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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, 2021**

**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**<br>**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 Global Select 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. ☐

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, 2021 (the last business day of the Registrant's most recently completed second fiscal quarter) was approximately $237.9 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 March 14, 2022 was 50,868,668 shares and 3,819,732 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 2022 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.

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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 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., or Gilead, 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;
- the effects of the ongoing coronavirus pandemic on business and operations;
- competitive companies, technologies and 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 expectations regarding the period during which we qualify as an emerging growth company under the Jumpstart Our Business Startups Act of 2012, as amended.

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/), 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.

- 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 FDA, the EMA 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.

- 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.

- 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 for the development of our hepatitis B virus programs, rely on funding from Gilead for development of our human immunodeficiency virus, 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.

- The ongoing effect of the COVID-19 pandemic has adversely impacted, and we expect it will continue to adversely impact our business, including our clinical trials.

- 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 a T cell and immune response to disease. 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 prophylactic and therapeutic purposes by inducing CD8+ T cell response levels previously not achieved by other immunotherapy approaches.

We are building a proprietary immuno-oncology pipeline by targeting oncoviral cancer antigens, self-antigens and next-generation antigens. Our lead replicating arenavirus oncology product candidates, HB-201 and HB-202, are in development for the treatment of Human Papillomavirus 16-positive (HPV16+) cancers in a Phase 1/2 clinical trial. Our non-replicating prophylactic Cytomegalovirus (CMV) vaccine candidate, HB-101, is a potential first-in-class compound in a Phase 2 clinical trial for patients awaiting kidney transplantation.

As announced in November 2021, based on the strength of our HB-200 data in HPV16+ cancers, we have prioritized our oncology portfolio and we plan to continue developing infectious disease therapies in partnership with other companies.

**Platform**

Our differentiated platform is based on engineered arenaviruses that are designed to activate the natural immune defense mechanism to trigger potent and target-specific T cell and B cell immunity. Arenaviruses have been used for decades as a preclinical tool to study CD8+ T cell responses. Our cofounder, 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. We believe that arenaviruses have several key advantages which give them the characteristics of an optimal immunotherapy, including:

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

We believe we are the first to reengineer arenaviruses for therapeutic purposes. Our systemic and reproduceable approach features two technologies capable of delivering disease-specific antigens for the prevention and treatment of disease. Our non-replicating technology is designed to induce a strong immune response for prophylactic and therapeutic use against infectious disease. Our replicating technology is engineered to produce an even more powerful immune response, which we are currently exploring in 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 have designed our platform to be modular in nature in order 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 exclusive rights in issued patents and patent applications related to our non-replicating technology and exclusive and joint rights in 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 efficacy, 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.

**Oncology Pipeline Highlights**

The HB-200 program is our first program in oncology and the first clinical exploration of our replicating technology. The HB-200 program is therapeutic agents for people with cancers caused by the Human Papillomavirus (HPV), specifically Human Papillomavirus type 16 (HPV16+).

HPV is estimated to cause about 5% of the worldwide burden of cancer. This includes approximately 99% of cases in cervical, up to 60% of head and neck, 70% of vaginal and 88% of anal cancers. Prevalence and recent studies have shown that approximately 70% of cancers of the tonsil and tongue base and the majority of cervical and anal cancers may be linked to HPV. It is estimated that the yearly incidence of metastatic head and neck cancers in Spain, France, Germany, Italy, Japan, the United Kingdom and the United States will be 44,000 by 2030. Tumors caused by HPV are referred to as HPV-positive tumors (HPV+) and can be characterized by their expression of proteins from the HPV genome, particularly the viral E6 and E7 proteins. These two proteins are expressed in tumors but are absent in normal cells, which makes them ideal target candidates for immunotherapy; however, to date, there are no therapeutically approved agents directed against these targets.

HPV16+ cancers include cancers of the head, neck, anus, vagina, cervix and penis. Based on a market research study we commissioned from an independent third party, we believe that in developed countries, approximately 70,000 patients annually are newly diagnosed with HPV16+ head and neck cancer. Each year, approximately 30,000 of these patients present with metastatic disease and an additional 10,000 patients progress to the recurrent and metastatic stages of the disease.

The HB-200 program encompasses our arenaviral-based immunotherapies for the treatment of patients with advanced/metastatic cancers caused by HPV16+. These arenaviral-based immunotherapies include

1. **HB-201 single vector therapy**: sequential injections of HB-201 (E7E6 fusion protein derived from HPV16 encoded in a Lymphocytic Choriomeningitis Virus (LCMV) vector);

2. **HB-201/HB-202 two vector therapy**: alternating sequential injections of HB-201 and HB-202 (the same E7E6 fusion protein encoded in a Pichinde Virus (PICV) vector).

In preclinical studies, HB-201, as a monotherapy, was observed to suppress tumor growth and eliminated up to 40% of HPV+ tumors. HB-201 generated a strong and durable T cell response with successfully treated animals demonstrating resistance to a tumor rechallenge. Based on these preliminary results, we believe that treating patients with HB-201 has the potential to both control metastatic disease and prevent relapse.

In December 2019, we opened the HB-200 Phase 1/2 trial (NCT04180215), investigating both Phase 1 dose optimization and Phase 2 dose expansion in a single trial. During the initial 10 months of the trial, the HB-201 single vector therapy was studied through escalating doses. Starting in October 2020, enrollment into the HB-201/HB-202 alternating sequential two vector therapy began, representing a parallel dose escalation.

As a first-in-human trial, the Phase 1 arm of the trial was designed to investigate multiple questions for HB-200 program, including:

- Route of administration: intravenous (IV) vs. intratumoral (IT)

- Dose optimization

- Dosing schedule: every two weeks (Q2W) or every three weeks (Q3W)

In November 2021, interim Phase 1 data on HB-201 single vector therapy and HB-201/HB-202 two vector therapy for advanced/metastatic HPV16+ cancers showed promising anti-tumor activity and favorable tolerability. The interim data was derived from 62 patients who received either HB-201 single vector therapy or HB-201/HB-202 two vector therapy for advanced/metastatic HPV16+ cancers. Data demonstrated responses and stable disease in head and neck cancer patients who failed prior standard of care therapy, platinum therapy, PD(L)1 inhibitor, or both. We believe that these early-stage data establish proof of concept for our replicating single-vector immunotherapy in oncology.

In addition, the interim Phase 1 data released in November 2021 enabled decisions on Phase 2 clinical plans for target tumor type as well as recommended schedule and route of administration for HB-200:

- IV administration was observed to be superior to IT administration; therefore, the IT route has been discontinued and IV only will be used in Phase 2;
- The initial Q3W dosing schedule was observed to be superior to Q2W; therefore, the Q2W regimen arm has been discontinued and the Q3W dosing will be used in Phase 2;
- The majority of data accrued to date has been from HNSCC patients; therefore, the Phase 2 target tumor type will be HNSCC.

In coordination with the November 2021 update, the Recommended Phase 2 Dose (RP2D) for HB-201 single vector therapy was determined. In January 2022, we dosed the first patient with a combination of HB-201 and pembrolizumab for the treatment of first line advanced/metastatic HPV16+ HNSCC in the Phase 2 expansion portion of the ongoing Phase 1/2 trial (NCT04180215). The Phase 2 portion of the trial is also open for enrollment of patients with second line advanced/metastatic HPV16+ HNSCC for treatment with a combination of HB-201 and pembrolizumab. Similarly, for the alternating sequential two vector HB-201/HB-202 therapy, a recommended Phase 2 Dose will be determined. Thereafter, enrollment of patients with first line or second line advanced/metastatic HPV16+ HNSCC will begin, using a combination treatment of HB-201/HB-202 and pembrolizumab. Enrollment of those patients will also proceed in the unrandomized Phase 2 dose expansion part of the ongoing Phase 1/2 trial (NCT04180215).

**Infectious Disease Pipeline Highlights**

Our lead product candidate in infectious diseases, HB-101, is a potential first-in-class vaccine for the prevention of CMV disease. CMV is a type of herpes virus that infects the majority of people over the course of their lifetime. The U.S. Centers for Disease Control and Prevention estimates that more than half of adults have been infected with CMV by age 40. The majority of CMV infections are not serious, and the virus can lay dormant in the body for years. However, CMV infection poses a considerable risk to infants in utero, as well as immune-compromised individuals, such as solid organ transplant recipients.

In a CMV-negative patient receiving an organ or stem cells from a CMV-positive donor, the spread of the virus through the bloodstream, known as viremia, can cause end-organ damage, such as hepatitis, pneumonitis, gastroenteritis and retinitis, and can result in transplant rejection and patient death. In this high-risk patient group, approximately 80% of kidney transplant recipients develop active CMV infections. CMV progression in the transplant setting varies according to the type of transplant, the immunosuppressive drugs used and the presence of any other comorbidity risk factors. Symptomatic CMV infections develop in patients in between 8% and 32% of kidney transplants, 22% and 29% of liver transplants, 9% and 23% of heart transplants and 50% and 75% of lung transplants. Based on a market research study we commissioned from an independent third party and reviewed by management, we believe that approximately 110,000 patients are added to the solid organ transplant waiting list annually in developed countries, with kidney transplantation representing approximately 60% of cases. Furthermore, more than 20,000 allogeneic cell transplants, in which cell and tissue donors are matched with transplant recipients, are carried out annually worldwide. In this group, the incidence of CMV infection is approximately 30% as a result of the donor being CMV positive. Current therapies to prevent the transmission of CMV during organ transplants utilize antiviral prophylactic and therapeutic strategies. However, these therapies are only partially protective in preventing viral disease while also being hampered by toxicity and resistance.

HB-101 uses our proprietary non-replicating technology and two antigens to stimulate both arms of the adaptive immune system: phosphoprotein 65 (pp65), to induce CMV-specific T cells and glycoprotein B (gB fusion protein) to elicit CMV-neutralizing antibodies. In our Phase 1 clinical trial, reviewed in the April 2020 issue of *The Journal of Infectious Diseases*, HB-101 was well-tolerated and elicited strong CMV-specific immune responses in all 42 of the treatment arm volunteers. Importantly, we observed robust CD8+ and CD4+ T cell responses, as well as CMV-neutralizing antibody responses, without meaningful vector-neutralizing antibody responses. These responses increased in a statistically significant manner upon repeat administration. We believe these results demonstrate the differentiating features of our arenavirus platform.

We reported interim safety, immunogenicity and efficacy data for HB-101 in evaluable patients in November 2021. The interim Phase 2 data were released for patients who received two- or three-doses of HB-101 prior to a kidney organ transplantation. These interim results showed a reduction in CMV viremia, reduction in antiviral use, and no CMV disease in these CMV-negative kidney transplant recipients as compared to placebo. Strong CMV-neutralizing antibody responses and a favorable tolerability profile were also observed. We concluded enrollment of this trial in June 2021 and anticipate the final data read-out in 2023. We plan to explore partnership opportunities for further development of HB-101 in order to focus on advancing our oncology portfolio.

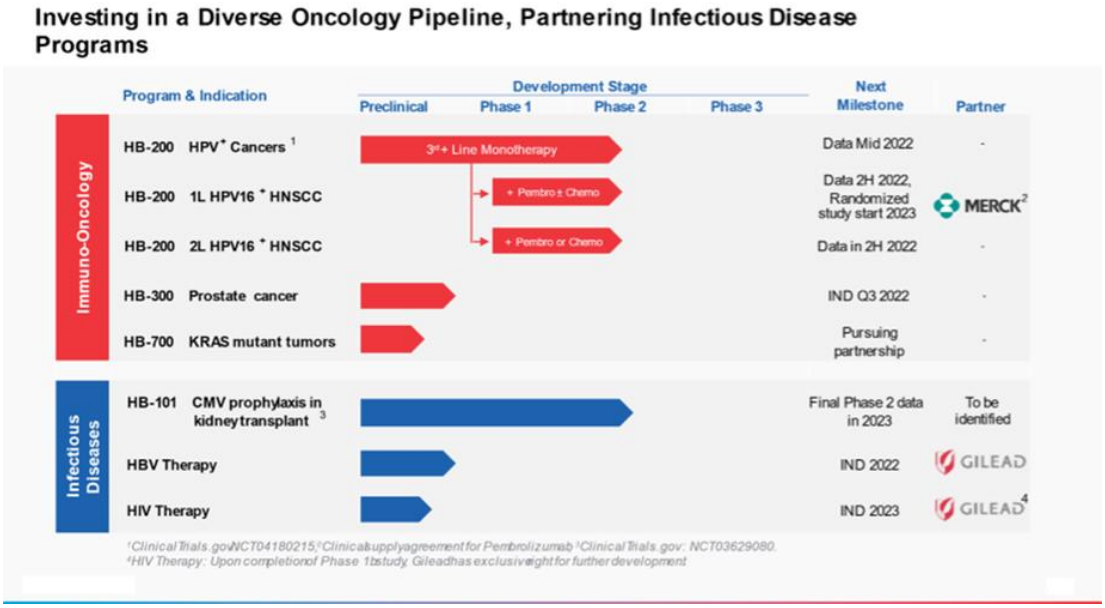
To expand our infectious disease portfolio, we entered into a collaboration and licensing agreement, the Collaboration Agreement, with Gilead in June 2018, to research arenavirus functional cures for HIV and chronic Hepatitis B infections. We received a one-time upfront payment of $10.0 million upon entering into the Collaboration Agreement.

In February 2022, we signed an amended and restated collaboration agreement, the Restated Collaboration Agreement, which revised the terms only for the HIV program, whereby we will take 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 and equity contributions of up to $35.0 million, pursuant to a Stock Purchase Agreement entered into by us and Gilead in February 2022. Pursuant to the Restated Collaboration Agreement, Gilead will retain an exclusive right, the Option, to take back 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 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 a further $167.5 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 an approved 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. Through to December 31, 2021, we have received from Gilead the non-refundable upfront payment of $10.0 million and $12.2 million in milestone payments for the achievement of pre-clinical research milestones. In addition, we have recognized $35.6 million of cost reimbursements for research and development services performed under the Restated Collaboration Agreement. In the first quarter of 2022, we received an additional milestone payment of $4.0 million and a payment of $15.0 million upon execution of the Restated Collaboration Agreement.

We are led by a team of highly experienced executives, clinicians, and scientists with focused and translational expertise in oncology, immunology, vaccinology, clinical development, and commercialization. Our Chief Executive Officer, Joern Aldag, was previously the Chief Executive Officer of uniQure, a company that under his leadership pioneered the approval of the first gene therapy product. Igor Matushansky, M.D., Ph.D., our Chief Medical Officer and Global Head of Research and Development was previously Global Head of Translational Development for Oncology at Daiichi Sankyo. The fundamental discoveries underlying our arenavirus platform originated with our co-founders, Nobel laureate Rolf Zinkernagel, M.D., and Daniel Pinschewer, M.D., an internationally recognized arenavirus expert who serves as Scientific Advisor to our Chief Executive Officer.

**Our Pipeline**

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




We are also pursuing the development of “off-the-shelf” cancer therapies by identifying the next generation cancer testis antigens, which are tumor associated antigens that are generally not expressed in normal tissue.

**Background**

***Immune System Function: Antigen Presentation by Dendritic and Other Antigen Presenting Cells***

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 APCs, such as dendritic cells.

***Immunotherapy and Current Limitations***

The clinical application of immunotherapy in the context of managing infectious diseases and cancers is distinctly different. The approach taken for infectious diseases is commonly that of "vaccination", whereby the aim is to prevent onset of disease by administering a derivative of the disease-causing agent to a healthy individual. In contrast, for cancer, the approach is typically one of therapeutic intervention in patients with active disease.

Infectious disease and cancer immunotherapies represent areas of medicine with high potential for prophylactic and therapeutic benefit and have generated significant interest and investment from leading biopharmaceutical companies. Data from ongoing industry and academic research have demonstrated the potential clinical benefit for patients in a range of infectious disease and cancer settings. Several immunotherapy products have been approved by the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), and other foreign regulatory agencies. However, despite ongoing development efforts and successes, we believe that the current immunotherapies are limited by several factors, including:

*Lack of Robust CD8+ T Cell Response.* APCs, like Dendritic cells, are the most efficient antigen presenting cells of the body and the natural mechanism by which to induce a robust CD8+ T cell response to fight the disease. However, we do not believe there are any existing immunotherapies that have the ability to independently and directly deliver full length proteins to target and activate dendritic cells to present antigens directly to CD8+ T cells. This limitation prevents them from inducing a robust and durable CD8+ T cell response.

*Presence of Virus Neutralizing Antibodies and Pre-Existing Immunity.* Nearly all viral vectors used to deliver antigens elicit neutralizing antibodies against both the desired target and the vectors themselves. In some cases, these circulating antibodies can be present before treatment is commenced owing to prior virus exposure. The presence of pre-existing vector neutralizing antibodies can reduce or eliminate the viral vector's ability to elicit CD8+ T cell and antibody responses to the desired antigen. For example, a significant proportion of the global population carries adenovirus 5 neutralizing antibodies from natural infection which can affect vector immunogenicity. Even in the absence of pre-existing immunity, if virus neutralizing antibodies are induced in response to immunization, such as is the case with recombinant adenovirus or poxvirus based vaccines, repeat doses administered to the patient may also be rendered ineffective or impractical.

*Safety and Toxicity Concerns.* Some immunotherapies, such as engineered T cells (CAR-T and TCR-T), use artificial constructs that bypass normal control mechanisms of the immune system. As a result, these approaches have the risk of causing life threatening immune reactions, including cytokine release syndrome, and can have various other toxicity concerns.

*Clinical Application.* Two common limiting factors of many immunotherapies are the inability to deliver full length proteins directly to antigen presenting cells and the inability to be administered systemically. The former limitation restricts these therapies to being patient specific as they can only deliver smaller proteins such as neoantigens and it furthermore prevents an "off-the-shelf" approach. The latter restricts their application only to tumors that are amenable to intratumoral administration, as is the case for oncolytic viruses.

*Handling and Manufacturing. Ex vivo* approaches, such as CAR-T, require CD8+ T lymphocytes to be isolated from cancer patients, manipulated, substantially expanded and delivered back into the patient. This represents a costly, time consuming and substantially more complex approach.

Unlike with cancer treatment, immunotherapies in the context of infectious diseases, commonly stimulate an antibody response that is dependent on the presence of CD4+ T cells. We believe that a vaccine approach that can generate the combination of CD8+ T cells with an antibody response offers a solution to optimally mobilize the immune response and potentially overcome many of the limitations that exist with current approaches.

**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 cofounder, 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 prophylactic and therapeutic applications. We believe we are the first to reengineer arenaviruses for the prevention and treatment of disease. We have created two types of viral technologies capable of delivering disease specific antigens: a replication defective vector, and a replication competent but attenuated vector.

Our non-replicating and replicating technologies utilize both LCMV and PICV, two of over 30 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 a prophylactic and immuno-therapeutic and prophylactic approach with potential for greater potency than existing prophylactic 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 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 in order 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 of the benefits of the non-replicating technology and the following additional benefits:

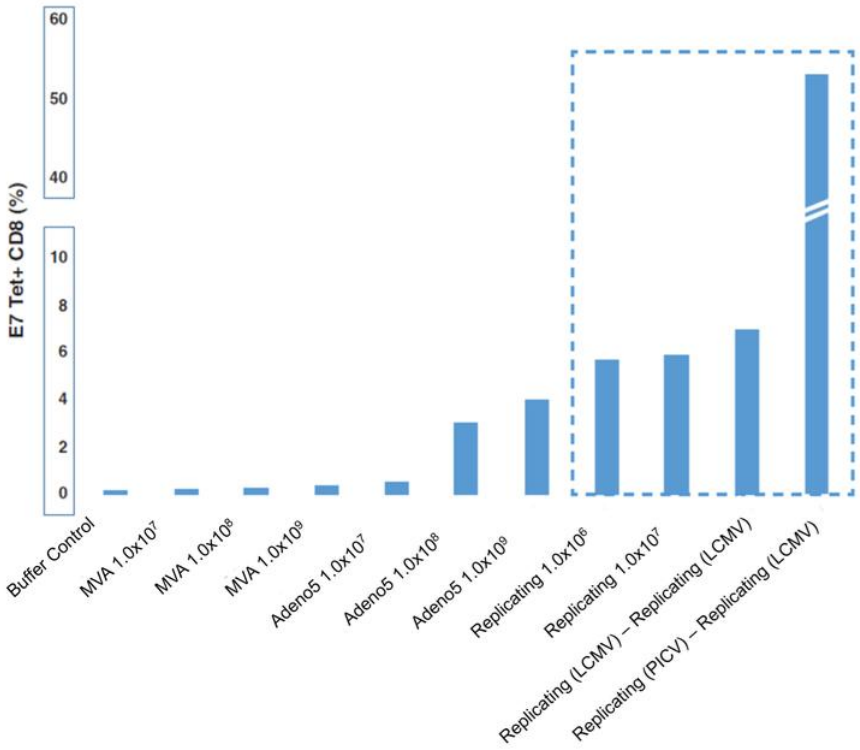
*Quantitatively: Even More Robust CD8+ T Cell Response.* In animal studies, our replicating technology has shown to induce a CD8+ T cell response that directs more than 50% of a body's T cells, which is approximately ten times greater than the response induced by our non-replicating technology, to focus on a single target of choice. 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.

To demonstrate the superior properties of our approach, we performed a head-to-head comparison in mice of our replicating LCMV and PICV E7 constructs versus modified vaccinia virus Ankara (MVA), and adenovirus 5 (Adeno5), each expressing E7 antigens for their ability to induce E7 specific CD8+ T cells. As shown below, our replicating constructs were superior to MVA and Adeno5, despite being dosed at concentrations 1,000 times lower than

the latter two vectors. Furthermore, sequential dosing of replicating PICV vector followed by administration of replicating (LCMV) vector resulted in over 50% of CD8+ T cells being targeted against E7.




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.

***Non-Replicating Preclinical Data***

We believe our preclinical data support the development of our non-replicating technology for prophylactic and therapeutic uses for infectious disease.

*HIV Model*

A third-party preclinical study was conducted in a monkey model of HIV infection using simian immunodeficiency virus (SIV). Ten monkeys were treated with an adenoviral vector carrying the SIV Env protein. The expression of the SIV Env protein is meant to prime the animal's immune system to detect and attack SIV. From earlier work, this initial adenoviral-prophylactic immunization on its own was shown not to prevent SIV infection. Monkeys were then boosted eight weeks later with our non-replicating LCMV vector encoding SIV Env. The ten monkeys were also treated with vectors encoding no relevant genes, identified as the null group below. Starting at week six, both groups were challenged with weekly SIV injections for 12 weeks. The dosing regimen of the study is shown in Figure 1 below. As depicted in the Figure 2 below, the non-replicating (LCMV)-Env vaccination resulted in over 70% of monkeys being SIV free at the end of the study, as compared to less than 20% in the null group.

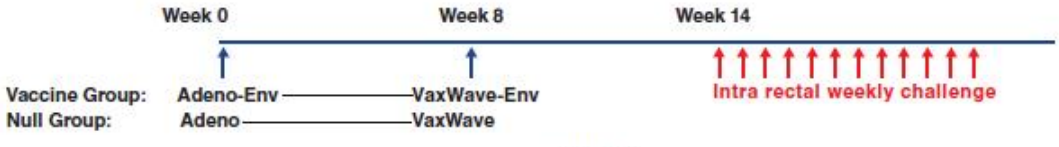



Figure 1

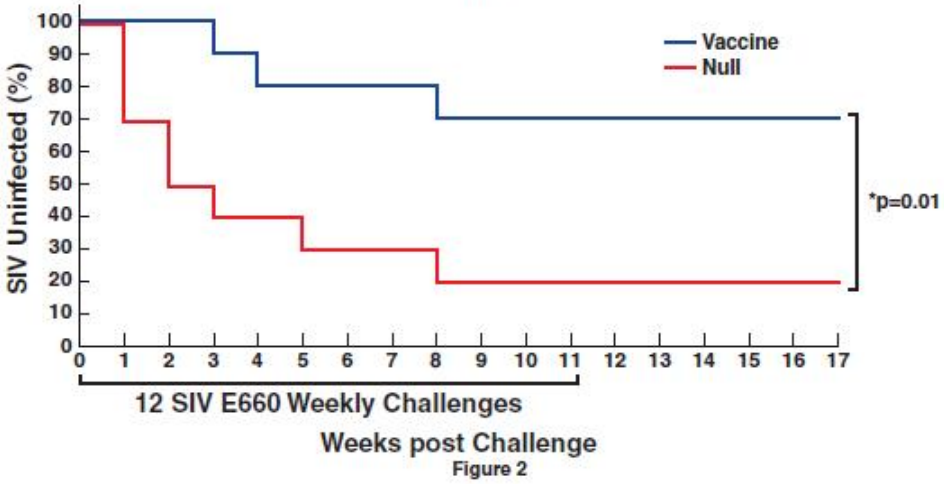



Figure 2

Figure: Flatz, L. et al. Gene-based vaccination with a mismatched envelope protects against simian immunodeficiency virus infection in nonhuman primates; https://pubmed.ncbi.nlm.nih.gov/22593152/

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* **A p-value of 0.05 or less represents statistical significance, meaning that there is a less than 1in20 likelihood that the observed results occurred by chance. A p-value of 0.01 or less means that there is a less than 1in100 likelihood that the observed results occurred by chance.**

*Hepatitis B Virus Model*

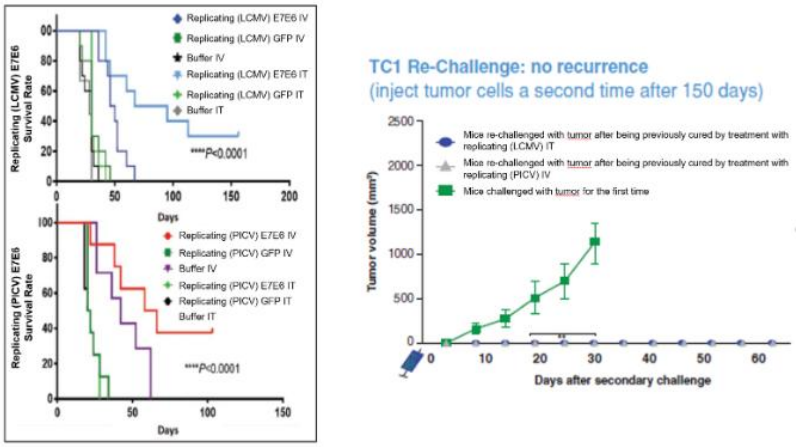
In addition to the HIV model, we explored the ability of our non-replicating vectors to induce immune responses against hepatitis B core, HBc, and hepatitis B surface, HBs, antigens. In our study, we observed that a non-replicating (LCMV) vector expressing both HBc and HBs was able to generate significant CD8+ T cell responses against both proteins. These data indicate that a single dose of a non-replicating LCMV vector expressing Hepatitis B Virus antigens elicits robust cellular immunity against both encoded proteins delivered in a single vector. We believe that non-replicating vector based immunotherapy may form an important cornerstone of a potential cure for the estimated 350 million people worldwide who are persistently infected with Hepatitis B Virus.

We believe that the combination of our HIV and Hepatitis B Virus preclinical and subsequent non-replicating vector clinical data facilitated our Gilead collaboration.

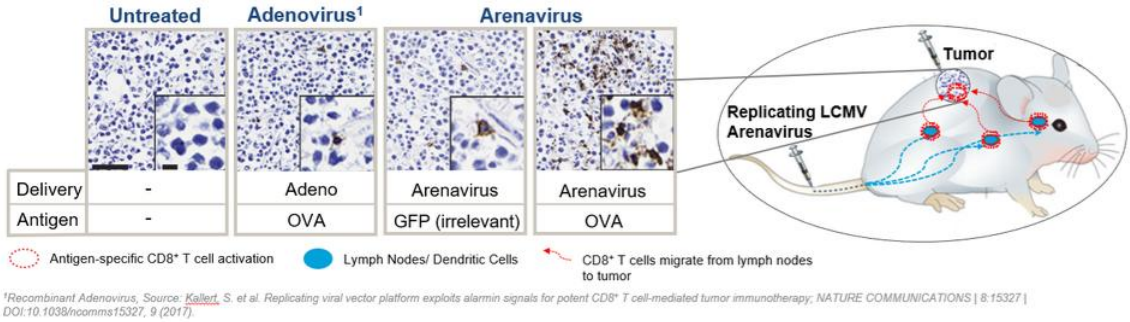
***Replicating Vector Preclinical Data***

We have conducted several preclinical studies assessing the efficacy of our replicating technology, for both LCMV and PICV constructs, carrying the HPV specific E7E6 fusion protein through intravenous (IV) and intratumoral (IT) administration. Mice treated with the replicating vectors showed no evidence of toxicity. In a mouse model of HPV-induced cancer (TC1), we observed that a single intravenous administration of replicating LCMV significantly suppressed and delayed tumor growth while a single IT administration of replicating LCMV eliminated the tumor in approximately half of the mice (top left panel). IV administration of replicating PICV eliminated the tumor in

approximately half of the mice, by the same definition, while IT administration of replicating PICV significantly suppressed and delayed tumor growth (bottom left panel). These mice had complete remission without recurrence for at least six months, which represents over 25% of a mouse's lifetime (right panel). In contrast, replicating vectors carrying non-tumor specific antigens, such as GFP, demonstrated no anti-tumor activity. In these studies, we also observed resistance to a tumor re-challenge after six months (right panel).



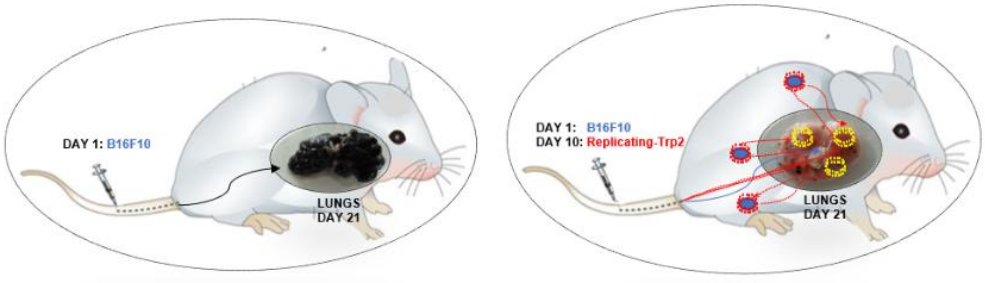

We have also performed "tracking" experiments wherein we observed that while our intravenous replicating vectors travel to APCs, such as dendritic cells, the reprogrammed antigen CD8+ T cells travel to tumors. We illustrated this in an EG7-OVA model, which analyzed subcutaneous tumors for the presence of antigen specific CD8+T cells. In mice injected with a replicating vector, histopathology showed clear evidence of strong CD8+ T cell infiltration, as shown by the brown staining in the pictures below.



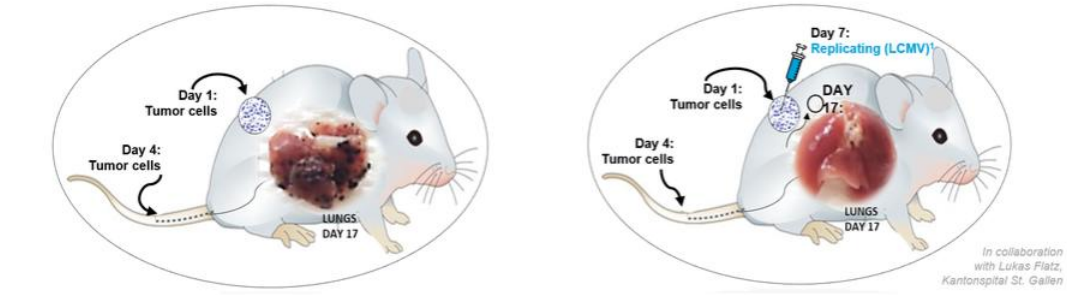

¹Recombinant Adenovirus, Source: Kallert, S. et al. Replicating viral vector platform exploits alarmin signals for potent CD8⁺ T cell-mediated tumor immunotherapy; NATURE COMMUNICATIONS | 8:15327 | DOI:10.1038/ncomms15327, 9 (2017).

We observed similar results in a more aggressive B16F10 melanoma mouse model. In this experiment B16F10 malignant cells were introduced into the tail vein of mice, resulting in lung metastases within three weeks. Ten days after the introduction of B16F10, a replicating vector expressing Trp2, a melanoma antigen, was introduced intravenously

leading to a significant delay in disease progression. Similarly, in subcutaneously growing B16F10 tumors treated intravenously, histopathology showed clear evidence of strong CD8+ T cell infiltration.




When we combined the above two experiments, by initially introducing B16F10 malignant cells subcutaneously, and then intravenously, we achieved both a localized subcutaneous tumor and metastatic lung lesions. Subsequent administration of our intratumoral replicating vector demonstrated both a localized response, through subcutaneous tumor shrinkage, and systemic response, through clearance of lung metastases. The long-term survivor mice were then rechallenged with B16F10 several months after remission with no observed subsequent tumor regrowth.




[1] Intratumoral treatment leads to a 40% cure rate on main tumor (complete remission until end of observation period (100 days)).

***Advantages of sequential administration of replicating PICV and replicating LCMV***

We have observed increased antitumor activity and survival of animals that received sequential administration of replicating PICV and replicating LCMV in a preclinical mastocytoma model. In this model, tumor cells expressed a cancer testis self-antigen known as P1A. In the absence of treatment, tumors grew rapidly and most of the mice died by day 25. When given a first dose with a replicating LCMV P1A vector, followed by a second dose with the same vector, there was a delay in tumor growth of approximately ten days and an increase in survival rates, with some mice surviving to almost 100 days (left panel below). In contrast, mice that were treated first with replicating PICV P1A followed by a second dose with a different arenavirus, replicating LCMV P1A, had an average tumor growth delay of approximately 25 days and in 18% of the mice the tumors were eliminated, and they survived beyond the 160 days of the study.

Furthermore, and as seen in our other studies, mice with eliminated tumors demonstrated resistance to a tumor rechallenge (right panel below).

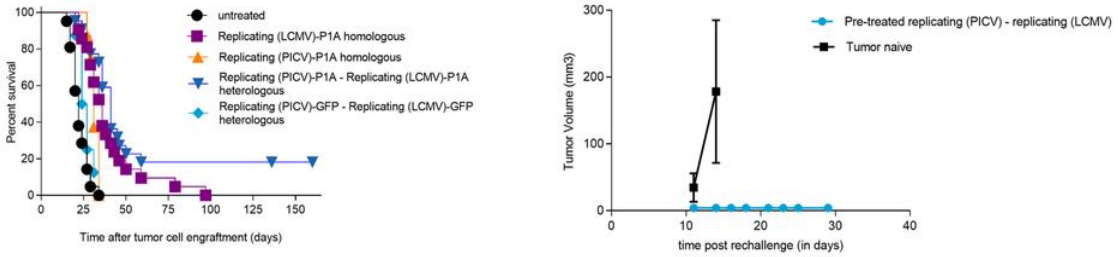



Figure: Bonilla, W. et al. Heterologous arenavirus vector prime-boost overrules self-tolerance for efficient tumor-specific CD8 T cell attack. journal.ppat. 100209. Cell Reports Medicine

**Our Product Candidates**

**HB-200 Program for the Treatment of HPV16+ Cancers**

We are currently developing two immunotherapeutics targeting HPV16+ cancers, referred to as our HB-200 program.

HB-201 is a replicating LCMV-based product candidate expressing the E7E6 fusion protein specific to HPV16+ cells and being developed for the treatment of HPV16+ cancers, including head and neck squamous cell carcinoma (HNSCC) cervical and anal cancer. HB-201 is being evaluated as both monotherapy and in combination with a checkpoint inhibitor.

HB-202 is a replicating PICV-based product candidate expressing the same E7E6 fusion protein as HB-201. HB-202 is being evaluated as an alternating vector therapy with HB-201, so called “HB-201/HB-202 therapy”.

The “HB-200 program” encompasses our arenaviral-based immunotherapies for the treatment of patients with advanced/metastatic cancers caused by HPV16+. These two arenaviral-based immunotherapy regimens include:

- **HB-201 single vector therapy**: sequential injections of HB-201 (E7E6 fusion protein derived from HPV16 encoded in a Lymphocytic Choriomeningitis Virus (LCMV) vector);

- **HB-201/HB-202 two vector therapy**: alternating sequential injections of HB-201 and HB-202 (the same E7E6 fusion protein encoded in a Pichinde Virus (PICV) vector).

In preclinical studies, HB-201, as a monotherapy, was observed to suppress tumor growth and eliminated up to 40% of HPV+ tumors. HB-201 generated a strong and durable T cell response with successfully treated animals demonstrating resistance to a tumor rechallenge. Based on these preliminary results, we believe that treating patients with HB-201 has the potential to both control metastatic disease and prevent relapse. Additionally, our preclinical data support the concept that the alternating vector therapy of two different replicating constructs based on different arenaviruses, but carrying the same tumor antigen, results in an exponentially more robust immune response with potential improvements in antitumor activity.

In December 2019, we opened the HB-200 Phase 1/2 trial (NCT04180215), investigating both Phase 1 dose optimization and Phase 2 dose expansion in a single trial. During the initial 10 months of the trial, the HB-201 single vector therapy was studied through escalating doses. Starting in October 2020, enrollment into the HB-201/HB-202 alternating sequential two vector therapy began, representing a parallel dose escalation.

In November 2021, interim Phase 1 data on HB-201 for the treatment of advanced HPV16+ cancers continued to show promising anti-tumor activity and favorable tolerability as a monotherapy. The interim data was derived from 62 patients who received either HB-201 single vector therapy or HB-201/HB-202 two vector therapy for advanced/metastatic HPV16+ cancers. Data demonstrated responses and stable disease in head and neck cancer patients who failed prior standard of care therapy, platinum therapy, PD(L)1 inhibitor, or both.

In coordination with the November 2021 update, the Recommended Phase 2 Dose (RP2D) for HB-201 single vector therapy was determined. In January 2022, we dosed the first patient with a combination of HB-201 and pembrolizumab for the treatment of first line advanced/metastatic HPV16+ HNSCC in the Phase 2 expansion portion of the ongoing Phase 1/2 trial (NCT04180215). The Phase 2 portion of the trial is also open for enrollment of patients with second line advanced/metastatic HPV16+ HNSCC for treatment with a combination of HB-201 and pembrolizumab. Similarly, for the alternating sequential two vector HB-201/HB-202 therapy, a recommended Phase 2 Dose will be determined. Thereafter, enrollment of patients with first line or second line advanced/metastatic HPV16+ HNSCC will begin, using a combination treatment of HB-201/HB-202 and pembrolizumab. Enrollment of those patients will also proceed in the unrandomized Phase 2 dose expansion part of the ongoing Phase 1/2 trial (NCT04180215).

The first data from Phase 2 arms with combination therapy of HB-200 and pembrolizumab in first line and second line advanced/metastatic HPV16+ HNSCC are anticipated in the second half of 2022.

***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, the majority of which are caused by the HPV serotype 16. 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.

While the rates of HNSCC from causes such as smoking and alcohol are decreasing, the rates of HPV16+ HNSCC are increasing. HNSCC is the sixth most common form of cancer. Each year, HNSCC is diagnosed in more than 600,000 people worldwide, with 65,000 new cases and more than 14,500 deaths occurring in the United States alone. HNSCC includes tumors of the oral cavity, oropharynx, larynx and hypopharynx. The current standard of care for HNSCC is the same regardless of HPV status. Treatment typically involves immunotherapy, chemotherapy, radiation and surgery, the precise regimen varying based on the Stage of cancer and responses to prior therapies. These treatments are associated with acute and long-term effects including mucositis, swallowing dysfunction, dry mouth, and dental problems. The overall survival time for patients with advanced metastatic HNSCC progressing on platinum and checkpoint-based therapies is less than six months. 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.

We believe that HB-200 has potential to provide beneficial treatment to persons with HPV16+ HNSCC, in the post-standard of care therapy OR in combination with pembrolizumab in earlier line (e.g., first-line or second-line) therapy. Proof of concept in either HPV16+ HNSCC or HPV16+ non-HNSCC could support the potential of our product candidates to be effective for all HPV16+ cancers, regardless of the cancer's tissue of origin.

***Our Solution HB-200 Programs: HB-201 and HB-202***

Both HB-201 (LCMV) and HB-202 (PICV) are replicating based product candidates expressing a non-oncogenic but highly antigenic E7E6 fusion protein from HPV16. In animal models, HB-201 was observed to be highly immunogenic, resulting in a robust CD8+ T cell response. Based on the levels of antigen-specific CD8+ T cells induced by HB-201 in preclinical models, notably when compared to therapeutic levels induced by other published approaches including adoptive cell therapies, as observed in separately designed and conducted third-party clinical trials, we believe that HB-201 single vector therapy has the potential to provide therapeutic benefit to patients across the

broader HPV16+ cancer setting. We have observed strong immunogenicity and robust antitumor activity in mouse models for HB-201 alone as well as for the sequential administration of HB-201 and HB-202.

*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.

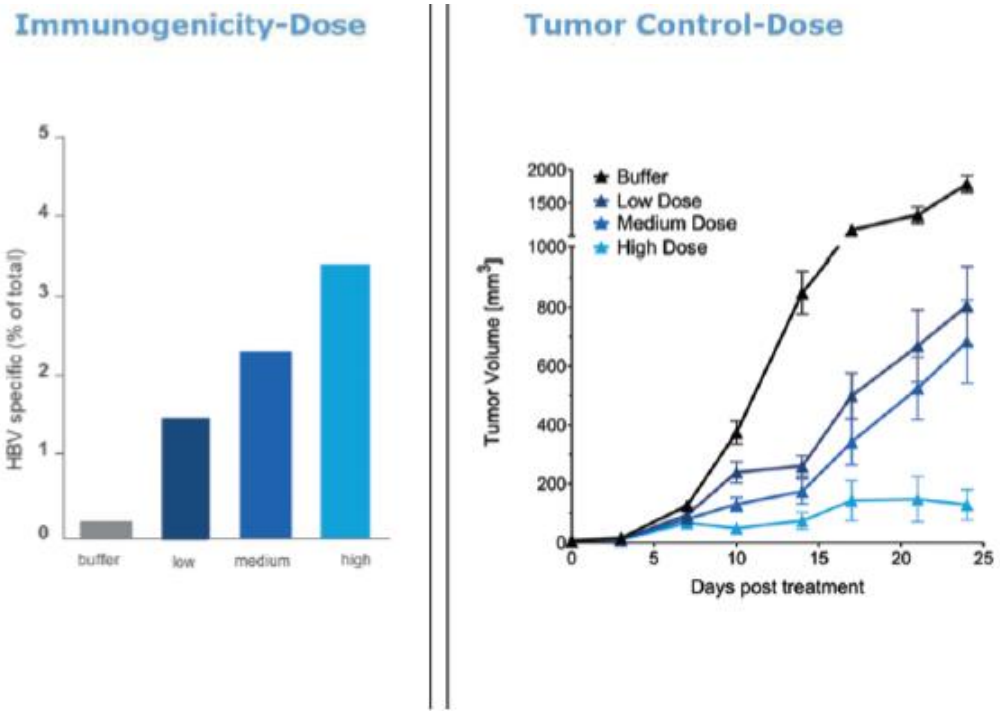
Profiling of immune cells isolated from patients with HPV16+ tumors has identified E6 and E7 specific T cells, indicating that the E6 and E7 proteins are immunogenic, meaning that they trigger antigen specific CD8+ T cell responses. Because both E6 and E7 are highly expressed in tumor cells and are absent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

*HB-201 Preclinical Results*

The ability of HB-201 to suppress tumor growth was tested in a TC1 mouse model of a transplantable HPV16+ E6/E7 expressing tumor. HB-201 was administered either intravenously or intratumorally to animals when tumor volume was approximately 100mm$^3$. In both cases, as depicted in the figures below, single doses of HB-201 led to suppression of tumor growth in a statistically significant manner ($p < 0.05$) in all treated mice, and intratumoral administrations resulted in an approximately 40% long term survival rate. When these long-term survivor mice were rechallenged with the same tumor six months later, no new tumor growth was detected. We believe that these results demonstrate the potential for HB-201 to be active both in treating primary tumors and also controlling metastatic and recurring disease.

