may change until agreed to by the receiving party.

Indemnification agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and senior management that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any claims under indemnification arrangements, and it has not accrued any liabilities related to such obligations in its consolidated financial statements as of December 31, 2024 or December 31, 2023.

Legal proceedings

The Company is not currently a party to any material legal proceedings. From time to time, the Company may become involved in litigation or legal proceedings relating to claims arising in the ordinary course of business. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses the costs related to such legal proceedings as incurred.

16. 401(k) Savings Plan

The Company established a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. This plan provides that eligible employees can elect to contribute to the 401(k) Plan, subject to certain limitations, on a pretax basis. The Company matches up to 100% of the first 4% of each employee's contribution. During the years ended December 31, 2024, December 31, 2023 and December 31, 2022 expenses recognized for the 401(k) Plan were $0.4 million, $0.6 million and $0.6 million, respectively.

HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

17. Net loss per share

The following table sets forth the computation of the basic and diluted net loss per share attributable to common stockholders (in thousands, except for share and per share amounts):

	Year ended December 31,		
	2024	2023	2022
Numerator:			
Net loss	$ (43,503)	$ (81,580)	$ (64,915)
Denominator:			
Weighted-average common shares outstanding, basic and diluted	9,894,994	7,242,268	5,074,308
Weighted-average Series A convertible preferred shares outstanding, basic and diluted, presented as if converted into common stock[(1)]	37,000	83,536	169,700
Weighted-average Series A-1 convertible preferred shares outstanding, basic and diluted, presented as if converted into common stock[(1)]	1,080,000	1,252,603	1,307,288
Weighted-average Series A-2 convertible preferred shares outstanding, basic and diluted, presented as if converted into common stock[(1)]	1,526,800	874,250	—
Total number of shares used to calculate net loss per share, basic and diluted	12,538,794	9,452,657	6,551,296
Net loss per share, basic and diluted	$ (3.47)	$ (8.63)	$ (9.91)

[(1)] Class A common stock and Series A, Series A-1 and Series A-2 convertible preferred stock are participating securities that have substantially the same terms and features as the Company's common stock. The Class A common stock and Series A, Series A-1 and Series A-2 convertible preferred stock are therefore included in the weighted-average number of shares outstanding to calculate net loss per share, basic and diluted as if converted into common stock. Each ten shares of Class A common stock and each share of Series A, Series A-1 and Series A-2 convertible preferred stock is independently convertible into one and 100 shares of common stock, respectively. In the year ended December 31, 2024, 239,952 shares of the Company's common stock were issuable upon conversion of the Class A common stock, 37,000 shares of the Company's common stock were issuable upon conversion of Series A convertible preferred stock, 1,080,000 shares of the Company's common stock were issuable upon conversion of Series A-1 convertible preferred stock and 1,526,800 shares of the Company's common stock were issuable upon conversion of Series A-2 convertible preferred stock (see Note 12).

Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share for all periods as the inclusion of all potential common shares (common stock and Class A common stock) outstanding would have been anti-dilutive. Potentially dilutive securities that were not included in the diluted per share calculations because they would be anti-dilutive were as follows:

	Year ended December 31,		
	2024	2023	2022
Options issued and outstanding	1,089,427	810,942	653,053
Unvested restricted stock units	369,070	—	—
Total	1,458,497	810,942	653,053

HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

18. Related parties

Effective September 15, 2023, Malte Peters, a member of the Company's board of directors, agreed to lead the Company's clinical activities as ad interim Senior Clinical Advisor. During the years ended December 31, 2024 and December 31, 2023, the Company recorded expense of $0.2 million and $0.1 million, respectively, related to a consultancy services agreement entered into with Dr. Peters, effective September 15, 2023. The consultancy services agreement was terminated on March 31, 2024. In the year ended December 31, 2022 the Company did not record any related party transactions.

19. Reportable segments

The following represents segment information for the Company's single operating segment, for the periods presented (in thousands):

	Year ended December 31,		
	2024	2023	2022
Revenue	$ 43,946	$ 20,129	$ 14,249
Add (deduct):			
Direct research and development expense	$ (39,635)	$ (48,168)	$ (35,828)
Consulting and professional services expense	(11,728)	(10,088)	(11,464)
Personnel expenses, excluding stock-based compensation[1]	(27,830)	(33,670)	(22,348)
Stock-based compensation	(2,014)	(2,345)	(5,043)
Depreciation and amortization expense[2]	(1,107)	(1,955)	(1,865)
Other segment items[3]	(8,940)	(10,091)	(3,332)
Interest income	3,701	5,293	1,633
Interest expense	(2)	(317)	(687)
Income tax benefit (expense)	$ 106	$ (368)	$ (230)
Segment net loss	$ (43,503)	$ (81,580)	$ (64,915)
Adjustments and reconciling items	$ —	$ —	$ —
Consolidated net loss	$ (43,503)	$ (81,580)	$ (64,915)

