Annual Report 2019

HOOKIPA PHARMA

HOOKIPA Key Highlights over last 12 months

› HOOKIPA completed its initial public offering (IPO), raising $84 million in gross proceeds, and commenced trading on the Nasdaq Global Select Market under the ticker symbol “HOOK”.

› Appointed Michael A. Kelly, an experienced financial and biotech executive with more than 25 years of industry experience, and David R. Kaufman, serving as Chief Medical Officer of The Bill & Melinda Gates Medical Research Institute, to HOOKIPA’s Board of Directors.

› HOOKIPA dosed the first patient in an open label, dose escalating Phase 1/2 clinical trial for HB-201, following FDA’s clearance of the IND submission. Preliminary results are expected in late 2020 or early 2021. We remain on track to file the HB-202 IND submission with the U.S. Food and Drug Administration in the first half of 2020. HOOKIPA’s second planned Phase 1/2 clinical trial will assess the safety and efficacy of the combination of HB-201 and HB-202 in HPV16+ cancers, with or without an approved checkpoint inhibitor. That trial is expected to commence later in 2020.

› Presented four posters during CICON Cancer Immunotherapy Conference highlighting the robust preclinical data and broad therapeutic potential for TheraT®-based immunotherapies.

› Extended its Executive team with the hiring of Christine D. Baker as Chief Business Officer (CBO) and Roman Necina, PhD, as Chief Technology Officer (CTO). These key hires have rounded out HOOKIPA’s corporate needs for strategic growth and future in-house manufacturing.

› Delivered an oral presentation at the American Transplant Congress (ATC) showing HB-101 CMV vaccine Phase 1 data. The Phase 1 data showed that the vaccine had a good safety profile, was well tolerated, and elicited strong humoral and cellular immune responses.

› HOOKIPA progressed in its collaboration with Gilead for novel arenavirus-based therapeutics intended to support functional cures for chronic Hepatitis B virus (HBV) and human immunodeficiency virus (HIV) infections. HOOKIPA received $6.0 million in milestone payments from Gilead for the delivery of research vectors and for advancing the programs towards clinical trials during 2019. Based on preclinical data generated to date, Gilead committed to preparations to advance the HBV and HIV vectors toward development, with the HBV development decision triggering a milestone payment of $4.0 million, which the Company received in early 2020.

Joern Aldag, CEO

“In 2019, HOOKIPA achieved its development progress and financial goals,” commented Joern Aldag, HOOKIPA’s Chief Executive Officer. “We dosed our first patient with Human Papilloma-virus-positive cancers in our first immuno-oncology clinical trial HB-201, and continued enrolling our Cytomegalovirus prophylaxis trial HB-101, and progressed our collaboration with Gilead for HBV and HIV successfully. We executed our Series D and IPO early in the year to fund our clinical trials beyond proof of concept. Preliminary data from these programs will be available during 2020 at major inflection time points as previously announced. While our lab operations continued during the pandemic, our ability to enroll patients in our clinical trials has been somewhat impacted, in particular for the CMV trial. As a consequence we have taken measures to adjust our cash burn and have sufficient cash to reach into 2022. As quarantine measures are loosened in Austria in May 2020 we expect to ramp up lab activities to full capacity. Our people are remarkable in doing everything under our control to deliver in the context of this situation.”

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, 2019

OR

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

Commission file number: 001-38869

HOOKIPA PHARMA INC.

(Exact name of registrant as specified in its charter)

Delaware	**81-5395687**
(State of Other Jurisdiction of incorporation or Organization)	(I.R.S. Employer Identification No.)
350 Fifth Avenue, 72nd Floor, Suite 7240 **New York, New York** (Address of principal executive offices)	**10118** (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 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 28, 2019 (the last business day of the Registrant's most recently completed second fiscal quarter) was approximately $100,500,000. 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 18, 2020 was 21,824,990 and 3,819,732 shares of Class A common stock outstanding, each $0.0001 par value per share.

Documents Incorporated by Reference

The registrant intends to file a proxy statement pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2019. Portions of such proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K.

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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., 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 VaxWave and TheraT technologies and the product candidates based on these technologies, the validity of intellectual property rights held by third parties, and our ability not to infringe, misappropriate or otherwise violate any third-party intellectual property rights;
- future agreements with third parties in connection with the commercialization of our product candidates and any other approved product;
- regulatory developments in the United States and foreign countries;
- competitive companies, 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 our trademarks and trade names, including, without limitation, VAXWAVE® and THERAT®, which are our property and are protected under applicable intellectual property laws. This 10-K report also 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.