Furthermore, we have observed that the dose of HB-201 strongly correlated with both immunogenicity, as depicted in the left side of the figure below, and antitumor activity, as depicted in the right side of the figure below. We believe that this indicates that antitumor activity is directly linked to immunogenicity. Specifically, low doses of HB-201 containing as few as 100 replication competent vector (RCV) particles per dose suppressed tumor growth by more than 50% as compared to untreated tumors. Dosing with the highest three doses of HB-201, ranging from 10,000 to 1,000,000 RCV particles per dose, led to greater suppression of tumor growth. These data suggest that the maximal effective dose

was already achieved at the lower of those three doses, or 10,000 RCV particles per dose. All doses of HB-201 were well tolerated in this model.




*HB-202 Preclinical Studies*

HB-202, like HB-201, is directed against HPV16+ E6/E7 tumors. In a mouse model of HPV16+ E6/E7 tumors, single doses of HB-202 were shown to be similarly effective as single doses of HB-201 when administered both intravenously and intratumorally. Also, as in HB-201, long term survivor mice were uniformly resistant to re-challenge at six months. The results of our preclinical studies of HB-202 are depicted below.

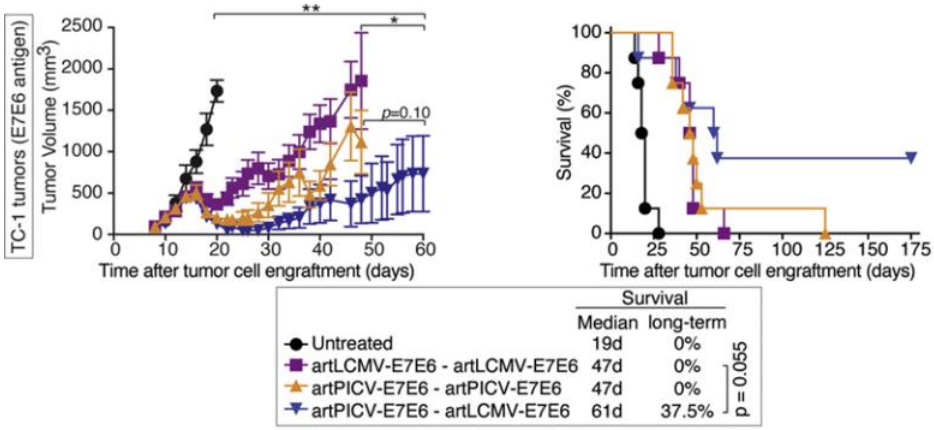
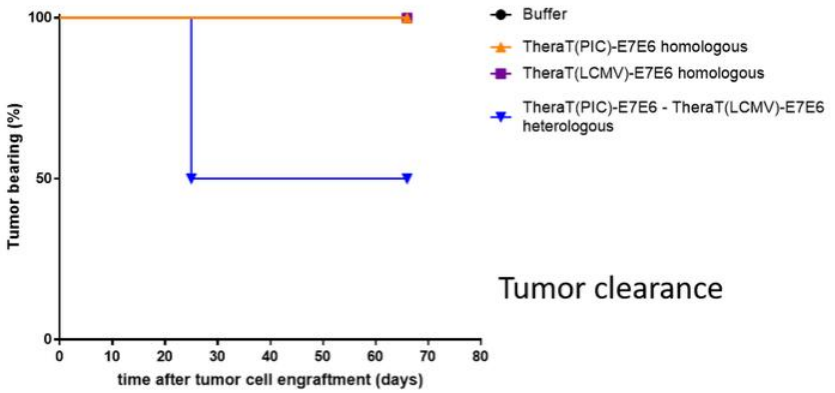


Figure: Bonilla, W. et al. Heterologous arenavirus vector prime-boost overrules self-tolerance for efficient tumor-specific CD8 T cell attack. journal.ppat. 100209. Cell Reports Medicine




Additionally, we have observed that if HB-202 and HB-201 are administered sequentially, activity levels, which tend to indicate effectiveness, are significantly superior to those observed after repeated administration of either one alone.

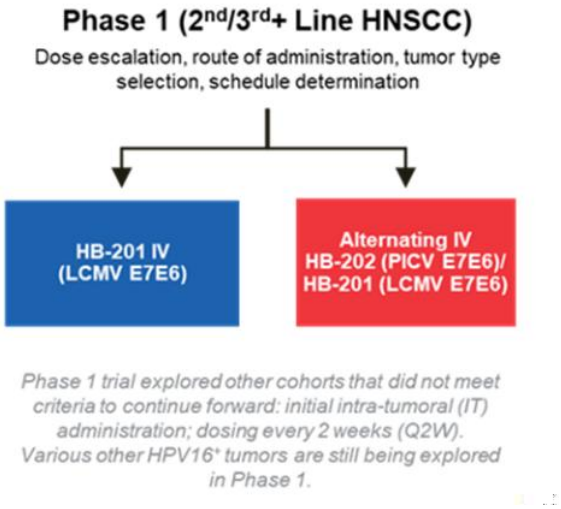
*HB-200 Clinical Trial (NCT04180215)*

Our oncology product candidates, HB-201 and HB-202, are in an ongoing Phase 1/2 clinical trial (NCT04180215) for the treatment of HPV16+ cancers.

In December 2019, we opened the HB-200 Phase 1/2 trial (NCT04180215), investigating both Phase 1 dose optimization and Phase 2 dose expansion in a single trial. During the initial 10 months of the trial, the HB-201 single vector therapy was studied through escalating doses. Starting in October 2020, enrollment into the HB-201/HB-202 alternating sequential two vector therapy began, representing a parallel dose escalation. The primary endpoint of the Phase 1 part of the Phase 1/2 trial is a recommended Phase 2 dose based on safety and tolerability. Secondary endpoints include anti-tumor activity as defined by RECIST 1.1, immunogenicity, safety, and tolerability.

As a first-in-human trial, the Phase 1 arm of the trial opened to investigate multiple questions for HB-200 program:

- Route of administration: intravenous (IV) vs. intratumoral (IT)
- Dose optimization
- Dosing schedule: every two weeks (Q2W) or every three weeks (Q3W)



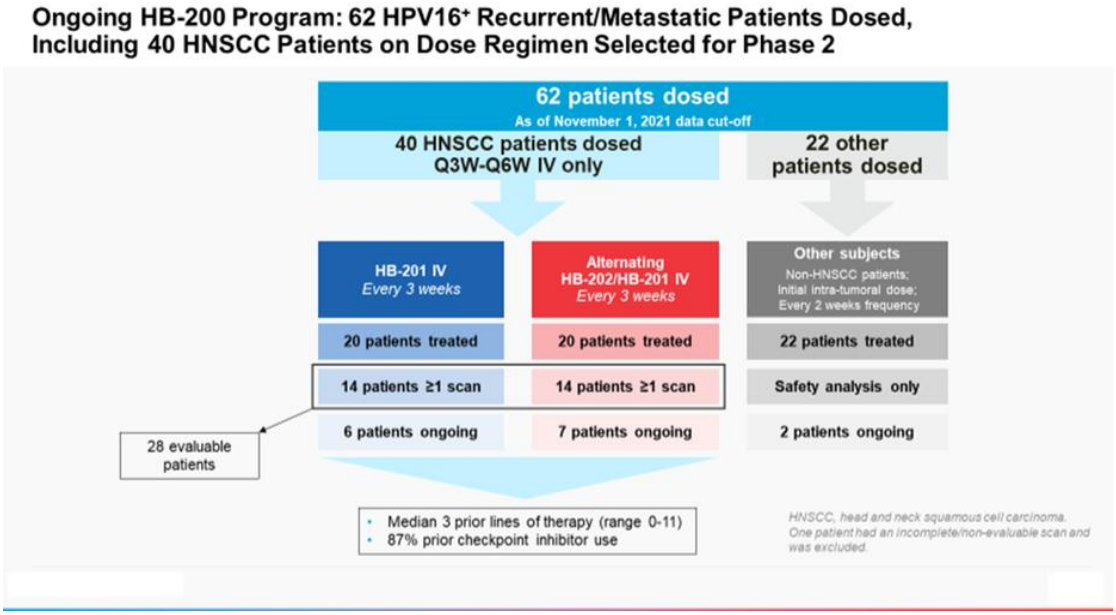

In November 2021, interim Phase 1 data on HB-201 single vector therapy and HB-201/HB-202 two vector therapy for advanced/metastatic HPV16+ cancers showed promising anti-tumor activity and favorable tolerability. The interim data was derived from 62 patients who received either HB-201 single vector therapy or HB-201/HB-202 two vector therapy for advanced/metastatic HPV16+ cancers. Data demonstrated responses and stable disease in head and neck cancer patients who failed prior standard of care therapy, platinum therapy, PD(L)1 inhibitor, or both. We believe that these early-stage data establish proof of concept for our replicating single-vector immunotherapy in oncology.

In addition, the interim Phase 1 data released in November 2021 enabled decisions on Phase 2 clinical plans for target tumor type as well as recommended schedule and route of administration for HB-200:

- IV administration was observed to be superior to IT administration; therefore, the IT route has been discontinued and IV only will be used in Phase 2;
- The initial Q3W dosing schedule was observed to be superior to Q2W; therefore, the Q2W regimen arm has been discontinued and the Q3W dosing will be used in Phase 2;
- The majority of data accrued to date has been from HNSCC patients; therefore, the Phase 2 target tumor type will be HNSCC.

*Patient Details*

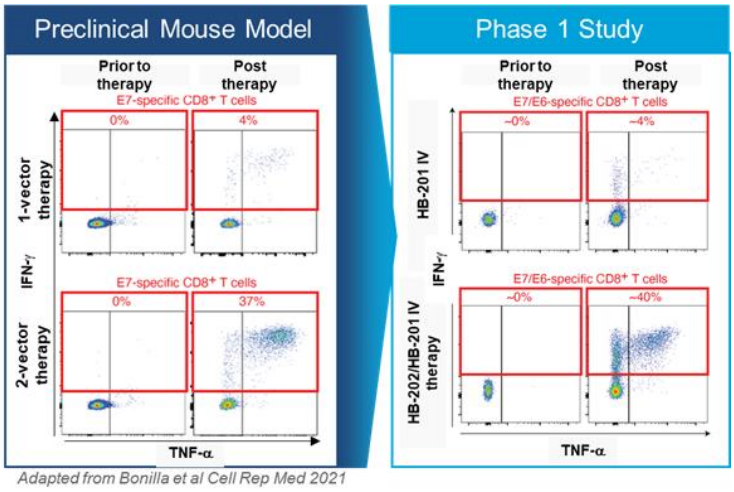
In the November 2021 data release, a total of 62 patients with advanced HPV16+ tumors had been enrolled and treated with HB-200 therapy. Forty patients with HNSCC tumors were treated intravenously every three weeks, including 20 patients who received single vector HB-201 and 20 patients who received alternating two-vector HB-202/HB-201. Twenty-eight of these 40 patients (14 who received single vector HB-201 and 14 who received alternating two-vector HB-202/HB-201) were evaluable (they had at least one scan). An additional 22 patients were dosed in cohorts dedicated to exploring other schedules and/or non-head and neck squamous cell carcinoma subtypes. Participants had received a median of three prior therapies (ranging from zero to eleven), and 87% had previously received a checkpoint inhibitor regimen.




*Clinical Biomarker Data*

The November 2021 data release included clinical biomarker data on 20 patients treated with the Q3W IV regimens (including 10 patients who received HB-201 and 10 who received alternating two-vector HB-201/HB-202). These data demonstrated that HB-200, either as a single or alternating two-vector, rapidly induced high levels of activated, tumor-specific CD8+ T cells. As depicted in the figures below, the clinical data showed remarkable similarity to the preclinical mouse models in terms of expansion of E7E6 specific CD8+ T cells.

- Induction of a substantial T cell response, with up to **40% of E7/E6-specific circulating CD8+ T cells**
- These activated cells are producing TNF-α and/or IFN-g




*Adapted from Bonilla et al Cell Rep Med 2021*

Important clinical biomarker findings in the November 2021 data update included:

- More than 90% of patients showed an increase in tumor-specific CD8+ T cells within 2 weeks of the initial HB-200 dose (*Figure A*);

- More than 50% of patients had tumor antigen-specific CD8+ T cell levels that exceeded the single-digit percentage threshold of the circulating T cell pool, which is generally considered a strong indicator of response (*Figure B*);

- 50% of patients with paired biopsies (3 of 6 patients) showed elevated tumor infiltrating lymphocytes (TILs), or an increase in CD8+ T cells in their tumors (*Figure C*).

*Figure A:* Fast induction of active tumor-specific T cell responses in nearly all patients (ELISpot: HPV16+ E6/E7 specific responses). Direct measurement without prior in vitro expansion of cells; data from HB-201 and HB-201/HB-202 combined.

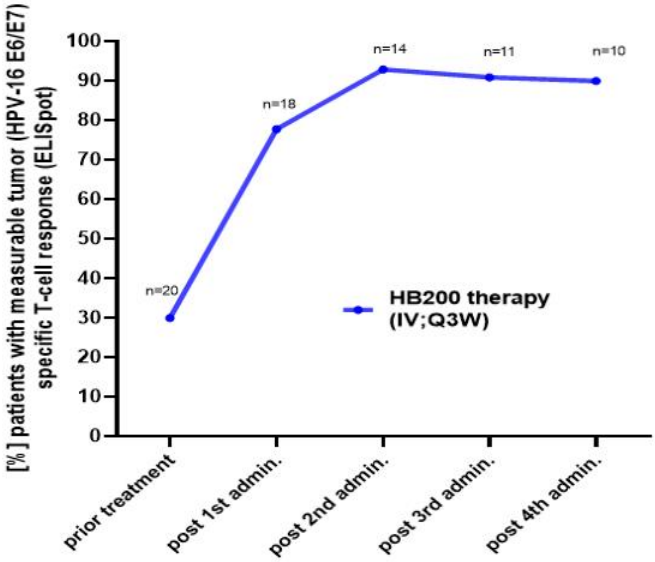



*Figure B:* More than 50% of patients achieved greater than single digit percentage increases of tumor specific systemic CD8+ T cells (HPV16+ E6/E7 specific CD8+ responses). Direct measurement without prior *in vitro* expansion of cells; majority of patients show peak responses within two to three weeks post the first administration of study drug.

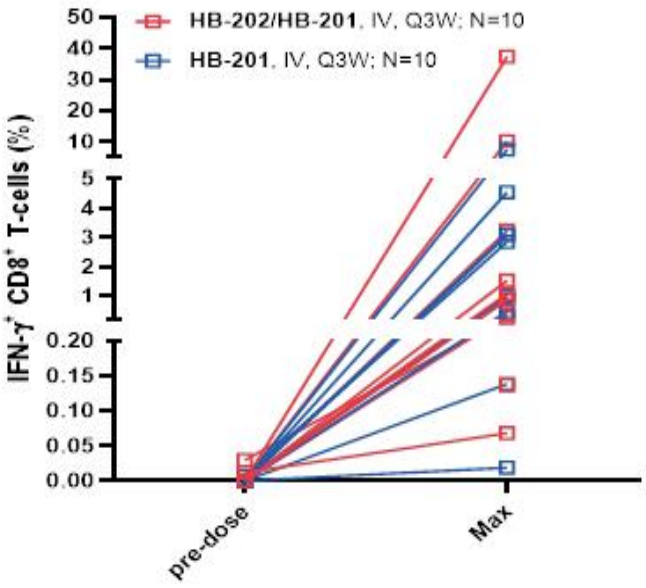
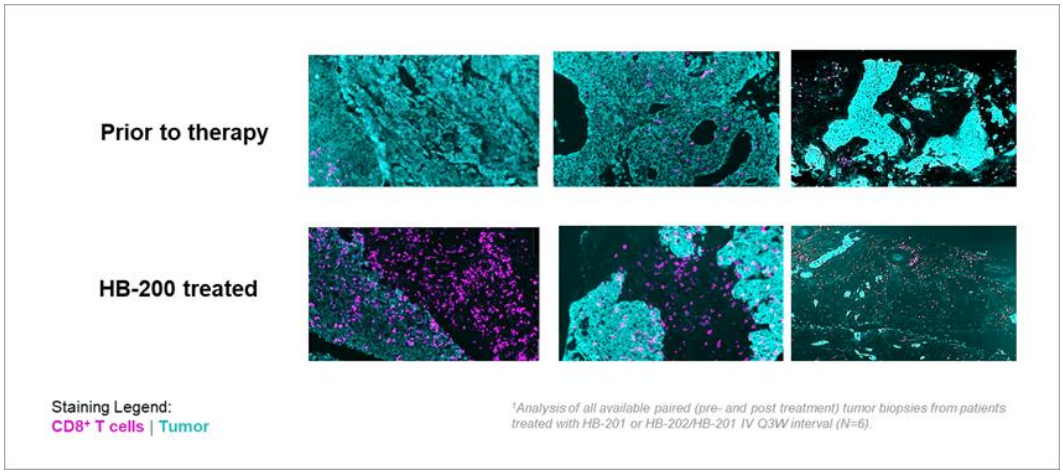



*Figure C*: Three of six of biopsied patients show TILs (i.e. CD8+ T cells infiltrating tumors)




*Clinical Safety Data*

HB-200 continued to demonstrate a favorable tolerability profile in heavily pre-treated patients with HPV16+ cancers, highlighting its potential in combination with checkpoint inhibitors and other agents. As of the November 2021 data release, safety was evaluated across all 62 patients who received any regimen of HB-200, inclusive of all doses, frequencies and routes of administration. As shown below, treatment-related adverse events were reported in 66% of the patients, with 8% experiencing treatment-related adverse events rated grade 3 or higher.

| All groups all cohorts (N=62) | Treatment Related AEs | All AEs |
|---|---|---|
| Any event | 41 (66%) | 56 (90%) |
| Grade ≥3 | 5 (8%) | 26 (42%) |
| Serious | 2 (3%) | 17 (27%) |
| Leading to dose reduction | 1 (2%) | 1 (2%) |
| Leading to discontinuation | 2 (3%) | 6 (10%) |
| Deaths | 0 | 3 (5%) |

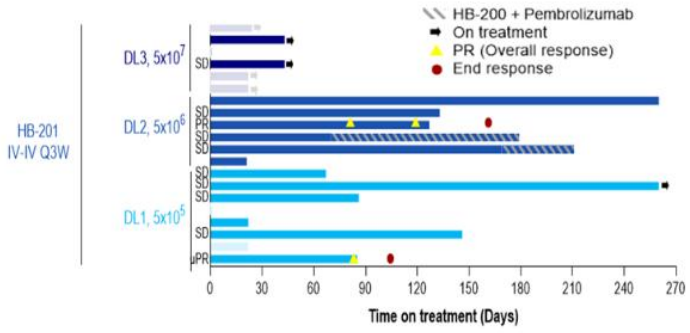
*Data as of 1 Nov 2021.*
*Preliminary Data: Includes unmonitored and unverified data based on current EDC data or data provided by Investigators. Data is subject to change.*

*Clinical Efficacy Data*

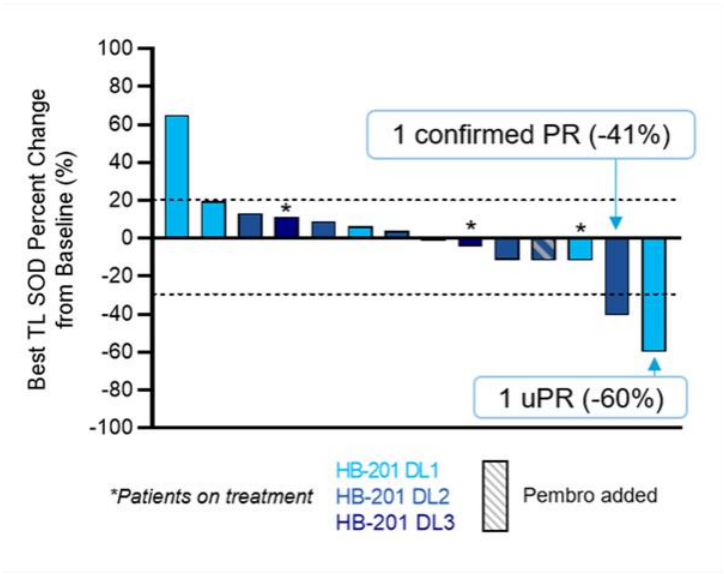
Efficacy was considered for the 40 patients who received the intended Phase 2 dose frequency (initial Q3W, moving to Q6W) and route of administration (IV) for treatment of HPV16+ advanced/metastatic HNSCC. As shown below, the efficacy was evaluated separately for the single vector therapy of HB-201 (20 patients) and for the alternating two vector therapy HB-201/HB-202 (also 20 patients). Combined, the regimens demonstrated tumor shrinkage in 53% of patients (15 of 28 evaluable patients) and an ongoing median progression-free survival (mPFS) of 3.45 months, which compares favorably with published, historical mPFS of 2.0 months for nivolumab in line 2+ HNSCC patients (Ferris et al, NEJM 2016; 375: 1856-1867).

*HB-201 Single Vector Therapy Efficacy Data*

For HB-201, the interim efficacy results released in November 2021 were based on 14 evaluable patients (who had at least one scan) and a median time on treatment of 107 days. As shown below, treatment was ongoing for six of the 14 evaluable patients.

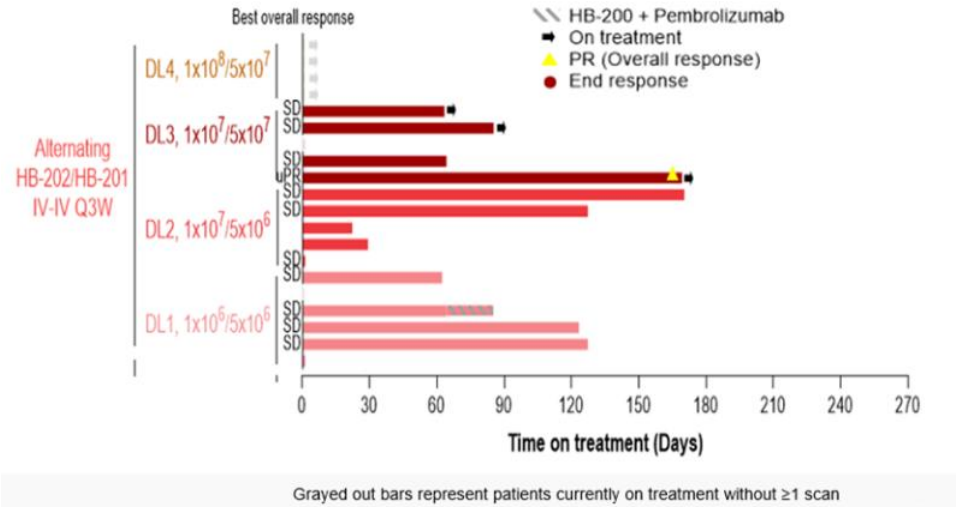


As shown below, the interim data for the HB-201 treated patients included one confirmed PR (41% tumor shrinkage), one unconfirmed PR (60% tumor shrinkage), a disease control rate of 71% (10 of 14 evaluable patients) and tumor shrinkage in 50% of patients.

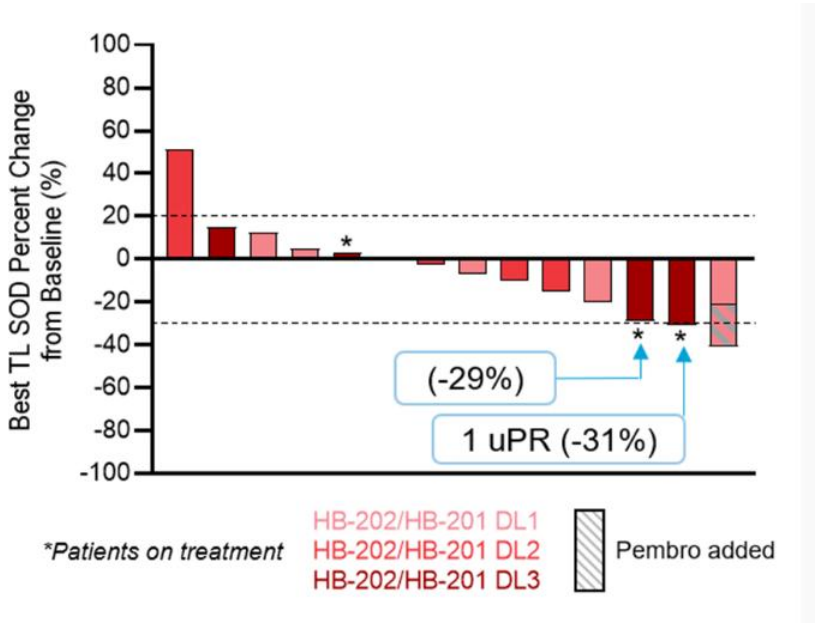



*HB-201/HB-202 Alternating Two Vector Therapy Efficacy Data*

For HB-201/HB-202, the interim efficacy results released in November 2021 were based 14 evaluable patients (who had at least one scan) and a median time on treatment of 75 days. As shown below, treatment was ongoing for seven of the 14 evaluable patients.



As shown below, the interim data for the HB-201 treated patients included one confirmed PR (31% tumor shrinkage), one near PR (29% tumor shrinkage), a disease control rate of 78% (11 of 14 evaluable patients) and tumor shrinkage in 57% of patients.




In connection with the November 2021 update, the Recommended Phase 2 Dose for HB-201 single vector therapy was determined. In January 2022, we dosed the first patient with a combination of HB-201 and pembrolizumab for the treatment of first line advanced/metastatic HPV16+ HNSCC in the Phase 2 expansion portion of the ongoing Phase 1/2 trial (NCT04180215). The Phase 2 portion of the trial is also open for enrollment of patients with second line advanced/metastatic HPV16+ HNSCC for treatment with a combination of HB-201 and pembrolizumab. Similarly, for the alternating sequential two vector HB-201/HB-202 therapy, a Recommended Phase 2 Dose will be determined. Thereafter, enrollment of patients with first line or second line advanced/metastatic HPV16+ HNSCC will begin, using a combination treatment of HB-201/HB-202 and pembrolizumab. Enrollment of those patients will also proceed in the unrandomized Phase 2 dose expansion part of the ongoing Phase 1/2 trial (NCT04180215). The initial data from the combination with pembrolizumab treatment groups of patients with first line or second line advanced/metastatic HPV16+ HNSCC is anticipated in the second half of 2022.

The FDA has granted Fast Track Designation to single-vector HB-201 and alternating two-vector HB-201/HB-202, both in combination with pembrolizumab, for the treatment of first-line advanced/metastatic HPV16+ HNSCC.

In addition to the ongoing nonrandomized Phase 1/2 clinical trial (NCT04180215), in September 2021 we announced a clinical collaboration with Merck & Co., Inc, Kenilworth, NJ, USA, to study HB-200 in combination with pembrolizumab in a randomized Phase 2 trial of patients with first-line advanced/metastatic HPV16+ HNSCC. We anticipate starting this Phase 2 clinical trial in the first half of 2023.

**HB-300 Program for Prostate Cancer**

***Targeting Self Antigens***

We believe that 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.

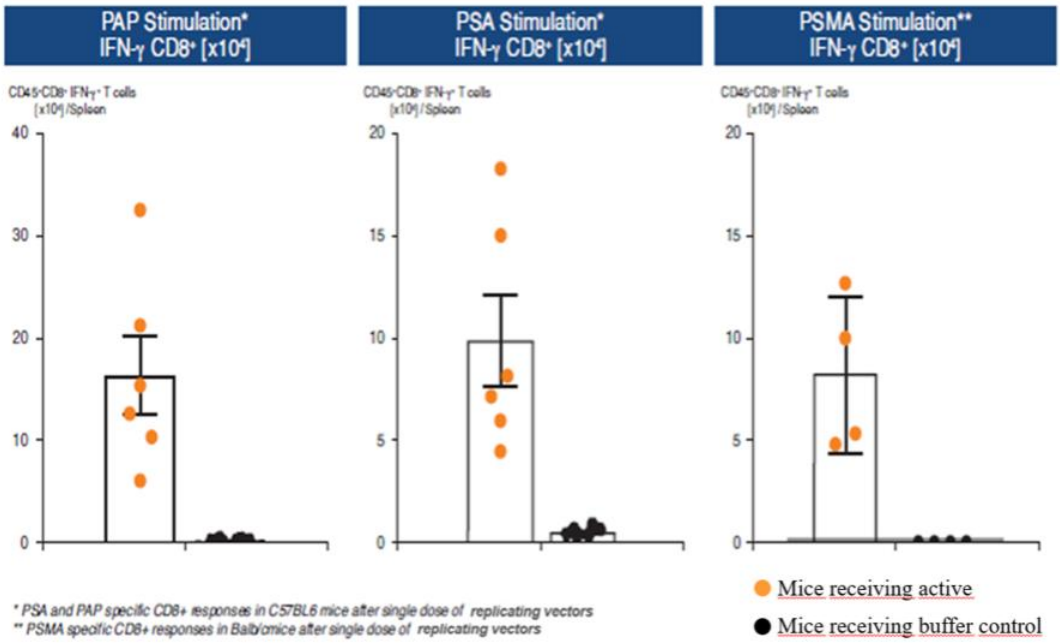
Our HB-200 program targets viral antigens associated with tumors induced by HPV16. In these programs, the viral, or non-self nature of the antigens, makes them a natural target for an immunotherapy approach. In addition, we are pursuing the development of product candidates based on our arenavirus platform to target self-antigens, nonviral antigenic proteins that are highly overexpressed in solid tumors or only minimally expressed in normal cells. Because self-antigens are found in certain normal cells as well as tumor cells, the immune system does not typically recognize them as foreign proteins and does not respond to them. This protection of self-antigens from immune system attack is known as immune tolerance. The results obtained by earlier-generation marketed products such as sipuleucel-T, developed as PROVENGE by Dendreon Pharmaceuticals, Inc. and currently marketed by Sanpower Group Co., Ltd., have proven that it is possible to overcome immune tolerance and activate the immune system to produce an antitumor response.

***Our Solution: HB-300 for Prostate Cancer***

We are developing our most advanced self-antigen candidate in this area, HB-300, based on our replicating technology in metastatic, hormone resistant prostate cancer. 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 targets three of these antigens: prostatic acid phosphatase (PAP), prostate specific antigen (PSA), and prostate specific membrane antigen (PSMA).

Direct evidence for the ability to induce a therapeutically relevant immune response to one of these antigens, PAP, comes from PROVENGE. To create PROVENGE, a personalized treatment, clinicians remove dendritic cells from the body, load them with PAP and then reintroduce them to the patient. The use of PROVENGE has been shown to increase survival in patients with metastatic, hormone resistant prostate cancer. Other companies are developing dendritic cell therapies similar to PROVENGE by using other tumor antigens. All of these dendritic cell therapies require complex, patient-specific therapeutic manufacturing processes involving isolating cells from patients, loading them *ex vivo* with tumor antigens and then readministering the cells to patients.

Our replicating technology has been engineered to contain two additional genes compared to the natural form of the arenavirus. This allows us to express multiple antigens in one construct. In HB-300, we are including the coding sequences for PAP, PSA and PSMA antigens in our vectors. Since it is a replicating-based product candidate, we can deliver HB-300 by simple infusion- and it can target APCs, such as dendritic cells, in the body, without the need for cellular isolation or *ex vivo* processing. We have shown in preclinical experiments that replicating vectors can lead to robust CD8+ T cell responses to the encoded antigens. We intend to maximize these CD8+ T cell responses using a combination of replicating vectors based on both LCMV and PICV in a sequential dosing regimen and are planning to file an IND for HB-300 in the second half of 2022.




In the future, we intend to develop further product candidates against other self-antigens with the aim of eventually establishing a franchise of dendritic cell-targeting agents that take advantage of the ability of arenaviruses to stimulate CD8+ T cell responses.

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

HB-700 is based on our replicating arenavirus platform and was designed for treatment of cancers encoding mutated KRAS. KRAS, as an immunotherapy target, is relevant in many cancers. Many modern, targeted cancer therapies are specific to a cancer type or even sub-groups within those cancer types. The fact that KRAS mutations are present in many different cancers offers the potential for a new therapy to add benefit to the treatment of many patients suffering from myriad cancer types.

Specifically, KRAS is a key regulator of cell proliferation and survival. It 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 is limited and focused on amino acid position 12 (G12D, G12V, G12R, and G12C) and position 13 (G13D), rendering these mutations an attractive target for immunotherapy. We plan to develop our KRAS targeted therapy for patients suffering from pancreatic adenocarcinoma (PAAD), colorectal cancer (CRC) and lung adenocarcinoma (LUAD).

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 showed 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). Hence, we believe that there is an urgent medical need to develop effective therapies for those patients.

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 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 14%. 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 (LUSC) 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 replicating technology has been engineered to encode fragments encoding multiple KRAS mutations found in Pancreatic, CRC and LUAD. Analogous 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, in the body, 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 (HB-201)- and PICV (HB-202)- based vectors have been shown to induce unprecedented tumor antigen-specific CD8+ T cell levels in the context of our HB-200 program, we also intend to maximize HB-700 induced CD8+ T cell responses of by using replicating vectors based on both LCMV and PICV in a sequential dosing regimen.

**Next Generation Product Candidates**

A critical advantage of our technology is that it is designed to deliver full length proteins directly to APCs, such as dendritic cells, for endogenous expression and direct presentation to CD8+ T cells. Having APCs, such as dendritic cells, express full-length proteins and present all fragments (epitopes) overcomes the major difficulty of attempting to predict which part of the protein, or epitope, will be presented by the patient's individual major histocompatibility complex (MHC) class I alleles. This presentation is important in immunotherapy because T cells will only recognize and respond to the antigen when it is bound to the individual's MHC class I molecules, of which several hundred different versions exist in the population. While this approach overcomes the major issue faced by neoepitope based personalized antigen approaches, it also has limitations in that the repertoire of known tumor associated proteins that could be used for targets is limited. The best example of full-length proteins that are, to a degree, cancer specific and immunogenic include the cancer testis antigens, examples of which include NYESO1, MAGE and CAGE. These cancer testis antigens

have been known for decades, and many of them are currently being pursued by other companies. For many tumor types the cancer testis type of antigens remains unknown. Furthermore, most of the known tumor associated antigens are not commonly expressed or are not sufficiently specific to tumor tissue, making them suboptimal targets for clinical development.

In November 2018, we entered into a research collaboration and license agreement with DarwinHealth, a New York City based bioinformatics company pioneering novel bioinformatic approaches, with the intent to identify the next generation of "cancer testis antigens." Our goal is to find novel immunogenic full-length transcripts that are specific for, and highly represented in specific tumor types, allowing for an "off-the-shelf" approach for many cancer types. During the initial collaboration period, we intend to develop and validate the bioinformatics approach and resulting proprietary algorithms. We will start out by identifying "off-the-shelf" next generation cancer-testis type antigens in mouse tumors and will assess the antitumor efficacy of our technology when targeting these same antigens in tumor bearing animals. Mice will thereby serve as a testing ground to validate and optimize our new proprietary bioinformatics algorithms. In parallel we will apply the same validated algorithms to human samples and will prepare the next generation of cancer testis antigens.

**HB-101, a Prophylactic Vaccine for Cytomegalovirus (CMV)**

HB-101 is a vector candidate based on our non-replicating technology that delivers two clinically validated antigens: pp65, to induce CMV-specific CD8+ T cells, and gB, to elicit CMV-neutralizing antibodies. CMV infections present a serious risk for patients with suppressed immune systems, such as solid organ and stem cell transplant recipients. In our Phase 1 clinical trial, HB-101 was well tolerated and elicited strong and durable CMV-specific immune responses in all 42 volunteers in the treatment arm. Importantly, we observed robust CD8+ and CD4+ T cell responses as well as CMV-neutralizing antibody responses. As anticipated, the LCMV vector did not elicit clinically meaningful vector-neutralizing antibodies, as only one volunteer developed a transient neutralizing antibody response against the vector after three administrations. Furthermore, upon repeat administration, the pp65 CD8+ T cell levels achieved by the non-replicating vector increased in a statistically significant manner. The Phase 1 clinical findings were published in the April 2020 issue of The Journal of Infectious Diseases.

In the fourth quarter of 2018, we commenced a randomized, double-blinded Phase 2 clinical trial for HB-101 in CMV-negative patients awaiting kidney transplantation from living CMV-positive donors. Based on HB-101's tolerability profile observed in the target patient population, and to gain further insights to inform a Phase 3 trial design, we added a new cohort of CMV-positive recipients awaiting kidney transplantation from CMV-positive or CMV-negative donors to the trial in early 2020 and amended the investigational new drug (IND) application accordingly in January 2020. The goal of our Phase 2 trial is to assess safety, immunogenicity and efficacy of HB-101 in individuals receiving a kidney transplant from live donors to measure the decrease of post-transplant viremia. In November 2020, we reported initial positive interim safety, immunogenicity and efficacy data in which we observed a pre-transplant three-dose vaccination schedule was able to reduce incidence of CMV viremia, reduce antiviral use and prevent CMV disease. In November 2021, we reported additional strong immunogenicity and reduced incidence of CMV viremia in people who received three doses of HB-101, consistent with results previously reported in November 2020.

The Phase 2 HB-101 clinical trial concluded recruitment in June 2021 with 80 patients dosed. Given the challenges of enrollment of voluntary, live donor kidney transplantation during the on-going COVID-19 pandemic, the total number of patients enrolled in the trial was smaller than the originally planned 150 patients. Patients continue on-trial to progress through transplantation and a 12-month follow-up period. We expect the last patient to complete follow-up in the second half of 2022 and a final data read-out in 2023. As announced in November 2021, based on the strength of our HB-200 data in HPV16+ cancers, we have prioritized our oncology portfolio and we plan to continue developing infectious disease therapies in partnership with other companies.

***Cytomegalovirus***

Cytomegalovirus is a virus that is commonly transmitted in childhood and early adulthood. Approximately 60% of the U.S. population has been exposed, and as such, is latently infected. Worldwide data indicate that while half the people in industrialized countries have been exposed, up to 99% of people in developing countries, including China and

India, have been exposed. Infections result in lifelong latent persistence of the virus with few symptoms, if any. However, in immunosuppressed patients, such as transplant recipients, primary CMV infection or reactivation generally causes significant morbidity, mortality and graft rejection. There are two scenarios in which CMV infections are relevant in the transplant setting. In one case, the recipient could be CMV negative, or previously uninfected, and the donor CMV positive. In this case, introduction of CMV into the immunocompromised recipient can lead to rapid virus spread and development of serious complications. In the other case, the recipient is already CMV positive, but the immunosuppressive treatments required as part of the transplant procedure can lead to reactivation of latent virus. Based on a market research study we commissioned from an independent third party, we believe that approximately 110,000 patients are added to the solid organ transplant waiting list annually in developed countries, with kidney transplantation representing approximately 60% of cases. Furthermore, more than 20,000 allogeneic cell transplants, in which cell and tissue donors are matched with transplant recipients, are carried out annually worldwide. In this group, the incidence of CMV infection is approximately 30% as a result of the donor being CMV positive. Current therapies to prevent the transmission of CMV during organ transplants utilize antiviral prophylactic and therapeutic strategies. However, these therapies are only partially protective in preventing viral disease while also being hampered by toxicity and resistance.

There are currently two standards of care to deal with CMV during solid organ transplant: prophylactic and preemptive. In prophylactic therapy, patients are given antiviral drugs for several months after transplant. Antivirals can reduce the rate of CMV viremia from approximately 70% to 36% in kidney transplant patients over a 12-month period. Of the 36% that present with viremia, most of these cases emerge once antiviral treatment has been stopped. In preemptive therapy, patients are intensively monitored posttransplant for CMV reactivation using laboratory diagnostics, and short term antiviral treatment is given only to those with significant viral loads, or CMV viremia, before symptoms and overt CMV disease occur. In preemptive therapy, most infections occur within a year following a transplant. However, the antiviral drugs used to treat CMV have the potential to induce significant toxicities, including bone marrow toxicity for ganciclovir, valganciclovir and cidofovir, and renal toxicity for foscarnet and cidofovir. In addition, CMV drug resistance mutations arise during this antiviral therapy. Despite the use of prophylactic and preemptive therapy using small molecule antivirals, many transplant patients develop serious symptomatic complications from CMV, highlighting the need for new treatments.

***Cytomegalovirus in Kidney Transplant Patients***

In 2018, approximately 92,000 of the approximately 141,000 solid organ transplants performed worldwide were kidney transplants, an increase of 8.2% compared to 2015. Approximately 80% of high-risk kidney transplant recipients develop active CMV infections. High-risk recipients are defined as CMV negative patients receiving kidney transplants from CMV positive donors. In most solid organ transplant patients, complications from CMV develop between 30 and 90 days after transplantation and rarely after 180 days.

***Our Solution, HB-101***

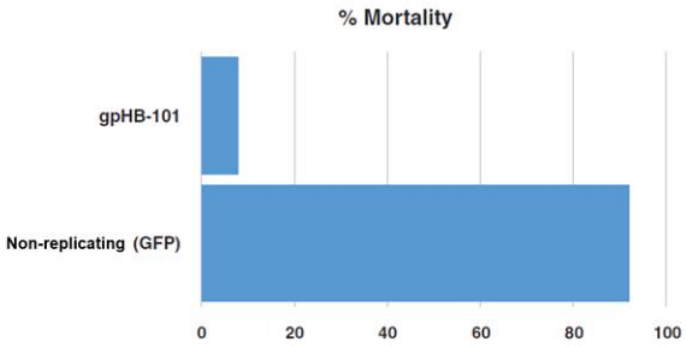
HB-101 is a non-replicating based product candidate designed to stimulate the immune system against CMV and to protect against future CMV infection or reactivation from latency. HB-101 is comprised of two non-replicating LCMV based vectors:

- one vector expresses the gene encoding the CMV 65 kD pp65 protein; and
- another vector expresses the gene encoding the CMV gB protein.

We, and third parties, have shown that pp65 is immunogenic. Adoptive T cell transfer approaches performed by third parties, in which CD8+ T cells directed against pp65 are isolated from exposed individuals and transferred to patients with active CMV viremia, have also demonstrated the therapeutic efficacy of pp65. However, no vaccine approach to date has been successful in achieving CD8+ T cell levels sufficiently high enough to be protective. gB has been shown in previous third-party clinical trials to be immunogenic and protective by inducing antibody responses but not CD8+ T cells. However, response rates were limited, immunity was transient and protection was incomplete. In our preclinical data, using pp65 and gB as targets, we have observed robust immunogenicity, activity and durability thereby potentially overcoming the limitations of current approaches.

*HB-101 Preclinical Results*

In preclinical studies, we have observed that HB-101 has the ability to improve the survival rates in animal models in a statistically significant manner. In our study, nonpregnant female guinea pigs were administered three doses of HB-101 at 30-day intervals. Thirty days after the last vaccination, females were allowed to mate. Following conception, the pregnant females were infected with CMV during the gestation period, putting the guinea pig pups at risk of severe viral infection, low birth weight and potential mortality. As depicted below, guinea pig pups born to CMV infected females that had received a guinea pig equivalent of HB-101 (gpHB101) had a statistically significant ($p<0.0001$) lower mortality rate at birth compared to those born to females who had only received a non-replicating vector carrying an irrelevant antigen, labeled as GFP in the figure below. CMV positive pups born to mothers that received gpHB101 vaccination also gained weight more rapidly and had improved survival rates as compared to those born to mothers vaccinated with placebo.

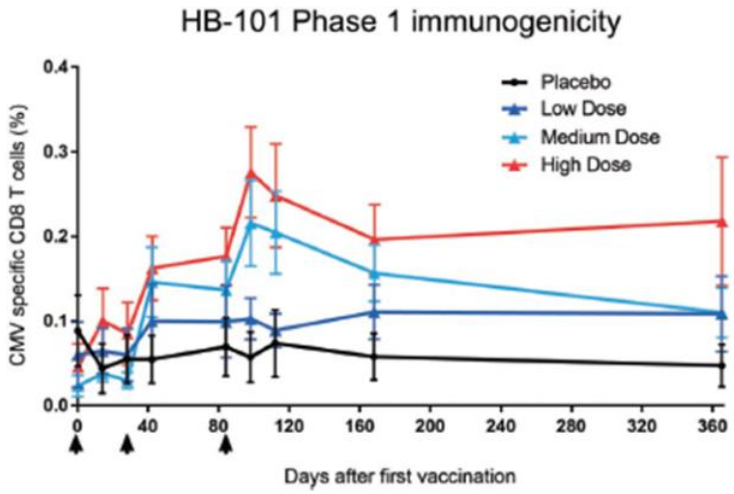



*HB-101 Phase 1 Clinical Results*

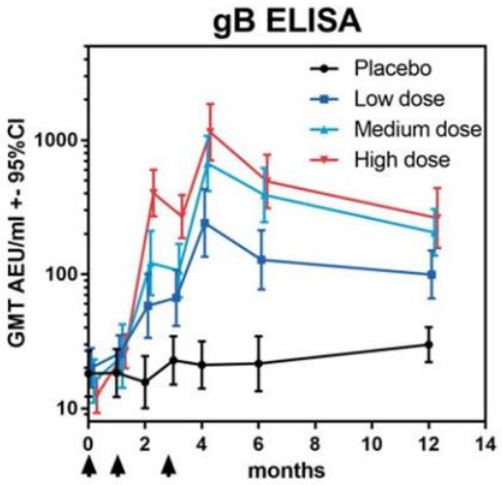
We conducted a placebo controlled, randomized doubleblinded dose escalating Phase 1 clinical trial of HB-101 to assess its safety and immunogenicity. In this trial (NCT02798692), 54 healthy volunteers aged 18 to 45 were administered three consecutive doses of either HB-101 or placebo by intramuscular injection at month zero, one and three, then monitored for one year after the initial dose. The volunteers were randomized into three cohorts of 18 volunteers, with 14 volunteers receiving the study drug and four receiving placebo in each cohort.