[1] Personnel expenses include expenses for personnel, recruiting, training and travel
[2] Depreciation and amortization expenses include depreciation for assets held for sale
[3] Other segment items primarily include expenses for restructuring, impairment, other overhead, as well as foreign currency exchange gains and losses, and grant income

20. Subsequent events

Potential combination of Poolbeg and HOOKIPA

On January 2, 2025, the Company and Poolbeg Pharma plc ("Poolbeg") released an announcement pursuant to Rule 2.4 of the U.K. City Code on Takeovers and Mergers that the Company and Poolbeg entered into non-binding discussions for the potential acquisition of the entire issued share capital of Poolbeg to create a clinical-stage biopharmaceutical company focused on developing and commercializing innovative medicines for critical unmet medical needs, with a special focus on next-generation immunotherapies for the treatment of cancer and other serious diseases. On February 20, 2025, the Company issued an announcement pursuant to Rule 2.8 of the U.K. City Code on Takeovers and Mergers disclosing that the Company's Board of Directors determined that it does not intend to make an

HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

offer for Poolbeg under Rule 2.7 of the U.K. City Code on Takeovers and Mergers. Accordingly, the Company's non-binding discussions with Poolbeg related to the Potential Combination have been terminated.

In connection with this potential combination, the Company has incurred transaction costs of $1.3 million in the year ended December 31, 2024 for consulting and professional services. These costs primarily relate to legal, financial advisory, and due diligence services.

Exhibit 10.14

T E R M I N A T I O N A G R E E M E N T

entered into by and between

HOOKIPA Biotech GmbH (FN 491551w)
Helmut-Qualtinger-Gasse 2
1030 Vienna, Austria
(the "Company")

and

Joern Aldag
Date of birth ****
Address ****
(the "Executive")

as follows:

1. The Company and the Executive are parties to an indefinite employment agreement. The Executive served as the Chief Executive Officer of HOOKIPA Pharma Inc. (as sole shareholder of the Company) and as Managing Director of the Company. The Executive was most recently removed from these positions with effect from 22.07.2024 by resolution of the responsible bodies. At the same time, the employment contract was terminated by the Company with 6 months' notice to the end of the month, i.e. to 31.01.2025. The Executive has also resigned as a director of HOOKIPA Pharma, Inc. on 23.07.2024.

2. The parties agree that the employment contract will end by mutual agreement on 31.07.2024 (the "Termination Date"). It is noted that there was never an employment contract between HOOKIPA Pharma Inc. and the Executive.

3. The Executive is released from his obligation to provide any services ("garden leave") with effect from 22.07.2024. Due to the revocation the Executive is no longer authorised or allowed to represent the Company externally, including sending any emails, making any phone calls or otherwise responding to other parties or acting on behalf of the Company. This obligation also covers any communication relating to the business to individuals within the company, including employees and contractors. Regardless the Executive will be available to a reasonable extent during the garden leave period

to answer questions by phone, videocalls, or his private email to the new CEO/CFO and/or supervisory board members, even after the Termination Date until 30.04.2026.

4. Until the Termination Date, the Executive must fully comply with all statutory, contractual, and ancillary contractual obligations, including those arising from the Austrian Limited Liability Companies Act (*GmbH-Gesetz*) and the Salaried Employees Act (*Angestelltengesetz*).

5. Until the Termination Date the Executive shall continue to receive his monthly base salary and all other monthly paid benefits.

6. The Executive shall return to the Company all keys, key cards, laptop, company phone, credit cards, and all equipment, which he used and kept during the employment at the latest on 31.08.2024. The Executive shall immediately return to the Company's registered office any equipment, company documents and objects made available to him as well as any (electronic) copies made of them, insofar as these are still in his possession, without further request, unless he has already fulfilled this obligation.

7. The Executive is strictly obliged, during and after the Termination Date, to keep secret from anyone all internal HOOKIPA Pharma Inc. and Company matters of which he became aware during his employment, in particular business and trade secrets within the meaning of the Austrian Unfair Competition Act (*UWG*) and all other information that is expressly marked as confidential by the Company or HOOKIPA Pharma Inc. or is to be regarded as confidential according to the Company's express will or the will discernible from the circumstances. This does not apply if the Executive is obliged to disclose such information by mandatory law.

   The obligations arising from the employment agreement under 6 (a) (Confidential Information), 6 (b) (Confidentiality) and 6 (c) (Documents, Records, etc.)) remain in force without any time limit.

8. The Executive will observe all obligations arising from the employment agreement under 6 (d) (Noncompetition and Nonsolicitation) for a period of six months from the Termination Date, i.e. until 31.01.2025.

9. The Company will pay the Executive (taking into consideration but exceeding 4 (b) (i) of the employment agreement) a Severance Amount equal to 150 % of the annual Executive's Base Salary, i.e. Euro 786,905.91 gross. Payment will be made with the final settlement of the employment relationship within 14 days.

10. The Executive is entitled to options according to the respective plans. Because of the termination of the employment, the options will continue to vest until the 31.01.2025. The parties agree that the vesting of the 2024 April Regrant Award is accelerated, so that all options under this 2024 April Regrant Award are fully vested on the 31.01.2025. As a result of the termination of employment, the exercise option period for the Executive ends on 30.4.2026. All options that have not fully vested as of 31.01.2025 will expire. The Executive is qualified as a Good Leaver. An overview of all options vested as at 31.01.2025 is provided below (for the avoidance of doubt, all options shown in the column "Vested after acc. Vesting" are fully vested on the 31.01.2025).

JAL - Stock Option Vesting & Vesting until Jan 31, 2025 post Reverse Stock Split						
Grant	Grant #	Plan	Vested 31.Jän.25	Unvested 31.Jän.25	Accelerated vesting	Vested after acc. Vesting
2016 YE Replacement Award - NQSO	1247	2018 ESOP	39.585	0	0	39.585
2019 April IPO Award - NQSO	1248	2019 ESOP	60.465	0	0	60.465
2020 April Regrant Award - NQSO	1468	2019 ESOP	20.000	0	0	20.000
2021 April Regrant Award - NQSO	2264	2019 ESOP	19.462	1.298	0	19.462
2022 January Bonus Conversion - NQSO	2466	2019 ESOP	3.985	0	0	3.985
2022 April Regrant Award - NQSO	2487	2019 ESOP	18.923	8.602	0	18.923
2022 Regrant Award Part 2 E-Team - NQSO	2642	2019 ESOP	18.923	8.602	0	18.923
2023 April Regrant Award - NQSO	3031	2019 ESOP	22.470	28.890	0	22.470
2024 April Regrant Award - NQSO	3514	2019 ESOP	0	97.140	97.140	97.140
Total			**203.813**	**144.532**	**97.140**	**300.953**

The Executive was granted RSUs that are fully vested and have already been converted into shares. It is noted that there is currently a black-out period, the duration of which is unknown.

11. The parties agree that, except for the obligations specified in this Termination Agreement and the indemnification provided by HOOKIPA Pharma Inc. for the Executive as a former board member against third party claims for the period previously provided for after the end of the membership to the management board, all employment related claims of the parties arising under or in connection with the employment contract and its termination, regardless of their legal basis, whether known or unknown, are finally settled (Settlement Clause).

12. No variation of this Agreement shall be valid unless it is in writing and signed by or on behalf of each of the parties.

13. This Agreement is governed by Austrian law.

Date: 30.08.2024

/s/ Malte Peters
HOOKIPA Biotech GmbH
represented by
Malte Peters
CEO

Date: 31.08.2024

/s/ Joern Aldag
Joern Aldag

Date: 30.08.2024

/s/ Jan van de Winkel
HOOKIPA Pharma Inc.
represented by
Jan van de Winkel
Chairman of the Board

HOOKIPA PHARMA INC.

INSIDER TRADING POLICY

This document sets forth the policy of HOOKIPA Pharma Inc. and its subsidiaries (collectively, the "Company") regarding trading in the Company's securities as described below and the disclosure of information concerning the Company. This Insider Trading Policy (the "Insider Trading Policy") is designed to prevent insider trading or the appearance of impropriety, to satisfy the Company's obligation to reasonably supervise the activities of Company personnel, and to help Company personnel avoid the severe consequences associated with violations of insider trading laws. **It is your obligation to understand and comply with this Insider Trading Policy.** Please contact Terry Coelho, the Chief Financial Officer, who is the Compliance Officer of the Company, if you have any questions regarding the policy.

PART I. OVERVIEW

A. To Whom does this Insider Trading Policy Apply?

This Insider Trading Policy is applicable to the Company's directors, officers, employees, and designated consultants and contractors and applies to any and all transactions by such persons and Affiliated Persons (as defined below) in the Company's securities, including its common stock, options to purchase common stock, any other type of securities that the Company may issue (such as preferred stock, convertible debentures, warrants, exchange-traded options or other derivative securities), and any derivative securities that provide the economic equivalent of ownership of any of the Company's securities or an opportunity, direct or indirect, to profit from any change in the value of the Company's securities. In addition, all members of the Board of Directors and officers and designated employees and consultants (collectively, and solely for the purposes of this Insider Trading Policy, these persons, together with their Affiliated Persons (as defined below) are referred to as "Insiders") also must comply with the Trading Procedures set forth in Part II of this Insider Trading Policy (the "Trading Procedures"). Generally, the Trading Procedures require the pre-clearance of all transactions in the Company's securities by such persons. You will be notified if you are required to comply with the Trading Procedures.

This Insider Trading Policy, including, if applicable, the Trading Procedures contained herein, also applies to the following persons (collectively, these persons and entities are referred to as "Affiliated Persons"):

- your spouse, child, parent, significant other or other family member, in each case, living in the same household;
- all trusts, family partnerships and other types of entities formed for your benefit of the Insider or for the benefit of a member of your family over which you have the ability to influence or direct investment decisions concerning securities;
- all persons who execute trades on your behalf; and

- all investment funds, trusts, retirement plans, partnerships, corporations and other types of entities over which you have the ability to influence or direct investment decisions concerning securities; provided, however, that the Trading Procedures shall not apply to any such entity that engages in the investment of securities in the ordinary course of its business (e.g., an investment fund or partnership) if such entity has established its own insider trading controls and procedures in compliance with applicable securities laws and an Insider has included such entity on that Insider's signed acknowledgment in the attached form.