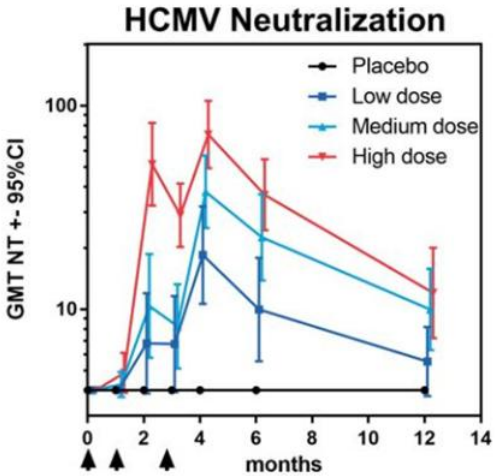
We observed that HB-101 was well tolerated with no dose limiting toxicities and no serious adverse events. Symptoms by volunteers were of mild to moderate intensity and 93.5% of reported symptoms were of short duration (18 days). The maximum duration of any symptom was 10 days. Pain at the injection site was the predominant solicited local adverse event. Malaise, fatigue and generalized myalgia were the most common solicited general symptoms. The percentage of subjects reporting unsolicited causally related adverse events of mild to moderate intensity was similar for placebo and the vaccine groups. Upper respiratory tract infections were the predominant adverse event, occurring at rates in the low dose group that were twice as high as those seen in all three other groups (placebo, middle and high dose). The percentage of volunteers reporting related adverse events of mild to moderate intensity was similar for placebo and vaccine groups. None of the adverse events appeared to be treatment related.

In addition, HB-101 elicited a strong, dose dependent, and durable response as measured by the frequency of pp65 specific interferon gamma (IFNγ) producing CD8+ T cells. Each administration of HB-101, as depicted by the black arrows in the figure below, resulted in an increase in IFNγ producing CD8+ T cells, demonstrating the potential and rationale for repeat administrations of HB-101. Importantly, the frequencies of IFNγ producing CD8+ T cells induced by the highest dose of HB-101 after the third administration in healthy volunteers were in the range of, or higher than, the therapeutic levels reported in human adoptive T cell therapy clinical trials which were separately designed and conducted by third parties for patients with active CMV viremia. These frequencies were observed to be therapeutic in patients experiencing active CMV infection following stem cell as well as organ transplantation.




Similarly, HB-101 administration also resulted in a strong neutralizing antibody response to the CMV antigen gB that increased with each additional dose, as depicted by the black arrows in the figures below, which was sustained over the 12-month follow up period. All volunteers receiving the highest or middle doses of HB-101, and 92% of the volunteers receiving the lowest dose, developed CMV neutralizing antibodies. The levels of antibodies generated in the highest dose after three doses were comparable to therapeutic levels reported with other CMV vaccine product candidates in development that have demonstrated clinical efficacy in separately designed and conducted, published third-party clinical trials. As anticipated, the LCMV vector did not elicit clinically meaningful vector neutralizing antibodies, as only one volunteer developed a transient neutralizing antibody response against the vector after three administrations. We believe that a fourth administration of the vaccine in all 42 of these volunteers could have resulted in an additional antibody response, if desired.



*HB-101 Phase 2 (H100-001) Clinical Development Plan and Results*

In the fourth quarter of 2018, we initiated a randomized, multi-center double blind Phase 2 trial (NCT03629080) of HB-101 to assess the safety, reactogenicity, immunogenicity and efficacy of HB-101 in CMV-negative patients receiving a kidney transplant from living CMV-positive donors. Based on HB-101's observed tolerability profile in the target patient through August 24, 2020 cut off date, and to gain further insights that will inform a potential Phase 3 trial design, we added a new cohort of CMV-positive recipients awaiting kidney transplantation from CMV-positive or CMV-negative donors to the trial in early 2020.

We enrolled patients in three treatment arms:

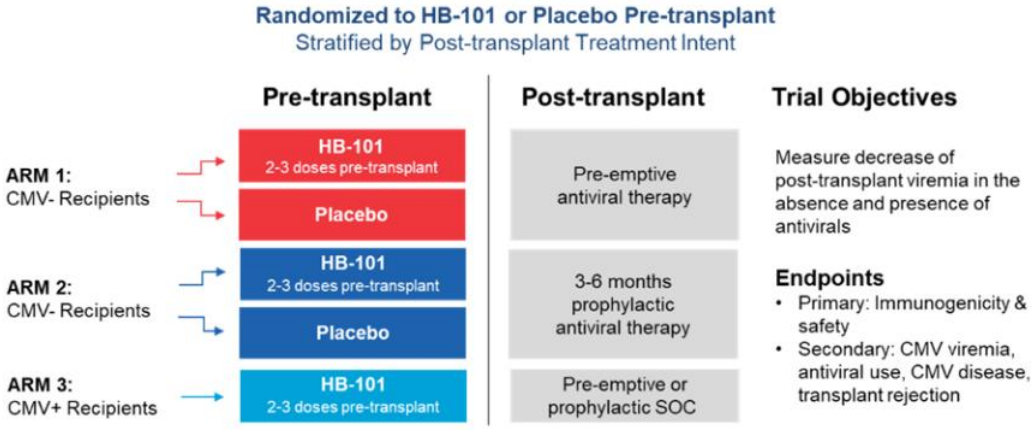
- Arm 1 (CMV-negative, pre-emptive antivirals): CMV-negative patients were randomized 2:1 to either receive two to three administrations of HB-101 or placebo prior to transplant and then treated with standard preemptive antiviral therapy post-transplant.

- Arm 2 (CMV-negative, prophylactic antivirals): CMV-negative patients were randomized 2:1 to either receive two to three administrations of HB-101 or placebo before transplant and will then receive three to six months of antiviral prophylaxis therapy post-transplant.

- Arm 3 (CMV-positive, prophylactic antivirals): CMV-positive patients received two to three administrations of HB-101 before transplant and will then receive up to six months of antiviral prophylaxis therapy post-transplant.

Patients are monitored for twelve months post-transplant to assess safety and T cell and antibody responses to pp65, gB and the LCMV vector, as well as CMV viremia and the need for use of antivirals.

The trial design is depicted in the figure below.




In June 2020, we reported initial interim safety and immunogenicity data (containing both CMV specific antibody and CMV specific CD8+ T cell responses) from the ongoing Phase 2 trial. HB-101 was observed to be well tolerated with fewer adverse events in patients with end-stage kidney disease than in the previous healthy volunteer trial. Patients who received three doses of HB-101 showed comparable immunogenicity to healthy volunteers in the Phase 1 clinical trial of HB-101.

Safety and tolerability data was reported in June 2020, which evaluated 51 CMV-negative patients prior to kidney transplantation. Of the 51 patients, eight patients (16%) across the combined, blinded HB-101 and placebo

groups showed adverse events related to the administration. Most of these adverse events were of mild intensity, indicating that HB-101 was generally well tolerated in this patient population.

CMV-neutralizing antibody titers on the day of transplantation were evaluated in all of the 30 CMV-negative patients who had been transplanted by the cutoff date and had valid results. Nineteen of the 30 patients received HB-101 and eleven received placebo. All five patients who received three doses of HB-101 mounted CMV-neutralizing antibodies. Three of the fourteen patients (21%) who received only two doses of HB-101 also mounted CMV-neutralizing antibodies. The antibody response of the kidney transplant recipients who completed the three-dose regimen was comparable to the antibody response observed in the Phase 1 trial.

Cellular immune (CD8+ T cell) responses to CMV on the day of transplantation were evaluated in 25 CMV-negative patients who had been transplanted in time for this interim analysis. Technically valid results from T cell assays on the day of transplantation were available for seven recipients (as a consequence of sample logistics and assay performance). Two of the seven patients received placebo and five received HB-101. All three patients (100%) who received three doses of HB-101 and one of the two patients who received only two doses (50%) mounted a CMV-specific cellular immune response.

In November 2021, we reported an additional interim data update on the ongoing Phase 2 trial, encompassing safety, immunogenicity, and preliminary efficacy data.

Safety and tolerability were evaluated in 80 participants who were dosed in the trial by the cut-off date. HB-101 was generally well tolerated with a low incidence of side effects, which were mostly mild to moderate. Specifically, 21.3% of participants across the combined HB-101 and placebo groups showed side effects related to vaccine administration. Five cases of human leukocyte antigen (HLA)-sensitization have been reported, two as serious adverse events. HLA-sensitization is a known complication of dialysis patients waiting for kidney transplantation, affecting an estimated 4% of this patient population.

The interim immunogenicity analysis included CMV-neutralizing antibody data assessed from 33 patients, a subset of the 52 included in the efficacy analysis. 21 participants were vaccinated with HB-101 and 12 received placebo. In line with the previous interim data, all of the participants who received three doses of HB-101 mounted CMV-neutralizing antibodies.

The preliminary efficacy analysis included data from 52 participants as of the cut-off date; 9 were vaccinated with three doses of HB-101 pre-transplant, 25 were vaccinated with two doses and 18 received placebo.

Compared to placebo, participants vaccinated with three HB-101 doses had:

- A 41% reduction in CMV viremia (presence of CMV DNA in the blood);
- A 41% reduction in the use of antiviral therapy; and
- No CMV disease (compared to 2 out of 14 cases in the placebo group)

Response to a two-dose schedule did not show an improvement compared to placebo, which is consistent with the low levels of CMV-neutralizing antibody in the two-dose cohort as well as with the T cell data reported in June 2020 for the two-dose group.

Enrollment of this trial concluded in June 2021. Dosed patients will continue on-study to progress through transplantation and a 12-month follow-up period. We expect the last patient to complete follow-up by the second half of 2022 and a final data read-out in 2023. We will explore partnership opportunities for further development of HB-101 in order to focus on advancing our oncology portfolio.

**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 February 24, 2022, we are the owner or exclusive licensee to nine issued U.S. patents and ten pending U.S. patent applications, two pending international Patent Cooperation Treaty (PCT) applications, five pending U.S. provisional patent applications, and 105 issued foreign patents and approximately 78 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 four patents granted in the United States and patents granted in Europe (validated in Austria, Belgium, Czech Republic, Denmark, France, Germany, Ireland, Italy, Netherlands, Poland, Spain, Sweden, Switzerland and the United Kingdom), Canada, China, India, Hong Kong and Japan. This patent family also includes pending applications in the United States, Europe, China, Hong Kong and India. 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), Hong Kong and Japan. The European patent in this family (European Patent No. 3218504) was opposed by a third party in April 2021. This patent family also includes pending applications in the United States, Europe, Canada, Australia, Japan, India, China and Hong Kong. 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 pending applications in various countries, including in the United States, Europe, Eurasia, Hong Kong, Korea, China, Canada, Australia, New Zealand, Mexico, Japan, Brazil, Singapore, India, and Israel. The granted United States patent from the first patent family is expected to expire in April 2037 due to patent term adjustment. The granted patents in Europe, Hong Kong and Japan, and the pending applications related to our replicating technology are expected to expire between 2035 and 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.

***Split Vector Technology Portfolio***

We have an exclusive license from the University of Basel to proprietary patent positions related to a novel molecular strategy to vectorize arenavirus genomes, which we refer to as the Split Vector Technology. Our patent portfolio related to the Split Vector Technology includes an international PCT application exclusively licensed from the University of Basel as well as a pending U.S. provisional patent application 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. Applications claiming priority to the respective PCT application are expected to expire in November 2040, 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 Split Vector technology is currently not employed in any of our clinical stage product candidates or late-stage preclinical programs.

***Oncology Technology Portfolio***

For the application of our non-replicating and replicating technologies in oncology, we own three patent families. Each of these patent families include pending applications in the United States, Europe, Australia, Canada, China, Hong Kong, India and Japan. These patent families relate to potential clinical uses of our product candidates, such as combination treatments and modes of administration. The pending applications are expected to expire between 2036 and 2038, 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-101 (Cytomegalovirus)***

Our HB-101 product candidate relies on our non-replicating technology. In addition to the non- replicating patent portfolio, we own one patent family that more specifically relates to our HB-101 product candidate. This patent family includes one patent granted in the United States with claims directed to pharmaceutical compositions. This patent family also includes granted patents 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, Hong°Kong and Japan, as well as pending applications in the United States, Europe, Australia, Canada, China, India and Japan. Excluding the non- replicating patent portfolio, the granted patent and pending applications specifically related to our HB-101 product candidate are expected to expire in 2034, 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.

***Hepatitis B Virus***

Our Hepatitis B Virus program, codeveloped with Gilead, is in the preclinical phase and is being built on either our non-replicating or replicating technologies. In addition to the non-replicating and replicating patent portfolios, we own one patent family that relates to the use of our platform technologies for prevention and treatment of Hepatitis B Virus. This patent family includes patents granted in the United States and Japan. 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 and replicating patent portfolios, the granted patents and pending applications related to the Hepatitis B Virus 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.

***HIV***

Our HIV program, codeveloped with Gilead, is in preclinical phase and is being built on either our non-replicating or replicating technologies. We announced an amended agreement wherein we will assume development

responsibilities through the end of Phase 1b. We currently do not own any patents or patent applications that more specifically relate to an HIV program outside of the non-replicating and replicating patent portfolios.

***HB-201 (HPV16+)***

Our HB-201 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 own two patent families that relate more specifically to our HB-201 product candidate. The first patent family includes one patent granted in the United States and one patent granted in Australia 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 currently includes a pending international Patent Cooperation Treaty (PCT) application relating to HB-201 treatment regimens. Excluding the replicating and oncology patent portfolios, the granted patents and pending applications specifically related to our HB-201 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-202 (HPV)***

Our HB-202 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 own two patent families that relate more specifically to our HB-202 product candidate. The first patent family includes one patent granted in the United States and one patent granted in Australia 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 currently includes a pending international Patent Cooperation Treaty (PCT) application relating to HB-202 treatment regimens. Excluding the replicating and oncology patent portfolios, the granted patents and pending applications specifically related to our HB-202 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-300***

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 pending U.S. provisional patent application that more specifically relates to our HB-300 product candidate. This provisional patent application is not eligible to become an issued patent until, among other things, we file a nonprovisional patent application within 12 months of the filing of our provisional patent application. If we do not timely file any nonprovisional patent applications, we may lose our priority date with respect to our provisional patent application and possibly any patent protection on the inventions disclosed in our provisional patent application. Subject to the timely filing of a non-provisional patent application, any patent claiming priority to this pending provisional patent application specifically related to our HB-300 product candidate is 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-700***

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 two pending U.S. provisional patent applications that more specifically relate to our HB-700 product candidate. These provisional patent applications are not eligible to become issued patents until, among other things, we file at least one nonprovisional patent application within 12 months of the filing of our provisional patent applications. If we do not timely file any nonprovisional patent applications, we may lose our priority date with respect to our provisional patent applications and possibly any patent protection on the inventions disclosed in

our provisional patent applications. Subject to the timely filing of at least one non-provisional patent application, any patent claiming priority to these pending provisional patent applications specifically related to our HB-700 product candidate is 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.

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 a Research Collaboration and License Agreement, 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 Hepatitis B Virus or HIV, which we refer to, collectively, as the Field.

Pursuant to the Collaboration Agreement, we granted Gilead an exclusive (even as to us and our affiliates), 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 Hepatitis B Virus 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 Collaboration Agreement, we will own all new intellectual property conceived or created out of the activities conducted under the 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 Collaboration Agreement.

On February 15, 2022, we entered into the Restated 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 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 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 Collaboration Agreement will be deemed terminated with respect to the HIV Development Plan and HIV Licensed Products (each as defined in the Restated Collaboration Agreement), and the Field and rights granted under the Restated 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 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 a Stock Purchase Agreement.

***Governance***

The development of the programs governed by the Collaboration Agreement is overseen by a six member joint steering committee (JSC), comprised of three representatives from each of us and Gilead. The JSC will oversee the activities carried out pursuant to the Collaboration Agreement, including settling disputes arising under the Restated Collaboration Agreement, and approving a Licensed Product as being ready for development. Similarly, the Collaboration Agreement establishes a four member joint development committee (JDC) to oversee HIV development activities.

***Research on Hepatitis B Virus and HIV products***

Under the original Collaboration Agreement, we are responsible for manufacturing and supplying to Gilead Lymphocytic Choriomeningitis Virus and Pichinde Virus based vectors expressing one or more Hepatitis B Virus antigens to the extent necessary for both us and Gilead to carry out our respective research activities under the research plans. These research plans are largely completed and both programs have advanced to development stage.

***Development and Commercialization of products***

Pursuant to the Restated Collaboration Agreement, Gilead is solely responsible for conducting the development activities, including all regulatory filings, at its expense for any product arising from the Restated Collaboration Agreement designated for development by Gilead and approved by the JSC with respect to the HBV product candidates and we are responsible for conducting development activities for the HIV product candidates through the end of a Phase 1b study. If Gilead exercises the Option for the HIV product candidates, Gilead will be solely responsible for further (post Phase 1b) development activities of the HIV product candidates. Gilead is also solely responsible, at its expense, for the manufacture and commercialization of any HBV Licensed Product developed and commercialized under the Restated Collaboration Agreement, and if the Option is exercised, it will responsible, at its expense, for the manufacture and commercialization of any HIV Licensed Product.

***Non-Compete***

We may not, directly or indirectly, conduct, participate in or fund any research, development, manufacture, or commercialization of, or with respect to products utilizing arenavirus based vectors for the treatment, cure, diagnosis, or prevention of Hepatitis B Virus or HIV, except for the activities we are expressly permitted to perform under the Restated Collaboration Agreement. If the Option expires or is terminated, the non-competition terms contained in the Restated Collaboration Agreement shall not be applicable to the development for HIV indications.

***Right of First Negotiation***

Pursuant to the 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 Collaboration Agreement will not be applicable to the development for HIV indications.

***Financial Terms***

Upon execution of the Collaboration Agreement, Gilead paid us a one-time upfront fee of $10.0 million and through to December 31, 2021, we received $12.2 million in milestone payments for the achievement of pre-clinical research milestones.

Upon execution of the Restated 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 Collaboration Agreement. In addition, Gilead is obligated to pay us for all out-of-pocket costs actually incurred by us in connection with the HBV program.

In addition, Gilead is obligated to pay us for all out-of-pocket costs actually incurred by us in connection with the Hepatitis B Virus 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 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 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 will provide Gilead with drug product for use in proof-of-concept clinical trials associated with the Licensed Products designated under the Collaboration Agreement. We will receive reimbursement at an agreed cost

in accordance with the terms of the Restated 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 Collaboration Agreement, on February 15, 2022, the Effective Date, we entered into a Stock Purchase Agreement, 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 1,666,666 unregistered shares of our common stock in exchange for approximately $5.0 million at a purchase price per share equal to $3.00. Pursuant to the terms of the Stock Purchase Agreement, we may require Gilead to purchase the balance of the $30.0 million of common stock in two subsequent purchases. The purchase price per share of the first subsequent purchase shall be equal to (a) the VWAP Purchase Price (as defined in the Stock Purchase Agreement), calculated at the date we exercise our right to require Gilead to purchase shares, plus (b) a premium of 30% on the VWAP Purchase Price, and the purchase price per share of the second subsequent purchase shall be equal to the VWAP Purchase Price, calculated at the date we exercise our right to require Gilead to purchase shares. 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 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 31, 2023.

Pursuant to the terms of the Stock Purchase Agreement, we and Gilead agreed to enter into a registration rights agreement within two months following the Effective Date, obligating us to file a registration statement on Form S-3 to register for resale the initial 1,666,666 shares of common stock issued to Gilead within six months of the issuance on the Effective Date and thereafter, within four months of any additional purchases of common stock by Gilead.

**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, the Basel Split Agreement. Pursuant to the Basel Split Agreement, the University of Basel granted us a worldwide, exclusive license under a currently pending international Patent Cooperation Treaty (PCT) application related to a novel molecular strategy to vectorize arenavirus genomes (Split Vector Technology as described in the Intellectual Property Section), including any patents and patent applications that claim priority thereto, the Basel Licensed Split Patent Rights, to make or to have made, to develop or have developed, to use, have used, sell, have sold, market, have marketed, offer for sale, distribute, have distributed, import or have imported products, the manufacture, use, sale, or importation of which would infringe a claim of the Basel Licensed Split Patent Rights, each a Basel Licensed Split Product. 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 a currently pending U.S. provisional patent application related to certain improvements of the Split Vector Technology, including any patents and patent applications that claim priority thereto, such patents and patent applications are further included in the Basel Licensed Split Patent Rights.

Pursuant to the terms of the Basel Split Agreement, we are obligated to use commercially reasonable efforts to develop and manufacture Basel Licensed Split Products and make commercially available Basel Licensed Split Products in the United States and at least three major European countries. In addition, we have to reach certain pre-clinical and clinical development milestones within specified time periods.

We have the right to request postponement of pre-defined pre-clinical or clinical development milestones against payment of rescheduling fees in the range of CHF 100,000 to CHF 1,000,000.

If we fail to perform any of our diligence obligations specified in the Basel Split Agreement, after having exercised all available postponement options, the University of Basel can demand a written development and marketing plan. If we fail to agree with the University of Basel on any amendments to our development and marketing plans based on the procedure specified in the Basel Split Agreement upon such demand for amendments from the University of Basel, the University of Basel has the right to send us a notice of its intention to terminate the Basel Split Agreement. If we are not in agreement, we may request that the matter is assessed by an independent expert arbitrator. If such an expert arbitrator determines that we fail to meet our diligence obligations, the University of Basel may terminate the Basel Split Agreement.

Beginning on January 1, 2021, and ending on the date of the first commercial sale of a Basel Licensed Split Products, we are required to provide the University of Basel with an annual report detailing our efforts to develop Basel Licensed Split Products and to obtain governmental approvals necessary for marketing the same.

We paid the University of Basel a nominal amount upon entering into the agreement and are required to pay a non-material annual maintenance fee, which is deductible from any milestone payments, royalties or sublicense payments payable by us to the University of Basel during the same year. We are required to pay the University of Basel, subject to the achievement of specified development and regulatory milestones, payments aggregating up to CHF 1,700,000 per Basel Licensed Split Product. While the Basel Split Agreement remains in effect, we are required to pay the University of Basel low single digit royalties on net sales of Basel Licensed Split Products. We must also pay the University of Basel a low double digit to low single digit percentage, decreasing as a Basel Licensed Split 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 Split Patent Rights, and the costs related thereto.

Unless earlier terminated, the Basel Split Agreement remains in effect until the expiration of the last to expire of the Basel Licensed Split Patent Rights. Following the expiry of the Basel Split Agreement due to the last to expire of the Basel Licensed Split Patent Rights, we will have a fully paid up, royalty free right to use, sell and commercialize Basel Licensed Split 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 Split Agreement if we file a petition for bankruptcy or insolvency or both, or reorganization relating to bankruptcy or insolvency, or in the event of an adjudication that we have become

bankrupt or insolvent or both. The University of Basel may further terminate the Basel Split Agreement if we oppose or dispute the validity of any of the Basel Licensed Split Patent Rights or assist a third party to do the same. If we fail to perform any of our diligence obligations specified in the Basel Split Agreement, after having exercised all available postponement options, and if we fail to agree with the University of Basel on any amendments to our development and marketing plans based on the procedure specified in the Basel Split Agreement upon such demand for amendments from the University of Basel, the University of Basel may terminate the Basel Split Agreement.

***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, or 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.

**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, making this a highly competitive market.

We face substantial competition 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.

Companies that compete with us directly on the level of the development of product candidates in our therapeutic areas include, among others:

- In CMV management, companies such as Helocyte, Inc., VBI Vaccines Inc., Moderna, Inc., SL VaxiGen Inc., and Merck & Co.

- In immunooncology for HPV+ cancers, companies such as ISA Pharmaceuticals B.V., Moderna, BioNTech, Kite, CureVac, Adaptimmune PLC Transgene, and TCR Cure;

- In metastatic Hormone Resistant Prostate Cancer, companies such as Bioray Labs, Regeneron, Allife Medical, Gemoab, BioNTech, Inovio and Madison Vaccine are investigating an immuno-oncology approach.

On the technology level, other direct competitors which can potentially develop competing product candidates in areas in and outside of HPV16+ cancers and CMV infection such as neoantigens, oncolytic viruses, bispecific

antibodies, engineered cell therapies and tumor specific antigens, and other active immunization technologies, include, among others, Gritstone Oncology, Inc., in collaboration with bluebird bio, Inc., Replimune Group, Inc., in collaboration with Bristol-Myers Squibb Company, Merck & Co., Abalos GmbH, BioNTech, Moderna, Turnstone Biologics Inc., Adaptimmune PLC, CureVac AG, Roche Holdings AG, Five Prime Therapeutics, Inc., and Novartis International AG.

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 based and replicating based product candidates. For GMP production and testing we rely on qualified CMOs to produce and test our clinical material. Currently we do not own or operate manufacturing facilities beyond laboratory scale non-GMP production. We require that our CMOs produce bulk drug substances and finished drug products in accordance with cGMP, and all other applicable laws and regulations. Although we plan to establish our own manufacturing facility, we may continue to rely on CMOs for parts of the process, like filling and labelling of our products for commercial sale, to reduce supply risks and cost of goods sold. 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.

We plan to ultimately establish our own manufacturing facility. By complementing CMO capacity with our own manufacturing facility, we aim to balance supply risks, reduce supply cycle time and optimize costs. We believe that having control over the whole manufacturing process will allow us to further increase the robustness and consistency of the process. We expect that control over our own manufacturing facility will also help to shorten overall timelines for new product candidates in our development pipeline, as well as help us develop drug formulations or presentations to simplify distribution as well as administration of future immuno-therapeutics. We also believe that having a dedicated manufacturing facility will allow us to optimize commercial scale processes and to develop a suitable workforce capable of supporting market launch.

**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. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws.

***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. According to the FDA's fee schedule, effective through September 30, 2022, the user fee for an application requiring clinical data, such as a BLA, is $3,117,218. The sponsor of an approved BLA is also subject to an annual prescription drug program fee, which for fiscal year 2022 is $369,413. 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 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. If the FDA concludes that a drug or biologic shown to be effective can be safely used only if distribution or use is restricted, it will require such post-marketing restrictions, as it deems necessary to assure safe use of the product. If the FDA determines that the conditions of approval are not being met, the FDA can withdraw its accelerated approval for such drug or biologic.

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.

***U.S. Healthcare Reform and 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, other divisions of the Department of Health and Human Services, 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 Anti-Kickback 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. The applicable federal, state and foreign healthcare laws and regulations that can affect a pharmaceutical company's operations include those referenced in the section titled "Business – U.S. Healthcare Reform and 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 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 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.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the ACA was passed, which substantially changes 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, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, 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 50% (70% commencing January 1, 2019) 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.

Since the ACA's enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an Executive Order to initiate a special enrollment period from February 15, 2021,

through August 15, 2021, for purposes of obtaining health insurance coverage through the ACA marketplace. The Executive Order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden administrations or other efforts, if any, to challenge repeal or replace the ACA, will impact our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013. Pursuant to the Coronavirus Aid, Relief, and Economic Security Act, also known as the CARES Act, as well as subsequent legislation, these cuts have been suspended from May 1, 2020, through March 31, 2022, due to COVID-19 pandemic. Following the suspension, a 1% payment reduction will occur beginning April 1, 2022, through June 30, 2022, and the 2% payment reduction will resume on July 1, 2022.

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.

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 (CCPA) was enacted in June 2018, became effective on January 1, 2020, and became subject to enforcement by the California Attorney General's office on July 1, 2020. The CCPA broadly defines personal information, and creates new 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. In addition to the CCPA, new privacy and data security laws have been proposed in more than half of the states in the U.S. and in the U.S. Congress, reflecting a trend toward more stringent privacy legislation in the U.S., which trend may accelerate depending on the new U.S. presidential administration. 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.

***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 as part of the ACA. This amendment to the PHSA, in part, attempts to minimize duplicative testing. 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 European Union (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 agencies 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, or Regulation, which replaced the Clinical Trials Directive 2001/20/EC, or Directive, on January 31, 2022. The transitory provisions of the new Regulation offer sponsors the possibility to choose between the requirements of the previous Directive and the new Regulation if the request for authorization of a clinical trial is submitted in the year after the new Regulation became applicable. If the sponsor chooses to submit under the previous Directive, the clinical trial

continues to be governed by the Directive until three years after the new Regulation became applicable. If a clinical trial continues for more than three years after the Regulation became applicable, the new Regulation will at that time begin to apply to the clinical trial.

The new Regulation aims to simplify and streamline the approval of clinical trials in the EU. The main characteristics of the regulation include: a streamlined application procedure via a single-entry point through the Clinical Trials Information System, or 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 contains scientific and medicinal product documentation and Part II contains the national and patient-level documentation). Part I is assessed by a coordinated review by the competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted (Member States concerned) of a draft report prepared by a Reference Member State. Part II is assessed separately by each Member State concerned. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned EU Member State. However, overall related timelines will be defined by the Regulation.

***European Union Drug Review and Approval***

In the EU, medicinal products can only be commercialized after obtaining a marketing authorization, or MA. There are two types of marketing authorizations.

- The centralized MA is issued by the European Commission through the centralized procedure, based on the opinion of the Committee for Medicinal Products for Human Use (CHMP) of the EMA and is valid throughout the entire territory of the EU, and in the additional Member States of the European Economic Area (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 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 EU.

- 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 a marketing authorization application, or 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 makes the final decision to grant an MA, which is issued within 67 days of receipt of the EMA's recommendation. 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.

- National MAs, which are issued by the competent authorities of the Member States of the EU and only cover their respective territory, are available for products not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in a Member State of the EU, this national MA can be recognized in other Member States through the mutual recognition procedure. If the product has not received a national MA in any Member State at the time of application, it can be approved simultaneously in various member states through the decentralized procedure. Under the

decentralized procedure an identical dossier is submitted to the competent authorities of each of the member state in which the MA is sought, one of which is selected by the applicant as the Reference Member State (RMS). The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics, or SmPC, and a draft of the labeling and package leaflet, which are sent to the other member state, referred to as the Concerned Member States, for their approval. If the Concerned Member States raise no objections, based on a potential serious risk to public health, to the assessment, SmPC, labeling, or packaging proposed by the RMS, the product is subsequently granted a national MA in all the member states (i.e., in the RMS and the Concerned Member States).

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

Now that the United Kingdom (which comprises Great Britain and Northern Ireland) has left the European Union, Great Britain will no longer be covered by centralized MAs (under the Northern Ireland Protocol, centralized MAs will continue to be recognized in Northern Ireland). All medicinal products with a current centralized MA were automatically converted to Great Britain MAs on January, 1, 2021. For a period of two years from January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or MHRA, the UK medicines regulator, may rely on a decision taken by the European Commission on the approval of a new MA in the centralized procedure, in order to more quickly grant a new Great Britain MA. A separate application will, however, still be required. The MHRA also has the power to have regard to MAs approved in EU Member States through decentralized or mutual recognition procedures with a view to more quickly granting an MA in the United Kingdom or Great Britain.

***European Union new Chemical Entity Exclusivity***

In the EU, innovative medicinal products approved on the basis of a complete independent data package qualify for eight years of data exclusivity upon 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 EMA to be an innovative medicinal product, and products may not qualify for data exclusivity. Even if a product is considered to be an innovative medicinal product so that the innovator gains the prescribed period of data exclusivity, however, another company could nevertheless also market another version of the product if such company obtained an MA based on an MAA with a complete independent data package of pharmaceutical tests, preclinical tests and clinical trials.

***European Union Orphan Designation and Exclusivity***

In the EU, the EMA's Committee for Orphan Medicinal Products grants orphan designation to promote the development of products that: (1) are 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.

In the EU, orphan designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity is granted following grant of an MA. During this market exclusivity period, neither the EMA nor the European Commission nor any of the competent authorities in the EU Members States can accept an

application or grant an MA for a "similar medicinal product approval." 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. This 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. Market exclusivity may also be revoked in very select cases, such as if (i) it is established that a similar medicinal product is safer, more effective or otherwise clinically superior to the authorized product; (ii) the marketing authorization holder of the authorized orphan product consents to such revocation; or (iii) the marketing authorization holder of the authorized orphan product cannot supply enough orphan medicinal product. Orphan designation must be requested before submitting an application for MA. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

***Regulatory Requirements After a Marketing Authorization has been Obtained***

If authorization 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.

- The manufacturing of authorized medicinal products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the applicable EU laws, regulations and guidance, including Directive 2001/83/EC, Directive 2003/94/EC, Regulation (EC) No 726/2004 and the European Commission Guidelines for Good Manufacturing Practice. These requirements include compliance with EU cGMP standards when manufacturing medicinal products and active pharmaceutical ingredients, including the manufacture of active pharmaceutical ingredients outside of the EU with the intention to import the active pharmaceutical ingredients into 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. The provision of benefits or advantages to physicians is sometimes governed by the national anti-bribery laws of the EU Member States, and the Bribery Act 2010 in the UK. Infringement of these laws could result in substantial fines and imprisonment. EU Directive 2001/83/EC, which is the EU Directive governing medicinal products for human use, further provides that, where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. This provision has been transposed into the Human Medicines Regulations 2012 and so remains applicable in the UK despite its departure from the EU.

- 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. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU Member States. 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, or 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 General Data Protection Regulation, or GDPR, which became effective May 25, 2018. The 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 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. The GDPR also imposes strict rules on the transfer of personal data outside of the EEA to countries that do not ensure an adequate level of protection, like the United States. Failure to comply with the requirements of the 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 GDPR grants data subjects the right to claim material and non-material damages resulting from infringement of the GDPR. Given the breadth and depth of changes in data protection obligations, maintaining compliance with the 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.

In addition, further to the United Kingdom's exit from the European Union on January 31, 2020, the 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 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 aligned to the European Union'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 UK is regarded as a third country under the European Union's GDPR, the European Commission 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 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.

***Brexit and the Regulatory Framework in the United Kingdom***

On June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union (commonly referred to as Brexit), and the UK formally left the EU on January 31, 2020. There was a transition period during which EU pharmaceutical laws continued to apply to the UK, which expired on December 31, 2020. However, the EU and the UK have concluded a trade and cooperation agreement, or TCA, which was provisionally applicable since January 1, 2021, and has been formally applicable since May 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not foresee wholesale mutual recognition of UK and EU pharmaceutical regulations. At present, Great Britain has implemented EU legislation on the marketing, promotion and sale of medicinal products through the Human Medicines Regulations 2012 (as amended) (under the Northern Ireland Protocol, the EU regulatory framework will continue to apply in Northern Ireland). The regulatory regime in Great Britain therefore largely aligns with current EU regulations, however it is possible that these regimes will diverge in future now that Great Britain's regulatory system is independent from the EU and the TCA does not provide for mutual recognition of UK and EU pharmaceutical legislation.

***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.

***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 U.S. Department of Health and Human Services. 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 Department of Health and Human Services 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.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Unlike Medicare Part A and B, Part D coverage is not standardized. While all Medicare drug plans must give at least a standard level of coverage set by Medicare, Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan likely will be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

For a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer. As of 2010, the ACA expanded the types of entities eligible to receive discounted 340B pricing, although, under the current state of the law, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs. In addition, as 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase.

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.

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. 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 February 28, 2022, we had 131 full-time employees and 26 part-time employees. Of our 157 full and part-time employees, 38, or 24.2%, have Ph.D. or M.D. degrees and 123, or 78.3%, 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 fully-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.

**Facilities**

Our principal executive offices are located in New York, New York, pursuant to a lease that expires in February 2024. Our European research and preclinical development operations are located in Vienna, Austria, where we lease and occupy approximately 30,656 square feet of office and laboratory space. Our first facility is leased pursuant to two operating leases, comprised of (i) a lease of unlimited duration for approximately 15,198 square feet of office and laboratory space and (ii) a lease set to expire in September 2028 and with no option to extend for approximately 2,357 square feet of storage space. In 2019, we entered into a lease for a second facility located in Vienna, Austria that is set to expire in February 2029, where we occupy approximately 15,440 square feet of office and laboratory space. In May 2021 we signed an agreement to purchase a parcel of land in the north of Vienna and have received building permission to build a GMP manufacturing plant. We are currently in the detailed engineering phase. We believe that our current facilities are adequate to meet our ongoing needs, and that, if we require additional space, we will be able to obtain additional facilities on commercially reasonable terms.

**Legal Proceedings**

We are currently a party to a patent opposition proceeding. In April 2021, a third party opposed European Patent No. 3218504, which was granted to the University of Geneva in July 2020 and is exclusively licensed to us. While the opposition was filed in the name and on behalf of Dr. Ursula Sprenzel, we believe that the real party in interest has not identified itself. The patent is directed to our replicating arenavirus platform technology and is part of our strategy to protect current product candidates based on this platform technology, including our lead oncology product candidates HB-201 and HB-202. We filed our formal response to the opposition with the European Patent Office (EPO) on September 3, 2021. It is expected that the EPO's opposition division will issue a preliminary opinion within the next 1 to 6 months and will summon the parties to oral proceedings within the next 6 to 12 months. Besides the European opposition proceeding, 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.

**Available Information**

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any amendments to these 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, 2020 and 2021, we reported a net loss of $44.1 million and $75.7 million, respectively. As of December 31, 2021, we had an accumulated deficit of $222.8 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.

***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, 2021, we had approximately $66.9 million in cash, cash equivalents and restricted cash. Based on our research and development plans, we expect that our existing cash and cash equivalents at December 31, 2021, together with the funds we received from our offering in March 2022 and the funds received under the Restated Collaboration Agreement with Gilead in February 2022, will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect. Changes may occur beyond our control that would cause us to consume our available capital before that time, including changes in and progress of our development activities and changes in regulation. 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.

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. 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.

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 candidates, HB-201 and HB-202, which are currently in a Phase 1/2 clinical trial, 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, for regulatory approval for any of our product candidates or whether any such IND or BLA will be accepted for review by the FDA, or subsequently whether any such IND will go into effect or BLA will be approved upon review.

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 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 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 EMA 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 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 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 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, 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 or other comparable foreign regulatory authorities may 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 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.

The FDA, the EMA and other comparable foreign regulatory authorities have substantial 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 EMA 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 HB-101, HB-201, HB-202 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, 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 or other comparable foreign regulatory authorities will view our product candidates as having efficacy even if positive results are observed in our planned clinical trials. To the extent that the results of the trials are not satisfactory to the FDA, the EMA 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 EMA 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 EMA or other comparable foreign regulatory authorities allowing clinical trials to begin.

We may also encounter challenges in collecting, transporting and analyzing clinical blood samples, which could cause delays or prevent the approval of our drug candidates. For example, we have encountered difficulties in the transport logistics for samples in our HB-101 trial, resulting in the failure of a number of assays, in particular with respect to CD-8 T Cells, which are a key surrogate marker in the trial. We repeated the testing of samples from the respective patients and established a validated assay with respect to HB-201 samples, and mitigated further impact by changing and improving processes and logistics.

***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 which is in a Phase 1/2 clinical trial. If our ongoing Phase 1/2 clinical trial for HB-201 and HB-201/HB-202 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.

***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 such as HB-101, HB-201 and HB-202, 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 EMA 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. In the Phase 1 dose escalation portion of our Phase 1/2 trial for HB-201, we expect to enroll two groups of 20 patients each and future trials for HB-201 or other product candidates may similarly enroll a small number of patients. The preliminary results of trials with smaller sample sizes, such as our Phase 1/2 trial for HB-201, 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, 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 EMA 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 EMA or other comparable foreign regulatory authorities, or local regulatory authorities such as IRBs, could order us to cease clinical trials. Competent national health authorities, such as the FDA, 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;
- 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 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 or managing a manufacturing facility for our product candidates.***

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 trial will be completed on time or if the planned clinical trials will begin or be completed on time, if at all. Largescale 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.

We do not have our own manufacturing facility for the production of clinical trial material or future commercial products and therefore depend on third-party contract manufacturing organizations (CMOs) and their knowhow for production of our product candidates. Because of our limited control of our third-party manufacturers and in part because of our inexperience, our third-party manufacturers may fail to produce our product in a reliable and consistent manner and in sufficient quality and quantity. 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.

As we continue to progress our product candidates into and through clinical trials, we intend to operate our own manufacturing facility, which will require significant resources, and we have limited experience as a company in expanding or managing a manufacturing facility. In part because of this lack of experience, we cannot be certain that our manufacturing facility will be completed on time, if at all, or if the planned clinical trials will begin or be completed on time, if at all. In addition, if we switch from one manufacturing facility to our own manufacturing facility for one or more of our product candidates in the future, we may need to conduct additional studies to bridge our modified product candidates to earlier versions. Failure to successfully create and operate our proposed manufacturing facility could adversely affect the commercial viability of our product candidates.

***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 often approves 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;
- 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 “Business – 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, or 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.

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. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. 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. 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 HB-201 and HB-202 product candidates are 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.

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 clinical trials of HB-201 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.

Specifically, we face significant competition in CMV management from companies such as Helocyte, Inc., VBI Vaccines, Inc., Moderna, Inc., SL VaxiGen, Inc., Merck & Co., GlaxoSmithKline plc and Pfizer, Inc. In immuno-oncology for HPV16+ cancers, we face competition from companies such as Kite Pharma, a Gilead company, Advaxis, Inc., ISA Pharmaceuticals B.V., in collaboration with Regeneron Pharmaceuticals, Inc. and BioNtech AG. 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 CMV and 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.***

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;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, as well as the developing conflict between Russia and Ukraine.

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, 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 deliver products to our customers.

***The ongoing effect of the COVID-19 pandemic, has adversely impacted and we expect will continue to adversely impact our business, including our preclinical studies and clinical trials.***

In December 2019, a novel strain of the coronavirus disease, COVID-19, was identified in Wuhan, China. This virus spread globally and in March 2020 the World Health Organization declared COVID-19 a pandemic. The ongoing pandemic and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. In response to the spread of COVID-19, we have closed our executive offices with our administrative employees continuing their work outside of our offices, and limited the number of staff in any given research and development laboratory. As a result of the COVID-19 pandemic, we have experienced and we expect to continue to experience disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- continued delays or difficulties in enrolling and retaining patients in our clinical trials;

- continued delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays in receiving authorizations from regulatory authorities to initiate our planned clinical trials;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures (such as endoscopies that are deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;
- risk that participants enrolled in our clinical trials will contract COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- risk that we are unable to enroll participants in our clinical trials in adequate numbers;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- interruptions in preclinical studies due to restricted or limited operations at our laboratory facility;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- changes in local regulations as part of a response to the COVID-19 pandemic, which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue such clinical trials altogether;
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- interruption or delays to our sourced discovery and clinical activities; and
- refusal of the FDA to accept data from clinical trials in affected geographies outside the United States.

The COVID-19 pandemic continues to rapidly evolve. The extent to which the pandemic impacts our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

***Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.***

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including

those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

In addition, the FDA's operations have been and may continue to be impacted by the ongoing COVID-19 pandemic. Since March 2020 when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. Since April 2021, the FDA has conducted limited inspections and employed remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates. Ongoing travel restrictions and other uncertainties continue to impact oversight operations both domestic and abroad and it is unclear when standard operational levels will resume. The FDA is continuing to complete mission-critical work, prioritize other higher-tiered inspectional needs (e.g., for-cause inspections), and carry out surveillance inspections using risk-based approaches for evaluating public health. Should FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the agency has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. During the COVID-19 public health emergency, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the ongoing COVID-19 pandemic and may experience delays in their regulatory activities.

Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities.

If a prolonged government shutdown or other disruption occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Future shutdowns or other disruptions could also affect other government agencies such as the SEC, which may also impact our business by delaying review of our public filings, to the extent such review is necessary, and our ability to access the public markets.

***The United Kingdom's withdrawal from the European Union could result in increased regulatory and legal complexity, which may make it more difficult for us to do business in Europe and impose additional challenges in securing regulatory approval of our product candidates in Europe and/or the United Kingdom.***

Pursuant to Article 50 of the Treaty on EU, the UK ceased being a Member State of the EU on January 31, 2020. There was a transitional period, during which EU laws, including pharmaceutical laws, continued to apply in the UK, however this ended on December 31, 2020. The UK reached a trade agreement with the European Union on December 24, 2020, which became provisionally applicable on January 1, 2021 and has been formally applicable since May 1, 2021. Under the terms of the deal, the EU and UK have separate regulatory regimes for pharmaceutical products, although there are some provisions for mutual recognition of standards, for example with regards to GMP. For instance, the UK is no longer covered by the centralized procedure for obtaining EU-wide marketing authorizations for medicinal products, and a separate process for authorization of medicinal products will be required in the UK, resulting in an authorization covering the UK or Great Britain (England, Scotland and Wales) only. At present, Great Britain has implemented EU legislation on the marketing, promotion and sale of medicinal products through the Human Medicines Regulations 2012 (as amended) (under the Northern Ireland Protocol, the EU regulatory framework will continue to apply in Northern Ireland). The regulatory regime in Great Britain therefore currently broadly aligns with EU regulations, however it is possible that these regimes will diverge in future now that Great Britain's regulatory system is independent from the EU and the TCA does not provide for mutual recognition of UK and EU pharmaceutical legislation.

The cumulative effects of the disruption to the regulatory framework may add considerably to the development lead time to marketing authorization and commercialization of products in the European Union and/or the United Kingdom. It is possible that there will be increased regulatory complexities which can disrupt the timing of our

clinical trials and regulatory approvals. In addition, changes in, and legal uncertainty with regard to, national and international laws and regulations may present difficulties for our clinical and regulatory strategy.

In addition, as a result of Brexit, other European countries may seek to conduct referenda with respect to their continuing membership with the European Union. Given these possibilities and others we may not anticipate, as well as the absence of comparable precedent, it is unclear what financial, regulatory and legal implications the withdrawal of the United Kingdom from the European Union would have and how such withdrawal would affect us, and the full extent to which our business could be adversely affected.

***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 hepatitis B virus programs, rely on funding from Gilead for development of our human immunodeficiency virus, 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***

In June 2018, we entered into a research collaboration and license agreement, or the Original Collaboration Agreement, with Gilead, which was amended and restated in February 2022, the Restated Collaboration Agreement. The Original Collaboration Agreement was entered into to evaluate potential vaccine products using or incorporating our Arenavirus technology platforms for the treatment, cure, diagnosis, or prevention of human immunodeficiency virus, or HIV, and hepatitis B virus, or HBV.

The Restated Collaboration Agreement, among other things, allocated to us additional research and development responsibility with respect to our HIV candidate and provided for later stage development and commercial milestone payments. The Restated Collaboration Agreement involves a complex allocation of rights, provides for milestone payments to us based on the achievement of specified clinical development, regulatory and commercial milestones, and provides us with royalty-based revenue if certain product candidates are successfully commercialized. Gilead is solely responsible for the preclinical and clinical development of the HBV program. In connection with the Restated Collaboration Agreement, we entered into a Stock Purchase Agreement, 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. Our lack of control over the clinical development of the HBV program under the Collaboration Agreement could result in delays or other difficulties in the development and commercialization of product candidates, which may prevent completion of intended investigational new drug applications in a timely fashion, if at all. Additionally, Gilead has the right to terminate the Restated Collaboration Agreement at any time for convenience. In the event Gilead terminates the Restated Collaboration Agreement, we would be prevented from receiving any milestone payments, royalty payments and other benefits under that agreement, as well as terminating our rights to future funding under the Stock Purchase Agreement with Gilead, any of which would have a materially adverse effect on our results of operations. We cannot provide any assurance with respect to the success of the Collaboration Agreement.

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 collaboration with Gilead poses, 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 Collaboration Agreement, we are prohibited from, directly or indirectly, researching, developing, manufacturing or commercializing product candidates targeted to HIV or HBV; and

- collaborations may be terminated by the collaborator, 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.

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 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 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. 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.

Although we do intend to develop our own manufacturing facility, we currently rely on third parties as part of our manufacturing process and may, in any event, never be successful in developing our own manufacturing facility. 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 agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards, of which we do not have 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 inclement weather, as well as natural or man-made 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.

Additionally, since the beginning of the COVID-19 pandemic, three vaccines for COVID-19 have received Emergency Use Authorization by the FDA and two of those later received marketing approval. Additional vaccines may be authorized or approved in the future. The resultant demand for vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials or manufacturing slots for the product candidates needed for our clinical trials which could lead to delays in these trials.

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.

***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. In addition, if the FDA, the EMA 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 EMA 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 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. 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 – U.S. Healthcare Reform and 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.

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. 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.

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 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.

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, or 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.

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 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 of 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 single-vector HB-201 and alternating 2-vector HB-202/HB-201, both 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 Europe, 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 grants 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 for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting no more than 5 in 10,000 persons in the EU and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or the product would be a significant benefit to those affected). Additionally, designation is granted for products intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the product in the EU would be sufficient to justify the necessary investment in developing the product. In the EU, orphan designation entitles a party to a number of incentives, such as protocol assistance and scientific advice specifically for designated orphan medicines, and potential fee reductions 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 EMA or the FDA from approving another marketing application for the same drug and indication for that time period, except in limited circumstances. The applicable period is seven years in the United States and ten years in Europe. The EU exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan designation or if the drug is sufficiently profitable such that market exclusivity is no longer justified.

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. 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 and state 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 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 – U.S. Healthcare Reform and 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 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.

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 generally 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 often must 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 European Economic Area is governed by the GDPR. The 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. The GDPR also imposes strict rules on the transfer of personal data out of the European Economic Area, including to the United States. Failure to comply with the requirements of the Data Protection Directive, the GDPR, and the related national data protection laws of the European Union 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. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR includes restrictions on cross-border data transfers. The 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 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, (SEC) 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.

***Comprehensive tax reform legislation could adversely affect our business and financial condition.***

On December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act (TCJA) that significantly reforms the Internal Revenue Code of 1986, as amended. The TCJA, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%; limitation of the tax deduction for interest expense; limitation of the deduction for net operating losses and elimination of net operating loss carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such tax losses may be carried forward indefinitely); and modifying or repealing many business deductions and credits, including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as "orphan drugs". We continue to examine the impact this tax reform legislation may have on our business in the future. However, the TCJA did not have an impact on us and our affiliates due to our loss making situation. You are urged to consult your tax adviser regarding the implications of the TCJA on an investment in our common stock.

***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 falls under the category of 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.

**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 and the University of Zurich 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, including our HB-101 product candidate, obtain patent protection with respect to our replicating technology, including our HB-201, HB-202 and HB-300 product candidates, the vaccine product candidates we are developing with Gilead for HBV and HIV, and other proprietary product candidates. Although we own or license from others certain patent applications that cover the foregoing technologies and product candidates, we do not currently own or license from others issued patents covering all of the foregoing. 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 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.

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. 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. Various post grant review proceedings, such as *inter partes* review and post grant review, are available for any interested third party to challenge the patentability of claims issued in patents to us. These procedures are relatively new and can be unpredictable. It is also possible for third parties to file observations with various patent offices during the patent application process. In our European patent application directed to our non-replicating technology, an unknown third party submitted such an observation. Despite that submission, the European Patent Office proceeded to grant our patent.

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, 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 another 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, 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 patent applications that we own or will own, related to HB-101, HB-201 and HB-202 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, 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 these rights 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 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.

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 on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. 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.

***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. Most of our patent portfolio is at the very 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 serves as our Scientific Advisor to the Chief Executive Officer, provided research services to us pursuant to a consulting agreement and will continue to do so upon execution of a new consultancy 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 current 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. The loss of the services of any of them may adversely impact the achievement of our objectives. 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 one or more of our current employees might impede the achievement of our research, development and commercialization objectives.

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.

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

As our development and commercialization plans and strategies develop, and as we transition into operating as a public company, 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;
- 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 The Nasdaq Global Select Market 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.

***If securities analysts publish negative evaluations of our stock, the price of our stock could decline.***

The trading market for our common stock depends in part on the research and reports that securities analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

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

Our Class A common stock has no voting rights. As a result, all matters submitted to our stockholders are decided by the vote of holders of our common stock. Our executive officers, directors, and 5% stockholders beneficially own approximately 65% 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.

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

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

***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 after we are no longer an emerging growth company, as defined in the JOBS Act, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Global Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. 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. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with SOX Section 404 within the prescribed period, we will be engaged 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 will designate the Court of Chancery of the State of Delaware, 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. When we lose our status as an "emerging growth company," 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.

In connection with our preparation and the audits of our financial statements as of and for the years ended December 31, 2017 and 2018, we and our independent registered public accounting firm identified material weaknesses as defined under the Exchange Act and by the Public Company Accounting Oversight Board (United States) in our internal control over financial reporting. We have implemented a variety of controls to remediate the material weaknesses identified which enabled us to broaden the scope and quality of our internal review of underlying information related to financial reporting and to enhance our internal control procedures. We believe that these efforts have remediated the material weaknesses, but we cannot assure that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. 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

The Nasdaq Stock Market LLC, 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**

***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.

***Our internal computer systems, or those used by our third-party CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of the development programs of our product candidates.***

We and these third parties rely extensively on information technology systems to conduct and manage our business. Despite the implementation of security measures, our internal computer systems and those of our current and future CROs and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. The risk of a security breach or disruption, particularly through cyber attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased.

In the ordinary course of our business, we collect and store sensitive data, including, among other things, legally protected patient health information, personally identifiable information about our employees, intellectual property and proprietary business information. 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. Such disruptions may be caused by events such as computer hacking, phishing attacks, ransomware, dissemination of computer viruses, worms and other destructive or disruptive software, denial of service attacks and other malicious activity, as well as power outages, natural disasters (including extreme weather), terrorist attacks or other similar events. 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. For example, the loss of clinical trial data for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the lost data.

Likewise, we rely on third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. Any breach in our information technology systems could lead to the unauthorized access, disclosure and use of non-public information, 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 these 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.

We could also be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of our company and our vendors, including personal information of our employees and patients, and company and vendor confidential data. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our

personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data and/or systems. We may experience threats to our data and systems, including malicious codes and viruses, phishing and other cyber-attacks. The number and complexity of these threats continue to increase over time. If a material breach of our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. 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 cyberattack, security breach, industrial espionage attacks or insider threat attacks which could result in financial, legal, business or reputational harm.

***We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.***

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, as amended (JOBS Act), enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended (Sarbanes-Oxley Act), being permitted to present only two years of audited financial statements and a correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure, as well as reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following the year in which we complete our initial public offering, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of our initial public offering in April 2019, (b) in which we have total annual gross revenue of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same 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. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of

U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

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

We are a smaller reporting company under Rule 12b-2 of the Exchange Act. For so long as we remain a smaller reporting company, we are permitted and plan to rely on exemptions from certain disclosure requirements, including reduced disclosure obligations regarding executive compensation. These exemptions and reduced disclosures in our SEC filings due to our status as a smaller reporting company also mean our auditors are not required to review our internal control over financial reporting and may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our common stock prices may be more volatile. We will remain a smaller reporting company until our public float exceeds $250 million or our annual revenues exceed $100 million with a public float greater than $700 million.

**Item 1B. Unresolved Staff Comments**

None.

**Item 2. Properties**

Our principal executive offices are located in New York, New York, pursuant to a lease that expires in February 2024. Our European research and preclinical development operations are located in Vienna, Austria, where we lease and occupy approximately 30,656 square feet of office and laboratory space. Our first facility is leased pursuant to two operating leases, comprised of (i) a lease of unlimited duration for approximately 15,198 square feet of office and laboratory space and (ii) a lease set to expire in September 2028 and with no option to extend for approximately 2,357 square feet of storage space. In 2019, we entered into a lease for a second facility located in Vienna, Austria that is set to expire in February 2029, where we occupy approximately 15,440 square feet of office and laboratory space. 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 December 2018, we entered into a collaboration and manufacturing agreement which included embedded leases of manufacturing facilities which are located in Solna, Sweden, and expire in April 2022. We believe that our current facilities are adequate to meet our ongoing needs, and that, if we require additional space, we will be able to obtain additional facilities on commercially reasonable terms.

## PART II—OTHER INFORMATION

**Item 3. Legal Proceedings.**

In April 2021, a third party opposed European Patent No. 3218504, or the EP '504 Patent, which was granted to the University of Geneva in July 2020 and is exclusively licensed to us. While the opposition was filed in the name and on behalf of Dr. Ursula Sprenzel, we believe that the real party in interest has not identified itself. The patent is directed to our replicating arenavirus platform technology and is part of our strategy to protect current product candidates based on this platform technology, including our lead oncology product candidates HB-201 and HB-202. We filed our formal response to the opposition with the European Patent Office (EPO) on September 3, 2021. It is expected that the EPO's opposition division will issue a preliminary opinion in the next three months, and summons the parties to oral proceedings within the next six to nine months.

**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 Global Select 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 March 4, 2022, there were approximately four holders 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. Selected Financial Data

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 at the end of 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 a T cell and immune response to disease. 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 prophylactic and therapeutic purposes by inducing CD8+ T cell response levels previously not achieved by other immunotherapy approaches.

We are building a proprietary immuno-oncology pipeline by targeting oncoviral cancer antigens, self-antigens and next-generation antigens. Our oncology portfolio includes three disclosed programs, HB-200, HB-300 and HB-700, which all use our replicating technology. HB-200 is in clinical development for the treatment of Human Papillomavirus 16-positive (HPV16+) cancers in an ongoing Phase 1/2 clinical trial. HB-300 is in development for the treatment of prostate cancer and expected to move into the clinic after the third quarter 2022 investigational new drug application filing. HB-700 is our newest asset in preclinical development for treatment of KRAS mutated cancers, including, lung, colorectal and pancreatic cancers.

Our HB-200 program is comprised of HB-201 single vector therapy and HB-201/HB-202 two vector therapy. Both therapies are being evaluated in an ongoing HB-200 Phase 1/2 study. In November 2021, we announced interim data on our ongoing Phase 1 portion of the study, showing promising anti-tumor activity against advanced/metastatic HPV16+ cancers and favorable tolerability. Data demonstrated responses and stable disease in head and neck cancer patients who failed prior standard of care therapy. We believe that these early-stage data establish proof of concept for our replicating single-vector immunotherapy in oncology.

In January 2022, we dosed the first patient with a combination of HB-201 and pembrolizumab for the treatment of first line advanced/metastatic HPV16+ HNSCC in the Phase 2 expansion portion of the ongoing Phase 1/2 trial. In September 2021, we entered into a clinical collaboration with Merck & Co., Inc. to evaluate the combination of HB-200 and Merck & Co., Inc's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab) in a separate randomized Phase 2 study.

Our non-replicating prophylactic Cytomegalovirus, or CMV, vaccine candidate, HB-101, is a potential first in-class compound in a Phase 2 clinical trial for patients awaiting kidney transplantation. In November 2021, we reported safety, immunogenicity and efficacy data, whereby the three-dose schedule of HB-101 pre-transplantation showed a trend of reducing incidence of CMV viremia and antiviral use. The trial will continue to follow patients currently on-study with final top-line data readout in the first half of 2023. We have decided to pursue HB-101 further only if we are able to partner the program with a collaborator, thereby enabling greater strategic focus on the immuno-oncology programs.

We have funded our operations to date primarily from private placements of our redeemable convertible preferred stock, with aggregate gross proceeds of approximately $142.5 million, grant funding and loans from an Austrian government agency, and $26.2 million in upfront and milestone payments from Gilead in connection with a research collaboration and license agreement. On April 23, 2019, we completed an initial public offering of our common stock (IPO) in which we issued 6.0 million shares of our common stock, at $14.00 per share, for gross proceeds of $84.0 million, or net proceeds of $74.6 million. On December 11, 2020, we completed a follow-on public offering in which we issued 3.9 million shares of our common stock, at $11.75 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. As of December 31, 2021, the principal amount outstanding under loans from government agencies was $6.1 million and we had cash, cash equivalents and restricted cash of $66.9 million. In February 2022 we received a $15.0 million initiation fee in connection with Restated Collaboration Agreement with Gilead. In addition, Gilead purchased unregistered shares of our common stock for $5.0 million. In March 2022, we issued and sold 21,700,000 shares of our common stock at $2.00 per share, and 15,800 shares of our Series A-1 convertible preferred stock at $2,000.00 per share in a follow-on public offering resulting in net proceeds of approximately $70.0 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, including our most advanced oncology product candidate, HB-200, 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. Before launching our first products, if approved, we plan to establish our own manufacturing facility to reduce or eliminate our reliance on contract manufacturing organizations (CMOs) which will require substantial capital expenditures and cause additional operating expenses. 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 net losses each year since our inception in 2011, including net losses of $75.7 million for the year ended December 31, 2021 and $44.1 million for the year ended December 31, 2020. As of December 31, 2021, we had an accumulated deficit of $222.8 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 a commercial manufacturing facility.

We believe that the net proceeds from our offering in March 2022, the funds received under Restated Collaboration Agreement with Gilead, both described below, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements at least through the next 12 months from the issuance date of the consolidated financial statement. See “—Liquidity and Capital Resources.”

**Special Note About Coronavirus (COVID-19)**

In March 2020, we announced initial potential business impacts related to the outbreak of a novel strain of virus named SARS-CoV-2 (severe acute respiratory syndrome 2), or coronavirus, which causes coronavirus disease, or COVID-19. As a result of the ongoing COVID-19 pandemic, we have experienced, and may further experience, disruptions that have and could further adversely impact our business operations as well as our preclinical studies and clinical trials. Specifically, nearly all of the Phase 2 trial sites we utilize for our HB-101 Phase 2 trial had temporarily suspended enrollment of patients, resumed patient enrollment, but suspended enrollment again during periods of increased confirmed infections in the United States and Europe. As a result, the total number of patients in the trial at the conclusion of enrollment in June 2021 was below the originally planned number of patients.

In addition, certain aspects of our supply chain were temporarily impacted as certain of our third-party suppliers and manufacturers had paused their operations in response to the COVID-19 pandemic or had otherwise encountered delays in providing their services. The uncertainties resulting from the COVID-19 pandemic have led us to temporarily focus on our core program, HB-200, as well as research and development activities under our collaboration with Gilead. Certain earlier stage programs, including HB-300 were temporarily de-prioritized only allocated the resources that could be made available without impacting our core programs. While we have resumed activities for these earlier stage programs in 2021, we continue to evaluate the extent to which potential constraints of our third-party suppliers and manufacturers will impact our ability to manufacture our product candidates for our clinical trials and conduct other research and development operations and maintain applicable timelines. The ultimate impact of the coronavirus pandemic on our business operations as well as our preclinical studies and clinical trials remains uncertain and subject to change and will depend on future developments, which cannot be accurately predicted. We will continue to monitor the situation closely.

Furthermore, in order to preserve resources and liquidity, all of our officers had waived at least 25% of their cash salaries for the three months ended June 30, 2020, and the vast majority of our employees agreed to a temporary salary reduction of 20% for the three months ended June 30, 2020. We compensated our officers and employees for the forgone cash salaries by issuing restricted stock units in July 2020. Our directors have also accepted to receive equity instead of cash for their accrued board fees. We encourage our staff to work from home where possible, and encourage our Vienna employees to make use of the readily-available PCR testing in order to enhance health and safety, in particular for laboratory work that has to be performed on site. Since October 2021 we have required our employees to be either fully vaccinated, cured from a COVID-19 infection or to have obtained a negative PCR-test to enter our offices.

**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 a research collaboration and license agreement with Gilead.

On June 4, 2018, we entered into a Research Collaboration and License Agreement, or the Collaboration Agreement, with Gilead 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 Collaboration Agreement, we granted Gilead an exclusive, royalty-bearing license to our technology platform for researching, developing, manufacturing and commercializing products for HIV or HBV. We received a non-refundable $10.0 million upfront payment upon entering the Collaboration Agreement. In February 2022, we signed an amended and restated collaboration agreement, the Restated Collaboration Agreement, which revised the terms only for the HIV program, whereby we will take on development responsibilities for the HIV program candidate through a Phase 1b clinical trial. Pursuant to the Restated Collaboration Agreement, Gilead will retain an exclusive right, the Option, to take back 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 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 $167.5 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 Collaboration Agreement with respect to the HBV program, and if the Option is exercised, the HIV program. Through to December 31, 2021, we have received from Gilead the non-refundable upfront payment of $10.0 million and $12.2 million in milestone payments for the achievement of pre-clinical research milestones. In addition, we have recognized $35.6 million of cost reimbursements for research and development services performed under the Collaboration Agreement. In the first quarter of 2022, we received an additional milestone payment of $4.0 million and the initiation payment of $15.0 million due upon execution of the Restated Collaboration Agreement to fund our future performance of development activities under the Restated Collaboration Agreement.

We determined that our performance obligations under the terms of the Restated 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 recognize 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.

***Operating Expenses***

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

***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 a Phase 1 clinical trial and the ongoing Phase 2 clinical trial for HB-101 as well as initiating a Phase 1/2 trial for HB-201 and preparing an investigational new drug, or IND, application for HB-202. 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
- intellectual property costs incurred in connection with filing and prosecuting patent applications as well as 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;
- 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;
- 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 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 and when approved;
- acceptance of the product candidates 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.

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 U.S. Food and Drug Administration 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.

***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, lease expenses related to our offices, premiums for directors and officers liability insurance, 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 Global Select Market and the Securities and Exchange Commission.

***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.

***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 Taxes***

Income tax expense results from 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, 2021, we had a deferred tax asset of $58.8 million primarily resulting from foreign net operating loss carryforwards of $219.7 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, 2021.

**Results of Operations**

***Comparison of Years Ended December 31, 2021 and 2020***

The following table summarizes our results of operations for the years ended December 31, 2021 and 2020 (in thousands):

| | Year ended December 31, 2021 | 2020 |
|---|---|---|
| Revenue from collaboration and licensing | $ 18,448 | $ 19,584 |
| Operating expenses: | | |
| Research and development | (82,853) | (54,787) |
| General and administrative | (17,269) | (18,082) |
| Total operating expenses | (100,122) | (72,869) |
| Loss from operations | (81,674) | (53,285) |
| Other income (expense): | | |
| Grant income | 9,724 | 6,517 |
| Interest income | 27 | 400 |
| Interest expense | (898) | (786) |
| Other income and expenses, net | (2,843) | 3,072 |
| Total other income (expense), net | 6,010 | 9,203 |
| Net loss before tax | (75,664) | (44,082) |
| Income tax expense | (1) | (0) |
| Net loss | $ (75,665) | $ (44,082) |

***Revenue from Collaboration and Licensing***

Revenue was $18.4 million for the year ended December 31, 2021, compared to $19.6 million for the year ended December 31, 2020.

The decrease of $1.2 million for the year ended December 31, 2021 compared to the year ended December 31, 2020 was due to lower revenue from research milestones, and lower recognition of deferred revenue related to upfront and milestone payments, partially offset by higher cost reimbursements received under the Restated Collaboration Agreement with Gilead.

For the year ended December 31, 2021, revenue included $16.3 million from reimbursement of research and development expenses, $0.6 million from partial recognition of deferred revenue related to the upfront payment of $10.0 million that we received in June 2018 and $1.5 million from partial recognition of the $4.0 million milestone payment that we received in 2020. In the year ended December 31, 2021 we completed the recognition of the deferred revenue related to the upfront payment of $10.0 million that we received in June 2018.

For the year ended December 31, 2020, revenue included $13.0 million from reimbursement of research and development expenses, $2.0 million from partial recognition of deferred revenue related to the upfront payment of $10.0 million that we received in June 2018 and $2.4 million from partial recognition of the $4.0 million milestone payment that we received in February 2020, as well as $2.2 million of revenue that was recognized upon the achievement of research milestones in June and December 2020.

***Research and Development Expenses***

For the year ended December 31, 2021, our research and development expenses were $82.9 million, compared to $54.8 million, for the year ended December 31, 2020.

The increase of $28.1 million for the year ended December 31, 2021 compared to the year ended December 31, 2020 was due to an increase in direct research and development expenses of $21.2 million, and an increase in internal research and development expenses of $6.9 million.

The primary drivers of the increase in direct research and development expenses for the year ended December 31, 2021 compared to the year ended December 31, 2020 were an increase in manufacturing and quality control expenses of $9.9 million, an increase in clinical study expenses of $3.2 million, along with an increase in other direct expenses and laboratory expenses of $8.1 million. The increase was mainly due to the progress in the clinical trial of our HB-200 program, particularly, the increased patient recruitment and related clinical trial monitoring and testing activities, as well as manufacturing and quality control work in preparation of a further extension of the trial. Manufacturing and quality control expenses were also driven by the progress towards clinical development in our Gilead partnered programs and other preclinical programs.

The increase in internal research and development expenses for the year ended December 31, 2021 compared to the year ended December 31, 2020 was primarily due to an increase in personnel expenses by $4.4 million, and an increase in facility related and other internal research and development expenses by $2.5 million. The increase in personnel-related research and development expenses resulted primarily from our increased research and development

headcount and an increase in stock compensation expenses. Other internal research and development costs and facility related costs also increased as a result of our expansion of research and development activities and headcount.

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

| | Year ended December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Direct research and development expenses by program: | | |
| HB-101 | $ 3,583 | $ 6,020 |
| HB-201/202 | 24,563 | 11,162 |
| Gilead partnered programs[(1)] | 11,736 | 9,129 |
| Other and earlier-stage programs | 14,905 | 7,298 |
| Sub-total direct expenses | 54,787 | 33,609 |
| Internal research and development expenses: | | |
| Personnel related (including stock-based compensation) | 19,251 | 14,833 |
| Facility related | 2,728 | 2,224 |
| Other internal costs | 6,087 | 4,121 |
| Sub-total internal expenses | 28,066 | 21,178 |
| Total research and development expenses | $ 82,853 | $ 54,787 |

(1) Expenses incurred by us in connection with Gilead partnered programs are reimbursed to us by Gilead and accounted for as revenue.

***General and Administrative Expenses***

General and administrative expenses for the year ended December 31, 2021 were $17.3 million, compared to $18.1 million for the year ended December 31, 2020.

The decrease of $0.8 million was primarily due to a decrease in personnel-related expenses of $0.4 million, and a decrease in other general and administrative expenses of $0.6 million, partially offset by an increase in professional and consulting fees of $0.2 million. The decrease in personnel-related expenses resulted from decreased stock compensation expenses, partially offset by a growth in headcount along with increased salaries in our general and administrative functions.

***Grant Income***

In the year ended December 31, 2021 we recorded grant income of $9.7 million, compared to $6.5 million in the year ended December 31, 2020 from grants, research incentives and imputed benefits from below market interest rates on loans from governmental agencies. The increase of $3.2 million was primarily due to higher income from Austrian research and development incentives.

***Interest Income and Expense***

Interest income was less than $0.1 million for the year ended December 31, 2021, compared to $0.4 million for the year ended December 31, 2020. This decrease of $0.3 million, despite higher cash balances over almost the entire year, was due to the drop in interest rates in the United States and Europe. Interest income represents interest from cash and cash equivalents held in US dollars resulting from the proceeds from the issuance of common and preferred stock as well as payments received under our Collaboration Agreement with Gilead. During the year ended December 31, 2021 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 at our Austrian subsidiary that produced no material interest income due to the low or zero interest rate policy in the European Monetary Union.

Interest expenses for loans from government agencies were $0.9 million for the year ended December 31, 2021, compared to $0.8 million for the year ended December 31, 2020. Interest expense was recorded at the market rate of interest, which exceeded the contractual interest.

**Other Income and Expenses**

Other expenses were $2.8 million for the year ended December 31, 2021, compared to other income of $3.1 million for the year ended December 31, 2020. The decrease of $5.9 million in the year ended December 31, 2021 resulted primarily from exchange rate differences and foreign currency remeasurements. In addition the prior year effect from the recognition of $0.2 million in support under the Corona Short Term Work Program in Austria contributed to the decrease in other income and expenses in the year ended December 31, 2021.

Discussion of the year ended December 31, 2020 compared with the year ended December 31, 2019 is included in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2020 filed with the SEC on March 18, 2021.

**Liquidity and Capital Resources**

Since our inception in 2011, we have funded our operations primarily through private placements of our convertible preferred stock and proceeds from our IPO and follow-on public offering, from grants, research incentives and borrowings under various agreements with public funding agencies, and from an upfront payment, milestone payments and reimbursement of research and development expenses pursuant to the Restated Collaboration Agreement with Gilead.

We have raised gross proceeds of approximately $142.5 million from the issuance of our convertible preferred stock and $26.2 million from non-refundable upfront and milestone payments pursuant to the Restated Collaboration Agreement with Gilead of which we received $4.0 million in January 2022. In April 2019, we completed our IPO in which we issued and sold 6,000,000 shares of our common stock, at $14.00 per share, for gross proceeds of $84.0 million, or net proceeds of $74.6 million. On December 11, 2020, we completed a follow-on public offering in which we issued 3,910,000 shares of our common stock, at $11.75 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. As of December 31, 2021, the principal amount outstanding under loans from government agencies was $6.1 million and we had cash, cash equivalents and restricted cash of $66.9 million. In February 2022 we received a $15.0 million initiation fee in connection with the amended and restated collaboration agreement with Gilead. In addition, Gilead purchased unregistered shares of our common stock for $5.0 million. In March 2022, we issued and sold 21,700,000 shares of our common stock at $2.00 per share, and 15,800 shares of our Series A-1 convertible preferred stock at $2,000.00 per share in a follow-on public offering resulting in net proceeds of approximately $70.0 million.

We entered into various funding agreements with the Austrian Research Promotion Agency (Österreichische Forschungsförderungsgesellschaft, or FFG). The loans by FFG, or 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 contain no financial covenants and are not secured by any of our assets. The debt obligation is $6.1 million, principal repayments are due as follows: $3.1 million are due in 2022, $1.8 million are due in 2023, and the remaining $1.2 million are due upon final maturity in 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, 2021, the unamortized debt discount related to FFG Loans was $1.1 million.

We entered into arrangements with contract manufacturing organizations. As of December 31, 2021, we had total non-cancellable obligations under such contracts of $10.5 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 and, if approved, proceed to commercialization of our most advanced oncology product candidate HB-200, continue our research and development efforts relating to our other and future product candidates, and invest in our manufacturing capabilities and our own manufacturing facility.

***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, 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. As of December 31, 2021, we had an accumulated deficit of $222.8 million. We expect to continue to incur significant losses for the foreseeable future. We anticipate that our expenses will increase substantially 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;
- 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; 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 expect that our existing cash and cash equivalents, including the funds we received from our offering in March 2022 and the funds received under the amended and restated research collaboration and license Agreement with Gilead, will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. 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.

***Cash Flows***

The following table sets forth a summary of the primary sources and uses of cash (in thousands):

| | Year ended December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Net cash used in operating activities | $ (66,016) | $ (39,339) |
| Net cash used in investing activities | (12,581) | (2,371) |
| Net cash (used in) provided by financing activities | (235) | 73,420 |
| Net increase (decrease) in cash and cash equivalents | (78,832) | 31,710 |

***Cash Used in Operating Activities***

During the year ended December 31, 2021, cash used in operating activities was $66.0 million, which consisted of a net loss of $75.7 million, adjusted by non-cash charges of $13.6 million and cash used due to changes in our operating assets and liabilities of $3.9 million. The non-cash charges consisted primarily of stock-based compensation of $7.6 million, depreciation and amortization expense of $4.7 million, and other non-cash items of $1.3 million. The change in our operating assets and liabilities was primarily due to an increase in prepaid expenses and other current assets of $7.1 million, an increase in accounts receivable of $1.9 million, a decrease in operating lease liabilities of $1.6 million, a decrease in other non-current liabilities of $0.4 million, and an increase in receivable research incentives of $0.3 million, partially offset by an increase in accrued expenses and other current liabilities of $4.8 million, an increase of deferred revenues of $1.4 million, an increase in accounts payable of $0.9 million, and a decrease in other non-current assets of $0.4 million. Changes in prepaid expenses and other current assets, accounts receivable, accounts payable, and other non-current assets in the year ended December 31, 2021 were generally due to growth in our business, the advancement of our research programs and the timing of invoicing and payments. Changes in operating lease liabilities in the year ended December 31, 2021 were mainly due to regular lease payments.

During the year ended December 31, 2020, cash used in operating activities was $39.3 million, which consisted of a net loss of $44.1 million, adjusted by non-cash charges of $12.9 million and changes in our operating assets and liabilities of $8.1 million. The non-cash charges consisted of stock-based compensation of $8.7 million, depreciation and amortization expense of $4.1 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 receivable research incentives of $5.8 million, an increase in accounts receivable of $3.6 million, an increase in prepaid expenses and other current assets of $2.3 million, a decrease in operating lease liabilities of $1.8 million, an increase in other non-current assets of $1.1 million, a decrease of accrued

expenses and other current liabilities of $0.2 million and a decrease in other non-current liabilities of $0.1 million, partially offset by an increase in accounts payable of $6.3 million and an increase of deferred revenues of $0.5 million. Changes in prepaid expenses and other current assets, accounts payable, accounts receivables and other non-current assets in the year ended December 31, 2020 were generally due to growth in our business, the advancement of our research programs and the timing of invoicing and payments. Changes in operating lease liabilities in the year ended December 31, 2020 were mainly due to regular lease payments.

***Cash Used in Investing Activities***

During the years ended December 31, 2021 and 2020, cash used in investing activities was $12.6 million and $2.4 million, respectively. The increase of $10.2 million compared to the year ended December 31, 2020 resulted from the acquisition of land and capital expenditures in connection with our own GMP manufacturing facility project and was partially offset by lower expenditures for laboratory and office space extension and purchase of equipment. Cash used in investing activities in the year ended December 31, 2020 resulted from capital expenditures in connection with leasehold improvements to expand our laboratory space and for purchase of property and equipment.

***Cash (Used in) Provided by Financing Activities***

During the year ended December 31, 2021, cash used in financing activities was $0.2 million and consisted primarily of payments related to finance leases, partially offset by proceeds from the exercise of stock options.

During the year ended December 31, 2020, cash provided by financing activities was $73.4 million, which consisted mainly of net proceeds of $75.0 million from our follow-on public offering in December 2020, partially offset by a repayment of a loan of $1.3 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 are required to use reasonable efforts to make commercially available licensed products. Pursuant to the license agreement, we are obligated to pay the University of Basel an annual fee which is fully deductible from any milestone, royalty or sublicense payments. We are also 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 double digit to low single digit percentage of the sublicense fees that we may receive from sublicensing.

In the year ended December 31, 2021, we recorded $1.3 million in licensing fees from intellectual property licenses as research and development expenses. At December 31, 2021, $0.3 million payable from sublicensing fees were included in accrued expenses and other current liabilities. In the year ended December 31, 2020, we recorded $1.2 million in licensing fees from intellectual property licenses as research and development expenses. At December 31, 2020, $0.1 million payable from sublicensing fees were included in accounts payable.

For additional information on these license agreements, please see “Business—Intellectual Property—License Agreements.”

**Critical Accounting Policies**

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, or 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, 2020 filed with the SEC on March 18, 2021.

***Recognition of revenue from contracts with customers***

We have entered into the Restated Collaboration Agreement with Gilead for the development and commercialization of certain of its 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 pre-clinical development and commercial milestones and royalties on product sales if certain future conditions are met.

We evaluate our collaboration and licensing arrangements pursuant to Accounting Standards Codification 606, or 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 Collaboration Agreement prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in our consolidated balance sheets. 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. Reimbursement of costs for or services under the Restated Collaboration Agreement are presented as revenue and not deducted from expenses. Amounts of consideration allocated to the performance of research or manufacturing services are recognized over the period in which services are performed. 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. The Restated 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 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.

All patent-related costs incurred in connection with filing and prosecuting patent applications are classified as research and development expenses and expensed as incurred due to the uncertainty about the recovery of the expenditure. 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 for the volatility of our common stock, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options and our expected dividend yield. 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. 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.

**Emerging Growth Company Status and Smaller Reporting Company**

As an “emerging growth company,” the Jumpstart Our Business Startups Act of 2012 allows us to delay adoption of new or revised accounting standards applicable to public companies until such standards are made applicable to private companies. However, we have irrevocably elected not to avail ourselves of this extended transition period for complying with new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We are also 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. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. 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 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, 2021 included small amounts of cash balances held by Hookipa Biotech GmbH in euro. We are exposed to market risk related to changes in interest rates. We had cash, cash equivalents and restricted cash of $66.9 million as of December 31, 2021, 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.

**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 founded 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, 2021, management, with the participation of our Principal Executive Officer and Principal Financial and Accounting 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 of 1934). 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 Chief Executive Officer and the Chief Financial and Accounting 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 and Accounting Officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of December 31, 2021.

**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 and Accounting Officer, our management assessed the effectiveness of our internal control over financial report as of December 31, 2021 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, 2021.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm on our internal control over financial reporting due to an exemption established by the JOBS Act for "emerging growth companies."

**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 three months ended December 31, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. Other Information.**

None.

**Item 9C. Disclosure regarding Foreign Jurisdictions that Prevent Inspections.**

Not applicable.

## PART III

### Item 10. Directors, Executive Officers, and Corporate Governance

Incorporated by reference from the information in our Proxy Statement for our 2022 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates. If the Proxy Statement is not filed within such 120-day period, the information required by this item will be contained in an amendment to this Annual Report on Form 10-K to be filed with the Securities and Exchange Commission, or the Form 10-K/A.

### Item 11. Executive Compensation

Incorporated by reference from the information in our Proxy Statement for our 2022 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates. If the Proxy Statement is not filed within such 120-day period, the information required by this item will be contained in an amendment to this Annual Report on Form 10-K to be filed with the Securities and Exchange Commission, or the Form 10-K/A.

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

Incorporated by reference from the information in our Proxy Statement for our 2022 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates. If the Proxy Statement is not filed within such 120-day period, the information required by this item will be contained in an amendment to this Annual Report on Form 10-K to be filed with the Securities and Exchange Commission, or the Form 10-K/A.

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

Incorporated by reference from the information in our Proxy Statement for our 2022 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates. If the Proxy Statement is not filed within such 120-day period, the information required by this item will be contained in an amendment to this Annual Report on Form 10-K to be filed with the Securities and Exchange Commission, or the Form 10-K/A.

### Item 14. Principal Accountant’s Fees and Services

Incorporated by reference from the information in our Proxy Statement for our 2022 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates. If the Proxy Statement is not filed within such 120-day period, the information required by this item will be contained in an amendment to this Annual Report on Form 10-K to be filed with the Securities and Exchange Commission, or the Form 10-K/A.

## Part IV

**Item 15. Exhibits.**

**(1) Financial Statements**

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 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 |
| 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 |
| 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# | 2019 Stock Option and Incentive Plan (filed as Exhibit 10.2 to the Company's Registration Statement on Form S-1 filed on April 8, 2019 (File No. 333-230451) and incorporated herein by reference) |
| 10.3# | 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) |

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|---|---|
| 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# | 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) |
| 10.11# | 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) |
| 10.12# | Employment Agreement between Joern Aldag and the Registrant (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) |
| 10.13# | Employment Agreement between Reinhard Kandera and the Registrant (filed as Exhibit 10.13 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# | Employment Agreement between Igor Matushansky and the Registrant (filed as Exhibit 10.14 to the Company's Registration Statement on Form S-1 filed on April 8, 2019 (File No. 333-230451) and incorporated herein by reference) |
| 10.15#* | Employment Agreement between Klaus Orlinger and the Registrant, dated January 1, 2022 |
| 10.16 | Lease by and between the Registrant 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) |
| 10.17 | Lease by and between the Registrant 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) |
| 10.18† | 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) |
| 10.19† | 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) |
| 10.20† | 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) |
| 10.21† | 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) |

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|---|---|
| 10.22† | 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) |
| 10.23 | 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) |
| 10.24* | 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 |
| 10.25 | 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) |
| 10.26 | Stock Purchase Agreement, by and between the Registrant 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 filed on February 15, 2022 (File No. 001-38869) and incorporated herein by reference) |
| 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 |
| 101.INS | XBRL Instance Document |
| 101.SCH | XBRL Taxonomy Extension Schema Document |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase Document |
| 101.LAB | XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document |

† Confidential treatment granted as to certain portions, which portions have been omitted and filed separately with the Securities and Exchange Commission.

# 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**

None.

## 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: March 24, 2022

By: /s/ Joern Aldag
Joern Aldag
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/ Joern Aldag<br>Joern Aldag | Chief Executive Officer and Director<br>(Principal Executive Officer) | March 24, 2022 |
| /s/ Reinhard Kandera<br>Reinhard Kandera | Chief Financial Officer and Director<br>(Principal Financial and Accounting Officer) | March 24, 2022 |
| /s/ Jan van de Winkel<br>Jan van de Winkel, Ph.D. | Chairman of the Board | March 24, 2022 |
| /s/ Michael A. Kelly<br>Michael A. Kelly | Director | March 24, 2022 |
| /s/ David Kaufman<br>David Kaufman | Director | March 24, 2022 |
| /s/ Christoph Lengauer<br>Christoph Lengauer, Ph.D. | Director | March 24, 2022 |
| /s/ Julie O'Neill<br>Julie O'Neill | Director | March 24, 2022 |

## 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, 2021 and 2020, and the related consolidated statements of operations and comprehensive loss, of convertible preferred stock and stockholders' equity (deficit) and of cash flows for each of the three years in the period ended December 31, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021 in conformity with accounting principles generally accepted in the United States of America

***Basis for Opinion***

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

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

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

***Emphasis of Matter***

As discussed in Note 2 to the consolidated financial statements, the Company will require additional financing to fund future operations. Management's plans in regard to this matter are described in Note 2.