You are responsible for ensuring compliance with this Insider Trading Policy, including the Trading Procedures contained herein, by all of your Affiliated Persons.

In the event that your employment with or service to the Company ceases for any reason, this Insider Trading Policy, including, if applicable, the Trading Procedures contained herein, will continue to apply to you and your Affiliated Persons until the later of: (1) the first trading day following the public release of earnings for the fiscal quarter in which you leave the Company or (2) the first trading day after any material nonpublic information known to you has become public or is no longer material.

B. What is Prohibited by this Insider Trading Policy?

1. No Trading Except During Open Trading Windows

You may trade in Company securities only during open trading windows that are announced by the Company. The opening of a trading window will be announced by the Company via email. The closing of the trading window will be announced by the Company via email in advance of the internal dissemination of information which could be considered material non-public information. You may not trade in Company securities once notified that the trading window is closed.

2. No Trading While in Possession of Material Non-Public Information.

It is generally illegal for you to trade in the securities of the Company or derivatives relating to the securities of the Company, whether for your account or for the account of another, while in the possession of material, nonpublic information about the Company, even if the Company has announced an open trading window. It is also generally illegal for you to disclose material, nonpublic information about the Company to others who may trade on the basis of that information. These illegal activities are commonly referred to as "*insider trading*."

Prohibited Activities

When you know or are in possession of material, nonpublic information about the Company, whether positive or negative, you are prohibited from the following activities:

- trading (whether for your account or for the account of another) in the Company's securities, which includes common stock, options to purchase common stock, any other type of securities that the Company may issue (such as preferred stock,

convertible debentures, warrants, exchange-traded options or other derivative securities), and any derivative securities that provide the economic equivalent of ownership of any of the Company's securities or an opportunity, direct or indirect, to profit from any change in the value of the Company's securities, except for trades made in compliance with the affirmative defense of Rule 10b5-1 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), such as when trades are made pursuant to a written plan that was adopted, or trading instructions that were given, before you knew or had possession of such material, nonpublic information and certain other conditions are satisfied;

- giving trading advice of any kind about the Company; and

- disclosing such material, nonpublic information about the Company, whether positive or negative, to anyone else (commonly known as "*tipping*").

This Insider Trading Policy does not apply to an exercise of an employee stock option when payment of the exercise price is made in cash. The policy does apply, however, to the use of outstanding Company securities to constitute part or all of the exercise price of an option, any sale of stock as part of a broker-assisted cashless exercise of an option, or any other market sale for the purpose of generating the cash needed to pay the exercise price of an option.

These prohibitions continue whenever and for as long as you know or are in possession of material, nonpublic information. Remember, anyone scrutinizing your transactions will be doing so after the fact, with the benefit of hindsight. As a practical matter, before engaging in any transaction, you should carefully consider how enforcement authorities and others might view the transaction in hindsight.

Definition of Material, Nonpublic Information

This Insider Trading Policy prohibits you from trading in the Company's securities if you are in possession of information about the Company that is both "*material*" and "*nonpublic*." If you have a question whether certain information you are aware of is material or has been made public, you are encouraged to consult with the Compliance Officer.

What is "Material" Information?

Information about the Company is "material" if it could reasonably be expected to affect the investment or voting decisions of a stockholder or investor, or if the disclosure of the information could reasonably be expected to significantly alter the total mix of information in the marketplace about the Company. In simple terms, material information is any type of information that could reasonably be expected to affect the market price of the Company's securities. Both positive and negative information may be material. While it is not possible to identify all information that would be deemed "material," the following items are types of information that should be considered carefully to determine whether they are material:

- developments regarding any programs in clinical development or subject to regulatory approval, including recent regulatory interaction and/or data that have been recently generated from ongoing or recently completed clinical trials;
- developments regarding the intellectual property and/or freedom to operate for any of the current programs or product candidates under development;
- projections of future earnings or losses, or other earnings guidance;
- earnings or revenue that are inconsistent with the consensus expectations of the investment community;
- potential restatements of the Company's financial statements, changes in auditors or auditor notification that the Company may no longer rely on an auditor's audit report;
- pending or proposed corporate mergers, acquisitions, tender offers, joint ventures or dispositions of significant assets;
- changes in management or the Board of Directors;
- significant actual or threatened litigation or governmental investigations or major developments in such matters;
- a cybersecurity incident;
- significant developments regarding products, customers, suppliers, orders, contracts or financing sources (e.g., the acquisition or loss of a contract);
- changes in dividend policy, declarations of stock splits, or public or private sales of additional securities;
- potential defaults under the Company's credit agreements or indentures, or the existence of material liquidity deficiencies; and
- bankruptcies or receiverships.

By including the list above, the Company does not mean to imply that each of these items above is per se material. The information and events on this list still require determinations as to their materiality (although some determinations will be reached more easily than others). For example, some new products or contracts may clearly be material to an issuer; yet that does not mean that all product developments or contracts will be material. This demonstrates, in our view, why no "bright-line" standard or list of items can adequately address the range of situations that may arise. Furthermore, the Company cannot create an exclusive list of events and information that have a higher probability of being considered material.

The Securities and Exchange Commission (the "SEC") has stated that there is no fixed quantitative threshold amount for determining materiality, and that even very small quantitative changes can be qualitatively material if they would result in a movement in the price of the Company's securities.

What is "Nonpublic" Information?

Material information is "nonpublic" if it has not been disseminated in a manner making it available to investors generally. To show that information is public, it is necessary to point to some fact that establishes that the information has become publicly available, such as the filing of a report with the SEC, the distribution of a press release through a widely disseminated news or wire service, or by other means that are reasonably designed to provide broad public access. Before a person who possesses material, nonpublic information can trade, there also must be adequate time for the market as a whole to absorb the information that has been disclosed.

For the purposes of this Insider Trading Policy, information will be considered public after the close of trading on the first full trading day following the Company's public release of the information. For example, if the Company announces material nonpublic information of which you are aware before trading begins on a Tuesday, the first time you can buy or sell Company securities is the opening of the market on Wednesday. However, if the Company announces this material information after trading begins on that Tuesday, the first time that you can buy or sell Company securities is the opening of the market on Thursday.

C. What are the Penalties for Insider Trading and Noncompliance with this Insider Trading Policy?

Both the SEC and the national securities exchanges, through the Financial Industry Regulatory Authority, investigate and are very effective at detecting insider trading. The SEC, together with U.S. Attorneys, pursue insider trading violations vigorously. For instance, cases have been successfully prosecuted against trading by employees in foreign accounts, trading by family members and friends, and trading involving only a small number of shares.

The penalties for violating insider trading or tipping rules can be severe and include:

- disgorgement of the profit gained or loss avoided by the trading;
- payment of the loss suffered by the persons who, contemporaneously with the purchase or sale of securities that are subject of such violation, have purchased or sold, as applicable, securities of the same class;
- payment of criminal penalties of up to $5,000,000;
- payment of civil penalties of up to three times the profit made or loss avoided; and
- imprisonment for up to 20 years.

The Company and/or the supervisors of the person engaged in insider trading may also be required to pay civil penalties of up to the greater of $1,525,000 or three times the profit made or loss avoided, as well as criminal penalties of up to $25,000,000, and could under certain circumstances be subject to private lawsuits.

Violation of this Insider Trading Policy or any federal or state insider trading laws may subject the person violating such policy or laws to disciplinary action by the Company up to and

including termination. The Company reserves the right to determine, in its own discretion and on the basis of the information available to it, whether this Insider Trading Policy has been violated. The Company may determine that specific conduct violates this Insider Trading Policy, whether or not the conduct also violates the law. It is not necessary for the Company to await the filing or conclusion of a civil or criminal action against the alleged violator before taking disciplinary action.

D. How Do You Report a Violation of this Insider Trading Policy?

If you have a question about this Insider Trading Policy, including whether certain information you are aware of is material or has been made public, you are encouraged to consult with the Compliance Officer. In addition, if you violate this Insider Trading Policy or any federal or state laws governing insider trading, or know of any such violation by any director, officer or employee of the Company, you must report the violation immediately to the Compliance Officer.

PART II. TRADING PROCEDURES

A. Special Trading Restrictions Applicable to Insiders

In addition to the restrictions on trading in Company securities set forth above, Insiders and their Affiliated Persons are subject to the following special trading restrictions:

1. All Trades Must be Precleared by the Compliance Officer

No Insider may trade in Company securities unless the trade has been approved by the Compliance Officer in accordance with the procedures set forth below. The Compliance Officer will review and either approve or prohibit all proposed trades by Insiders in accordance with the procedures set forth in Section B below. The Compliance Officer may consult with the Company's other officers and/or outside legal counsel and will receive approval for his or her own trades from the Company's Chief Executive Officer. If you are unable to contact the Compliance Officer, or if you do not feel you can discuss the matter with the Compliance Officer, you may contact the Head of Legal, who shall be the alternate Compliance Officer (the Compliance Officer and the alternate Compliance Officer are collectively referred to as the "Compliance Officer" in these Trading Procedures).

2. Special Blackout Periods

There are times when the Company or certain members of its Board of Directors or senior management or other team members may be aware of a material, nonpublic development. Although an Insider may not know the specifics of such development, if an Insider engages in a trade before such development is disclosed to the public or resolved, such Insider and the Company might be exposed to a charge of insider trading that could be costly and difficult to refute. In addition, a trade by an Insider during such period could result in adverse publicity for the Company.