Vienna, Austria
March 24, 2022

PwC Wirtschaftsprüfung GmbH
/s/ Stefano Mulas
German 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, 2021 | December 31, 2020 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 65,921 | $ 142,743 |
| Restricted cash | 566 | — |
| Accounts receivable | 6,895 | 5,542 |
| Receivable research incentives | 14,271 | 15,115 |
| Prepaid expenses and other current assets | 14,482 | 8,104 |
| Total current assets | 102,135 | 171,504 |
| Non-current assets: | | |
| Restricted cash | 425 | 434 |
| Property, plant and equipment, net | 16,352 | 6,219 |
| Operating lease right of use assets | 5,673 | 6,452 |
| Finance lease right of use assets | 90 | 1,298 |
| Other non-current assets | 1,370 | 1,910 |
| Total non-current assets | 23,910 | 16,313 |
| Total assets | $ 126,045 | $ 187,817 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities | | |
| Accounts payable | $ 8,762 | $ 8,009 |
| Deferred revenues | 5,538 | 3,750 |
| Operating lease liabilities, current | 1,682 | 1,998 |
| Accrued expenses and other current liabilities | 8,880 | 7,386 |
| Loans payable, current | 2,792 | — |
| Total current liabilities | 27,654 | 21,143 |
| Non-current liabilities | | |
| Loans payable, non-current | 2,219 | 4,537 |
| Operating lease liabilities, non-current | 3,911 | 3,819 |
| Deferred revenues, non-current | 21 | 784 |
| Other non-current liabilities | 2,648 | 1,411 |
| Total non-current liabilities | 8,799 | 10,551 |
| Total liabilities | 36,453 | 31,694 |
| Commitments and contingencies (Note 13) | | |
| Stockholders' equity: | | |
| Preferred stock, $0.0001 par value; 10,000,000 shares authorized at December 31, 2021 and December 31, 2020, respectively; Series A convertible preferred stock, 2,978 shares designated, 1,697 shares and 2,978 shares outstanding at December 31, 2021 and December 31, 2020, respectively | 0 | 0 |
| Common stock, $0.0001 par value; 100,000,000 shares authorized at December 31, 2021 and December 31, 2020, respectively; 27,383,483 shares and 25,948,712 shares issued and outstanding at December 31, 2021 and December 31, 2020, respectively | 3 | 3 |
| Class A common stock, $0.0001 par value; 3,900,000 shares authorized at December 31, 2021 and December 31, 2020; 3,819,732 shares issued and outstanding at December 31, 2021 and December 31, 2020 | 0 | 0 |
| Additional paid-in capital | 317,135 | 309,288 |
| Accumulated other comprehensive loss | (4,780) | (6,067) |
| Accumulated deficit | (222,766) | (147,101) |
| Total stockholders' equity | 89,592 | 156,123 |
| Total liabilities and stockholders' equity | $ 126,045 | $ 187,817 |

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, | | |
|---|---|---|---|
| | 2021 | 2020 | 2019 |
| Revenue from collaboration and licensing | $ 18,448 | $ 19,584 | $ 11,942 |
| Operating expenses: | | | |
| Research and development | (82,853) | (54,787) | (46,312) |
| General and administrative | (17,269) | (18,082) | (16,715) |
| Total operating expenses | (100,122) | (72,869) | (63,027) |
| Loss from operations | (81,674) | (53,285) | (51,085) |
| Other income (expense): | | | |
| Grant income | $ 9,724 | $ 6,517 | $ 6,737 |
| Interest income | 27 | 400 | 1,587 |
| Interest expense | (898) | (786) | (877) |
| Other income and (expenses), net | (2,843) | 3,072 | 601 |
| Total other income, net | 6,010 | 9,203 | 8,048 |
| Net loss before tax | (75,664) | (44,082) | (43,037) |
| Income tax expense | (1) | (0) | (0) |
| Net loss | (75,665) | (44,082) | (43,037) |
| Other comprehensive loss: | | | |
| Foreign currency translation gain (loss), net of tax | 1,287 | (1,414) | (933) |
| Comprehensive loss | $ (74,378) | $ (45,496) | $ (43,970) |
| Net loss per share — basic and diluted | $ (2.30) | $ (1.69) | $ (2.41) |

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

## HOOKIPA PHARMA INC.

## CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)

### (In thousands, except share amounts)

| | Redeemable Convertible Preferred Stock | | Convertible Preferred Stock | | Common Stock | | | | Additional Paid-In Capital | Accumulated Other Comprehensive Loss | Accumulated Deficit | Total Stockholders' Equity |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Common Stock | | Class A Common Stock | | | | | |
| | Shares | Amount | Shares | Amount | Shares | Amount | Shares | Amount | | | | |
| **Balances as of January 1, 2019** | **1,323,506** | **104,774** | **—** | **—** | **1,006,595** | **0** | **—** | **—** | **3,327** | **(3,720)** | **(59,982)** | **(60,375)** |
| Issuance of Series D preferred stock, net of issuance costs of $158 | 257,000 | 37,274 | — | — | — | — | — | — | — | — | — | — |
| Issuance of common stock upon initial public offering at $14.00 per share for cash, net of issuance costs of $9,386 | — | — | — | — | 6,000,000 | 1 | — | — | 74,614 | — | — | 74,615 |
| Conversion of Series A, B, C and D preferred stock into common stock upon initial public offering | (1,580,506) | (142,048) | — | — | 14,582,161 | 2 | 3,819,732 | 0 | 142,046 | — | — | 142,048 |
| Issuance of common stock upon exercise of stock options | — | — | — | — | 157,636 | 0 | — | — | 16 | — | — | 16 |
| Foreign currency translation adjustment, net of tax | — | — | — | — | — | — | — | — | — | (933) | — | (933) |
| Stock-based compensation expense | — | — | — | — | — | — | — | — | 5,565 | — | — | 5,565 |
| Net loss | — | — | — | — | — | — | — | — | — | — | (43,037) | (43,037) |
| **Balances as of December 31, 2019** | **—** | **$ —** | **—** | **$ —** | **21,746,392** | **$ 3** | **3,819,732** | **$ 0** | **$ 225,568** | **$ (4,653)** | **$ (103,019)** | **$ 117,899** |
| Issuance of Series A convertible preferred stock upon public offering at $11,750 per share for cash, net of issuance costs of $2,565 | — | — | 2,978 | 0 | — | — | — | — | 32,426 | — | — | 32,426 |
| Issuance of common stock upon public offering at $11.75 per share for cash, net of issuance costs of $3,368 | — | — | — | — | 3,910,000 | 0 | — | — | 42,574 | — | — | 42,574 |
| Issuance of common stock upon exercise of stock options | — | — | — | — | 255,011 | 0 | — | — | 63 | — | — | 63 |
| Vesting of restricted stock | — | — | — | — | 1,060 | 0 | — | — | (0) | — | — | — |
| Vesting of equity grants | — | — | — | — | 36,249 | 0 | — | — | (0) | — | — | — |
| Foreign currency translation adjustment, net of tax | — | — | — | — | — | — | — | — | — | (1,414) | — | (1,414) |
| Stock-based compensation expense | — | — | — | — | — | — | — | — | 8,657 | — | — | 8,657 |
| Net loss | — | — | — | — | — | — | — | — | — | — | (44,082) | (44,082) |
| **Balances as of December 31, 2020** | **—** | **$ —** | **2,978** | **$ 0** | **25,948,712** | **$ 3** | **3,819,732** | **$ 0** | **$ 309,288** | **$ (6,067)** | **$ (147,101)** | **$ 156,123** |
| Conversion of Series A convertible preferred stock to common stock | — | — | (1,281) | (0) | 1,281,000 | 0 | — | — | (0) | — | — | — |
| Issuance of common stock upon exercise of stock options | — | — | — | — | 110,071 | 0 | — | — | 203 | — | — | 203 |
| Vesting of restricted stock | — | — | — | — | 43,700 | 0 | — | — | (0) | — | — | — |
| Foreign currency translation adjustment, net of tax | — | — | — | — | — | — | — | — | — | 1,287 | — | 1,287 |
| Stock-based compensation expense | — | — | — | — | — | — | — | — | 7,644 | — | — | 7,644 |
| Net loss | — | — | — | — | — | — | — | — | — | — | (75,665) | (75,665) |
| **Balances as of December 31, 2021** | **—** | **$ —** | **1,697** | **$ 0** | **27,383,483** | **$ 3** | **3,819,732** | **$ 0** | **$ 317,135** | **$ (4,780)** | **$ (222,766)** | **$ 89,592** |

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, | | |
|---|---|---|---|
| | **2021** | **2020** | **2019** |
| **Operating activities:** | | | |
| Net loss | $ (75,665) | $ (44,082) | $ (43,037) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Stock-based compensation expense | 7,644 | 8,657 | 5,565 |
| Depreciation and amortization expense | 4,640 | 4,150 | 3,067 |
| Other non-cash items | 1,226 | 53 | 52 |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable | (1,943) | (3,576) | (3,619) |
| Receivable research incentives | (295) | (5,825) | (5,892) |
| Prepaid expenses and other current assets | (7,091) | (2,286) | (113) |
| Other non-current assets | 416 | (1,080) | 869 |
| Accounts payable | 858 | 6,298 | 4,203 |
| Deferred revenues | 1,422 | 511 | (4,442) |
| Operating lease liabilities | (1,588) | (1,833) | (2,396) |
| Accrued expenses and other liabilities | 4,776 | (184) | 5,142 |
| Other non-current liabilities | (416) | (142) | (1,130) |
| Net cash used in operating activities | (66,016) | (39,339) | (41,731) |
| **Investing activities:** | | | |
| Purchases of property and equipment | (12,581) | (2,371) | (1,999) |
| Net cash used in investing activities | (12,581) | (2,371) | (1,999) |
| **Financing activities:** | | | |
| Payments related to finance leases | (438) | (108) | (1,437) |
| Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs | — | — | 37,274 |
| Proceeds from issuance of convertible preferred stock, net of issuance costs | — | 32,426 | — |
| Proceeds from issuance of common stock, net of issuance costs | 203 | 42,637 | 74,756 |
| Payments for deferred offering costs | — | (224) | — |
| Repayments of borrowings | — | (1,311) | (842) |
| Net cash (used in) provided by financing activities | (235) | 73,420 | 109,751 |
| **Net (decrease) increase in cash, cash equivalents and restricted cash** | (78,832) | 31,710 | 66,021 |
| Cash, cash equivalents and restricted cash at beginning of period | 143,177 | 113,575 | 48,580 |
| Effect of exchange rate changes on cash, cash equivalents and restricted cash | 2,567 | (2,108) | (1,026) |
| Cash, cash equivalents and restricted cash at end of period | $ 66,912 | $ 143,177 | $ 113,575 |
| **Supplemental disclosure of cash flow information:** | | | |
| Cash paid for interest | $ (48) | $ (97) | $ (64) |
| Cash paid for income taxes | $ (1) | $ (0) | $ — |
| **Supplemental disclosure of non-cash financing activities:** | | | |
| Conversion of redeemable preferred shares upon the IPO | $ — | $ — | $ 142,048 |
| Property and equipment additions in accounts payable and accrued expenses | $ (742) | $ 16 | $ (10) |
| Lease assets obtained in exchange for new operating lease liabilities | $ 2,727 | $ 12 | $ — |
| Lease assets derecognized upon lease cancellation | $ 1,061 | $ 30 | $ 182 |

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 started trading on the Nasdaq Global Select 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*

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, 2021, 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 $75.7 million, $44.1 million and $43.0 million for the years ended December 31, 2021, 2020 and 2019, respectively. As of December 31, 2021, the Company had an accumulated deficit of $222.8 million. The Company expects to continue to generate operating losses in the foreseeable future. As of March 24, 2022, the filing date of this Annual Report on Form 10-K, the Company expects that its cash and cash equivalents, together with the net proceeds from the offering in March 2022, and the funds received under the Restated Collaboration Agreement with Gilead, both described below, would be sufficient to fund its operating expenses, capital expenditure requirements and debt service payments through at least 12 months from the issuance date of the consolidated financial statements.

**HOOKIPA PHARMA INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)**

The Company will seek additional funding in order to reach its development and commercialization objectives. The Company will seek funds through further equity financings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. The Company may not be able to obtain financing on acceptable terms, or at all, and the Company may not be able to enter into collaborations or other arrangements. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders. If the Company is unable to obtain funding, the Company could be forced to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects.

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 be necessary if the Company is unable to continue as a going concern.

***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 and the valuation of current and non-current loans payable. 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.

On March 11, 2020, the World Health Organization designated COVID-19 as a global pandemic. The Company believes the extent of the COVID-19 pandemic's impact on the Company's business, results of operations and financial condition has been and will continue to be driven by many factors, most of which are beyond the Company's control and ability to forecast. Because of these uncertainties, the Company cannot estimate how long or to what extent the pandemic will impact its operations. The Company's accounting estimates and assumptions may change over time in response to COVID-19 and the change could be material in future periods. 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 Redeemable Convertible Preferred Stock, Convertible Preferred Stock and Stockholders' Equity (Deficit) 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.

**HOOKIPA PHARMA INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)**

***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, 2021 and December 31, 2020 the net proceeds from the Company's offerings have been deposited in interest-bearing bank accounts with investment grade U.S. financial institutions and have been partially invested in a money market fund. The money market fund, held in U.S. dollars, is primarily invested in U.S. and foreign short-term debt obligations. As of December 31, 2021 and December 31, 2020, the Company's cash and cash equivalents included smaller amounts of cash balances held in accounts with 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, 2021 and December 31, 2020, respectively, Gilead accounted for the majority of the accounts receivable balance. For the years ended December 31, 2021, December 31, 2020 and December 31, 2019 Gilead accounted for the majority of the Company's revenues. No other customers accounted for more than 10.0% of accounts receivable or net sales. 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.

***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, 2021 and December 31, 2020 cash equivalents consisted of money market funds.

***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.

**HOOKIPA PHARMA INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)**

- 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 4).

***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 Company adopted the new leasing standards as of January 1, 2019. 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.

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.

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 Accounting Standards Codification ("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 less than $0.1 million associated with the Company's cloud computing arrangements has been recognized during the fiscal year ended December 31, 2021. No amortization expense associated with the Company's cloud computing arrangements has been recognized during the fiscal year ended December 31, 2020 (see Note 5). The Company tests for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable.

***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, determined based on discounted cash flows. The Company did not record any impairment losses on long-lived assets during the years ended December 31, 2021, 2020 and 2019.

***Segment information***

The Company manages its operations as a single segment 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. The majority of the Company's tangible assets are held in Austria.

**HOOKIPA PHARMA INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)**

***Revenue recognition from contracts with customers***

The Company entered into a collaboration and license agreement (the "Gilead Agreement") with Gilead whereby 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"). The Company's performance obligations under the terms of this 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 licenses do not represent distinct performance obligations, because they cannot be used without the research and development services. Payments to the Company under this 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.

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 obligations under the collaboration and licensing arrangement, represent separate or one or more combined performance obligations, the allocation of the transaction price to identified performance obligations, and the determination of when milestone payments are probable of being received.

*Upfront payment*

The non-refundable upfront-payment received by the Company under the Gilead Agreement is 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.

*Reimbursement for services*

Under the Gilead Agreement, the Company incurs employee expenses as well as external costs for research and manufacturing activities presented as operating expenses or prepaid expenses. Based on the nature of the Company's responsibilities under the collaboration arrangement, 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 in the period in which the goods or services are received and external costs are recognized. Unpaid reimbursement amounts are presented as Accounts receivable.

*Research and development milestones*

The Gilead Agreement includes 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. The Company will continue to assess the probability of significant reversals for any amounts that become likely to be realized prior to recognizing the variable consideration associated with these payments within the transaction price.

*Sales-based milestones and royalty payments*

The Gilead Agreement also includes 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 agreement. 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.

All patent-related costs incurred in connection with filing and prosecuting patent applications are classified as research and development expenses and expensed as incurred due to the uncertainty about the recovery of the expenditure. 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.

**HOOKIPA PHARMA INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)**

***Government grant agreements and research incentives***

The Company recognizes funding from grants and research incentives received from Austrian government agencies 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, 2021, comprehensive loss included $1.3 million of foreign currency translation gain adjustments. For the years ended December 31, 2020 and 2019, comprehensive loss included $1.4 million and $0.9 million of foreign currency translation loss adjustments, respectively.

***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.

**HOOKIPA PHARMA INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)**

The Company reported a net loss attributable to common stockholders for the years ended December 31, 2021, 2020 and 2019.

***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.

***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.

*Recently Issued Accounting Pronouncements*

In November 2021, the FASB issued ASU 2021-10, Government Assistance (Topic 832): Disclosures by Business Entities about Government Assistance, which requires business entities to provide certain disclosures when they have received government assistance and when they use a grant or contribution accounting model by analogy to other accounting guidance (e.g., a grant model under IAS 20, Accounting for Government Grants and Disclosure of Government Assistance, or ASC 958-605, Not-For-Profit Entities — Revenue Recognition). Topic 832 requires the annual disclosures about transactions with a government that are accounted for by applying a grant or contribution accounting model by analogy of information about the nature of the transactions and the related accounting policy used to account for the transactions, the line items on the balance sheet and income statement that are affected by the transactions, and the amounts applicable to each financial statement line item, significant terms and conditions of the transactions, including commitments and contingencies. The guidance in ASU 2021-10 is effective for all entities for fiscal years beginning after December 15, 2021. Entities may apply the ASU’s provisions either prospectively to all transactions within the scope of ASC 832 that are reflected in the financial statements as of the adoption date and all new transactions entered into after the date of adoption or retrospectively. Early adoption is permitted. The Company analyzed ASU 2021-10 and does not believe the guidance will have a material impact on its consolidated financial statements since the Company has already provided disclosures regarding Government Assistance on its consolidated financial statements.

**HOOKIPA PHARMA INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)**

In August 2020, the FASB issued ASU 2020-06, Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40). The ASU provides guidance that simplified the accounting for certain financial instruments with characteristics of liabilities and equity. The new guidance reduced the number of accounting models for convertible debt and convertible preferred stock instruments and made certain disclosure amendments intended to improve the information provided to users. The guidance also amended the derivative guidance for the "own stock" scope exception, which exempts qualifying instruments from being accounted for as derivatives if certain criteria are met. Finally, the standard changed the way certain convertible instruments are treated when calculating earnings per share. This guidance is effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years with early adoption permitted. The Company is currently assessing the impact that this guidance will have on its consolidated financial statements.

**3. Collaboration and Licensing Agreements**

***Gilead Collaboration and License Agreement***

In June 2018, the Company entered into the Gilead 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 an Amended and Restated Collaboration Agreement, which altered key aspects of the collaboration pertaining to the HIV therapeutic (see Note 17).

Under the Gilead Agreement, the Company granted Gilead an exclusive, royalty-bearing license to the Company's technology platforms. Upon entering into the agreement, the Company received a non-refundable $10.0 million upfront payment from Gilead. 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 over $300 million. The commercial milestones amount to a total of $115 million. Additionally, Gilead is obligated to pay royalties on net sales for each program. Payments from Gilead generally have a 60 days payment term.

The $10.0 million upfront payment and $8.0 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, 2021, $4.3 million of upfront and milestone payments were included as a liability in deferred revenues, current. As of December 31, 2020, $2.5 million of upfront and milestone payments were included as a liability in deferred revenues, current and non-current.

As of December 31, 2021, $1.2 million of cost reimbursements for research and development services were included as a liability in deferred revenues. As of December 31, 2020, $2.0 million of cost reimbursements for research and development services were included as a liability in deferred revenues. Reimbursements for external costs are recognized as revenues in the period in which the services are provided and external costs are recognized.

In the year ended December 31, 2021, the Company recognized $0.6 million of the upfront payment received in 2018 and $1.5 million of a $4.0 million milestone payment received in 2020. Furthermore, the Company recognized $16.3 million revenue from cost reimbursements for research and development services, of which $2.2 million were initially recorded as deferred revenue in the consolidated balance sheet. No revenue has yet been recognized for another $4.0 million milestone payment that was recorded as deferred revenue in December 2021. For the year ended December 31, 2020, revenue from reimbursement of research and development expenses was $13.0 million, of which $1.1 million were initially recorded as deferred revenue in the consolidated balance sheet. Furthermore, the Company recognized $2.0 million of the upfront payment of $10.0 million received in 2018 and $2.4 million of the $4.0 million milestone payment received in 2020 as revenue. In addition, the Company fully recognized revenue for $2.2 million milestone payments for milestones achieved in the year ended December 31, 2020. For the year ended December 31, 2019, revenue from reimbursement of research and development expenses was $4.3 million, and revenue

**HOOKIPA PHARMA INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)**

from partial recognition of the upfront payment of $10.0 million received in 2018 was $4.4 million. Additionally, the Company recognized $3.2 million in milestone payments for milestones achieved in the year ended December 31, 2019.

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, 2021 and December 31, 2020, the contract asset and the liability relating to the sublicense payment was $0.3 million and $0.1 million, respectively.

**4. 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, 2021 Using | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| Cash equivalents: | | | | |
| Money market funds | $ 35,403 | $ — | $ — | $ 35,403 |
| Total | $ 35,403 | $ — | $ — | $ 35,403 |

| | Fair Value Measurement at December 31, 2020 Using | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| Cash equivalents: | | | | |
| Money market funds | $ 35,397 | $ — | $ — | $ 35,397 |
| Total | $ 35,397 | $ — | $ — | $ 35,397 |

During the year ended December 31, 2021, there were no transfers between Level 1, Level 2 and Level 3.

**5. Property, plant and equipment, net**

Property, plant and equipment, net consisted of the following (in thousands):

| | December 31, 2021 | December 31, 2020 |
|---|---|---|
| Land | $ 2,072 | $ — |
| Leasehold improvements | 3,348 | 3,322 |
| Construction in progress | 7,746 | 28 |
| Laboratory equipment | 7,025 | 5,982 |
| Furniture and fixtures | 651 | 430 |
| Computer equipment and software | 1,876 | 1,554 |
| Property and equipment, gross | 22,718 | 11,316 |
| Less: Accumulated depreciation | (6,366) | (5,097) |
| Property and equipment, net | $ 16,352 | $ 6,219 |

Depreciation expense for the years ended December 31, 2021, 2020 and 2019 was $2.1 million, $1.7 million and $1.1 million, respectively. Construction-in-progress as of December 31, 2021 related to investments in connection with the Company's GMP manufacturing facility project. Construction-in-progress as of December 31, 2020 related to implementation costs for a cloud computing arrangement which is a service contract.

**HOOKIPA PHARMA INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)**

**6. 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.

As of December 31, 2021, the Company recognized receivables of $14.3 million from the research incentive program, which are reported in research incentive receivables in the Company's consolidated balance sheet. As of December 31, 2020, the receivables from the research incentive program were $15.1 million.

During the years ended December 31, 2021, 2020 and 2019, the Company recorded $8.9 million, $5.8 million and $5.9 million, respectively, of income related to the incentive program within the Company's consolidated statements of operations as part of the grant income.

**7. 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 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 is required to maintain a cash balance of $0.4 million to secure letters of credit associated with real estate leases. This amount was classified as non-current restricted cash in the consolidated balance sheet as of December 31, 2021.

Certain of the Company's leases qualify as operating leases, and certain of its leases qualify as finance leases. The following table summarizes the presentation in the consolidated balance sheets (in thousands):

| | Balance sheet location | December 31, 2021 | December 31, 2020 |
|---|---|---|---|
| **Assets** | | | |
| Operating lease assets, net | Operating lease right of use assets | $ 5,673 | $ 6,452 |
| Finance lease assets, net | Finance lease right of use assets | 90 | 1,298 |
| Total lease assets | | 5,763 | 7,750 |
| **Liabilities** | | | |
| Current operating lease liability | Operating lease liabilities, current | 1,682 | 1,998 |
| Current finance lease liability | Accrued expenses and other current liabilities | 21 | 155 |
| Total current lease liabilities | | 1,703 | 2,153 |
| Non-current operating lease liability | Operating lease liabilities, non-current | 3,911 | 3,819 |
| Non-current finance lease liability | Other non-current liabilities | — | 258 |
| Total non-current lease liabilities | | 3,911 | 4,077 |
| Total lease liabilities | | $ 5,614 | $ 6,230 |

In the years ended December 31, 2021 and 2020 the Company terminated leases of parking spaces and derecognized the relating right of use asset and the lease liability which were insignificant.

**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, 2021 | Year ended December 31, 2020 |
|---|---|---|---|
| Operating lease expenses | Research and development expenses | $ 1,910 | $ 1,654 |
| | General and administrative expenses | 203 | 376 |
| Finance lease amortization expenses | Research and development expenses | 425 | 395 |
| | General and administrative expenses | 7 | 21 |
| Interest on finance lease liabilities | Interest expenses | 5 | 8 |
| Sublease income | Other income (expense) | (40) | (155) |
| Net lease expense | | $ 2,510 | $ 2,299 |

The minimum lease payments for the next five years and thereafter are expected to be as follows (in thousands):

| | December 31, 2021 | | |
|---|---|---|---|
| | Operating lease | Finance lease | Total |
| 2022 | 1,585 | 21 | 1,606 |
| 2023 | 1,547 | — | 1,547 |
| 2024 | 1,340 | — | 1,340 |
| 2025 | 1,242 | — | 1,242 |
| 2026 | — | — | — |
| Thereafter | — | — | — |
| Total lease payments | 5,714 | 21 | 5,735 |
| Less: interest | 121 | 0 | 121 |
| Present value of lease liabilities | $ 5,593 | $ 21 | $ 5,614 |

The weighted average remaining lease term and weighted average discount rate of operating leases are as follows:

| | December 31, 2021 | December 31, 2020 |
|---|---|---|
| Weighted average remaining lease term in years | 3.7 | 3.1 |
| Weighted average discount rate [1] | 1.3 % | 2.3 % |

[1] The majority of the contracts are denominated in euros. The discount rate was determined on a currency-equivalent basis.

The weighted average remaining lease term and weighted average discount rate of finance leases are as follows:

| | December 31, 2021 | December 31, 2020 |
|---|---|---|
| Weighted average remaining lease term in years | 0.2 | 3.0 |
| Weighted average discount rate [1] | 0.4 % | 1.7 % |

[1] The contracts are denominated in euros. The discount rate was determined on a currency-equivalent basis.

In December 2021 the Company extended the lease term of existing operating leases for the office and laboratory space in Vienna, Austria. The respective lease liabilities were remeasured and the amounts resulting from the remeasurement of the lease liability were recognized as an adjustment to the corresponding right of use asset. Also in December 2021, the Company reduced the lease term for existing operating and finance leases related to an agreement

with a contract manufacturing organization for the production of clinical trial material and accounted for the proportionate decrease in the lease liability and the right of use asset with the difference recognized as a loss of $1.0 million on lease modification in operating research and development expenses on the income statement.

Until March 2021, the Company subleased certain of its leased real estate that it did not utilize to a third party. The sublease was qualified as an operating lease. The Company recognized sublease income in its consolidated statements of operations and comprehensive loss. The sublease had no influence on the Company's accounting for the head lease.

**8. Accrued expenses and other current liabilities**

Accrued expenses and other current liabilities consisted of the following (in thousands):

| | December 31, 2021 | December 31, 2020 |
|---|---|---|
| Salaries and bonuses | 4,754 | 4,381 |
| Social security contributions | 250 | 211 |
| Unearned grant income (current) | 693 | 878 |
| Sublicense fees | 304 | — |
| Accrued external research and development expenses | 2,165 | 895 |
| Accrued external general and administration expenses | 629 | 634 |
| Accrued for property and equipment acquisitions | 7 | — |
| Finance lease liabilities | 21 | 155 |
| Other accruals and liabilities | 57 | 232 |
| | $ 8,880 | $ 7,386 |

**9. Loans payable**

As of December 31, 2021 and December 31, 2020, loans payable consisted of the following (in thousands):

| | December 31, 2021 | December 31, 2020 |
|---|---|---|
| Loans from FFG | $ 6,074 | $ 6,564 |
| Unamortized debt discount | (1,063) | (2,027) |
| Total Loans payable, net | $ 5,011 | $ 4,537 |

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. Amounts due under the FFG Loans bear interest at a rate of 0.75% per annum and mature at various dates between June 2022 and March 2024. Interest on amounts due under the loans is payable semi-annually in arrears, with all principal and remaining accrued interest due upon maturity.

The FFG Loans bear interest at rates that are below market rates of interest. The Company accounts 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 recognizes 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 recognized as grant income over the term of the funding agreement.

The Company recognized grant income of $0.8 million, $0.7 million and $0.8 million during the years ended December 31, 2021, 2020 and 2019, respectively, related to the recognition of the unearned income recorded for the

imputed benefit of FFG Loans at below-market interest rates. Unearned income (current) related to the imputed benefit of FFG Loans at below-market interest rates was $0.7 million and $0.9 million as of December 31, 2021 and 2020, respectively, and unearned income (non-current) presented under loans payable non-current related to such benefit was $0.4 million and $1.1 million as of December 31, 2021 and 2020, respectively.

In addition, the Company has recorded a discount to the carrying value of each FFG Loan for the portion of the loan proceeds allocated to grant funding, which is being amortized to interest expense over the term of the loan using the effective interest method. As of December 31, 2021 and 2020, the unamortized debt discount related to FFG Loans was $1.1 million and $2.0 million, respectively.

The Company recognized interest expense of $0.9 million, $0.8 million and $0.9 million during the years ended December 31, 2021, 2020 and 2019, respectively, related to the FFG Loans, which included interest expense related to the amortization of debt discount of $0.8 million, $0.7 million and $0.8 million during the years ended December 31, 2021, 2020 and 2019, respectively. No principal payment and a principal payment of $1.3 million was made in the years ended December 31, 2021 and 2020, respectively.

The Company uses 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 no material impact on grant income or liabilities.

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 on a project-by-project basis. The FFG Loans contain no financial covenants and are not secured by any of the Company's assets.

In November 2019, the Company agreed to an earlier repayment schedule for $3.3 million of the outstanding loans with FFG. As a result of the change, the Company reduced the deferred income attributable to the imputed benefit from below market interest by $0.3 million and increased the carrying value of the loans by the same amount. The change had no effect on the income of the year ended December 31, 2019 and the effect on the aggregate future cash flows under the loans is immaterial.

As of December 31, 2021, the aggregate minimum future principal payments due in connection with the FFG Loans are summarized as follows (in thousands):

| Payments Due by Calendar Year | Amount |
|---|---|
| 2022 | 3,054 |
| 2023 | 1,821 |
| 2024 | 1,199 |
| 2025 | — |
| 2026 | — |
| Thereafter | — |
| Total | $ 6,074 |

**10. 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. As of December 31, 2021, the Company was authorized to issue 100,000,000 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. As of December 31, 2021, the Company had 27,383,483 shares of common stock, 3,819,732 shares of Class A common stock and 1,697 shares of preferred stock outstanding and issued.

**HOOKIPA PHARMA INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)**

On April 23, 2019, the Company closed its IPO of 6,000,000 shares of common stock, at an offering price to the public of $14.00 per share. The Company received net proceeds of $74.6 million, after deducting $9.4 million in underwriting discounts and commissions and offering expenses. Upon the closing of the Company's IPO all then outstanding shares of Preferred Stock converted into 14,582,161 shares of common stock and 3,819,732 shares of Class A common stock.

On December 11, 2020, the Company closed a public offering of 3,910,000 shares of its common stock, which included the full exercise of the underwriters' option to purchase additional shares and of 2,978 shares of Series A convertible preferred stock at a public offering price of $11.75 and $11,750.00 per share, respectively, for net proceeds of $75.0 million after deducting underwriting discounts and commissions and offering expenses.

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 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 one share of common stock at such holder's election. Each holder of Series A convertible preferred stock has the right to convert each share of Series A convertible preferred stock into 1,000 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 preferred stock into shares of our 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 our 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 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 our 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 our Series A preferred stock will receive a payment equal to $0.001 per share of Series A 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 1,697 and 2,978 shares of Series A convertible preferred stock outstanding as of December 31, 2021 and December 31, 2020, respectively. In October 2021 and December 2021 certain of the Company's stockholders elected to convert an aggregate of 1,281 shares (55 and 1,226 shares, respectively) of Series A convertible preferred stock owned by such holders into an aggregate of 1,281,000 shares of the Company's common stock.

**11. Stock-based compensation**

***2018 Stock Option and Grant Plan***

In connection with a transaction between entities under common control by which the Company became the reporting entity in June 2018, the Board of Directors approved the 2018 Stock Option and Grant Plan, by which options granted by the previous reporting entity under the 2016 Stock Option Plan and outstanding at the time of the effectiveness of the transaction were replaced at similar commercial terms. In the accompanying consolidated financial statements and notes, options issued under previous stock option plans and respective compensation expenses are

**HOOKIPA PHARMA INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)**

retrospectively presented as if such options had been issued and outstanding under the 2018 Stock Option and Grant Plan.

The exercise price for options granted as a replacement of the 2016 Stock Option Plan is the U.S. dollar equivalent of €0.09, except for 23,286 options granted to an US employee, for which the exercise price is $2.93 following a repricing of these options in December 2018. For any new options, the exercise price shall not be less than 100% of the fair market value of the common stock on the grant date.

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 10$^{th}$ anniversary of the grant date. As of December 31, 2021, 968,504 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.

***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. 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 is 3,630,686 shares which shall be cumulatively increased each year by up to 4.0% of the then outstanding number of shares. 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. Option re-grants to non-executive directors generally vest on the first anniversary of the grant date. The options expire on the 10$^{th}$ 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.

***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, on a weighted average basis, the assumptions used in the Black-Scholes option-pricing model for estimating the fair value of stock options granted during:

**HOOKIPA PHARMA INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)**

| | Year ended Year ended December 31, 2021 | 2020 | 2019 |
|---|---|---|---|
| Risk-free interest rate | 1.07 % | 0.44 % | 2.21 % |
| Expected term (in years) | 6.1 | 6.1 | 6.1 |
| Expected volatility | 85.5 % | 80.2 % | 74.2 % |
| Expected dividends | — % | — % | — % |

For the 2019, 2020 and 2021 grants, the Company used the simplified method in developing an estimate of the expected term due to a lack of historical exercise data.

***Stock option activity***

The following table summarizes the Company's stock option activity since January 1, 2021 (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, 2020 | 3,555,945 | $ 8.45 | 7.9 | $ 12,839 |
| Granted | 990,548 | 11.46 | | |
| Exercised | (125,020) | 1.93 | | |
| Forfeited | (190,295) | 11.50 | | |
| Outstanding as of December 31, 2021 | 4,231,178 | $ 9.21 | 7.5 | $ 1,640 |
| | | | | |
| Options exercisable as of December 31, 2021 | 2,224,349 | $ 7.62 | 6.6 | $ 1,624 |
| Options unvested as of December 31, 2021 | 2,006,829 | $ 10.96 | 8.5 | $ 16 |

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, 2021, December 31, 2020 and December 31, 2019, was $2.33, $11.09 and $12.23, respectively.

The aggregate intrinsic value of options exercised during the years ended December 31, 2021, 2020 and 2019 was $1.0 million, $2.9 million and $1.4 million, respectively.

The weighted average grant-date fair value per share of stock options granted during the years ended December 31, 2021, 2020 and 2019 was $11.46, $8.95 and $7.92, respectively.

The total fair value of stock options vested during the years ended December 31, 2021 and 2020 was $6.0 million and $5.6 million, respectively.

Cash received from stock option exercise under share-based payment arrangements for the years ended December 31, 2021, 2020 and 2019 was $203 thousand, $63 thousand and $16 thousand, respectively.

**HOOKIPA PHARMA INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)**

***Restricted Stock Units***

In the year ended December 31, 2020, the Company granted restricted stock units with time-based vesting conditions to officers, employees and a consultant to compensate them for a temporary salary or fee reduction in response to the coronavirus pandemic. The restricted stock units are subject to time-based vesting conditions and generally vested in four equal installments between March 2021 and November 2021. The Company measures the fair value of restricted stock units on the date of grant using the grant date market price of the underlying shares. Expenses are recorded using the graded-vesting method. The table below summarizes the Company's restricted stock unit activity since December 31, 2020:

| | Number of Shares | Weighted Average Grant Date Fair Value |
|---|---|---|
| Outstanding as of December 31, 2020 | 43,700 | $ 11.87 |
| Granted | — | — |
| Vested | (43,700) | 11.87 |
| Forfeited | — | — |
| Outstanding as of December 31, 2021 | — | $ — |

The total fair value of restricted stock vested during the year ended December 31, 2021 was $0.5 million. The total fair value of restricted stock vested during the year ended December 31, 2020 was insignificant. The Company had no restricted stock outstanding in the year ended 2019.

***Common Stock Awards***

In the year ended December 31, 2020, the Company issued 36,249 unrestricted shares of common stock to the non-executive members of its Board of Directors. The Company's directors received equity instead of cash as their 2020 board remuneration as part of the Company's response to the coronavirus pandemic. The total fair value of common stock awards issued during the year ended December 31, 2020 was $0.3 million. The grant date fair value per share of common stock was $9.56 and was measured at the closing price of the common stock on the date of grant. Expenses were recorded immediately and are included in stock based compensation in the year ended December 31, 2020.

In the years ended 2021 and 2019, the Company has not issued common stock awards.

***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, | | |
|---|---|---|---|
| | 2021 | 2020 | 2019 |
| Research and development expenses | $ 3,200 | $ 3,084 | $ 1,981 |
| General and administrative expenses | 4,444 | 5,573 | 3,584 |
| | $ 7,644 | $ 8,657 | $ 5,565 |

**HOOKIPA PHARMA INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)**

As of December 31, 2021 total unrecognized compensation cost related to the unvested stock-based awards was $5.7 million, which is expected to be recognized over a weighted average period of 1.6 years.

**12. Income taxes**

During the years ended December 31, 2021, 2020 and 2019, 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, 2021, 2020 and 2019 consisted of the following (in thousands):

| | Year ended December 31, | | |
|---|---|---|---|
| | 2021 | 2020 | 2019 |
| United States | $ (11,403) | $ (11,603) | $ (7,886) |
| Foreign (Austria) | (64,261) | (32,479) | (35,151) |
| Net loss before tax | $ (75,664) | $ (44,082) | $ (43,037) |

The Company's worldwide effective tax rate for the years ended December 31, 2021, 2020 and 2019 was 0.0%, 0.0% and 0.0%, 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, 2021, 2020 and 2019 and the effective tax rate:

| | Year ended December 31, | | |
|---|---|---|---|
| | 2021 | 2020 | 2019 |
| U.S. federal statutory income tax rate | (21.0)% | (21.0)% | (21.0)% |
| State income taxes, net of federal benefit | — | — | — |
| Foreign tax rate differential[(1)] | (4.0) | (4.0) | (4.0) |
| Not taxable government grants[(2)] | (3.8) | (4.7) | (5.4) |
| Stock-based compensation[(3)] | (1.5) | (1.0) | (0.3) |
| Other | 0.1 | 0.5 | (0.3) |
| Change in deferred tax asset valuation allowance[(4)] | 30.2 | 30.2 | 31.0 |
| Effective income tax rate | — % | — % | — % |

[(1)] The 4% increase for the years ended December 31, 2021, 2020 and 2019, respectively, 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 25%.

[(2)] For the years ended December 31, 2021, 2020 and 2019, 3.8%, 4.7% and 5.4% increase, respectively, resulted from non-taxable research subsidies received from Austrian government agencies.

[(3)] For the years ended December 31, 2021, 2020 and 2019, 1.5%, 1.0% and 0.3% increase, respectively, resulted from non-taxable Stock-based compensation expense.

[(4)] For the years ended December 31, 2021, 2020 and 2019, 30.2% reduction, 30.2% reduction and 31.0% 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 have been fully impaired.

**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, 2021 and 2020 consisted of the following (in thousands):

| | Year ended December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Deferred tax assets: | | |
| Net operating loss carryforwards | $ 55,752 | $ 43,563 |
| Credit carryforwards | 64 | 64 |
| Accrued expenses and other | 357 | (36) |
| Stock-based compensation | 1,209 | 2,725 |
| Operating lease liabilities | 1,378 | 1,513 |
| Finance lease liabilities | 5 | 103 |
| Total deferred tax assets | 58,765 | 47,932 |
| Valuation allowance | (53,728) | (46,064) |
| Total deferred tax assets | 5,037 | 1,868 |
| | | |
| Deferred tax liabilities: | | |
| Accrued expenses and other | (3,604) | — |
| Fixed assets and intangible assets | (11) | — |
| Operating lease right of use asset | (1,400) | (1,614) |
| Finance lease right of use asset | (22) | (254) |
| Total deferred tax liabilities | (5,037) | (1,868) |
| | | |
| Net deferred tax assets | $ — | $ — |

As of December 31, 2021, 2020 and 2019, the Company had Austrian net operating loss carryforwards of $219.7 million, $163.2 million and $112.3 million, respectively, and US Federal net operating loss carryforwards of $17.9 million, $8.3 million and $4.9 million, respectively, all of them with no expiry date. The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. Management has considered the Company's history of cumulative net losses incurred since inception and its lack of commercialization of any products or generation of any revenue from product sales since inception 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, 2021, 2020 and 2019. 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, 2021, 2020 and 2019 related primarily to the increases in net operating loss carryforwards as follows (in thousands):

| | Year ended December 31, | | |
|---|---|---|---|
| | 2021 | 2020 | 2019 |
| Valuation allowance at beginning of period | $ (46,064) | $ (32,583) | $ (19,156) |
| Increases | (7,664) | (13,481) | (13,427) |
| Valuation allowance at end of period | $ (53,728) | $ (46,064) | $ (32,583) |

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,” or “GILTI”. 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 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, 2021 and 2020, the Company had no unrecognized income tax benefits that would affect the Company’s effective tax rate if recognized.

**13. 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, 2021, the Company’s total non-cancellable obligations under contracts with CMOs, excluding embedded lease liabilities, were $10.5 million, of which $10.4 million relate to 2022 deliverables and $0.1 million relate to 2023 deliverables.

In December 2018, the Company entered into an agreement with a contract manufacturing organization for the production of clinical trial material, including seed lots, drug substance for toxicology studies, stability studies and clinical studies as well as related technology transfer, quality control and process optimization activities which commenced in February 2019. Under the financial terms of the agreement the Company is obliged to pay non-cancellable minimum service fees totaling $13.9 million through January 2022. The Company has determined that the agreement includes embedded leases which resulted in recognition of operating and finance lease assets and corresponding liabilities on the Consolidated Balance Sheet. The agreement was not extended beyond the initial term and its wind-down during the first quarter of 2022 has been agreed.

**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, 2021, 2020 and 2019, the Company recorded $1.3 million, $1.2 million and $1.9 million, respectively, in licensing fees related to intellectual property licenses as research and development expenses. These amounts mainly related to the upfront payment and milestone payments received by the Company under the Gilead Agreement. The amounts recognized as expenses have 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, 2021 or December 31, 2020.

*Legal proceedings*

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 is currently a party to a patent proceeding opposing European Patent No. 3218504, which was granted to the University of Geneva in July 2020 and is exclusively licensed to the Company. While it is not feasible to predict the outcome of these matters with certainty, and some lawsuits, claims or proceedings may be disposed or decided unfavorably, the Company does not expect that the pending patent opposition, and any asserted or un-asserted legal claims or proceedings, individually or in the aggregate, will have a material adverse effect on the Company. However, if, as a result of the current patent proceeding, the Company would lose all, or at least part, of the protection under the opposed patent, such loss could erode the Company’s competitive position and harm its business and ability to achieve profitability. The Company expenses the costs related to the pending and other such legal proceedings as incurred.

**14. 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, 2021 and December 31, 2020 expenses recognized for the 401(k) Plan were $0.4 million and $0.2 million, respectively. During the year ended December 31, 2019 expenses recognized for the 401(k) Plan were insignificant.

**HOOKIPA PHARMA INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)**

**15. 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 per share amounts):

| | Year ended December 31, | | |
|---|---|---|---|
| | 2021 | 2020 | 2019 |
| Numerator: | | | |
| Net loss | $ (75,665) | $ (44,082) | $ (43,037) |
| | | | |
| Denominator: | | | |
| Weighted-average common shares outstanding, basic and diluted | 29,945,954 | 25,876,376 | 17,859,935 |
| Weighted-average Series A convertible preferred shares outstanding, basic and diluted, presented as if converted into common stock[(1)] | 2,887,636 | 162,732 | — |
| Total number of shares used to calculate net loss per share, basic and diluted | 32,833,590 | 26,039,108 | 17,859,935 |
| | | | |
| Net loss per share, basic and diluted | $ (2.30) | $ (1.69) | $ (2.41) |

[(1)] Series A convertible preferred stock are participating securities that have substantially the same terms and features as the Company's common stock. Series A convertible preferred stock is therefore included in the weighted-average number of shares outstanding to calculate net loss per share, basic and diluted as if converted in common stock. Each share of Series A convertible preferred stock is convertible into 1,000 shares of common stock. 1,697,000 shares of the Company's common stock are issuable upon conversion of Series A convertible preferred stock (see Note 10).

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 (upon exercise) that were not included in the diluted per share calculations because they would be anti-dilutive were as follows:

| | Year ended December 31, | | |
|---|---|---|---|
| | 2021 | 2020 | 2019 |
| Options issued and outstanding | 4,231,178 | 3,555,945 | 2,999,284 |
| Unvested restricted stock units | — | 43,700 | — |
| Total | 4,231,178 | 3,599,645 | 2,999,284 |

**16. Related parties**

Following the expiry of the consultancy agreement between the Company and its Chief Scientific Officer, Daniel Pinschewer, on March 19, 2020 the Company entered into a new consultancy agreement with Daniel Pinschewer on March 20, 2020, pursuant to which he serves as Scientific Advisor to the Chief Executive Officer.

The Company is party to research and service arrangements with the University of Basel. Daniel Pinschewer, formerly Chief Scientific Officer, and his spouse are employees of the University of Basel and both involved in providing the services under these arrangements. Payments to the University of Basel during Daniel Pinschewer's term as Chief Scientific Officer were reported as related party transactions but payments following the expiry of that role in March 2020 were no longer considered related party transactions.

**HOOKIPA PHARMA INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)**

In the year ended December 31, 2021, the Company did not record any related party transactions. In the years ended December 31, 2020 and 2019, the Company recorded $0.3 million and $0.3 million, respectively, in research and development expenses for service fees paid to the University of Basel, which represented related party transactions.

The University of Basel is also entitled to receive de minimis royalties on the net sales of any product that is based on a patent created by the Company's Scientific Advisor to the Chief Executive Officer in the course of his consulting services to the Company. In the years ended December 31, 2021, 2020 and 2019, no royalties were paid pursuant to the terms of this arrangement.