Therefore, Insiders may not trade in Company securities if they are notified that the trading window is closed because of the existence of a material, nonpublic development. The Compliance Officer will subsequently notify the Insiders once the material nonpublic development is disclosed to the public or resolved and that, as a result, the trading window is again open. While the Compliance Officer will undertake reasonable efforts to notify the Insiders that material, nonpublic events have developed, or are soon likely to develop, it is each Insider's individual duty to ensure that they do not make any trade in Company securities when material, nonpublic information exists, regardless of whether such Insider is aware of such development.

3. Distributions, Gifts and Other Transfers for No Consideration are Subject to Same Restrictions as All Other Securities Trades

No Insider may give or make any other transfer of Company securities without consideration (e.g., an investment fund or partnership distribution or a gift) during a period when the Insider is not permitted to trade.

4. Prohibited Transactions

- ***No Short Sales***. No Insider may at any time sell any securities of the Company that are not owned by such Insider at the time of the sale (a "short sale").

- ***No Purchases or Sales of Derivative Securities or Hedging Transactions***. No Insider may buy or sell puts, calls, other derivative securities of the Company or any derivative securities that provide the economic equivalent of ownership of any of the Company's securities or an opportunity, direct or indirect, to profit from any change in the value of the Company's securities or engage in any other hedging transaction with respect to the Company's securities, at any time.

- ***No Company Securities Subject to Margin Calls***. No Insider may use the Company's securities as collateral in a margin account.

- ***No Pledges***. No Insider may pledge Company securities as collateral for a loan (or modify an existing pledge).

B. Pre-Clearance Procedures

The Compliance Officer will review and either approve or prohibit all proposed trades by Insiders in accordance with the procedures set forth below.

Procedures. No Insider may trade in Company securities until:

- The Insider has notified the Compliance Officer of the amount and nature of the proposed trade(s) using the Stock Transaction Request form attached to this Insider Trading Policy. In order to provide adequate time for the preparation of any required reports under Section 16 of the Exchange Act, a Stock Transaction Request form should, if practicable,

be received by the Compliance Officer at least two (2) business days prior to the intended trade date;

- The Insider has certified to the Compliance Officer in writing prior to the proposed trade(s) that the Insider is not in possession of material, nonpublic information concerning the Company;

- The Insider has informed the Compliance Officer, using the Stock Transaction Request form attached hereto, whether, to the Insider's best knowledge, (a) the Insider has (or is deemed to have) engaged in any opposite way transactions within the previous six months that were not exempt from Section 16(b) of the Exchange Act and (b) if the transaction involves a sale by an "affiliate" of the Company or of "restricted securities" (as such terms are defined under Rule 144 under the Securities Act of 1933, as amended ("Rule 144")), whether the transaction meets all of the applicable conditions of Rule 144; and

- The Compliance Officer or his or her designee has approved the trade(s) and has certified such approval in writing. Such certification may be made via digitally-signed electronic mail.

The Compliance Officer does not assume the responsibility for, and approval from the Compliance Officer does not protect the Insider from, the consequences of prohibited insider trading.

Additional Information. Insiders shall provide to the Compliance Officer any documentation reasonably requested by him or her in furtherance of the foregoing procedures. Any failure to provide such requested information will be grounds for denial of approval by the Compliance Officer.

No Obligation to Approve Trades. The existence of the foregoing approval procedures does not in any way obligate the Compliance Officer to approve any trade requested by an Insider. The Compliance Officer may reject any trading request in his or her sole discretion and without disclosing the reason for any such rejection, which may be confidential.

Completion of Trades. After receiving written clearance to engage in a trade signed by the Compliance Officer, an Insider must complete the proposed trade within two (2) business days or make a new trading request.

Post-Trade Reporting. Any transactions in the Company's securities by an Insider (including transactions effected pursuant to a Rule 10b5-1 Plan) must be reported to the Compliance Officer by completing the "Confirmation of Transaction" section of the Stock Transaction Request form attached to this Insider Trading Policy on the same day in which such a transaction occurs. Each report an Insider makes to the Compliance Officer should include the date of the transaction, quantity of shares, price and broker-dealer through which the transaction was effected. This reporting requirement may be satisfied by sending (or having such Insider's broker send) duplicate confirmations of trades to the Compliance Officer if such information is received by the Compliance Officer on or before the required date. Compliance by directors and executive officers with this provision is imperative given the requirement of Section 16 of the

Exchange Act that these persons generally must report changes in ownership of Company securities within two (2) business days. The sanctions for noncompliance with this reporting deadline may include mandatory disclosure in the Company's proxy statement for the next annual meeting of stockholders, as well as possible civil or criminal sanctions for chronic or egregious violators.