**17. Subsequent events**

**Stock option and equity grant to senior management**

On February 1, 2022, members of the Company's executive team received 50% of their 2021 annual bonus in the form of a grant of fully vested stock options, determined based on a value of $3.00 per share and resulting in the issuance of a total number of 145,071 options. The granted options have an exercise price of $1.50 per share, the closing price of the Company's common stock on January 31, 2022.

At the same time, the members of the Company's executive team agreed to convert a portion of their base salaries, for the six months ending June 30, 2022 for shares of the Company's fully vested common stock having a value equal to their foregone salary, determined based on a value of $3.00 per share, resulting in the issuance of an aggregate of 112,551 shares of common stock.

**Amended and restated research collaboration and license agreement**

In February 2022, the Company and Gilead entered into an amended and restated research collaboration and license agreement. For the future performance of development activities under the amended agreement, the Company received a $4 million milestone payment and a $15.0 million program initiation fee, which have been initially recorded as deferred revenue in the consolidated balance sheet and will be recognized as revenue when revenue recognition criteria are met.

In connection with the Restated Collaboration Agreement, the Company entered into a stock purchase agreement with Gilead. Pursuant to, and subject to the terms and conditions of, the stock purchase agreement, Gilead will be required, at the Company's option, to purchase up to $35,000,000 of the Company's common stock, par value $0.0001 per share. In February 2022 Gilead purchased an initial amount of 1,666,666 unregistered shares of the Company's common stock for $5.0 million, corresponding to a purchase price per share of $3.00.

**Follow-on public offering**

In March 2022, the Company issued and sold 21,700,000 shares of its common stock, and 15,800 shares of its Series A-1 convertible preferred stock in a follow-on public offering at a public offering price of $2.0 per share of common stock and $2,000 per share of Series A-1 convertible preferred stock, resulting in net proceeds of $70.5 million after underwriting discounts and commission but before other offering expenses. The Company granted the underwriters an option for a period of 30 days to purchase up to 5,625,000 additional shares of its common stock.

**War between Russia and Ukraine**

On February 24, 2022, Russian forces began an invasion of the Ukraine. While we have no operations in the Ukraine or Russia and do not perform research, conduct clinical trials, or otherwise do business in these two countries,

**HOOKIPA PHARMA INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)**

the geopolitical effects of the war and its potential further escalation, including the effects of other nations' responses and economic sanctions, are currently unpredictable and may adversely affect our business in the future.

**AMENDED AND RESTATED**

**CERTIFICATE OF INCORPORATION**

**OF**

**HOOKIPA PHARMA INC.**

HOOKIPA Pharma Inc., a corporation organized and existing under the laws of the State of Delaware (the "Corporation"), hereby certifies as follows:

1. The name of the Corporation is HOOKIPA Pharma Inc. The date of the filing of its original Certificate of Incorporation with the Secretary of State of the State of Delaware was February 15, 2017 (the "Original Certificate"). The name under which the Corporation filed the Original Certificate was HOOKIPA Biotech, Inc.

2. This Amended and Restated Certificate of Incorporation (the "Certificate") amends, restates and integrates the provisions of the Amended and Restated Certificate of Incorporation that was filed with the Secretary of State of the State of Delaware on February 15, 2019 (as amended, the "Amended and Restated Certificate"), and was duly adopted in accordance with the provisions of Sections 228, 242 and 245 of the General Corporation Law of the State of Delaware (the "DGCL").

3. The text of the Amended and Restated Certificate is hereby amended and restated in its entirety to provide as herein set forth in full.

ARTICLE I

The name of the Corporation is HOOKIPA Pharma Inc.

ARTICLE II

The address of the Corporation's registered office in the State of Delaware is c/o The Corporation Trust Company, 1209 Orange Street in the City of Wilmington, County of New Castle, 19801. The name of its registered agent at such address is The Corporation Trust Company.

ARTICLE III

The purpose of the Corporation is to engage in any lawful act or activity for which corporations may be organized under the DGCL.

ARTICLE IV

CAPITAL STOCK

The total number of shares of capital stock which the Corporation shall have authority to issue is one hundred thirteen million nine hundred thousand (113,900,000) shares of which (i) one hundred million (100,000,000) shares shall be a class designated as common stock, par value $0.0001 per share (the "Common Stock"), (ii) three million nine hundred thousand (3,900,000) shares shall be a class designated as Class A common stock, par value $0.0001 per share (the "Class A Common Stock") and (iii) ten million (10,000,000) shares shall be a class designated as undesignated preferred stock, par value $0.0001 per share (the "Undesignated Preferred Stock").

Except as otherwise provided in any certificate of designations of any series of Undesignated Preferred Stock, the number of authorized shares of the class of Common Stock or Undesignated Preferred Stock may from

time to time be increased or decreased (but not below the number of shares of such class outstanding) by the affirmative vote of the holders of a majority in voting power of the outstanding shares of capital stock of the Corporation irrespective of the provisions of Section 242(b)(2) of the DGCL.

The powers, preferences and rights of, and the qualifications, limitations and restrictions upon, each class or series of stock shall be determined in accordance with, or as set forth below in, this Article IV.

A. COMMON STOCK; CLASS A COMMON STOCK

Subject to all the rights, powers and preferences of the Undesignated Preferred Stock and except as provided by law or in this Certificate (or in any certificate of designations of any series of Undesignated Preferred Stock):

(a) the holders of the Common Stock shall have the exclusive right to vote for the election of directors of the Corporation (the "Directors") and on all other matters requiring stockholder action, each outstanding share entitling the holder thereof to one vote on each matter properly submitted to the stockholders of the Corporation for their vote; provided, however, that, except as otherwise required by law, holders of Common Stock, as such, shall not be entitled to vote on any amendment to this Certificate (or on any amendment to a certificate of designations of any series of Undesignated Preferred Stock) that alters or changes the powers, preferences, rights or other terms of one or more outstanding series of Undesignated Preferred Stock if the holders of such affected series of Undesignated Preferred Stock are entitled to vote, either separately or together with the holders of one or more other such series, on such amendment pursuant to this Certificate (or pursuant to a certificate of designations of any series of Undesignated Preferred Stock) or pursuant to the DGCL;

(b) the holders of the Class A Common Stock shall be non-voting shares, except as required by law;

(c) dividends may be declared and paid or set apart for payment upon the Common Stock out of any assets or funds of the Corporation legally available for the payment of dividends, but only when and as declared by the Board of Directors or any authorized committee thereof; in the event that such dividend is paid in the form of shares of capital stock of the Corporation, holders of Common Stock shall receive Common Stock and holders of Class A Common Stock shall receive Class A Common Stock;

(d) upon the voluntary or involuntary liquidation, dissolution or winding up of the Corporation, the net assets of the Corporation shall be distributed pro rata to the holders of the Common Stock and Class A Common Stock, treated equally and identically;

(e) in connection with any merger or consolidation of the Corporation with or into any other entity, shares of Common Stock and shares of Class A Common Stock shall be treated equally, identically and ratably, on a per share basis, with respect to any consideration into which such shares are converted or any other consideration paid or otherwise distributed to stockholders of the Corporation in the merger or consolidation, unless different treatment of the shares of each class is approved by the affirmative vote of the holders of a majority of the outstanding shares of Common Stock and Class A Common Stock, each voting separately as a class; and

(f) in no event shall any stock dividends or stock splits or combinations of stock be declared or made on Common Stock or Class A Common Stock unless the shares of Common Stock and Class A Common Stock at the time outstanding are treated equally and identically, except that such dividends or stock splits or combinations shall be made in respect of shares of Common Stock and Class A Common Stock in the form of shares of Common Stock or Class A Common Stock, respectively.

B. CONVERSION OF CLASS A COMMON STOCK

1. Each holder of shares of Class A Common Stock shall have the right to convert each share of Class A Common Stock held by such holder into one share of Common Stock at such holder's election, which shall be made upon written notice to the Corporation delivered, provided that, the shares of Class A Common Stock may only be converted into shares of Common Stock during such time or times as immediately prior to or as a result of such conversion would not result in the holder(s) thereof beneficially owning (for purposes of Section 13(d) of the

Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder (collectively, the "Exchange Act")), when aggregated with affiliates with whom such holder is required to aggregate beneficial ownership for purposes of Section 13(d) of the Exchange Act, in excess of the Beneficial Ownership Limitation. The "Beneficial Ownership Limitation" means initially 4.99% of any class of securities of the Corporation registered under the Exchange Act, which percentage may be increased or decreased by a holder of outstanding shares of Class A Common Stock to such other percentage as such holder may designate in writing upon 61 days' notice the Corporation, provided, however, that such increase or decrease shall only be applicable to such holder.

2. In order for a holder of Series A Common Stock to voluntarily convert shares of Class A Common Stock to Common Stock, such holder shall deliver written notice to the transfer agent (or by the Corporation if the Corporation serves as its own transfer agent) of the Corporation that such holder elects to convert all or any number of the shares of the Class A Common Stock to Common Stock. Such notice shall state such holder's name or the names of the nominees in which such holder wishes the certificate or certificates for shares of Common Stock to be issued. The close of business on the date of receipt by the transfer agent (or by the Corporation if the Corporation serves as its own transfer agent) of such notice shall be the time of conversion, and the shares of Common Stock issuable upon conversion of the Class A Common Stock set forth in the notice shall be deemed to be outstanding of record as of such date. For any remaining fraction of a share of Common Stock, the Corporation shall, in lieu of issuing a fractional share, pay cash to such holder equal to the product of such fraction multiplied by the fair market value of one share of Common Stock.

3. The one-to-one conversion ratio for the conversion of the Class A Common Stock into Common Stock shall in all events be equitably adjusted in the event of any recapitalization of the Corporation by means of a stock dividend on, or a stock split or combination of, outstanding Common Stock or Class A Common Stock, or in the event of any merger, consolidation or other reorganization of the Corporation with another corporation.

4. The Corporation shall at all times reserve and keep available out of its authorized but unissued shares of Common Stock, solely for the purpose of effecting the conversion of the shares of Class A Common Stock, such number of its shares of Common Stock as shall from time to time be sufficient to effect the conversion of all outstanding shares of Class A Common Stock.

5. If any shares of Class A Common Stock shall be converted pursuant to this Article IV(B), the shares so converted shall be retired and returned to the authorized but unissued shares of Class A Common Stock.

C. UNDESIGNATED PREFERRED STOCK

The Board of Directors or any authorized committee thereof is expressly authorized, to the fullest extent permitted by law, to provide by resolution or resolutions for, out of the unissued shares of Undesignated Preferred Stock, the issuance of the shares of Undesignated Preferred Stock in one or more series of such stock, and by filing a certificate of designations pursuant to applicable law of the State of Delaware, to establish or change from time to time the number of shares of each such series, and to fix the designations, powers, including voting powers, full or limited, or no voting powers, preferences and the relative, participating, optional or other special rights of the shares of each series and any qualifications, limitations and restrictions thereof.

ARTICLE V

STOCKHOLDER ACTION

1. Action without Meeting. Any action required or permitted to be taken by the stockholders of the Corporation at any annual or special meeting of stockholders of the Corporation must be effected at a duly called annual or special meeting of stockholders and may not be taken or effected by a written consent of stockholders in lieu thereof. Notwithstanding anything herein to the contrary, the affirmative vote of not less than two thirds (2/3) of the outstanding shares of capital stock entitled to vote thereon, and the affirmative vote of not less than two thirds (2/3) of the outstanding shares of each class entitled to vote thereon as a class, shall be required to amend or repeal any provision of this Article V, Section 1.

2. Special Meetings. Except as otherwise required by statute and subject to the rights, if any, of the holders of any series of Undesignated Preferred Stock, special meetings of the stockholders of the Corporation may be called only by the Board of Directors acting pursuant to a resolution approved by the affirmative vote of a majority of the Directors then in office, and special meetings of stockholders may not be called by any other person or persons. Only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders of the Corporation.

ARTICLE VI

DIRECTORS

1. General. The business and affairs of the Corporation shall be managed by or under the direction of the Board of Directors except as otherwise provided herein or required by law.

2. Election of Directors. Election of Directors need not be by written ballot unless the By-laws of the Corporation (the "By-laws") shall so provide.

3. Number of Directors; Term of Office. The number of Directors of the Corporation shall be fixed solely and exclusively by resolution duly adopted from time to time by the Board of Directors. The Directors, other than those who may be elected by the holders of any series of Undesignated Preferred Stock, shall be classified, with respect to the term for which they severally hold office, into three classes. The initial Class I Directors of the Corporation shall be Joern Aldag, Jan van de Winkel and David Kaufman; the initial Class II Directors of the Corporation shall be Sander van Deventer, Graziano Seghezzi and Michael A. Kelly; and the initial Class III Directors of the Corporation shall be Julie O'Neill, Christoph Lengauer and Reinhard Kandera. The initial Class I Directors shall serve for a term expiring at the annual meeting of stockholders to be held in 2020, the initial Class II Directors shall serve for a term expiring at the annual meeting of stockholders to be held in 2021, and the initial Class III Directors shall serve for a term expiring at the annual meeting of stockholders to be held in 2022. The mailing address of each person who is to serve initially as a director is c/o HOOKIPA Pharma Inc., 350 Fifth Avenue, 72nd Floor, Suite 7240, New York, New York 10118. At each annual meeting of stockholders, Directors elected to succeed those Directors whose terms expire shall be elected for a term of office to expire at the third succeeding annual meeting of stockholders after their election. Notwithstanding the foregoing, the Directors elected to each class shall hold office until their successors are duly elected and qualified or until their earlier resignation, death or removal.

Notwithstanding the foregoing, whenever, pursuant to the provisions of Article IV of this Certificate, the holders of any one or more series of Undesignated Preferred Stock shall have the right, voting separately as a series or together with holders of other such series, to elect Directors at an annual or special meeting of stockholders, the election, term of office, filling of vacancies and other features of such directorships shall be governed by the terms of this Certificate and any certificate of designations applicable to such series.

Notwithstanding anything herein to the contrary, the affirmative vote of not less than two thirds (2/3) of the outstanding shares of capital stock entitled to vote thereon, and the affirmative vote of not less than two thirds (2/3) of the outstanding shares of each class entitled to vote thereon as a class, shall be required to amend or repeal any provision of this Article VI, Section 3.

4. Vacancies. Subject to the rights, if any, of the holders of any series of Undesignated Preferred Stock to elect Directors and to fill vacancies in the Board of Directors relating thereto, any and all vacancies in the Board of Directors, however occurring, including, without limitation, by reason of an increase in the size of the Board of Directors, or the death, resignation, disqualification or removal of a Director, shall be filled solely and exclusively by the affirmative vote of a majority of the remaining Directors then in office, even if less than a quorum of the Board of Directors, and not by the stockholders. Any Director appointed in accordance with the preceding sentence shall hold office for the remainder of the full term of the class of Directors in which the new directorship was created or the vacancy occurred and until such Director's successor shall have been duly elected and qualified or until his or her earlier resignation, death or removal. Subject to the rights, if any, of the holders of any series of Undesignated Preferred Stock to elect Directors, when the number of Directors is increased or decreased, the Board of Directors shall, subject to Article VI, Section 3 hereof, determine the class or classes to which the increased or

decreased number of Directors shall be apportioned; provided, however, that no decrease in the number of Directors shall shorten the term of any incumbent Director. In the event of a vacancy in the Board of Directors, the remaining Directors, except as otherwise provided by law, shall exercise the powers of the full Board of Directors until the vacancy is filled.

5. Removal. Subject to the rights, if any, of any series of Undesignated Preferred Stock to elect Directors and to remove any Director whom the holders of any such series have the right to elect, any Director (including persons elected by Directors to fill vacancies in the Board of Directors) may be removed from office (i) only with cause and (ii) only by the affirmative vote of the holders of not less than two thirds (2/3) of the outstanding shares of capital stock then entitled to vote at an election of Directors. At least forty-five (45) days prior to any annual or special meeting of stockholders at which it is proposed that any Director be removed from office, written notice of such proposed removal and the alleged grounds thereof shall be sent to the Director whose removal will be considered at the meeting.

ARTICLE VII

LIMITATION OF LIABILITY

A Director of the Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for breach of his or her fiduciary duty as a Director, except for liability (a) for any breach of the Director's duty of loyalty to the Corporation or its stockholders, (b) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (c) under Section 174 of the DGCL or (d) for any transaction from which the Director derived an improper personal benefit. If the DGCL is amended after the effective date of this Certificate to authorize corporate action further eliminating or limiting the personal liability of Directors, then the liability of a Director of the Corporation shall be eliminated or limited to the fullest extent permitted by the DGCL, as so amended.

Any amendment, repeal or modification of this Article VII by either of (i) the stockholders of the Corporation or (ii) an amendment to the DGCL, shall not adversely affect any right or protection existing at the time of such amendment, repeal or modification with respect to any acts or omissions occurring before such amendment, repeal or modification of a person serving as a Director at the time of such amendment, repeal or modification.

Notwithstanding anything herein to the contrary, the affirmative vote of not less than two thirds (2/3) of the outstanding shares of capital stock entitled to vote thereon, and the affirmative vote of not less than two thirds (2/3) of the outstanding shares of each class entitled to vote thereon as a class, shall be required to amend or repeal any provision of this Article VII.

ARTICLE VIII

AMENDMENT OF BY-LAWS

1. Amendment by Directors. Except as otherwise provided by law, the By-laws of the Corporation may be amended or repealed by the Board of Directors by the affirmative vote of a majority of the Directors then in office.

2. Amendment by Stockholders. Except as otherwise provided therein, the By-laws of the Corporation may be amended or repealed at any annual meeting of stockholders, or special meeting of stockholders called for such purpose, by the affirmative vote of not less than two thirds (2/3) of the outstanding shares of capital stock entitled to vote on such amendment or repeal, voting together as a single class; provided, however, that if the Board of Directors recommends that stockholders approve such amendment or repeal at such meeting of stockholders, such amendment or repeal shall only require the affirmative vote of the majority of the outstanding shares of capital stock entitled to vote on such amendment or repeal, voting together as a single class.

ARTICLE IX

AMENDMENT OF CERTIFICATE OF INCORPORATION

The Corporation reserves the right to amend or repeal this Certificate in the manner now or hereafter prescribed by statute and this Certificate, and all rights conferred upon stockholders herein are granted subject to this reservation. Except as otherwise required by this Certificate or by law, whenever any vote of the holders of capital stock of the Corporation is required to amend or repeal any provision of this Certificate, such amendment or repeal shall require the affirmative vote of the majority of the outstanding shares of capital stock entitled to vote on such amendment or repeal, and the affirmative vote of the majority of the outstanding shares of each class entitled to vote thereon as a class, at a duly constituted meeting of stockholders called expressly for such purpose.

THIS AMENDED AND RESTATED CERTIFICATE OF INCORPORATION is executed as of this 23rd day of April, 2019.

HOOKIPA PHARMA INC.
By: /s/ Joern Aldag
Name: Joern Aldag
Title: Chief Executive Officer

**HOOKIPA PHARMA INC.**

**CERTIFICATE OF DESIGNATION OF PREFERENCES,
RIGHTS AND LIMITATIONS
OF
SERIES A CONVERTIBLE PREFERRED STOCK**

PURSUANT TO SECTION 151 OF THE
DELAWARE GENERAL CORPORATION LAW

**HOOKIPA PHARMA INC.**, a Delaware corporation (the "**Corporation**"), in accordance with the provisions of Section 103 of the Delaware General Corporation Law (the "**DGCL**") does hereby certify that, in accordance with Sections 141(c) and 151 of the DGCL, the following resolution was duly adopted by a committee of the Board of Directors of the Corporation on December 8, 2020:

**RESOLVED**, pursuant to authority expressly set forth in the Amended and Restated Certificate of Incorporation of the Corporation (the "**Certificate of Incorporation**"), the issuance of a series of Preferred Stock designated as the Series A Convertible Preferred Stock, par value $0.0001 per share, of the Corporation is hereby authorized and the designation, number of shares, powers, preferences, rights, qualifications, limitations and restrictions thereof (in addition to any provisions set forth in the Certificate of Incorporation that are applicable to the Preferred Stock of all classes and series) are hereby fixed, and the Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock is hereby approved as follows:

**SERIES A CONVERTIBLE PREFERRED STOCK**

Section 1. Definitions. For the purposes hereof, the following terms shall have the following meanings:

"**Affiliate**" means any person or entity that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a person or entity, as such terms are used in and construed under Rule 144 under the Securities Act. With respect to a Holder, any investment fund or managed account that is managed on a discretionary basis by the same investment manager as such Holder will be deemed to be an Affiliate of such Holder.

"**Beneficial Ownership Limitation**" shall have the meaning set forth in Section 6(c).

"**Business Day**" means any day except Saturday, Sunday, any day which shall be a federal legal holiday in the United States or any day on which banking institutions in the State of New York are authorized or required by law or other governmental action to close.

"**Class A Common Stock**" means the Corporation's class A common stock, par value $0.0001 per share.

"**Closing Sale Price**" means, for any security as of any date, the last closing trade price for such security prior to 4:00 p.m., New York City time, on the principal securities exchange or trading market where such security is listed or traded, as reported by Bloomberg, L.P. (or an equivalent, reliable

reporting service mutually acceptable to and hereafter designated by Holders of a majority of the then-outstanding Series A Preferred Stock and the Corporation), or if the foregoing do not apply, the last trade price of such security in the principal trading market for such security as reported by Bloomberg, L.P., or, if no last trade price is reported for such security by Bloomberg, L.P., the average of the bid prices of any market makers for such security as reported on the Nasdaq Global Select Market. If the Closing Sale Price cannot be calculated for a security on a particular date on any of the foregoing bases, the Closing Sale Price of such security on such date shall be the fair market value as determined in good faith by the Board of Directors of the Corporation.

"**Commission**" means the Securities and Exchange Commission.

"**Common Stock**" means the Corporation's common stock, par value $0.0001 per share, and stock of any other class of securities into which such securities may hereafter be reclassified or changed into.

"**Conversion Date**" shall have the meaning set forth in Section 6(a).

"**Conversion Price**" shall mean $11.75, as adjusted pursuant to paragraph 7 hereof.

"**Conversion Ratio**" shall have the meaning set forth in Section 6(b).

"**Conversion Shares**" means, collectively, the shares of Common Stock issuable upon conversion of the shares of Series A Preferred Stock in accordance with the terms hereof.

"**Daily Failure Amount**" means the product of (x) .005 multiplied by (y) the Closing Sale Price of the Common Stock on the applicable Share Delivery Date.

"**DGCL**" shall mean the Delaware General Corporation Law.

"**Distributions**" shall have the meaning set forth in Section 5(a).

"**DTC**" shall have the meaning set forth in Section 6(a).

"**DWAC Delivery**" shall have the meaning set forth in Section 6(a).

"**Exchange Act**" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

"**Fundamental Transaction**" shall have the meaning set forth in Section 7(b).

"**Holder**" means any holder of Series A Preferred Stock.

"**Issuance Date**" means December 11, 2020.

"**Junior Securities**" shall have the meaning set forth in Section 5(a).

"**Notice of Conversion**" shall have the meaning set forth in Section 6(a).

"**Parity Securities**" shall have the meaning set forth in Section 5(a).

"**Person**" means any individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

"**Securities Act**" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

"**Senior Securities**" shall have the meaning set forth in Section 5(a).

"**Series A Preferred Stock**" shall have the meaning set forth in Section 2(a).

"**Series A Preferred Stock Register**" shall have the meaning set forth in Section 2(b).

"**Share Delivery Date**" shall have the meaning set forth in Section 6(d)(i).

"**Stated Value**" shall mean $11,750.

"**Trading Day**" means a day on which the Common Stock is traded for any period on the principal securities exchange or if the Common Stock is not traded on a principal securities exchange, on a day that the Common Stock is traded on another securities market on which the Common Stock is then being traded.

Section 2. Designation, Amount and Par Value; Assignment.

(a) The series of preferred stock designated by this Certificate of Designation shall be designated as the Corporation's Series A Convertible Preferred Stock (the "**Series A Preferred Stock**") and the number of shares so designated shall be 2,978. Each share of Series A Preferred Stock shall have a par value of $0.0001 per share. The Series A Preferred Stock may be issued in certificated form or in book-entry form at the election of the Holder. To the extent that any shares of Series A Preferred Stock are issued in book-entry form, references herein to "certificates" shall instead refer to the book-entry notation relating to such shares.

(b) The Corporation or its designee shall register shares of the Series A Preferred Stock, upon records to be maintained by the Corporation for that purpose (the "**Series A Preferred Stock Register**"), in the name of the Holders thereof from time to time. The Corporation may deem and treat the registered Holder of shares of Series A Preferred Stock as the absolute owner thereof for the purpose of any conversion thereof and for all other purposes. The Corporation or its designee shall register the transfer of any shares of Series A Preferred Stock in the Series A Preferred Stock Register, upon surrender of the certificates evidencing such shares to be transferred, duly endorsed by the Holder thereof, to the Corporation at its address specified herein. Upon any such registration or transfer, a new certificate evidencing the shares of Series A Preferred Stock so transferred shall be issued to the transferee and a new certificate evidencing the remaining portion of the shares not so transferred, if any, shall be issued to the transferring Holder, in each case, within three (3) Business Days. The provisions of this Certificate of Designation are intended to be for the benefit of all Holders from time to time and shall be enforceable by any such Holder.

Section 3. Dividends. Holders shall be entitled to receive, and the Corporation shall pay, dividends on shares of the Series A Preferred Stock equal (on an as-if-converted-to-Common-Stock basis, without regard to the Beneficial Ownership Limitation) to and in the same form, and in the same manner, as dividends (other than dividends in the form of Common Stock) actually paid on shares of the Common Stock when, as and if such dividends (other than dividends in the form of Common Stock) are paid on shares of the Common Stock. Other than as set forth in the previous sentence, no other dividends shall be paid on shares of Series A Preferred Stock, and the Corporation shall pay no dividends (other than dividends in the form of Common Stock) on shares of the Common Stock unless it simultaneously complies with the previous sentence.

Section 4. Voting Rights; Amendments. Except as otherwise provided herein or as otherwise required by the DGCL, the Series A Preferred Stock shall have no voting rights. However, as long as any shares of Series A Preferred Stock are outstanding, the Corporation shall not, without the affirmative vote of the Holders of a majority of the then outstanding shares of the Series A Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Series A Preferred Stock or alter or amend this Certificate of Designation, (b) issue further shares of Series A Preferred Stock or increase or decrease (other than by conversion) the number of authorized shares of Series A Preferred Stock or (c) enter into any agreement with respect to any of the foregoing.

Section 5. Rank; Liquidation.

(a) The Series A Preferred Stock shall rank (i) senior to any class or series of capital stock of the Corporation hereafter created specifically ranking by its terms junior to any Series A Preferred Stock ("**Junior Securities**"); (ii) on parity with the Common Stock, Class A Common Stock and any class or series of capital stock of the Corporation hereafter created specifically ranking by its terms on parity with the Series A Preferred Stock (the "**Parity Securities**"); (iii) junior to any class or series of capital stock of the Corporation hereafter created specifically ranking by its terms senior to any Series A Preferred Stock ("**Senior Securities**"), in each case, as to distributions of assets upon liquidation, dissolution or winding up of the Corporation, whether voluntarily or involuntarily (all such distributions being referred to collectively as "**Distributions**").

(b) Subject to the prior and superior rights of the holders of any Senior Securities of the Corporation, upon liquidation, dissolution or winding up of the Corporation, whether voluntary or involuntary, each holder of shares of Series A Preferred Stock shall be entitled to receive, in preference to any distributions of any of the assets or surplus funds of the Corporation to the holders of the Junior Securities and *pari passu* with any distribution to the holders of Parity Securities, an amount equal to $0.001 per share of Series A Preferred Stock, plus an additional amount equal to any dividends declared but unpaid on such shares, before any payments shall be made or any assets distributed to holders of Junior Securities. If, upon any such liquidation, dissolution or winding up of the Corporation, the assets of the Corporation shall be insufficient to pay the holders of shares of the Series A Preferred Stock the amount required under the preceding sentence, then all remaining assets of the Corporation shall be distributed ratably to holders of the shares of the Series A Preferred Stock and Parity Securities in proportion to the respective amounts which would otherwise be payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full.

Section 6. Conversion.

(a) Conversions at Option of Holder. Each share of Series A Preferred Stock shall be convertible, at any time and from time to time from and after the Issuance Date, at the option of the Holder thereof, into a number of shares of Common Stock equal to the Conversion Ratio. Holders shall effect conversions by providing the Corporation with the form of conversion notice attached hereto as **Annex A** (a "**Notice of Conversion**"), duly completed and executed. Other than a conversion following a notice provided for under Section 7(b) or Section 7(d)(ii) hereof, the Notice of Conversion must specify at least a number of shares of Series A Preferred Stock to be converted equal to the lesser of (x) 100 shares (such number subject to appropriate adjustment following the occurrence of an event specified in Section 7(a) hereof) and (y) the number of shares of Series A Preferred Stock then held by the Holder. Provided the Corporation's transfer agent is participating in the Depository Trust Company ("**DTC**") Fast Automated Securities Transfer program, the Notice of Conversion may specify, at the Holder's election, whether the

applicable Conversion Shares shall be credited to the account of the Holder's prime broker with DTC through its Deposit Withdrawal Agent Commission system (a "**DWAC Delivery**"). The "**Conversion Date**", or the date on which a conversion shall be deemed effective, shall be defined as the Trading Day that the Notice of Conversion, completed and executed, is sent by facsimile or other electronic transmission to, and received during regular business hours by, the Corporation; provided that the original certificate(s) (if applicable) representing such shares of Series A Preferred Stock being converted, duly endorsed, and the accompanying Notice of Conversion, are received by the Corporation within two (2) Trading Days thereafter. In all other cases, the Conversion Date shall be defined as the Trading Day on which the original share certificate(s) (if applicable) of Series A Preferred Stock being converted, duly endorsed, and the accompanying Notice of Conversion, are received by the Corporation. The calculations set forth in the Notice of Conversion shall control in the absence of manifest or mathematical error.

(b) Conversion Ratio. The "**Conversion Ratio**" for each share of Series A Preferred Stock shall be equal to the Stated Value divided by the Conversion Price.

(c) Beneficial Ownership Limitation. Notwithstanding anything herein to the contrary, the Corporation shall not effect any conversion of the Series A Preferred Stock, and a Holder shall not have the right to convert any portion of the Series A Preferred Stock, to the extent that, immediately prior to or after giving effect to an attempted conversion set forth on an applicable Notice of Conversion, such Holder (together with such Holder's Affiliates, and any other Person whose beneficial ownership of Common Stock would be aggregated with the Holder's for purposes of Section 13(d) or Section 16 of the Exchange Act and the applicable regulations of the Commission, including any "group" of which the Holder is a member (the foregoing, "**Attribution Parties**")) would beneficially own a number of shares of Common Stock in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by such Holder and its Attribution Parties shall include the number of shares of Common Stock issuable upon conversion of the Series A Preferred Stock subject to the Notice of Conversion with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which are issuable upon (A) conversion of the remaining, unconverted Series A Preferred Stock beneficially owned by such Holder or any of its Attribution Parties, and (B) exercise or conversion of the unexercised or unconverted portion of any other securities of the Corporation (including any warrants) beneficially owned by such Holder or any of its Attribution Parties that are subject to a limitation on conversion or exercise similar to the limitation contained herein. For purposes of this Section 6(c), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the applicable regulations of the Commission. In addition, for purposes hereof, "group" has the meaning set forth in Section 13(d) of the Exchange Act and the applicable regulations of the Commission. For purposes of this Section 6(c), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as stated in the most recent of the following: (A) the Corporation's most recent periodic or annual filing with the Commission, as the case may be, (B) a more recent public announcement by the Corporation that is filed with the Commission, or (C) a more recent notice by the Corporation or the Corporation's transfer agent to the Holder setting forth the number of shares of Common Stock then outstanding. Upon the written request of a Holder (which may be by email), the Corporation shall, within three (3) Trading Days thereof, confirm in writing to such Holder (which may be via email) the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined immediately prior to or after giving effect to any actual conversion or exercise of securities of the Corporation, including shares of Series A Preferred Stock, by such Holder or its Attribution Parties since the date as of which such number of outstanding shares of Common Stock was

last publicly reported or confirmed to the Holder. The "**Beneficial Ownership Limitation**" shall be 9.99% of the number of shares of the Common Stock outstanding immediately prior to or after giving effect to the issuance of shares of Common Stock pursuant to such Notice of Conversion (to the extent permitted pursuant to this Section 6(c)); provided, however, that by written notice to the Corporation, which will not be effective until the 61st day after such notice is delivered to the Corporation, the Holder may waive or amend the provisions of this Section 6(c) to change the Beneficial Ownership Limitation to any other number less than or equal to 19.99%, and the provisions of this Section 6(c) shall continue to apply. The Corporation shall be entitled to rely on representations made to it by the Holder in any Notice of Conversion regarding its Beneficial Ownership Limitation.

(d) Mechanics of Conversion

(i) Delivery of Certificate or Electronic Issuance Upon Conversion. Not later than three (3) Trading Days after the applicable Conversion Date, or if the Holder requests the issuance of physical certificate(s), two (2) Trading Days after receipt by the Corporation of the original certificate(s) representing such shares of Series A Preferred Stock being converted, duly endorsed, and the accompanying Notice of Conversion (the "**Share Delivery Date**"), the Corporation shall (a) deliver, or cause to be delivered, to the converting Holder a physical certificate or certificates representing the number of Conversion Shares being acquired upon the conversion of shares of Series A Preferred Stock or (b) in the case of a DWAC Delivery, electronically transfer such Conversion Shares by crediting the account of the Holder's prime broker with DTC through its DWAC system. If in the case of any Notice of Conversion such certificate or certificates are not delivered to or as directed by or, in the case of a DWAC Delivery, such shares are not electronically delivered to or as directed by, the applicable Holder by the Share Delivery Date, the applicable Holder shall be entitled to elect to rescind such Notice of Conversion by written notice to the Corporation at any time on or before its receipt of such certificate or certificates for Conversion Shares or electronic receipt of such shares, as applicable, in which event the Corporation shall promptly return to such Holder any original Series A Preferred Stock certificate delivered to the Corporation and such Holder shall promptly return to the Corporation any Common Stock certificates or otherwise direct the return of any shares of Common Stock delivered to the Holder through the DWAC system, representing the shares of Series A Preferred Stock unsuccessfully tendered for conversion to the Corporation.

(ii) Obligation Absolute. Subject to Section 6(c) hereof and subject to Holder's right to rescind a Notice of Conversion pursuant to Section 6(d)(i) above, the Corporation's obligation to issue and deliver the Conversion Shares upon conversion of Series A Preferred Stock in accordance with the terms hereof are absolute and unconditional, irrespective of any action or inaction by a Holder to enforce the same, any waiver or consent with respect to any provision hereof, the recovery of any judgment against any Person or any action to enforce the same, or any setoff, counterclaim, recoupment, limitation or termination, or any breach or alleged breach by such Holder or any other Person of any obligation to the Corporation or any violation or alleged violation of law by such Holder or any other Person, and irrespective of any other circumstance which might otherwise limit such obligation of the Corporation to such Holder in connection with the issuance of such Conversion Shares. Subject to Section 6(c) hereof and subject to Holder's right to rescind a Notice of Conversion pursuant to Section 6(d)(i) above, in the event a Holder shall elect to convert any or all of its Series A Preferred Stock, the Corporation may not refuse conversion based on any claim that such Holder or anyone associated or affiliated with such Holder has been engaged in any violation of law, agreement or for any other reason, unless an injunction from a court, on notice to Holder, restraining and/or enjoining conversion of all or part of the Series A Preferred Stock of such Holder shall have been sought and obtained by the Corporation, and the Corporation posts a surety bond for the benefit of such Holder in the amount of 150% of the value of the Conversion Shares into which

would be converted the Series A Preferred Stock which is subject to such injunction, which bond shall remain in effect until the completion of arbitration/litigation of the underlying dispute and the proceeds of which shall be payable to such Holder to the extent it obtains judgment. In the absence of such injunction, the Corporation shall, subject to Section 6(c) hereof and subject to Holder's right to rescind a Notice of Conversion pursuant to Section 6(d)(i) above, issue Conversion Shares upon a properly noticed conversion. If the Corporation fails to deliver to a Holder such certificate or certificates, or electronically deliver (or cause its transfer agent to electronically deliver) such shares in the case of a DWAC Delivery, pursuant to Section 6(d)(i) on or prior to the fifth (5th) Trading Day after the Share Delivery Date applicable to such conversion (other than a failure caused by incorrect or incomplete information provided by Holder to the Corporation), then, unless the Holder has rescinded the applicable Notice of Conversion pursuant to Section 6(d)(i) above, the Corporation shall pay (as liquidated damages and not as a penalty) to such Holder an amount payable, at the Holder's option, either (a) in cash or (b) to the extent that it would not cause the Holder or its Attribution Parties to exceed the Beneficial Ownership Limitation, in shares of Common Stock that are valued for these purposes at the Closing Sale Price on the date of such calculation, in each case equal to the product of (x) the number of Conversion Shares required to have been issued by the Corporation on such Share Delivery Date, (y) an amount equal to the Daily Failure Amount and (z) the number of Trading Days actually lapsed after such fifth (5th) Trading Day after the Share Delivery Date during which such certificates have not been delivered, or, in the case of a DWAC Delivery, such shares have not been electronically delivered; *provided*, *however*, the Holder shall only receive up to such amount of shares of Common Stock such that Holder and its Attribution Parties and any other persons or entities whose beneficial ownership of Common Stock would be aggregated with the Holder's for purposes of Section 13(d) of the Exchange Act (including shares held by any "group" of which the Holder is a member, but excluding shares beneficially owned by virtue of the ownership of securities or rights to acquire securities that have limitations on the right to convert, exercise or purchase similar to the limitation set forth herein) shall not collectively beneficially own greater than the Beneficial Ownership Limitation. Nothing herein shall limit a Holder's right to pursue actual damages for the Corporation's failure to deliver Conversion Shares within the period specified herein and such Holder shall have the right to pursue all remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief; provided that Holder shall not receive duplicate damages for the Corporation's failure to deliver Conversion Shares within the period specified herein. The exercise of any such rights shall not prohibit a Holder from seeking to enforce damages pursuant to any other Section hereof or under applicable law.

(iii) Compensation for Buy-In on Failure to Timely Deliver Certificates Upon Conversion. If the Corporation fails to deliver to a Holder the applicable certificate or certificates or to effect a DWAC Delivery, as applicable, by the Share Delivery Date pursuant to Section 6(d)(i) (other than a failure caused by incorrect or incomplete information provided by Holder to the Corporation), and if after such Share Delivery Date such Holder is required by its brokerage firm to purchase (in an open market transaction or otherwise), or the Holder's brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by such Holder of the Conversion Shares which such Holder was entitled to receive upon the conversion relating to such Share Delivery Date (a "**Buy-In**"), then the Corporation shall (A) pay in cash to such Holder (in addition to any other remedies available to or elected by such Holder) the amount by which (x) such Holder's total purchase price (including any brokerage commissions) for the shares of Common Stock so purchased exceeds (y) the product of (1) the aggregate number of shares of Common Stock that such Holder was entitled to receive from the conversion at issue multiplied by (2) the actual sale price at which the sell order giving rise to such purchase obligation was executed (including any brokerage commissions) and (B) at the option of such Holder, either reissue (if surrendered) the shares of

Series A Preferred Stock equal to the number of shares of Series A Preferred Stock submitted for conversion or deliver to such Holder the number of shares of Common Stock that would have been issued if the Corporation had timely complied with its delivery requirements under Section 6(d)(i). For example, if a Holder purchases shares of Common Stock having a total purchase price of $11,000 to cover a Buy-In with respect to an attempted conversion of shares of Series A Preferred Stock with respect to which the actual sale price (including any brokerage commissions) giving rise to such purchase obligation was a total of $10,000 under clause (A) of the immediately preceding sentence, the Corporation shall be required to pay such Holder $1,000. The Holder shall provide the Corporation written notice, within three (3) Trading Days after the occurrence of a Buy-In, indicating the amounts payable to such Holder in respect of such Buy-In together with applicable confirmations and other evidence reasonably requested by the Corporation. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Corporation's failure to timely deliver certificates representing shares of Common Stock upon conversion of the shares of Series A Preferred Stock as required pursuant to the terms hereof; provided, however, that the Holder shall not be entitled to both (i) require the reissuance of the shares of Series A Preferred Stock submitted for conversion for which such conversion was not timely honored and (ii) receive the number of shares of Common Stock that would have been issued if the Corporation had timely complied with its delivery requirements under Section 6(d)(i).

(iv) Reservation of Shares Issuable Upon Conversion. The Corporation covenants that it will at all times reserve and keep available out of its authorized and unissued shares of Common Stock for the sole purpose of issuance upon conversion of the Series A Preferred Stock, free from preemptive rights or any other actual contingent purchase rights of Persons other than the Holders of the Series A Preferred Stock, not less than such aggregate number of shares of the Common Stock as shall be issuable (taking into account the adjustments of Section 7) upon the conversion of all outstanding shares of Series A Preferred Stock. The Corporation covenants that all shares of Common Stock that shall be so issuable shall, upon issue, be duly authorized, validly issued, fully paid, nonassessable and free and clear of all liens and encumbrances.

(v) Fractional Shares. No fractional shares or scrip representing fractional shares of Common Stock shall be issued upon the conversion of the Series A Preferred Stock. As to any fraction of a share which a Holder would otherwise be entitled to receive upon such conversion, the Corporation shall pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Conversion Price.

(vi) Transfer Taxes. The issuance of certificates for shares of the Common Stock upon conversion of the Series A Preferred Stock shall be made without charge to any Holder for any documentary stamp or similar taxes that may be payable in respect of the issue or delivery of such certificates, provided that the Corporation shall not be required to pay any tax that may be payable in respect of any transfer involved in the issuance and delivery of any such certificate upon conversion in a name other than that of the registered Holder(s) of such shares of Series A Preferred Stock and the Corporation shall not be required to issue or deliver such certificates unless or until the Person or Persons requesting the issuance thereof shall have paid to the Corporation the amount of such tax or shall have established to the satisfaction of the Corporation that such tax has been paid.

(e) Status as Stockholder. Upon each Conversion Date, (i) the shares of Series A Preferred Stock being converted shall be deemed converted into shares of Common Stock and (ii) the Holder's rights as a holder of such converted shares of Series A Preferred Stock shall cease and terminate, excepting only the right to receive certificates for such shares of Common Stock and to any remedies provided herein or otherwise

available at law or in equity to such Holder because of a failure by the Corporation to comply with the terms of this Certificate of Designation. In all cases, the Holder shall retain all of its rights and remedies for the Corporation's failure to convert Series A Preferred Stock.

Section 7. Certain Adjustments.

(a) Stock Dividends and Stock Splits. If the Corporation, at any time while this Series A Preferred Stock is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Corporation upon conversion of this Series A Preferred Stock) with respect to the then outstanding shares of Common Stock; (ii) subdivides outstanding shares of Common Stock into a larger number of shares; or (iii) combines (including by way of a reverse stock split) outstanding shares of Common Stock into a smaller number of shares, then the Conversion Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding any treasury shares of the Corporation) outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event (excluding any treasury shares of the Corporation). Any adjustment made pursuant to this Section 7(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision or combination.

(b) Fundamental Transaction. If, at any time while this Series A Preferred Stock is outstanding, (i) the Corporation enters into a binding agreement to effect any merger or consolidation of the Corporation with or into another Person or any stock sale to, or other business combination (including, without limitation, a reorganization, recapitalization, spin-off, share exchange or scheme of arrangement) with or into another Person (other than such a transaction in which the Corporation would be the surviving or continuing entity and its Common Stock is not exchanged for or converted into other securities, cash or property), (ii) the Corporation enters into a binding agreement to effect any sale of all or substantially all of its assets in one transaction or a series of related transactions, (iii) any tender offer or exchange offer (whether by the Corporation or another Person) is completed pursuant to which more than 50% of the Common Stock not held by the Corporation or such Person is exchanged for or converted into other securities, cash or property, or (iv) the Corporation announces its intent to effect any reclassification of the Common Stock or any compulsory share exchange pursuant (other than as a result of a dividend, subdivision or combination covered by Section 7(a) above) to which the Common Stock is effectively converted into or exchanged for other securities, cash or property (in any such case, a "**Fundamental Transaction**"), then at least 20 calendar days prior to the anticipated date prior to when such Fundamental Transaction is expected to be consummated or closed, the Company shall provide written notice all Holders of such Fundamental Transaction to allow such holder to give notice of conversion and entitle such holders to receive, in lieu of the right to receive Conversion Shares, for each Conversion Share that would have been issuable upon such conversion immediately prior to the occurrence of such Fundamental Transaction, the same kind and amount of securities, cash or property as it would have been entitled to receive upon the occurrence of such Fundamental Transaction if it had been, immediately prior to such Fundamental Transaction, the holder of one share of Common Stock (the "**Alternate Consideration**"). If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holders shall be given the same choice as to the Alternate Consideration it receives upon any conversion of this Series A Preferred Stock following such Fundamental Transaction.