C. Exemptions

Pre-Approved Rule 10b5-1 Plan. Transactions effected pursuant to a Rule 10b5-1 Plan (as defined below) will not be subject to the Company's trading windows or pre-clearance procedures, and Insiders are not required to complete a Stock Transaction Request form for such transactions. Rule 10b5-1 of the Exchange Act provides an affirmative defense from insider trading liability under the federal securities laws for trading plans, arrangements or instructions that meet certain requirements. A trading plan, arrangement or instruction that meets the requirements of Rule 10b5-1 (a "Rule 10b5-1 Plan") enables Insiders to establish arrangements to trade in Company securities outside of the Company's trading windows, even when in possession of material, nonpublic information. If an Insider intends to trade pursuant to a Rule 10b5-1 Plan, such plan, arrangement or instruction must:

- satisfy the requirements of Rule 10b5-1 and any Company policies related to Rule 10b5-1 Plans;
- be documented in writing;
- be established during an open trading window announced by the Company and when such Insider does not possess material, nonpublic information; and
- be pre-approved by the Compliance Officer.

Any deviation from, or alteration to, the specifications of an approved Rule 10b5-1 Plan (including, without limitation, the amount, price or timing of a purchase or sale) must be reported immediately to the Compliance Officer. Any transaction pursuant to a Rule 10b5-1 Plan must be timely reported following the transaction in accordance with the procedures set forth above.

The Compliance Officer may refuse to approve a Rule 10b5-1 Plan as he or she deems appropriate including, without limitation, if he or she determines that such plan does not satisfy the requirements of Rule 10b5-1 or any Company policies related to Rule 10b5-1 Plans.

Any modification of an Insider's prior Rule 10b5-1 Plan requires pre-approval by the Compliance Officer. A modification must occur during an open trading window announced by the Company and while such Insider is not aware of material, nonpublic information.

Employee Benefit Plans.

1. **Exercise of Stock Options**. The trading prohibitions and restrictions set forth in the Trading Procedures do not apply to the exercise of an option to purchase securities of the Company when payment of the exercise price is made in cash. However, the exercise of an option to purchase securities of the Company is subject to the current reporting requirements of

Section 16 of the Exchange Act and, therefore, Insiders must comply with the post-trade reporting requirement described in Section C above for any such transaction. In addition, the securities acquired upon the exercise of an option to purchase Company securities are subject to all of the requirements of this Insider Trading Policy, including the Trading Procedures contained herein. Moreover, the Trading Procedures apply to the use of outstanding Company securities to constitute part or all of the exercise price of an option, any net option exercise, any exercise of a stock appreciation right, share withholding, any sale of stock as part of a broker- assisted cashless exercise of an option, or any other market sale for the purpose of generating the cash needed to pay the exercise price of an option.

2. **Tax Withholding on Restricted Stock/Units**. The trading prohibitions and restrictions set forth in the Trading Procedures do not apply to the withholding by the Company of shares of stock upon vesting of restricted stock or upon settlement of restricted stock units to satisfy applicable tax withholding requirements if (a) such withholding is required by the applicable plan or award agreement or Company policy or (b) the election to exercise such tax withholding right was made by the Insider in compliance with the Trading Procedures.

3. **Employee Stock Purchase Plan**. The trading prohibitions and restrictions set forth in the Trading Procedures do not apply to periodic wage withholding contributions by the Company or employees of the Company which are used to purchase the Company's securities pursuant to the employees' advance instructions under the Company's 2019 Employee Stock Purchase Plan. However, no Insider may: (a) elect to participate in the plan or alter his or her instructions regarding the level of withholding or purchase by the Insider of Company securities under such plan; or (b) make cash contributions to such plan (other than through periodic wage withholding) without complying with the Trading Procedures. Any sale of securities acquired under such plan is subject to the prohibitions and restrictions of the Trading Procedures.

D. Waivers

A waiver of any provision of this Insider Trading Policy, or the Trading Procedures contained herein, in a specific instance may be authorized in writing by the Audit Committee, and any such waiver shall be reported to the Company's Board of Directors.

PART III. ACKNOWLEDGMENT

This Insider Trading Policy will be delivered to all current Insiders and to all directors, officers, employees and designated consultants at the start of their employment or relationship with the Company. Upon first receiving a copy of this Insider Trading Policy, each individual must acknowledge that he or she has received a copy and agrees to comply with the terms of this Insider Trading Policy, and, if applicable, the Trading Procedures contained herein. The acknowledgment attached hereto must be returned within ten (10) days of receipt to:

Terry Coelho
Chief Financial Officer
HOOKIPA Pharma Inc.
350 Fifth Avenue, Room/Suite 7240

New York, NY 10118

This acknowledgment will constitute consent for the Company to impose sanctions for violation of the Insider Trading Policy, including the Trading Procedures, and to issue any necessary stop-transfer orders to the Company's transfer agent to ensure compliance.

All directors, officers, employees and designated consultants will be required upon the Company's request to re-acknowledge and agree to comply with the Insider Trading Policy (including any amendments or modifications). For such purpose, an individual will be deemed to have acknowledged and agreed to comply with the Insider Trading Policy, as amended from time to time, when copies of such items have been delivered by regular or electronic mail (or other delivery option used by the Company) by the Compliance Officer or his or her designee.

Questions regarding this Insider Trading Policy are encouraged and may be directed to the Compliance Officer.