(c) Calculations. All calculations under this Section 7 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 7, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding any treasury shares of the Corporation) issued and outstanding.

(d) Notice to the Holders.

(i) Adjustment to Conversion Price. Whenever the Conversion Price is adjusted pursuant to any provision of this Section 7, the Corporation shall promptly deliver to each Holder a notice setting forth the Conversion Ratio after such adjustment and setting forth a brief statement of the facts requiring such adjustment.

(ii) Other Notices. If (A) the Corporation shall declare a dividend (or any other distribution in whatever form) on the Common Stock or Class A Common Stock, (B) the Corporation shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock or Class A Common Stock, (C) the Corporation shall authorize the granting to all holders of the Common Stock or Class A Common Stock of rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any stockholders of the Corporation shall be required in connection with any reclassification of the Common Stock or Class A Common Stock, any consolidation or merger to which the Corporation is a party, any sale or transfer of all or substantially all of the assets of the Corporation, or any compulsory share exchange whereby the Common Stock or Class A Common Stock is converted into other securities, cash or property, or (E) the Corporation shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Corporation, then, in each case, the Corporation shall cause to be filed at each office or agency maintained for the purpose of conversion of this Series A Preferred Stock, and, except if such notice and the contents thereof shall be deemed to constitute material non-public information shall cause to be delivered to each Holder at its last address as it shall appear upon the stock books of the Corporation, at least 20 calendar days prior to the applicable record or effective date hereinafter specified, a notice stating the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock or Class A Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined.

Section 8. Miscellaneous.

(a) Notices. Any and all notices or other communications or deliveries to be provided by the Holders hereunder including, without limitation, any Notice of Conversion, shall be in writing and delivered personally, by facsimile, via email or sent by a nationally recognized overnight courier service, addressed to the Corporation, at 350 Fifth Avenue, 72nd Floor, Suite 7240, New York, New York 10118, facsimile number +43 1 890 63 60 399, email Reinhard.Kandera@hookipapharma.com, or such other facsimile number, email address or mailing address as the Corporation may specify for such purposes by notice to the Holders delivered in accordance with this Section. Any and all notices or other communications or deliveries to be provided by the Corporation hereunder shall be in writing and delivered personally, by facsimile, or sent by a nationally recognized overnight courier service addressed to each Holder at the facsimile number or address of such Holder appearing on the books of the Corporation, or if no such facsimile number or address appears on the books of the Corporation, at the principal place of business of such Holder. Any notice or other communication or deliveries hereunder shall be deemed given and effective on the earliest of (i) the date of transmission, if such notice or communication is delivered via facsimile at the facsimile number, or via email at the email address, specified in this Section prior to 5:30 p.m. (New York City time) on any date, (ii) the date immediately following the date of transmission, if such notice or communication is delivered via facsimile at the

facsimile number, or via email at the email address, specified in this Section between 5:30 p.m. and 11:59 p.m. (New York City time) on any date, (iii) the second Business Day following the date of mailing, if sent by nationally recognized overnight courier service, or (iv) upon actual receipt by the party to whom such notice is required to be given.

(b) Lost or Mutilated Series A Preferred Stock Certificate. If a Holder's Series A Preferred Stock certificate shall be mutilated, lost, stolen or destroyed, the Corporation shall execute and deliver, in exchange and substitution for and upon cancellation of a mutilated certificate, or in lieu of or in substitution for a lost, stolen or destroyed certificate, a new certificate for the shares of Series A Preferred Stock so mutilated, lost, stolen or destroyed, but only upon receipt of evidence of such loss, theft or destruction of such certificate, and of the ownership thereof, reasonably satisfactory to the Corporation and, in each case, customary and reasonable indemnity, if requested. Applicants for a new certificate under such circumstances shall also comply with such other reasonable regulations and procedures and pay such other reasonable third-party costs as the Corporation may prescribe.

(c) Waiver. Any waiver by the Corporation or a Holder of a breach of any provision of this Certificate of Designation shall not operate as or be construed to be a waiver of any other breach of such provision or of any breach of any other provision of this Certificate of Designation or a waiver by any other Holders. The failure of the Corporation or a Holder to insist upon strict adherence to any term of this Certificate of Designation on one or more occasions shall not be considered a waiver or deprive that party (or any other Holder) of the right thereafter to insist upon strict adherence to that term or any other term of this Certificate of Designation. Any waiver by the Corporation or a Holder must be in writing. Notwithstanding any provision in this Certificate of Designation to the contrary, any provision contained herein and any right of the Holders of Series A Preferred Stock granted hereunder may be waived as to all shares of Series A Preferred Stock (and the Holders thereof) upon the written consent of the Holders of not less than a majority of the shares of Series A Preferred Stock then outstanding, unless a higher percentage is required by the DGCL, in which case the written consent of the Holders of not less than such higher percentage shall be required.

(d) Severability. If any provision of this Certificate of Designation is invalid, illegal or unenforceable, the balance of this Certificate of Designation shall remain in effect, and if any provision is inapplicable to any Person or circumstance, it shall nevertheless remain applicable to all other Persons and circumstances. If it shall be found that any interest or other amount deemed interest due hereunder violates the applicable law governing usury, the applicable rate of interest due hereunder shall automatically be lowered to equal the maximum rate of interest permitted under applicable law.

(e) Next Business Day. Whenever any payment or other obligation hereunder shall be due on a day other than a Business Day, such payment shall be made on the next succeeding Business Day.

(f) Headings. The headings contained herein are for convenience only, do not constitute a part of this Certificate of Designation and shall not be deemed to limit or affect any of the provisions hereof.

(g) Status of Converted Series A Preferred Stock. If any shares of Series A Preferred Stock shall be converted or reacquired by the Corporation, such shares shall resume the status of authorized but unissued shares of preferred stock and shall no longer be designated as Series A Preferred Stock.

**IN WITNESS WHEREOF**, the undersigned has executed this Certificate of Designation this 11th day of December 2020.

/s/ Jörn Aldag
Jörn Aldag, Chief Executive Officer

SIGNATURE PAGE TO CERTIFICATE OF DESIGNATION OF PREFERENCES,
RIGHTS AND LIMITATIONS OF SERIES A PREFERRED STOCK

**ANNEX A**

NOTICE OF CONVERSION

(TO BE EXECUTED BY THE REGISTERED HOLDER IN ORDER
TO CONVERT SHARES OF SERIES A PREFERRED STOCK)

The undersigned Holder hereby irrevocably elects to convert the number of shares of Series A Preferred Stock indicated below, represented by stock certificate No(s). (the "**Preferred Stock Certificates**"), into shares of common stock, par value $0.0001 per share (the "**Common Stock**"), of HOOKIPA Pharma Inc., a Delaware corporation (the "**Corporation**"), as of the date written below. If securities are to be issued in the name of a person other than the undersigned, the undersigned will pay all transfer taxes payable with respect thereto. Capitalized terms utilized but not defined herein shall have the meaning ascribed to such terms in that certain Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (the "**Certificate of Designation**") filed by the Corporation with the Secretary of State of the State of Delaware on December 11, 2020.

As of the date hereof, the number of shares of Common Stock beneficially owned by the undersigned Holder (together with such Holder's Affiliates, and any other Person whose beneficial ownership of Common Stock would be aggregated with the Holder's for purposes of Section 13(d) or Section 16 of the Exchange Act and the applicable regulations of the Commission, including any "group" of which the Holder is a member (the foregoing, "**Attribution Parties**")), including the number of shares of Common Stock issuable upon conversion of the Series A Preferred Stock subject to this Notice of Conversion, but excluding the number of shares of Common Stock which are issuable upon (A) conversion of the remaining, unconverted Series A Preferred Stock beneficially owned by such Holder or any of its Attribution Parties, and (B) exercise or conversion of the unexercised or unconverted portion of any other securities of the Corporation (including any warrants) beneficially owned by such Holder or any of its Attribution Parties that are subject to a limitation on conversion or exercise similar to the limitation contained in Section 6(c) of the Certificate of Designation, is 9.99%. For purposes hereof, beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the applicable regulations of the Commission. In addition, for purposes hereof, "group" has the meaning set forth in Section 13(d) of the Exchange Act and the applicable regulations of the Commission.

Conversion calculations:

Date to Effect
Conversion: _____

Number of shares of Series
A Preferred Stock owned prior to Conversion: _____

Number of shares of Series
A Preferred Stock to be Converted: _____

Number of shares of Common Stock to be
Issued: _____

Address for delivery of physical certificates:

or

for DWAC Delivery: _____

DWAC Instructions: _____

Broker no: _____

Account no: _____

**HOOKIPA PHARMA INC.**

**CERTIFICATE OF DESIGNATION OF PREFERENCES,
RIGHTS AND LIMITATIONS
OF
SERIES A-1 CONVERTIBLE PREFERRED STOCK**

PURSUANT TO SECTION 151 OF THE
DELAWARE GENERAL CORPORATION LAW

**HOOKIPA PHARMA INC.**, a Delaware corporation (the "**Corporation**"), in accordance with the provisions of Section 103 of the Delaware General Corporation Law (the "**DGCL**") does hereby certify that, in accordance with Sections 141(c) and 151 of the DGCL, the following resolution was duly adopted by a committee of the Board of Directors of the Corporation on March 1, 2022:

**RESOLVED**, pursuant to authority expressly set forth in the Amended and Restated Certificate of Incorporation of the Corporation (the "**Certificate of Incorporation**"), the issuance of a series of Preferred Stock designated as the Series A-1 Convertible Preferred Stock, par value $0.0001 per share, of the Corporation is hereby authorized and the designation, number of shares, powers, preferences, rights, qualifications, limitations and restrictions thereof (in addition to any provisions set forth in the Certificate of Incorporation that are applicable to the Preferred Stock of all classes and series) are hereby fixed, and the Certificate of Designation of Preferences, Rights and Limitations of Series A-1 Convertible Preferred Stock is hereby approved as follows:

**SERIES A-1 CONVERTIBLE PREFERRED STOCK**

Section 1. Definitions. For the purposes hereof, the following terms shall have the following meanings:

"**Affiliate**" means any person or entity that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a person or entity, as such terms are used in and construed under Rule 144 under the Securities Act. With respect to a Holder, any investment fund or managed account that is managed on a discretionary basis by the same investment manager as such Holder will be deemed to be an Affiliate of such Holder.

"**Beneficial Ownership Limitation**" shall have the meaning set forth in Section 6(c).

"**Business Day**" means any day except Saturday, Sunday, any day which shall be a federal legal holiday in the United States or any day on which banking institutions in the State of New York are authorized or required by law or other governmental action to close.

"**Class A Common Stock**" means the Corporation's class A common stock, par value $0.0001 per share.

"**Closing Sale Price**" means, for any security as of any date, the last closing trade price for such security prior to 4:00 p.m., New York City time, on the principal securities exchange or trading market where such security is listed or traded, as reported by Bloomberg, L.P. (or an equivalent, reliable

reporting service mutually acceptable to and hereafter designated by Holders of a majority of the then-outstanding Series A-1 Preferred Stock and the Corporation), or if the foregoing do not apply, the last trade price of such security in the principal trading market for such security as reported by Bloomberg, L.P., or, if no last trade price is reported for such security by Bloomberg, L.P., the average of the bid prices of any market makers for such security as reported on the Nasdaq Global Select Market. If the Closing Sale Price cannot be calculated for a security on a particular date on any of the foregoing bases, the Closing Sale Price of such security on such date shall be the fair market value as determined in good faith by the Board of Directors of the Corporation.

"**Commission**" means the Securities and Exchange Commission.

"**Common Stock**" means the Corporation's common stock, par value $0.0001 per share, and stock of any other class of securities into which such securities may hereafter be reclassified or changed into.

"**Conversion Date**" shall have the meaning set forth in Section 6(a).

"**Conversion Price**" shall mean $2.00, as adjusted pursuant to paragraph 7 hereof.

"**Conversion Ratio**" shall have the meaning set forth in Section 6(b).

"**Conversion Shares**" means, collectively, the shares of Common Stock issuable upon conversion of the shares of Series A-1 Preferred Stock in accordance with the terms hereof.

"**Daily Failure Amount**" means the product of (x) .005 multiplied by (y) the Closing Sale Price of the Common Stock on the applicable Share Delivery Date.

"**DGCL**" shall mean the Delaware General Corporation Law.

"**Distributions**" shall have the meaning set forth in Section 5(a).

"**DTC**" shall have the meaning set forth in Section 6(a).

"**DWAC Delivery**" shall have the meaning set forth in Section 6(a).

"**Exchange Act**" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

"**Fundamental Transaction**" shall have the meaning set forth in Section 7(b).

"**Holder**" means any holder of Series A-1 Preferred Stock.

"**Issuance Date**" means March 4, 2022.

"**Junior Securities**" shall have the meaning set forth in Section 5(a).

"**Notice of Conversion**" shall have the meaning set forth in Section 6(a).

"**Parity Securities**" shall have the meaning set forth in Section 5(a).

"**Person**" means any individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

"**Securities Act**" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

"**Senior Securities**" shall have the meaning set forth in Section 5(a).

"**Series A-1 Preferred Stock**" shall have the meaning set forth in Section 2(a).

"**Series A-1 Preferred Stock Register**" shall have the meaning set forth in Section 2(b).

"**Share Delivery Date**" shall have the meaning set forth in Section 6(d)(i).

"**Stated Value**" shall mean $2,000.

"**Trading Day**" means a day on which the Common Stock is traded for any period on the principal securities exchange or if the Common Stock is not traded on a principal securities exchange, on a day that the Common Stock is traded on another securities market on which the Common Stock is then being traded.

Section 2. Designation, Amount and Par Value; Assignment.

(c) The series of preferred stock designated by this Certificate of Designation shall be designated as the Corporation's Series A-1 Convertible Preferred Stock (the "**Series A-1 Preferred Stock**") and the number of shares so designated shall be 15,800. Each share of Series A-1 Preferred Stock shall have a par value of $0.0001 per share. The Series A-1 Preferred Stock may be issued in certificated form or in book-entry form at the election of the Holder. To the extent that any shares of Series A-1 Preferred Stock are issued in book-entry form, references herein to "certificates" shall instead refer to the book-entry notation relating to such shares.

(d) The Corporation or its designee shall register shares of the Series A-1 Preferred Stock, upon records to be maintained by the Corporation for that purpose (the "**Series A-1 Preferred Stock Register**"), in the name of the Holders thereof from time to time. The Corporation may deem and treat the registered Holder of shares of Series A-1 Preferred Stock as the absolute owner thereof for the purpose of any conversion thereof and for all other purposes. The Corporation or its designee shall register the transfer of any shares of Series A-1 Preferred Stock in the Series A-1 Preferred Stock Register, upon surrender of the certificates evidencing such shares to be transferred, duly endorsed by the Holder thereof, to the Corporation at its address specified herein. Upon any such registration or transfer, a new certificate evidencing the shares of Series A-1 Preferred Stock so transferred shall be issued to the transferee and a new certificate evidencing the remaining portion of the shares not so transferred, if any, shall be issued to the transferring Holder, in each case, within three (3) Business Days. The provisions of this Certificate of Designation are intended to be for the benefit of all Holders from time to time and shall be enforceable by any such Holder.

Section 3. Dividends. Holders shall be entitled to receive, and the Corporation shall pay, dividends on shares of the Series A-1 Preferred Stock equal (on an as-if-converted-to-Common-Stock basis, without regard to the Beneficial Ownership Limitation) to and in the same form, and in the same manner, as dividends (other than dividends in the form of Common Stock) actually paid on shares of the Common Stock when, as and if such dividends (other than dividends in the form of Common Stock) are paid on shares of the Common Stock. Other than as set forth in the previous sentence, no other dividends shall be paid on shares of Series A-1 Preferred Stock, and the Corporation shall pay no dividends (other than dividends in the form of Common Stock) on shares of the Common Stock unless it simultaneously complies with the previous sentence.

Section 4. Voting Rights; Amendments. Except as otherwise provided herein or as otherwise required by the DGCL, the Series A-1 Preferred Stock shall have no voting rights. However, as long as any shares of Series A-1 Preferred Stock are outstanding, the Corporation shall not, without the affirmative vote of the Holders of a majority of the then outstanding shares of the Series A-1 Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Series A-1 Preferred Stock or alter or amend this Certificate of Designation, (b) issue further shares of Series A-1 Preferred Stock or increase or decrease (other than by conversion) the number of authorized shares of Series A-1 Preferred Stock or (c) enter into any agreement with respect to any of the foregoing.

Section 5. Rank; Liquidation.

(c) The Series A-1 Preferred Stock shall rank (i) senior to any class or series of capital stock of the Corporation hereafter created specifically ranking by its terms junior to any Series A-1 Preferred Stock ("**Junior Securities**"); (ii) on parity with the Common Stock, Class A Common Stock, Series A Preferred Stock and any class or series of capital stock of the Corporation hereafter created specifically ranking by its terms on parity with the Series A-1 Preferred Stock (the "**Parity Securities**"); (iii) junior to any class or series of capital stock of the Corporation hereafter created specifically ranking by its terms senior to any Series A-1 Preferred Stock ("**Senior Securities**"), in each case, as to distributions of assets upon liquidation, dissolution or winding up of the Corporation, whether voluntarily or involuntarily (all such distributions being referred to collectively as "**Distributions**").

(d) Subject to the prior and superior rights of the holders of any Senior Securities of the Corporation, upon liquidation, dissolution or winding up of the Corporation, whether voluntary or involuntary, each holder of shares of Series A-1 Preferred Stock shall be entitled to receive, in preference to any distributions of any of the assets or surplus funds of the Corporation to the holders of the Junior Securities and *pari passu* with any distribution to the holders of Parity Securities, an amount equal to $0.001 per share of Series A-1 Preferred Stock, plus an additional amount equal to any dividends declared but unpaid on such shares, before any payments shall be made or any assets distributed to holders of Junior Securities. If, upon any such liquidation, dissolution or winding up of the Corporation, the assets of the Corporation shall be insufficient to pay the holders of shares of the Series A-1 Preferred Stock the amount required under the preceding sentence, then all remaining assets of the Corporation shall be distributed ratably to holders of the shares of the Series A-1 Preferred Stock and Parity Securities in proportion to the respective amounts which would otherwise be payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full.

Section 6. Conversion.

(f) Conversions at Option of Holder. Each share of Series A-1 Preferred Stock shall be convertible, at any time and from time to time from and after the Issuance Date, at the option of the Holder thereof, into a number of shares of Common Stock equal to the Conversion Ratio. Holders shall effect conversions by providing the Corporation with the form of conversion notice attached hereto as **Annex A** (a "**Notice of Conversion**"), duly completed and executed. Other than a conversion following a notice provided for under Section 7(b) or Section 7(d)(ii) hereof, the Notice of Conversion must specify at least a number of shares of Series A-1 Preferred Stock to be converted equal to the lesser of (x) 100 shares (such number subject to appropriate adjustment following the occurrence of an event specified in Section 7(a) hereof) and (y) the number of shares of Series A-1 Preferred Stock then held by the Holder. Provided the Corporation's transfer agent is participating in the Depository Trust Company ("**DTC**") Fast Automated Securities Transfer program, the Notice of Conversion may specify, at the Holder's election, whether the

applicable Conversion Shares shall be credited to the account of the Holder's prime broker with DTC through its Deposit Withdrawal Agent Commission system (a "**DWAC Delivery**"). The "**Conversion Date**", or the date on which a conversion shall be deemed effective, shall be defined as the Trading Day that the Notice of Conversion, completed and executed, is sent by facsimile or other electronic transmission to, and received during regular business hours by, the Corporation; provided that the original certificate(s) (if applicable) representing such shares of Series A-1 Preferred Stock being converted, duly endorsed, and the accompanying Notice of Conversion, are received by the Corporation within two (2) Trading Days thereafter. In all other cases, the Conversion Date shall be defined as the Trading Day on which the original share certificate(s) (if applicable) of Series A-1 Preferred Stock being converted, duly endorsed, and the accompanying Notice of Conversion, are received by the Corporation. The calculations set forth in the Notice of Conversion shall control in the absence of manifest or mathematical error.

(g) Conversion Ratio. The "**Conversion Ratio**" for each share of Series A-1 Preferred Stock shall be equal to the Stated Value divided by the Conversion Price.

(h) Beneficial Ownership Limitation. Notwithstanding anything herein to the contrary, the Corporation shall not effect any conversion of the Series A-1 Preferred Stock, and a Holder shall not have the right to convert any portion of the Series A-1 Preferred Stock, to the extent that, immediately prior to or after giving effect to an attempted conversion set forth on an applicable Notice of Conversion, such Holder (together with such Holder's Affiliates, and any other Person whose beneficial ownership of Common Stock would be aggregated with the Holder's for purposes of Section 13(d) or Section 16 of the Exchange Act and the applicable regulations of the Commission, including any "group" of which the Holder is a member (the foregoing, "**Attribution Parties**")) would beneficially own a number of shares of Common Stock in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by such Holder and its Attribution Parties shall include the number of shares of Common Stock issuable upon conversion of the Series A-1 Preferred Stock subject to the Notice of Conversion with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which are issuable upon (A) conversion of the remaining, unconverted Series A-1 Preferred Stock beneficially owned by such Holder or any of its Attribution Parties, and (B) exercise or conversion of the unexercised or unconverted portion of any other securities of the Corporation (including any warrants) beneficially owned by such Holder or any of its Attribution Parties that are subject to a limitation on conversion or exercise similar to the limitation contained herein. For purposes of this Section 6(c), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the applicable regulations of the Commission. In addition, for purposes hereof, "group" has the meaning set forth in Section 13(d) of the Exchange Act and the applicable regulations of the Commission. For purposes of this Section 6(c), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as stated in the most recent of the following: (A) the Corporation's most recent periodic or annual filing with the Commission, as the case may be, (B) a more recent public announcement by the Corporation that is filed with the Commission, or (C) a more recent notice by the Corporation or the Corporation's transfer agent to the Holder setting forth the number of shares of Common Stock then outstanding. Upon the written request of a Holder (which may be by email), the Corporation shall, within three (3) Trading Days thereof, confirm in writing to such Holder (which may be via email) the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined immediately prior to or after giving effect to any actual conversion or exercise of securities of the Corporation, including shares of Series A-1 Preferred Stock, by such Holder or its

Attribution Parties since the date as of which such number of outstanding shares of Common Stock was last publicly reported or confirmed to the Holder. The "**Beneficial Ownership Limitation**" shall be 9.99% of the number of shares of the Common Stock outstanding immediately prior to or after giving effect to the issuance of shares of Common Stock pursuant to such Notice of Conversion (to the extent permitted pursuant to this Section 6(c)); provided, however, that by written notice to the Corporation, which will not be effective until the 61st day after such notice is delivered to the Corporation, the Holder may waive or amend the provisions of this Section 6(c) to change the Beneficial Ownership Limitation to any other number less than or equal to 19.99%, and the provisions of this Section 6(c) shall continue to apply. The Corporation shall be entitled to rely on representations made to it by the Holder in any Notice of Conversion regarding its Beneficial Ownership Limitation.

(i) Mechanics of Conversion

(i) Delivery of Certificate or Electronic Issuance Upon Conversion. Not later than three (3) Trading Days after the applicable Conversion Date, or if the Holder requests the issuance of physical certificate(s), two (2) Trading Days after receipt by the Corporation of the original certificate(s) representing such shares of Series A-1 Preferred Stock being converted, duly endorsed, and the accompanying Notice of Conversion (the "**Share Delivery Date**"), the Corporation shall (a) deliver, or cause to be delivered, to the converting Holder a physical certificate or certificates representing the number of Conversion Shares being acquired upon the conversion of shares of Series A-1 Preferred Stock or (b) in the case of a DWAC Delivery, electronically transfer such Conversion Shares by crediting the account of the Holder's prime broker with DTC through its DWAC system. If in the case of any Notice of Conversion such certificate or certificates are not delivered to or as directed by or, in the case of a DWAC Delivery, such shares are not electronically delivered to or as directed by, the applicable Holder by the Share Delivery Date, the applicable Holder shall be entitled to elect to rescind such Notice of Conversion by written notice to the Corporation at any time on or before its receipt of such certificate or certificates for Conversion Shares or electronic receipt of such shares, as applicable, in which event the Corporation shall promptly return to such Holder any original Series A-1 Preferred Stock certificate delivered to the Corporation and such Holder shall promptly return to the Corporation any Common Stock certificates or otherwise direct the return of any shares of Common Stock delivered to the Holder through the DWAC system, representing the shares of Series A-1 Preferred Stock unsuccessfully tendered for conversion to the Corporation.

(ii) Obligation Absolute. Subject to Section 6(c) hereof and subject to Holder's right to rescind a Notice of Conversion pursuant to Section 6(d)(i) above, the Corporation's obligation to issue and deliver the Conversion Shares upon conversion of Series A-1 Preferred Stock in accordance with the terms hereof are absolute and unconditional, irrespective of any action or inaction by a Holder to enforce the same, any waiver or consent with respect to any provision hereof, the recovery of any judgment against any Person or any action to enforce the same, or any setoff, counterclaim, recoupment, limitation or termination, or any breach or alleged breach by such Holder or any other Person of any obligation to the Corporation or any violation or alleged violation of law by such Holder or any other Person, and irrespective of any other circumstance which might otherwise limit such obligation of the Corporation to such Holder in connection with the issuance of such Conversion Shares. Subject to Section 6(c) hereof and subject to Holder's right to rescind a Notice of Conversion pursuant to Section 6(d)(i) above, in the event a Holder shall elect to convert any or all of its Series A-1 Preferred Stock, the Corporation may not refuse conversion based on any claim that such Holder or anyone associated or affiliated with such Holder has been engaged in any violation of law, agreement or for any other reason, unless an injunction from a court, on notice to Holder, restraining and/or enjoining conversion of all or part of the Series A-1 Preferred Stock of such Holder shall have been sought and obtained by the Corporation, and the

Corporation posts a surety bond for the benefit of such Holder in the amount of 150% of the value of the Conversion Shares into which would be converted the Series A-1 Preferred Stock which is subject to such injunction, which bond shall remain in effect until the completion of arbitration/litigation of the underlying dispute and the proceeds of which shall be payable to such Holder to the extent it obtains judgment. In the absence of such injunction, the Corporation shall, subject to Section 6(c) hereof and subject to Holder's right to rescind a Notice of Conversion pursuant to Section 6(d)(i) above, issue Conversion Shares upon a properly noticed conversion. If the Corporation fails to deliver to a Holder such certificate or certificates, or electronically deliver (or cause its transfer agent to electronically deliver) such shares in the case of a DWAC Delivery, pursuant to Section 6(d)(i) on or prior to the fifth (5th) Trading Day after the Share Delivery Date applicable to such conversion (other than a failure caused by incorrect or incomplete information provided by Holder to the Corporation), then, unless the Holder has rescinded the applicable Notice of Conversion pursuant to Section 6(d)(i) above, the Corporation shall pay (as liquidated damages and not as a penalty) to such Holder an amount payable, at the Holder's option, either (a) in cash or (b) to the extent that it would not cause the Holder or its Attribution Parties to exceed the Beneficial Ownership Limitation, in shares of Common Stock that are valued for these purposes at the Closing Sale Price on the date of such calculation, in each case equal to the product of (x) the number of Conversion Shares required to have been issued by the Corporation on such Share Delivery Date, (y) an amount equal to the Daily Failure Amount and (z) the number of Trading Days actually lapsed after such fifth (5th) Trading Day after the Share Delivery Date during which such certificates have not been delivered, or, in the case of a DWAC Delivery, such shares have not been electronically delivered; *provided, however,* the Holder shall only receive up to such amount of shares of Common Stock such that Holder and its Attribution Parties and any other persons or entities whose beneficial ownership of Common Stock would be aggregated with the Holder's for purposes of Section 13(d) of the Exchange Act (including shares held by any "group" of which the Holder is a member, but excluding shares beneficially owned by virtue of the ownership of securities or rights to acquire securities that have limitations on the right to convert, exercise or purchase similar to the limitation set forth herein) shall not collectively beneficially own greater than the Beneficial Ownership Limitation. Nothing herein shall limit a Holder's right to pursue actual damages for the Corporation's failure to deliver Conversion Shares within the period specified herein and such Holder shall have the right to pursue all remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief; provided that Holder shall not receive duplicate damages for the Corporation's failure to deliver Conversion Shares within the period specified herein. The exercise of any such rights shall not prohibit a Holder from seeking to enforce damages pursuant to any other Section hereof or under applicable law.

(iii) Compensation for Buy-In on Failure to Timely Deliver Certificates Upon Conversion. If the Corporation fails to deliver to a Holder the applicable certificate or certificates or to effect a DWAC Delivery, as applicable, by the Share Delivery Date pursuant to Section 6(d)(i) (other than a failure caused by incorrect or incomplete information provided by Holder to the Corporation), and if after such Share Delivery Date such Holder is required by its brokerage firm to purchase (in an open market transaction or otherwise), or the Holder's brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by such Holder of the Conversion Shares which such Holder was entitled to receive upon the conversion relating to such Share Delivery Date (a "**Buy-In**"), then the Corporation shall (A) pay in cash to such Holder (in addition to any other remedies available to or elected by such Holder) the amount by which (x) such Holder's total purchase price (including any brokerage commissions) for the shares of Common Stock so purchased exceeds (y) the product of (1) the aggregate number of shares of Common Stock that such Holder was entitled to receive from the conversion at issue multiplied by (2) the actual

sale price at which the sell order giving rise to such purchase obligation was executed (including any brokerage commissions) and (B) at the option of such Holder, either reissue (if surrendered) the shares of Series A-1 Preferred Stock equal to the number of shares of Series A-1 Preferred Stock submitted for conversion or deliver to such Holder the number of shares of Common Stock that would have been issued if the Corporation had timely complied with its delivery requirements under Section 6(d)(i). For example, if a Holder purchases shares of Common Stock having a total purchase price of $11,000 to cover a Buy-In with respect to an attempted conversion of shares of Series A-1 Preferred Stock with respect to which the actual sale price (including any brokerage commissions) giving rise to such purchase obligation was a total of $10,000 under clause (A) of the immediately preceding sentence, the Corporation shall be required to pay such Holder $1,000. The Holder shall provide the Corporation written notice, within three (3) Trading Days after the occurrence of a Buy-In, indicating the amounts payable to such Holder in respect of such Buy-In together with applicable confirmations and other evidence reasonably requested by the Corporation. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Corporation's failure to timely deliver certificates representing shares of Common Stock upon conversion of the shares of Series A-1 Preferred Stock as required pursuant to the terms hereof; provided, however, that the Holder shall not be entitled to both (i) require the reissuance of the shares of Series A-1 Preferred Stock submitted for conversion for which such conversion was not timely honored and (ii) receive the number of shares of Common Stock that would have been issued if the Corporation had timely complied with its delivery requirements under Section 6(d)(i).

(iv) Reservation of Shares Issuable Upon Conversion. The Corporation covenants that it will at all times reserve and keep available out of its authorized and unissued shares of Common Stock for the sole purpose of issuance upon conversion of the Series A-1 Preferred Stock, free from preemptive rights or any other actual contingent purchase rights of Persons other than the Holders of the Series A-1 Preferred Stock, not less than such aggregate number of shares of the Common Stock as shall be issuable (taking into account the adjustments of Section 7) upon the conversion of all outstanding shares of Series A-1 Preferred Stock. The Corporation covenants that all shares of Common Stock that shall be so issuable shall, upon issue, be duly authorized, validly issued, fully paid, nonassessable and free and clear of all liens and encumbrances.

(v) Fractional Shares. No fractional shares or scrip representing fractional shares of Common Stock shall be issued upon the conversion of the Series A-1 Preferred Stock. As to any fraction of a share which a Holder would otherwise be entitled to receive upon such conversion, the Corporation shall pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Conversion Price.

(vi) Transfer Taxes. The issuance of certificates for shares of the Common Stock upon conversion of the Series A-1 Preferred Stock shall be made without charge to any Holder for any documentary stamp or similar taxes that may be payable in respect of the issue or delivery of such certificates, provided that the Corporation shall not be required to pay any tax that may be payable in respect of any transfer involved in the issuance and delivery of any such certificate upon conversion in a name other than that of the registered Holder(s) of such shares of Series A-1 Preferred Stock and the Corporation shall not be required to issue or deliver such certificates unless or until the Person or Persons requesting the issuance thereof shall have paid to the Corporation the amount of such tax or shall have established to the satisfaction of the Corporation that such tax has been paid.

(j) Status as Stockholder. Upon each Conversion Date, (i) the shares of Series A-1 Preferred Stock being converted shall be deemed converted into shares of Common Stock and (ii) the Holder's rights as a holder of such converted shares of Series A-1 Preferred Stock shall cease and terminate, excepting only the right to receive certificates for such shares of Common Stock and to any remedies provided herein or otherwise available at law or in equity to such Holder because of a failure by the Corporation to comply with the terms of this Certificate of Designation. In all cases, the Holder shall retain all of its rights and remedies for the Corporation's failure to convert Series A-1 Preferred Stock.

Section 7. Certain Adjustments.

(e) Stock Dividends and Stock Splits. If the Corporation, at any time while this Series A-1 Preferred Stock is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Corporation upon conversion of this Series A-1 Preferred Stock) with respect to the then outstanding shares of Common Stock; (ii) subdivides outstanding shares of Common Stock into a larger number of shares; or (iii) combines (including by way of a reverse stock split) outstanding shares of Common Stock into a smaller number of shares, then the Conversion Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding any treasury shares of the Corporation) outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event (excluding any treasury shares of the Corporation). Any adjustment made pursuant to this Section 7(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision or combination.

(f) Fundamental Transaction. If, at any time while this Series A-1 Preferred Stock is outstanding, (i) the Corporation enters into a binding agreement to effect any merger or consolidation of the Corporation with or into another Person or any stock sale to, or other business combination (including, without limitation, a reorganization, recapitalization, spin-off, share exchange or scheme of arrangement) with or into another Person (other than such a transaction in which the Corporation would be the surviving or continuing entity and its Common Stock is not exchanged for or converted into other securities, cash or property), (ii) the Corporation enters into a binding agreement to effect any sale of all or substantially all of its assets in one transaction or a series of related transactions, (iii) any tender offer or exchange offer (whether by the Corporation or another Person) is completed pursuant to which more than 50% of the Common Stock not held by the Corporation or such Person is exchanged for or converted into other securities, cash or property, or (iv) the Corporation announces its intent to effect any reclassification of the Common Stock or any compulsory share exchange pursuant (other than as a result of a dividend, subdivision or combination covered by Section 7(a) above) to which the Common Stock is effectively converted into or exchanged for other securities, cash or property (in any such case, a "**Fundamental Transaction**"), then at least 20 calendar days prior to the anticipated date prior to when such Fundamental Transaction is expected to be consummated or closed, the Company shall provide written notice all Holders of such Fundamental Transaction to allow such holder to give notice of conversion and entitle such holders to receive, in lieu of the right to receive Conversion Shares, for each Conversion Share that would have been issuable upon such conversion immediately prior to the occurrence of such Fundamental Transaction, the same kind and amount of securities, cash or property as it would have been entitled to receive upon the occurrence of such Fundamental Transaction if it had been, immediately prior to such Fundamental Transaction, the holder of one share of Common Stock (the "**Alternate Consideration**"). If holders of

Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holders shall be given the same choice as to the Alternate Consideration it receives upon any conversion of this Series A-1 Preferred Stock following such Fundamental Transaction.

(g) Calculations. All calculations under this Section 7 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 7, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding any treasury shares of the Corporation) issued and outstanding.

(h) Notice to the Holders.

(i) Adjustment to Conversion Price. Whenever the Conversion Price is adjusted pursuant to any provision of this Section 7, the Corporation shall promptly deliver to each Holder a notice setting forth the Conversion Ratio after such adjustment and setting forth a brief statement of the facts requiring such adjustment.

(ii) Other Notices. If (A) the Corporation shall declare a dividend (or any other distribution in whatever form) on the Common Stock, Class A Common Stock or Series A Preferred Stock, (B) the Corporation shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock, Class A Common Stock or Series A Preferred Stock, (C) the Corporation shall authorize the granting to all holders of the Common Stock, Class A Common Stock or Series A Preferred Stock of rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any stockholders of the Corporation shall be required in connection with any reclassification of the Common Stock, Class A Common Stock or Series A Preferred Stock, any consolidation or merger to which the Corporation is a party, any sale or transfer of all or substantially all of the assets of the Corporation, or any compulsory share exchange whereby the Common Stock, Class A Common Stock or Series A Preferred Stock is converted into other securities, cash or property, or (E) the Corporation shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Corporation, then, in each case, the Corporation shall cause to be filed at each office or agency maintained for the purpose of conversion of this Series A-1 Preferred Stock, and, except if such notice and the contents thereof shall be deemed to constitute material non-public information shall cause to be delivered to each Holder at its last address as it shall appear upon the stock books of the Corporation, at least 20 calendar days prior to the applicable record or effective date hereinafter specified, a notice stating the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock, Class A Common Stock or Series A Preferred Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined.

Section 8. Miscellaneous.

(h) Notices. Any and all notices or other communications or deliveries to be provided by the Holders hereunder including, without limitation, any Notice of Conversion, shall be in writing and delivered personally, by facsimile, via email or sent by a nationally recognized overnight courier service, addressed to the Corporation, at 350 Fifth Avenue, 72nd Floor, Suite 7240, New York, New York 10118, facsimile number +43 1 890 63 60 399, email Reinhard.Kandera@hookipapharma.com, or such other facsimile number, email address or mailing address as the Corporation may specify for such purposes by notice to the Holders delivered in accordance with this Section. Any and all notices or other communications or deliveries to be provided by the Corporation hereunder shall be in writing and delivered personally, by facsimile, or sent by a nationally recognized overnight courier service addressed to each Holder at the facsimile number or address of such Holder appearing on the books of the

Corporation, or if no such facsimile number or address appears on the books of the Corporation, at the principal place of business of such Holder. Any notice or other communication or deliveries hereunder shall be deemed given and effective on the earliest of (i) the date of transmission, if such notice or communication is delivered via facsimile at the facsimile number, or via email at the email address, specified in this Section prior to 5:30 p.m. (New York City time) on any date, (ii) the date immediately following the date of transmission, if such notice or communication is delivered via facsimile at the facsimile number, or via email at the email address, specified in this Section between 5:30 p.m. and 11:59 p.m. (New York City time) on any date, (iii) the second Business Day following the date of mailing, if sent by nationally recognized overnight courier service, or (iv) upon actual receipt by the party to whom such notice is required to be given.

(i) Lost or Mutilated Series A-1 Preferred Stock Certificate. If a Holder's Series A-1 Preferred Stock certificate shall be mutilated, lost, stolen or destroyed, the Corporation shall execute and deliver, in exchange and substitution for and upon cancellation of a mutilated certificate, or in lieu of or in substitution for a lost, stolen or destroyed certificate, a new certificate for the shares of Series A-1 Preferred Stock so mutilated, lost, stolen or destroyed, but only upon receipt of evidence of such loss, theft or destruction of such certificate, and of the ownership thereof, reasonably satisfactory to the Corporation and, in each case, customary and reasonable indemnity, if requested. Applicants for a new certificate under such circumstances shall also comply with such other reasonable regulations and procedures and pay such other reasonable third-party costs as the Corporation may prescribe.

(j) Waiver. Any waiver by the Corporation or a Holder of a breach of any provision of this Certificate of Designation shall not operate as or be construed to be a waiver of any other breach of such provision or of any breach of any other provision of this Certificate of Designation or a waiver by any other Holders. The failure of the Corporation or a Holder to insist upon strict adherence to any term of this Certificate of Designation on one or more occasions shall not be considered a waiver or deprive that party (or any other Holder) of the right thereafter to insist upon strict adherence to that term or any other term of this Certificate of Designation. Any waiver by the Corporation or a Holder must be in writing. Notwithstanding any provision in this Certificate of Designation to the contrary, any provision contained herein and any right of the Holders of Series A-1 Preferred Stock granted hereunder may be waived as to all shares of Series A-1 Preferred Stock (and the Holders thereof) upon the written consent of the Holders of not less than a majority of the shares of Series A-1 Preferred Stock then outstanding, unless a higher percentage is required by the DGCL, in which case the written consent of the Holders of not less than such higher percentage shall be required.

(k) Severability. If any provision of this Certificate of Designation is invalid, illegal or unenforceable, the balance of this Certificate of Designation shall remain in effect, and if any provision is inapplicable to any Person or circumstance, it shall nevertheless remain applicable to all other Persons and circumstances. If it shall be found that any interest or other amount deemed interest due hereunder violates the applicable law governing usury, the applicable rate of interest due hereunder shall automatically be lowered to equal the maximum rate of interest permitted under applicable law.

(l) Next Business Day. Whenever any payment or other obligation hereunder shall be due on a day other than a Business Day, such payment shall be made on the next succeeding Business Day.

(m) Headings. The headings contained herein are for convenience only, do not constitute a part of this Certificate of Designation and shall not be deemed to limit or affect any of the provisions hereof.

(n) Status of Converted Series A-1 Preferred Stock. If any shares of Series A-1 Preferred Stock shall be converted or reacquired by the Corporation, such shares shall resume the status of authorized but unissued shares of preferred stock and shall no longer be designated as Series A-1 Preferred Stock.

**IN WITNESS WHEREOF**, the undersigned has executed this Certificate of Designation this 3rd day of March 2022.

/s/ Jörn Aldag
Jörn Aldag, Chief Executive Officer

SIGNATURE PAGE TO CERTIFICATE OF DESIGNATION OF PREFERENCES,
RIGHTS AND LIMITATIONS OF SERIES A-1 PREFERRED STOCK

**ANNEX A**

NOTICE OF CONVERSION

(TO BE EXECUTED BY THE REGISTERED HOLDER IN ORDER
TO CONVERT SHARES OF SERIES A-1 PREFERRED STOCK)

The undersigned Holder hereby irrevocably elects to convert the number of shares of Series A-1 Preferred Stock indicated below, represented by stock certificate No(s). (the "**Preferred Stock Certificates**"), into shares of common stock, par value $0.0001 per share (the "**Common Stock**"), of HOOKIPA Pharma Inc., a Delaware corporation (the "**Corporation**"), as of the date written below. If securities are to be issued in the name of a person other than the undersigned, the undersigned will pay all transfer taxes payable with respect thereto. Capitalized terms utilized but not defined herein shall have the meaning ascribed to such terms in that certain Certificate of Designation of Preferences, Rights and Limitations of Series A-1 Convertible Preferred Stock (the "**Certificate of Designation**") filed by the Corporation with the Secretary of State of the State of Delaware on March 3, 2022.

As of the date hereof, the number of shares of Common Stock beneficially owned by the undersigned Holder (together with such Holder's Affiliates, and any other Person whose beneficial ownership of Common Stock would be aggregated with the Holder's for purposes of Section 13(d) or Section 16 of the Exchange Act and the applicable regulations of the Commission, including any "group" of which the Holder is a member (the foregoing, "**Attribution Parties**")), including the number of shares of Common Stock issuable upon conversion of the Series A-1 Preferred Stock subject to this Notice of Conversion, but excluding the number of shares of Common Stock which are issuable upon (A) conversion of the remaining, unconverted Series A-1 Preferred Stock beneficially owned by such Holder or any of its Attribution Parties, and (B) exercise or conversion of the unexercised or unconverted portion of any other securities of the Corporation (including any warrants) beneficially owned by such Holder or any of its Attribution Parties that are subject to a limitation on conversion or exercise similar to the limitation contained in Section 6(c) of the Certificate of Designation, is 9.99%. For purposes hereof, beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the applicable regulations of the Commission. In addition, for purposes hereof, "group" has the meaning set forth in Section 13(d) of the Exchange Act and the applicable regulations of the Commission.