Adopted January 25, 2019, subject to effectiveness of the Company's Registration Statement on Form S-1.

ACKNOWLEDGMENT

I hereby acknowledge that I have read, that I understand, and that I agree to comply with, the Insider Trading Policy (the "**Insider Trading Policy**") of HOOKIPA Pharma Inc. (the "**Company**"). I further acknowledge and agree that I am responsible for ensuring compliance with the Insider Trading Policy and the Trading Procedures by all of my "Affiliated Persons" (including such persons listed below). I also understand and agree that I will be subject to sanctions, including termination of employment, that may be imposed by the Company, in its sole discretion, for violation of the Insider Trading Policy, and that the Company may give stop- transfer and other instructions to the Company's transfer agent against the transfer of any Company securities in a transaction that the Company considers to be in contravention of the Insider Trading Policy.

[I hereby designate the following Affiliated Persons as entities for which the Trading Procedures shall not apply:

_____

I hereby represent to the Company that such entities: (a) engage in the investment of securities in the ordinary course of their respective businesses; (b) have established insider trading controls and procedures in compliance with applicable securities laws; and (c) are aware such securities laws prohibit any person or entity who has material, nonpublic information concerning the Company from communicating such information to any other person under circumstances in which it is reasonably foreseeable that such person is likely to purchase or sell securities.]

Date: _____ Signature: _____

Name: _____

Title: _____

Pursuant to HOOKIPA Pharma Inc.'s Trading Procedures (the "Trading Procedures"), I hereby notify HOOKIPA Pharma Inc. (the "Company") of my intent to trade the securities of the Company as indicated below:

REQUESTER INFORMATION

Insider's Name: _____

INTENT TO PURCHASE

Number of shares: _____

Intended trade date: _____

Means of acquiring shares:

☐ Acquisition through employee benefit plan (please specify): _____

☐ Purchase through a broker on the open market

☐ Other (please specify): _____

INTENT TO SELL

Number of shares: _____

Intended trade date: _____

Means of selling shares:

☐ Sale through employee benefit plan (please specify): _____

☐ Sale through a broker on the open market

☐ Other (please specify): _____

SECTION 16

I am not subject to Section 16 of the Securities Exchange Act of 1934, as amended.

To the best of my knowledge, I have not (and am not deemed to have) engaged in an opposite way transaction within the previous 6 months that was not exempt from Section 16(b) of the Exchange Act.

None of the above.

RULE 144 (Not applicable if transaction requested involves a purchase)

☐ I am not an "affiliate" of the Company and the transaction requested above does not involve the sale of "restricted securities" (as such terms are defined under Rule 144 under the Securities Act of 1933, as amended).

☐ To the best of my knowledge, the transaction requested above will meet all of the applicable conditions of Rule 144.

☐ The transaction requested is being made pursuant to an effective registration statement covering such transaction.

☐ None of the above.

CERTIFICATION

I hereby certify that (1) I am not in possession of any material, nonpublic information concerning the Company, as defined in the Company's Statement of Company Policy on Insider Trading and Disclosure, and (2) I am not purchasing any securities of the Company on margin in contravention of the Company's Trading Procedures. I understand that, if I trade while possessing such information or in violation of such trading restrictions, I may be subject to severe civil and/or criminal penalties, and may be subject to discipline by the Company including termination.

_____ _____

Insider's Signature Date

AUTHORIZED APPROVAL

_____ _____

Signature of Compliance Officer (or designee) Date

CONFIRMATION OF TRANSACTION

I hereby confirm that the transaction(s) requested above was (were) executed as follows:

☐ Purchase of shares:
*Number of shares: _____ Price per share: _____ Date and approximate time of purchase: _____

☐ Sale of shares:
*Number of shares: _____ Price per share: _____ Date and approximate time of sale: _____

_____ _____
Insider's Signature Date

Signature _____ Date _____

** NOTE: Multiple lots must be listed on separate forms or broken out herein.*

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-266084, 333-266104 and 333-276220) and Form S-8 (No. 333-230995, 333-237285, 333-264587 and 333-271238) of HOOKIPA Pharma Inc. of our report dated February 27, 2025 relating to the financial statements, which appears in this Form 10-K.

Vienna, Austria
February 27, 2025

PwC Wirtschaftsprüfung GmbH
/s/ Gabor Kruepl
Austrian Certified Public Accountant

Exhibit 31.1

CERTIFICATIONS 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, Malte Peters, certify that:

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

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

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

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2025

/s/ Malte Peters
Malte Peters
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS 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 Coelho, certify that:

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

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

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

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2025

/s/ Terry Coelho
Terry Coelho
Executive Vice President and 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 HOOKIPA Pharma 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"), the undersigned hereby certify that to the best of their knowledge:

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

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

Date: February 27, 2025

/s/ Malte Peters
Malte Peters
Chief Executive Officer
(Principal Executive Officer)

Date: February 27, 2025

/s/ Terry Coelho
Terry Coelho
Executive Vice President and Chief Financial Officer
(Principal Financial Officer)