Conversion calculations:

Date to Effect Conversion: _____

Number of shares of Series A-1 Preferred Stock owned prior to Conversion: _____

Number of shares of Series A-1 Preferred Stock to be Converted: _____

Number of shares of Common Stock to be Issued: _____

Address for delivery of physical certificates:

or

for DWAC Delivery: _____

DWAC Instructions: _____

Broker no: _____

Account no: _____

**Exhibit 4.3**

**DESCRIPTION OF SECURITIES REGISTERED UNDER SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934**

The following description of the registered capital stock of HOOKIPA Pharma Inc. ("us," "our," "we" or the "Company") does not purport to be complete and is subject to, and qualified in its entirety by, reference to our amended and restated certificate of incorporation ("Certificate of Incorporation") and our amended and restated bylaws ("Bylaws"), which are incorporated by reference as exhibits to our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, and applicable provisions of the Delaware General Corporation Law (the "DGCL"). Our common stock, par value $0.0001 per share (the "common stock") is the only security of the Company registered under Section 12 of the Securities Exchange Act of 1934, as amended. The summaries below do not purport to be complete statements of the relevant provisions of our Certificate of Incorporation, our Bylaws or the DGCL.

Our authorized capital stock consists of 100,000,000 shares of common stock, 3,900,000 shares of Class A common stock, par value $0.0001 per share (the "Class A common stock") and 10,000,000 shares of undesignated preferred stock, par value $0.0001 per share (the "preferred stock"), of which 2,978 shares are designated as Series A convertible preferred stock (the "Series A preferred stock") and 15,800 shares are designated as Series A-1 convertible preferred stock (the "Series A-1 preferred stock").

**Common Stock**

*Annual Meeting*. Annual meetings of our stockholders are held on the date designated in accordance with our Bylaws. Written notice must be mailed to each stockholder entitled to vote not less than ten (10) nor more than sixty (60) days before the date of the meeting. The presence in person or by proxy of the holders of record of a majority of our issued and outstanding shares entitled to vote at such meeting constitutes a quorum for the transaction of business at meetings of the stockholders. Special meetings of the stockholders may be called for any purpose only by the board of directors pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office. Except as may be otherwise provided by applicable law, our Certificate of Incorporation or our Bylaws, all elections of directors shall be decided by a plurality, and all other questions shall be decided by a majority, of the votes cast by stockholders entitled to vote thereon at a duly held meeting of stockholders at which a quorum is present.

*Voting Rights*. Holders of common stock are entitled to one vote for each share held of record on all matters to be voted upon by stockholders and do not have cumulative voting rights.

*Dividends*. Subject to the rights, powers and preferences of any outstanding preferred stock that we may designate and issue in the future, and except as provided by law or in our Certificate of Incorporation, dividends may be declared and paid or set aside for payment on the common stock out of legally available assets or funds when and as declared by our board of directors.

*Liquidation, Dissolution and Winding Up*. Subject to the rights, powers and preferences of any outstanding preferred stock that we may designate and issue in the future, in the event of our liquidation, dissolution or winding up, our net assets will be distributed pro rata to the holders of common stock.

*Other Rights*. Our common stock has no preemptive rights, conversion rights, or other subscription rights or redemption or sinking fund provisions. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future. Holders of common stock are not required to make additional capital contributions.

Our common stock is listed on the Nasdaq Global Select Market under the trading symbol “HOOK.”
The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC.

**Class A Common Stock**

The rights of the holders of our common stock and class A common stock are identical, except with respect to voting and conversion. The shares of class A common stock do not have associated voting rights and each share of class A common stock is convertible at any time at the election of the holder into one share of common stock.

**Preferred Stock**

Our board of directors has the authority to designate and issue up to ten million (10,000,000) shares of preferred stock in one or more series. The authorized shares of our preferred stock are available for issuance without further action by our stockholders, unless such action is required by applicable law or the rules of any stock exchange on which our securities may be listed. Our board of directors may also designate the rights, powers, preferences and the relative, participating, optional or other special rights and any qualifications, limitations and restrictions of the shares of each series of preferred stock.

17,552 shares of preferred stock are outstanding as of the date of our Annual Report on Form 10-K with which this Exhibit 4.3 is filed as an exhibit, consisting of 1,752 shares of Series A preferred stock and 15,800 shares of Series A-1 preferred stock.

***Series A Preferred Stock***

*Rank.* The Series A preferred stock will rank:

- on parity with our common stock, Class A common stock and Series A-1 preferred stock;
- on parity with any class or series of capital stock hereafter created specifically ranking by its terms on parity with the Series A preferred stock;
- senior to any class or series of our capital stock hereafter created specifically ranking by its terms junior to the Series A preferred stock; and
- junior to any class or series of capital stock hereafter created specifically ranking by its terms senior to the Series A preferred stock;

in each case, as to distributions of assets upon our liquidation, dissolution or winding up whether voluntarily or involuntarily.

*Conversion.* Each share of the Series A preferred stock is convertible into 1,000 shares of our common stock (subject to adjustment as provided in the related certificate of designation of preferences rights and limitations) at any time at the option of the holder, provided that the holder will be prohibited, subject to certain exceptions, from converting Series A preferred stock into shares of our 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 our common stock then issued and outstanding, which percentage may be changed at the holder’s election to any other number less than or equal to 19.99% upon 61 days’ notice to us.

*Liquidation Preference.* In the event of our liquidation, dissolution or winding up, holders of the Series A preferred stock will receive a payment equal to $0.001 per share of Series A preferred stock *pari passu* with the common stock, Class A common stock and Series A-1 preferred stock.

*Fundamental Transaction*. Upon consummation of a Fundamental Transaction (as defined below) pursuant to which holders of shares of our common stock are entitled to receive securities, cash or property, then upon any subsequent conversion of the Series A preferred stock, the holder thereof shall have the right to receive, in lieu of the right to receive the shares of our common stock underlying the Series A preferred stock, for each share of

common stock that it would have otherwise been entitled to receive upon such conversion immediately prior to the occurrence of such Fundamental Transaction, the same kind and amount of securities, cash or property as it would have been entitled to receive upon the occurrence of such Fundamental Transaction if it had been, immediately prior to such Fundamental Transaction, the holder of one share of our common stock. If holders of our common stock are given a choice as to the securities, cash or property to be received in a Fundamental Transaction, then the holder of the Series A preferred stock shall be given the same choice as to the consideration it receives upon any exercise of the Series A preferred stock following such Fundamental Transaction.

A "Fundamental Transaction" means:

- we effect any merger or consolidation with or into another person or any stock sale to, or other business combination (including, without limitation, a reorganization, recapitalization, spin-off, share exchange or scheme of arrangement) with or into another person (other than such a transaction in which we are the surviving or continuing entity and our common stock is not exchanged for or converted into other securities, cash or property);
- we effect any sale of all or substantially all of our assets in one transaction or a series of related transactions;
- any tender offer or exchange offer (whether by us or another person) is completed pursuant to which more than 50% of the common stock not held by us or such person is exchanged for or converted into other securities, cash or property; or
- we effect any reclassification of our common stock or any compulsory share exchange pursuant (other than specified dividends, subdivisions or combinations) to which our common stock is effectively converted into or exchanged for other securities, cash or property.

*Voting Rights.* Shares of Series A preferred stock will generally have no voting rights, except as required by law and except that the consent of the holders of a majority of the outstanding shares of Series A preferred stock will be required to amend the terms of the Series A preferred stock.

*Dividends.* Shares of Series A 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 common stock.

*Redemption.* We are not obligated to redeem or repurchase any shares of Series A preferred stock. Shares of Series A preferred stock are not otherwise entitled to any redemption rights or mandatory sinking fund or analogous fund provisions.

*Exchange Listing.* We do not plan on making an application to list the Series A preferred stock on The Nasdaq Global Select Market, any national securities exchange or other nationally recognized trading system. We expect the common stock issuable upon conversion of the Series A preferred stock to be listed on the Nasdaq Global Select Market.

The transfer agent and registrar for shares of our Series A preferred stock (and the underlying shares of common stock) is American Stock Transfer & Trust Company, LLC.

***Series A-1 Preferred Stock***

*Rank.* The Series A-1 preferred stock will rank:

- on parity with our common stock, Class A common stock and Series A preferred stock;
- on parity with any class or series of capital stock hereafter created specifically ranking by its terms on parity with the Series A-1 preferred stock;
- senior to any class or series of our capital stock hereafter created specifically ranking by its terms junior to the Series A-1 preferred stock; and

- junior to any class or series of capital stock hereafter created specifically ranking by its terms senior to the Series A-1 preferred stock;

in each case, as to distributions of assets upon our liquidation, dissolution or winding up whether voluntarily or involuntarily.

*Conversion.* Each share of the Series A-1 preferred stock is convertible into 1,000 shares of our common stock (subject to adjustment as provided in the related certificate of designation of preferences rights and limitations) at any time at the option of the holder, provided that the holder will be prohibited, subject to certain exceptions, from converting Series A-1 preferred stock into shares of our 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 our common stock then issued and outstanding, which percentage may be changed at the holder's election to any other number less than or equal to 19.99% upon 61 days' notice to us.

*Liquidation Preference.* In the event of our liquidation, dissolution or winding up, holders of the Series A-1 preferred stock will receive a payment equal to $0.001 per share of Series A-1 preferred stock *pari passu* with the common stock, Class A common stock and Series A preferred stock.

*Fundamental Transaction.* Upon consummation of a Fundamental Transaction (as defined below) pursuant to which holders of shares of our common stock are entitled to receive securities, cash or property, then upon any subsequent conversion of the Series A-1 preferred stock, the holder thereof shall have the right to receive, in lieu of the right to receive the shares of our common stock underlying the Series A-1 preferred stock, for each share of common stock that it would have otherwise been entitled to receive upon such conversion immediately prior to the occurrence of such Fundamental Transaction, the same kind and amount of securities, cash or property as it would have been entitled to receive upon the occurrence of such Fundamental Transaction if it had been, immediately prior to such Fundamental Transaction, the holder of one share of our common stock. If holders of our common stock are given a choice as to the securities, cash or property to be received in a Fundamental Transaction, then the holder of the Series A-1 preferred stock shall be given the same choice as to the consideration it receives upon any exercise of the Series A-1 preferred stock following such Fundamental Transaction.

A "Fundamental Transaction" means:

- we effect any merger or consolidation with or into another person or any stock sale to, or other business combination (including, without limitation, a reorganization, recapitalization, spin-off, share exchange or scheme of arrangement) with or into another person (other than such a transaction in which we are the surviving or continuing entity and our common stock is not exchanged for or converted into other securities, cash or property);
- we effect any sale of all or substantially all of our assets in one transaction or a series of related transactions;
- any tender offer or exchange offer (whether by us or another person) is completed pursuant to which more than 50% of the common stock not held by us or such person is exchanged for or converted into other securities, cash or property; or
- we effect any reclassification of our common stock or any compulsory share exchange pursuant (other than specified dividends, subdivisions or combinations) to which our common stock is effectively converted into or exchanged for other securities, cash or property.

*Voting Rights.* Shares of Series A-1 preferred stock will generally have no voting rights, except as required by law and except that the consent of the holders of a majority of the outstanding shares of Series A-1 preferred stock will be required to amend the terms of the Series A-1 preferred stock.

*Dividends.* Shares of Series A-1 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 common stock.

*Redemption.* We are not obligated to redeem or repurchase any shares of Series A-1 preferred stock. Shares of Series A-1 preferred stock are not otherwise entitled to any redemption rights or mandatory sinking fund or analogous fund provisions.

*Exchange Listing.* We do not plan on making an application to list the Series A-1 preferred stock on The Nasdaq Global Select Market, any national securities exchange or other nationally recognized trading system. We expect the common stock issuable upon conversion of the Series A-1 preferred stock to be listed on the Nasdaq Global Select Market.

The transfer agent and registrar for shares of our Series A-1 preferred stock (and the underlying shares of common stock) is American Stock Transfer & Trust Company, LLC.

**Registration Rights**

Pursuant to the terms of our shareholders' agreement, dated as of February 15, 2019, certain of our stockholders are entitled to rights with respect to the registration of their shares under Securities Act of 1933, as amended (the "Securities Act").

*Demand Registration Rights.* Pursuant to the terms of our shareholders' agreement, certain holders of shares of our common stock are entitled to demand registration rights.

*Short-Form Registration Rights.* Pursuant to the terms of our shareholders' agreement, certain holders of shares of our common stock are entitled to short-form registration rights. If we are eligible to file a registration statement on Form S-3, upon the written request of a majority of our stockholders to sell securities at an anticipated aggregate price of at least $10.0 million, we will be required to use commercially reasonable efforts to effect a registration of such shares.

*Piggyback Registration Rights.* Pursuant to the terms of our shareholders' agreement, certain holders of shares of our common stock are entitled to piggyback registration rights. If we register any of our securities either for our own account or for the account of other security holders, the holders of these shares are entitled to include their shares in the registration.

*Expiration of Registration Rights*. The demand registration rights and short form registration rights will terminate as to a given stockholder at such time as Rule 144 or another similar exemption under the Securities Act is available for the sale of all of such stockholder's shares without limitation during a three-month period without registration.

**Provisions of Our Certificate of Incorporation and Bylaws and Delaware Law That May Have Anti-Takeover Effects**

The provisions of Delaware law and our Certificate of Incorporation and Bylaws could discourage or make it more difficult to accomplish a proxy contest or other change in our management or the acquisition of control by a holder of a substantial amount of our voting stock. It is possible that these provisions could make it more difficult to accomplish, or could deter, transactions that stockholders may otherwise consider to be in their best interests or in our best interests. These provisions are intended to enhance the likelihood of continuity and stability in the composition of our board of directors and in the policies formulated by the board of directors and to discourage certain types of transactions that may involve an actual or threatened change of our control. These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy fights. Such provisions also may have the effect of preventing changes in our management.

*Board of Directors*. Our Certificate of Incorporation and Bylaws provide for a board of directors divided into three classes. Each class is elected to a term expiring at the annual meeting of stockholders held in the third year following the year of such election. The number of directors comprising our board of directors is fixed from time to time by the board of directors.

*Removal of Directors by Stockholders*. Our Certificate of Incorporation provides that members of our board of directors may only be removed for cause by a vote of the holders of at least two-thirds (2/3) of the outstanding shares entitled to vote on the election of the directors.

*Issuance of Preferred Stock*. Our board of directors is authorized, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series, and to fix the designations, powers, preferences and the relative, participating, optional or other special rights, and any qualifications, limitations and restrictions of the shares of each series of preferred stock. The issuance of preferred stock could impede the completion of a merger, tender offer or other takeover attempt.

*Stockholder Nomination of Directors*. Our Bylaws provide that a stockholder must notify us in writing of any stockholder nomination of a director not earlier than the close of business on the 120th day and not later than the close of business on the 90th day prior to the first anniversary of the preceding year's annual meeting; provided, that if the date of the annual meeting is advanced by more than 30 days before such anniversary date, delayed by more than 60 days after such anniversary date or if no annual meeting were held in the prior year, notice by the stockholder to be timely must be so delivered not later than the close of business on the later of (x) the 90th day prior to the date of such meeting and (y) the 10th day following the day on which public announcement of the date of such annual meeting is first made by us.

*No Action By Written Consent*. Our Certificate of Incorporation provides that our stockholders may not act by written consent and may only act at duly called meetings of stockholders.

*Exclusive Forum Selection*. Our Bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for state law claims for (1) any derivative action or proceeding brought on behalf of the Company, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers, or other employees to the Company or our stockholders, (3) any action asserting a claim arising against the Company or any of our current or former directors, officers, or other employees pursuant to any provision of the DGCL or our Certificate of Incorporation or Bylaws, (4) any action to interpret, apply, enforce or determine the validity of our Certificate of Incorporation or Bylaws, or (5) any action asserting a claim against the Company or any of our current or former directors, officers, or other employees that is governed by the internal affairs doctrine. In addition, our Bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing provisions.

**Section 203 of the Delaware General Corporation Law.**

We are subject to the provisions of Section 203 of the DGCL. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock

plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or

- at or after the time the stockholder became interested, the business combination was approved by our board of directors and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, lease, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

# EMPLOYMENT AGREEMENT

This Employment Agreement ("Agreement") is made between HOOKIPA Biotech GmbH (the "Company"), and Klaus Orlinger (the "Executive") and is made effective as of January 1, 2022 (the "Effective Date").

WHEREAS, the Company desires to employ the Executive and the Executive desires to be employed by the Company on the terms and conditions contained herein.

WHERAS, the Executive was previously employed by the Company as EVP Research and is currently classed as follows under the applicable collective bargaining agreement:

Service category: VI Years of service: 3

and based on this classification, the minimum wage under collective bargaining agreements and the basic wage for 40 hours per week as defined in §2 Sec 2 Nr. 9 AVRAG in connection with §2g AVRAG, excluding the monthly extra allowance for dirt work ("SEG") amount to EUR 4,396.90 gross per month.

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

1. Employment.

(a) Term. The term of this Agreement shall commence on the Effective Date and continue until terminated in accordance with the provisions hereof (the "Term").

Position and Duties. During the Term, the Executive shall serve as the Chief Scientific Officer of HOOKIPA Pharma Inc. ("Parent") and the Company, and shall have supervision and control over and responsibility for the day-to-day business and affairs of Parent and the Company and shall have such other powers and duties as may from time to time be prescribed by the Chief Executive Officer of Parent or the Board of Directors of Parent (the "Board"). The executive shall report to the Head of Research and Chief Medical Officer. The Executive shall devote his full working time and efforts to the business and affairs of the Company. Notwithstanding the foregoing, the Executive may serve on other boards of directors, with the approval of the Board, or engage in religious, charitable or other community activities as long as such services and activities are disclosed to the Board and do not materially interfere with the Executive's performance of his duties to the Company as provided in this Agreement.

(b) Place of Employment. The place of employment of the Executive is Vienna. The Company reserves the right to change the place of employment due to business reasons.

2. Compensation and Related Matters.

(a) Base Salary. During the Term, the Executive's initial annual base salary shall be gross EUR 237,609 (two hundred thirty seven thousand six hundred and nine Euros) payable in 14 equal monthly instalments. The Executive's base salary shall be re-determined

annually by the Compensation Committee of the Board (the "Compensation Committee"). The base salary in effect at any given time is referred to herein as "Base Salary." The Base Salary shall be payable in a manner that is consistent with the Company's usual payroll practices for senior executives.

(b) Incentive Compensation. During the Term, the Executive shall be eligible to receive cash incentive compensation as determined by the Compensation Committee from time to time. The Executive's target annual incentive compensation shall be 40 percent of his Base Salary.

(c) Expenses. The Executive shall be entitled to receive prompt reimbursement for all reasonable expenses incurred by him during the Term in performing services hereunder, in accordance with the policies and procedures then in effect and established by the Company for its senior executive officers.

(d) Other Benefits. During the Term, the Executive shall be eligible to participate in or receive benefits under the Company's employee benefit plans in effect from time to time, subject to the terms of such plans.

(e) Equity Compensation. The Executive shall also be eligible to participate in Parent's 2019 Stock Option and Incentive Plan on such terms and conditions as determined by the Compensation Committee.

(f) The compensation provided for in (a) to (e) compensates the Executive for all services performed by him under this Agreement also outside the regular working hours. It is well understood that the Executive will render such extra services, as well as additional services on Saturdays, Sundays and holidays if required.

(g) Vacations. During the Term, the Executive shall be entitled to vacation of 25 paid working days in each year. The Executive shall also be entitled to all paid holidays given by the Company to its executives. The Austrian Leave Entitlement Act (*Urlaubsgesetz*) applies in its currently valid version.

(h) Company phone and laptop. The Company agrees to provide the Executive with a company mobile phone and a company laptop at its own expense and agrees to pay for reasonable related costs incurred, for both business and reasonable private use. Upon termination of his employment, the Executive shall return his company laptop, company mobile phone and any other assets supplied by the Company in the course of his employment.

3. Termination. During the Term, the Executive's employment hereunder may be terminated without any breach of this Agreement under the following circumstances:

(a) Death. The Executive's employment hereunder shall terminate upon his death.

(b) Disability. For the termination of the Agreement in case of disability of the Executive, the Austrian Act on the Employment of Disabled Persons (*Behinderteneinstellungsgesetz*) as amended from time to time shall apply.

(c) Termination by Company for Cause. The Company may terminate the Executive's employment hereunder with immediate effect for Cause. For purposes of this Agreement, "Cause" shall mean in particular: (i) conduct by the Executive constituting a

material act of misconduct in connection with the performance of his duties, including, without limitation, misappropriation of funds or property of Parent or any of its subsidiaries or affiliates other than the occasional, customary and de minimis use of Parent or Company property for personal purposes; (ii) the commission by the Executive of any felony or a misdemeanor involving moral turpitude, deceit, dishonesty or fraud, or any conduct by the Executive that would reasonably be expected to result in material injury or reputational harm to Parent or any of its subsidiaries and affiliates if he were retained in his position; (iii) continued non- performance by the Executive of his duties hereunder (other than by reason of the Executive's physical or mental illness, incapacity or disability) which has continued for more than 30 days following written notice of such non-performance from the Board; (iv) a breach by the Executive of any of the provisions contained in Section 6 of this Agreement; (v) a material violation by the Executive of Parent or the Company's written employment policies, including without limitation, Parent or Company policies concerning substance abuse or sexual harassment; or (vi) failure to cooperate with a bona fide internal investigation or an investigation by regulatory or law enforcement authorities, after being instructed by Parent or the Company to cooperate, or the willful destruction or failure to preserve documents or other materials known to be relevant to such investigation or the inducement of others to fail to cooperate or to produce documents or other materials in connection with such investigation. Sec 27 of the Austrian Salaried Employees Act (*Angestelltengesetz*) applies in its currently valid version.

(d) Termination Without Cause. The Agreement, which runs for an indefinite period, may be terminated by either party at the end of each calendar month by giving six months' prior notice.

(e) Termination by the Executive for Cause. The Executive may terminate his employment hereunder for cause without respecting the notice period and notice date mentioned under (d) for the following reasons: (i) a material diminution in the Executive's responsibilities, authority or duties; (ii) a material diminution in the Executive's Base Salary except for across-the-board salary reductions based on the Company's financial performance similarly affecting all or substantially all senior management employees of the Company; (iii) a material change in the geographic location (outside of Austria) at which the Executive provides services to the Company; or (iv) the material breach of this Agreement by the Company. Sec 26 of the Austrian Salaried Employees Act (*Angestelltengesetz*) applies in its currently valid version.

(f) Notice of Termination. Except for termination as specified in Section 3(a), any termination of the Executive's employment by the Company or any such termination by the Executive shall be communicated by written Notice of Termination to the other party hereto.

(g) Date of Termination. "Date of Termination" shall mean: (i) if the Executive's employment is terminated by his death, the date of his death; (ii) if the Executive's employment is terminated on account of disability according to the Austrian Act on the Employment of Disabled Persons (*Behinderteneinstellungsgesetz*), the date respecting the notice period and notice date; (iii) if the Executive's employment is terminated by the Company or the Executive under Section 3(d), the date respecting the notice period and notice date; (iv) if the Executive's employment is terminated for cause by the Company the date Notice of Termination is given and received, and (v) if the Executive's employment is terminated by the Executive for cause the date Notice of Termination is given and received.

4. Compensation Upon Termination.

(a) Termination Generally. If the Executive's employment with the Company is terminated for any reason, the Company shall pay or provide to the Executive (or to his authorized representative or estate) any Base Salary earned until the Date of Termination and unpaid expense reimbursements (subject to, and in accordance with, Section 2(c) of this Agreement). Unused vacation that accrued until the Date of Termination will be paid according to the Austrian Leave Entitlement Act (*Urlaubsgesetz*). Any vested benefits the Executive may have under any employee benefit plan of the Company through the Date of Termination shall be paid and/or provided in accordance with the terms of such employee benefit plans (collectively, the "Accrued Benefit").

(b) Termination by the Company Without Cause or by the Executive with Cause. During the Term, if the Executive's employment is terminated by the Company without Cause as provided in Section 3(d), or the Executive terminates his employment for cause as provided in Section 3(e), then the Company shall pay the Executive his Accrued Benefit. In addition, subject to the Executive signing a separation agreement containing, among other provisions, a general release of claims in favor of the Company and related persons and entities, confidentiality, return of property and non-disparagement, in a form and manner satisfactory to the Company (the "Separation Agreement and Release") and the Separation Agreement and Release becoming irrevocable within the time period set forth in the Separation Agreement and Release, and in no event longer than 60 days after the Date of Termination:

(i) the Company shall pay the Executive an amount equal to 100 percent of the annual Executive's Base Salary (the "Severance Amount"); provided that the Severance Amount shall be reduced by the amount of any payment Executive receives in lieu of the notice period specified in Section 3(d) above. Notwithstanding the foregoing, if the Executive breaches any of the provisions contained in this Agreement or the Separation Agreement and Release, all payments of the Severance Amount shall immediately cease; and

(ii) continued participation at active employee rates in the benefit plans set forth under Section 2(d) for the 12-month period following the Date of Termination; and

(iii) the amounts payable under this Section 4(b) shall be paid out in 14 equal installments in accordance with the Company's payroll practice over 12 months commencing within 60 days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, the Severance Amount shall begin to be paid in the second calendar year by the last day of such 60-day period; provided, further, that the initial payment shall include a catch- up payment to cover amounts retroactive to the day immediately following the Date of Termination.

5. Change in Control Payment. The provisions of this Section 5 set forth certain terms of an agreement reached between the Executive and the Company regarding the Executive's rights and obligations upon the occurrence of a Change in Control. These provisions are intended to assure and encourage in advance the Executive's continued attention and dedication to his assigned duties and his objectivity during the pendency and after the occurrence of any such event. These provisions shall apply in lieu of, and expressly supersede, the provisions of Section 4(b) regarding severance pay and benefits upon a termination of

employment, if such termination of employment occurs within 12 months after the occurrence of the first event constituting a Change in Control. These provisions shall terminate and be of no further force or effect beginning 12 months after the occurrence of a Change in Control.

(a) Change in Control. During the Term, if within 12 months after a Change in Control, the Executive's employment is terminated by the Company without cause as provided in Section 3(d) or the Executive terminates his employment for cause as provided in Section 3(e), then, subject to the signing of the Separation Agreement and Release by the Executive and the Separation Agreement and Release becoming irrevocable, within the time period set forth in the Separation Agreement and Release, and in no event longer than 60 days after the Date of Termination,

(i) the Company shall pay the Executive a lump sum in cash in an amount equal to 1.0 times the sum of (A) the Executive's current annual Base Salary (or the Executive's annual Base Salary in effect immediately prior to the Change in Control, if higher) plus (B) the Executive's target annual incentive compensation; provided that any amounts payable under this Section 5(a)(i) shall be reduced by the amount of any payment Executive receives in lieu of the notice period specified in Section 3(d) above; and

(ii) continued participation at active employee rates in the benefit plans set forth under Section 2(d) for the 12-month period following the Date of Termination; and

(iii) notwithstanding anything to the contrary in any applicable option agreement or stock-based award agreement, all stock options and other stock-based awards held by the Executive shall immediately accelerate and become fully exercisable or non-forfeitable as of the Date of Termination; and

(iv) The amounts payable under this Section 5(a) shall be paid or commence to be paid within 60 days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, such payment shall be paid or commence to be paid in the second calendar year by the last day of such 60-day period.

(b) Definitions. For purposes of this Section 5, the following terms shall have the following meanings:

"Change in Control" shall mean any of the following:

(i) any "person," as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the "Act") (other than Parent, any of its subsidiaries, or any trustee, fiduciary or other person or entity holding securities under any employee benefit plan or trust of the Company or any of its subsidiaries), together with all "affiliates" and "associates" (as such terms are defined in Rule 12b-2 under the Act) of such person, shall become the "beneficial owner" (as such term is defined in Rule 13d-3 under the Act), directly or indirectly, of securities of Parent representing 50 percent or more of the combined voting power of Parent's then outstanding securities having the right to vote in an election of the Board ("Voting Securities") (in such case other than as a result of an acquisition of securities directly from Parent); or

(ii) the date a majority of the members of the Board is replaced during any 12-month period by directors whose appointment or election is not endorsed by a majority of the members of the Board before the date of the appointment or election; or

(iii) the consummation of (A) any consolidation or merger of Parent where the stockholders of Parent, immediately prior to the consolidation or merger, would not, immediately after the consolidation or merger, beneficially own (as such term is defined in Rule 13d-3 under the Act), directly or indirectly, shares representing in the aggregate more than 50 percent of the voting shares of Parent issuing cash or securities in the consolidation or merger (or of its ultimate parent corporation, if any), or (B) any sale or other transfer (in one transaction or a series of transactions contemplated or arranged by any party as a single plan) of all or substantially all of the assets of Parent.

Notwithstanding the foregoing, a "Change in Control" shall not be deemed to have occurred for purposes of the foregoing clause (i) solely as the result of an acquisition of securities by Parent which, by reducing the number of shares of Voting Securities outstanding, increases the proportionate number of Voting Securities beneficially owned by any person to 50 percent or more of the combined voting power of all of the then outstanding Voting Securities; provided, however, that if any person referred to in this sentence shall thereafter become the beneficial owner of any additional shares of Voting Securities (other than pursuant to a stock split, stock dividend, or similar transaction or as a result of an acquisition of securities directly from Parent) and immediately thereafter beneficially owns 50 percent or more of the combined voting power of all of the then outstanding Voting Securities, then a "Change in Control" shall be deemed to have occurred for purposes of the foregoing clause (i).

6. Confidential Information, Noncompetition and Cooperation.

(a) Confidential Information. As used in this Agreement, "Confidential Information" means information belonging to Parent or the Company which is of value to Parent or the Company in the course of conducting its business and the disclosure of which could result in a competitive or other disadvantage to Parent or the Company. Confidential Information includes, without limitation, financial information, reports, and forecasts; inventions, improvements and other intellectual property; trade secrets; know-how; designs, processes or formulae; software; market or sales information or plans; customer lists; and business plans, prospects and opportunities (such as possible acquisitions or dispositions of businesses or facilities) which have been discussed or considered by the management of Parent and/or the Company. Confidential Information includes information developed by the Executive in the course of the Executive's employment by the Company or function as an executive of Parent, as well as other information to which the Executive may have access in connection with the Executive's employment. Confidential Information also includes the confidential information of others with which Parent or the Company has a business relationship. Notwithstanding the foregoing, Confidential Information does not include information in the public domain, unless due to breach of the Executive's duties under Section 6 (b).

(b) Confidentiality. The Executive understands and agrees that the Executive's employment creates a relationship of confidence and trust between the Executive and the Company with respect to all Confidential Information. At all times, both during the Executive's employment with the Company and after its termination, the Executive will keep

in confidence and trust all such Confidential Information and will not use or disclose any such Confidential Information without the written consent of Parent, except as may be necessary in the ordinary course of performing the Executive's duties to the Company. For avoidance of doubt, nothing in this Agreement shall be interpreted or applied to prohibit the Executive from making any good faith report to any governmental agency or other governmental entity concerning any act or omission that the Executive reasonably believes constitutes a possible violation of law or making other disclosures that are protected under the anti-retaliation or whistleblower provisions of applicable law.

(c) Documents, Records, etc. All documents, records, data, apparatus, equipment and other physical property, whether or not pertaining to Confidential Information, which are furnished to the Executive by Parent or the Company or are produced by the Executive in connection with the Executive's employment will be and remain the sole property of Parent or the Company, as applicable. The Executive will return to the Company all such materials and property as and when requested by the Company. In any event, the Executive will return all such materials and property immediately upon termination of the Executive's employment for any reason. The Executive will not retain with the Executive any such material or property or any copies thereof after such termination.

(d) Noncompetition and Nonsolicitation. During the Executive's employment with the Company and for 12 months thereafter (subject to automatic extension for an additional period equal to the period of any breach of the covenants in this Section 6 (d), within the framework of Sec 7, 36 to 38 Austrian Salaried Employees Act (*Angestelltengesetz*), the Executive (i) will not, directly or indirectly, whether as owner, partner, shareholder, consultant, agent, employee, co-venturer or otherwise, engage, participate, assist or invest in any Competing Business (as hereinafter defined); (ii) will refrain from directly or indirectly employing, attempting to employ, recruiting or otherwise soliciting, inducing or influencing any person to leave employment with Parent or the Company (other than terminations of employment of subordinate employees undertaken in the course of the Executive's employment with the Company); and (iii) will refrain from soliciting or encouraging any customer or supplier to terminate or otherwise modify adversely its business relationship with Parent or the Company. The Executive understands that the restrictions set forth in this Section 6 (d) are intended to protect Parent's and the Company's interest in its Confidential Information and established employee, customer and supplier relationships and goodwill, and agrees that such restrictions are reasonable and appropriate for this purpose. For purposes of this Agreement, the term "Competing Business" shall mean a business conducted anywhere in the world which is primarily engaged in viral immunotherapy (for prophylactic or therapeutic use) in indication areas in which the Company is active at the time of termination of the Executive's employment. Notwithstanding the foregoing, the Executive may own (i) up to one percent (1%) of the outstanding stock of a publicly held corporation which constitutes or is affiliated with a Competing Business, and (ii) up to five percent (5%) in companies which do not directly compete with the Company.

(e) Third-Party Agreements and Rights. The Executive hereby confirms that the Executive is not bound by the terms of any agreement with any previous employer or other party which restricts in any way the Executive's use or disclosure of information or the Executive's engagement in any business. The Executive represents to the Company that the Executive's execution of this Agreement, the Executive's employment with the Company and the performance of the Executive's proposed duties for the Company will not violate any obligations the Executive may have to any such previous employer or other party. In the

Executive's work for the Company, the Executive will not disclose or make use of any information in violation of any agreements with or rights of any such previous employer or other party, and the Executive will not bring to the premises of the Company any copies or other tangible embodiments of non-public information belonging to or obtained from any such previous employment or other party.

(f) Litigation and Regulatory Cooperation. During and after the Executive's employment, the Executive shall cooperate fully with Parent or the Company in the defense or prosecution of any claims or actions now in existence or which may be brought in the future against or on behalf of Parent or the Company which relate to events or occurrences that transpired while the Executive was employed by the Company. The Executive's full cooperation in connection with such claims or actions shall include, but not be limited to, being available to meet with counsel to prepare for discovery or trial and to act as a witness on behalf of Parent or the Company at mutually convenient times. During and after the Executive's employment, the Executive also shall cooperate fully with Parent and the Company in connection with any investigation or review of any authority as any such investigation or review relates to events or occurrences that transpired while the Executive was employed by the Company. The Parent and the Company shall reimburse the Executive for any reasonable out-of-pocket expenses incurred in connection with the Executive's performance of obligations pursuant to this Section 6 (f).

(g) Injunction. The Executive agrees that it would be difficult to measure any damages caused to the Company which might result from any breach by the Executive of the promises set forth in this Section 6. In event of violation of the provision 6 (d) Noncompetition and Nonsolicitation, the Executive shall be obliged to pay the Company a contractual penalty in the amount of his last net monthly remuneration multiplied by six. The contractual penalty is due at the time of the violation of the contractual provision. The agreement to pay a contractual penalty does not eliminate any claim to cease and desist such actions or any other damage.

7. Inventions.

The Executive assigns to the Company the exclusive right of use and exploitation, unrestricted in time, territory and content, for all work output which is capable of copy right protection or of protection under trademark, patent, registered design and utility model and other intellectual property rights, which the Executive produces during the period of his relationship with the Company, insofar as they relate to his duties under this Agreement. The Executive is obliged to notify the Company immediately of any invention. The provisions of the Austrian Patent Act (*Patentgesetz*), as amended from time to time, apply to inventions made by the Executive.

The assignment of the use and exploitation rights includes the authorization to further modify and issue licenses and is fully compensated for by the remuneration set out in this Agreement. The Executive expressly waives all other rights as holder of copyright or other intellectual property rights in the work output, in particular the right to determining a name and to make the work accessible.

This applies mutatis mutandis to all inventions, discoveries, designs, developments and improvements that are not capable of copyright protection or of protection under a trademark, patent, registered design and/or utility model or any other intellectual property rights.

8. Data Protection.

The Executive acknowledges that the Company will process the Executive's personal data electronically in order to manage the employment relationship and fulfill legal obligations. Furthermore, the Company is obliged by law to transfer certain personal data of the Company to authorities or legal entities. Such communications are made only to the extent required by law.

In the context of his work for the Company as well as for Parent personal data (Art 4 Paragraph 1 General Data Protection Regulation) will become accessible to the Executive. He therefore is obliged to data protection and data security (Art 32 General Data Protection Regulation), whether data is processed automatically or not. He must always carefully store user IDs, passwords and other access authorizations available to him. He is obliged to follow the data protection rules in the currently applicable version (Art 5 General Data Protection Regulation) for each processing of personal data. Additionally, he must comply with all company regulations concerning the use of personal data in the currently applicable version. Personal data may only be processed for the legitimate performance of official duties.

The Executive is also obliged to maintain data secrecy in accordance with the data protection laws in force at the time, currently Sec 6 DSG 2018 (*Datenschutzgesetz*). He will treat all personal data as confidential for an unlimited period of time, even after the end of the employment relationship, and will keep it secret from everyone. This applies also to data regarding his executive function of Parent.

The Executive is prohibited from making personal data available to unauthorized bodies or third parties or from making it possible or easier for them to gain knowledge of it. He is also prohibited from using data for any purpose other than required for the lawful performance of his or her duties. He will only disclose accessible personal data as a result of his work, if expressly ordered to do so by the Company or its representative verbally or in writing. Only if there is a legal obligation for the processing of personal data by the Executive, an explicit order from the Company is not required.

The violation of data secrecy can make the Executive liable for damages and/or have consequences under Austrian labor law.

9. Section 409A. This Section 9 shall apply only to the extent the Executive is subject to U.S. income tax.

(a) Anything in this Agreement to the contrary notwithstanding, if at the time of the Executive’s separation from service within the meaning of Section 409A of the Code, the Company determines that the Executive is a “specified employee” within the meaning of Section 409A(a)(2)(B)(i) of the Code, then to the extent any payment or benefit that the Executive becomes entitled to under this Agreement on account of the Executive’s separation from service would be considered deferred compensation otherwise subject to the 20 percent additional tax imposed pursuant to Section 409A(a) of the Code as a result of the application of Section 409A(a)(2)(B)(i) of the Code, such payment shall not be payable and such benefit shall not be provided until the date that is the earlier of (A) six months and one day after the Executive’s separation from service, or (B) the Executive’s death. If any such delayed cash payment is otherwise payable on an installment basis, the first payment shall include a catch-up payment covering amounts that would otherwise have been paid during the six-month period but for the application of this provision, and the balance of the installments shall be payable in accordance with their original schedule.

(b) All in-kind benefits provided and expenses eligible for reimbursement under this Agreement shall be provided by the Company or incurred by the Executive during the time periods set forth in this Agreement. All reimbursements shall be paid as soon as administratively practicable, but in no event shall any reimbursement be paid after the last day of the taxable year following the taxable year in which the expense was incurred. The amount of in-kind benefits provided or reimbursable expenses incurred in one taxable year shall not affect the in-kind benefits to be provided or the expenses eligible for reimbursement in any other taxable year (except for any lifetime or other aggregate limitation applicable to medical expenses). Such right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit.

(c) To the extent that any payment or benefit described in this Agreement constitutes "non-qualified deferred compensation" under Section 409A of the Code, and to the extent that such payment or benefit is payable upon the Executive's termination of employment, then such payments or benefits shall be payable only upon the Executive's "separation from service." The determination of whether and when a separation from service has occurred shall be made in accordance with the presumptions set forth in Treasury Regulation Section 1.409A-1(h).

(d) The parties intend that this Agreement will be administered in accordance with Section 409A of the Code. To the extent that any provision of this Agreement is ambiguous as to its compliance with Section 409A of the Code, the provision shall be read in such a manner so that all payments hereunder comply with Section 409A of the Code. Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2). The parties agree that this Agreement may be amended, as reasonably requested by either party, and as may be necessary to fully comply with Section 409A of the Code and all related rules and regulations in order to preserve the payments and benefits provided hereunder without additional cost to either party.

(e) The Company makes no representation or warranty and shall have no liability to the Executive or any other person if any provisions of this Agreement are determined to constitute deferred compensation subject to Section 409A of the Code but do not satisfy an exemption from, or the conditions of, such Section.

10. Consent to Jurisdiction. The locally competent courts in Austria shall have jurisdiction over any disputes arising from this Agreement.

11. Integration. This Agreement constitutes the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior agreements between the parties concerning such subject matter. For the avoidance of doubt, the Executive shall remain entitled to all benefits, including holiday entitlement, accrued through the Executive's ongoing employment with the Company up until the effective date of this Agreement.

12. Withholding. All payments made by the Company to the Executive under this Agreement shall be net.

13. Successor to the Executive. This Agreement shall inure to the benefit of and be enforceable by the Executive's personal representatives, executors, administrators, heirs, distributees, devisees and legatees. In the event of the Executive's death after his termination of employment but prior to the completion by the Company of all payments due him under this Agreement, the Company shall continue such payments to the Executive's beneficiary

designated in writing to the Company prior to his death (or to his estate, if the Executive fails to make such designation).

14. Enforceability. If any portion or provision of this Agreement (including, without limitation, any portion or provision of any section of this Agreement) shall to any extent be declared illegal or unenforceable by a court of competent jurisdiction of Austria, then the remainder of this Agreement, or the application of such portion or provision in circumstances other than those as to which it is so declared illegal or unenforceable, shall not be affected thereby, and each portion and provision of this Agreement shall be valid and enforceable to the fullest extent permitted by law.

15. Waiver. No waiver of any provision hereof shall be effective unless made in writing and signed by the waiving party. The failure of any party to require the performance of any term or obligation of this Agreement, or the waiver by any party of any breach of this Agreement, shall not prevent any subsequent enforcement of such term or obligation or be deemed a waiver of any subsequent breach.

16. Notices. Any notices, requests, demands and other communications provided for by this Agreement shall be sufficient if in writing and delivered in person or sent by a nationally recognized overnight courier service or by registered or certified mail, postage prepaid, return receipt requested, to the Executive at the last address the Executive has filed in writing with the Company or, in the case of the Company, at its main offices, attention of the Board.

17. Amendment. This Agreement may be amended or modified only by a written instrument signed by the Executive and by a duly authorized representative of the Company. In addition, the Company requires approval by resolution of the Board. This provision shall also apply to any waiver of the requirement of written form.

18. Governing Law. This Agreement is exclusively governed by Austrian law.

19. Counterparts. This Agreement may be executed in any number of counterparts, each of which when so executed and delivered shall be taken to be an original; but such counterparts shall together constitute one and the same document.

20. Successor to Company. The Company shall require any successor (whether direct or indirect, by purchase, merger, consolidation or otherwise) to all or substantially all of the business or assets of the Company expressly to assume and agree to perform this Agreement to the same extent that the Company would be required to perform it if no succession had taken place. Failure of the Company to obtain an assumption of this Agreement at or prior to the effectiveness of any succession shall be a material breach of this Agreement.

21. D&O Insurance. The Parent has concluded a directors and officers insurance policy (D&O insurance) at its own expense for the benefit of the Executive, which includes civil and criminal defense coverage.

22. Gender Neutral. Wherever used herein, a pronoun in the masculine gender shall be considered as including the feminine gender unless the context clearly indicates otherwise.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties have executed this Agreement effective on the date and year first above written.

HOOKIPA Biotech GmbH.

By: /s/ Joern Aldag
Its: CEO

Date signature: 31 December, 2021

EXECUTIVE

/s/ Klaus Orlinger
Klaus Orlinger

Date signature: 14 March 2022

**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. 333-238311) and Form S-8 (Nos. 333-230995 and 333-237285) of HOOKIPA Pharma Inc. of our report dated March 24, 2022 relating to the financial statements, which appears in this Form 10-K.

Vienna, Austria
March 24, 2022

PwC Wirtschaftsprüfung GmbH
/s/ Stefano Mulas
German 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, Joern Aldag, 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: March 24, 2022

/s/ Joern Aldag
Joern Aldag
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, Reinhard Kandera, 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: March 24, 2022

/s/ Reinhard Kandera
Reinhard Kandera
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, 2021, 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: March 24, 2022

/s/ Joern Aldag
Joern Aldag
Chief Executive Officer
(Principal Executive Officer)

Date: March 24, 2022

/s/ Reinhard Kandera
Reinhard Kandera
Chief Financial Officer
(Principal Financial Officer)