PART I

Item 1. Business

Overview

We are a clinical-stage biopharmaceutical company developing a new class of immunotherapeutics targeting infectious diseases and cancers based on our proprietary arenavirus platform that is designed to reprogram the body's immune system. We are using our "off-the-shelf" technologies, VaxWave and TheraT, to elicit directly within patients a powerful and durable response of antigen-specific killer T cells and antibodies, thereby activating essential immune defenses against infectious diseases and cancers. We believe that our technologies can meaningfully leverage the human immune system for prophylactic and therapeutic purposes by eliciting killer T cell response levels previously not achieved by

other published immunotherapy approaches. Our lead infectious disease product candidate, HB-101, is in a randomized, double-blinded Phase 2 clinical trial in patients awaiting kidney transplantation from Cytomegalovirus, or CMV,-positive donors. Our lead oncology product candidates, HB-201 and HB-202, are in development for the treatment of Human Papillomavirus-positive cancers. In December 2019, we initiated the Phase 1/2 clinical trial for HB-201 and expect preliminary results in late 2020 or early 2021.We plan to file an investigational new drug, or IND, application with the U.S. Food and Drug Administration, or FDA, for HB-202 in first half 2020. We have also entered into a strategic partnership with Gilead Sciences, Inc., or Gilead, to develop infectious disease product candidates intended to support functional cures for chronic Hepatitis B virus, or HBV, and human immunodeficiency virus, or HIV, infections. Based on preclinical data generated to date, Gilead has committed to preparations to advance the HBV and HIV candidates toward development.

Our platform is based on engineering arenaviruses to carry and deliver virus-specific or tumor-specific genes directly in patients to antigen presenting cells, or APCs, such as dendritic cells, which are natural activators of killer T cells, also known as cytotoxic T cells, or CD8+ T cells. Arenaviruses have been used for decades as a preclinical tool to study CD8+ T cell responses. Our co-founder, Rolf Zinkernagel, was awarded a Nobel Prize in Physiology or Medicine for his arenavirus-based work on how CD8+ T cells recognize virus-infected cells. We believe that arenaviruses have several key advantages which give them the characteristics of an optimal antigen-specific immunotherapy, including:

- 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;
- ability to induce a robust antibody response to disease-specific target antigens;
- are not neutralized by vector-specific antibodies, thereby allowing for repeat administration that can boost immune response;
- do not require an adjuvant to stimulate the immune system; and
- have been observed to be well tolerated in preclinical studies and clinical trials.

We believe we are the first to reengineer arenaviruses for therapeutic purposes. We have created two technologies capable of delivering disease-specific antigens for the prevention and treatment of disease. Our first technology, VaxWave, is a replication-defective arenavirus which induces a strong immune response for prophylactic use against infectious disease. Our second technology, TheraT, is a replication-attenuated arenavirus which produces an even more powerful immune response that we believe is more appropriate for use in oncology. In preclinical studies, our TheraT 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 antigen target of our choice 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 VaxWave technology and exclusive and joint rights in patent applications related to our TheraT technology. These platform technologies can be used with a broad spectrum of antigens in therapeutic applications in immunotherapy ranging from infectious diseases to oncology. We believe the breadth and depth of our intellectual property 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 antigen-encoding genes 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 "off-the-shelf" immunotherapy is simpler, more straightforward and cost effective to manufacture and administer than CAR-T cells or other patient-derived cellular approaches.

Our lead product candidate in infectious diseases, utilizing VaxWave technology, is HB-101, which is being developed for the prevention of pathology associated with CMV infections. A majority of the worldwide human population is latently infected with CMV and can transmit the infection through bodily fluids. While infection in immunocompetent persons typically presents as mild or asymptomatic, CMV remains a major cause of morbidity and mortality in persons with a compromised immune system and in patients undergoing solid organ or hematopoietic stem cell transplants. 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 disease, such as hepatitis, pneumonitis, gastroenteritis and retinitis, and can result in transplant rejection and death. In this high risk patient group, approximately 80% of kidney transplant recipients develop active CMV infections. CMV disease 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 delivers two clinically validated antigens, phosphoprotein 65, or pp65, to induce CMV-specific CD8+ T cells and glycoprotein B, or gB, to elicit CMV-neutralizing antibodies. In our Phase 1 clinical trial, HB-101 was well tolerated and elicited a 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. In the fourth quarter of 2018, we commenced a 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 in the target patient population, and to gain further insights that will inform Phase 3 trial design, we added a new cohort of CMV-positive recipients awaiting kidney transplantation from CMV-positive or -negative donors to the trial in early 2020. We believe that the addition of CMV-positive patients will help to expedite trial recruitment and we expect full enrollment of the trial to be completed by the end of 2020. We expect safety and immunogenicity data from approximately one-third of the total 150 patients to be enrolled in this trial in the first half of 2020, and preliminary efficacy data to follow in the late second half of 2020.

We are developing our lead oncology product candidates, HB-201 and HB-202, both utilizing TheraT technology, for cancers caused by Human Papillomavirus, or HPV. These cancers account for approximately 5% of the total worldwide cancer 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. Tumors caused by HPV are referred to as HPV-positive tumors, or 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 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.

HB-201 utilizes our TheraT replication-attenuated viral vector technology to target E6 and E7 proteins on HPV16+ cancer cells. In preclinical studies, HB-201 as a monotherapy was effective at suppressing 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 re-challenge. Based on these preliminary results, we believe that treating patients with HB-201 has the potential to both control metastatic disease and prevent relapse. 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. We

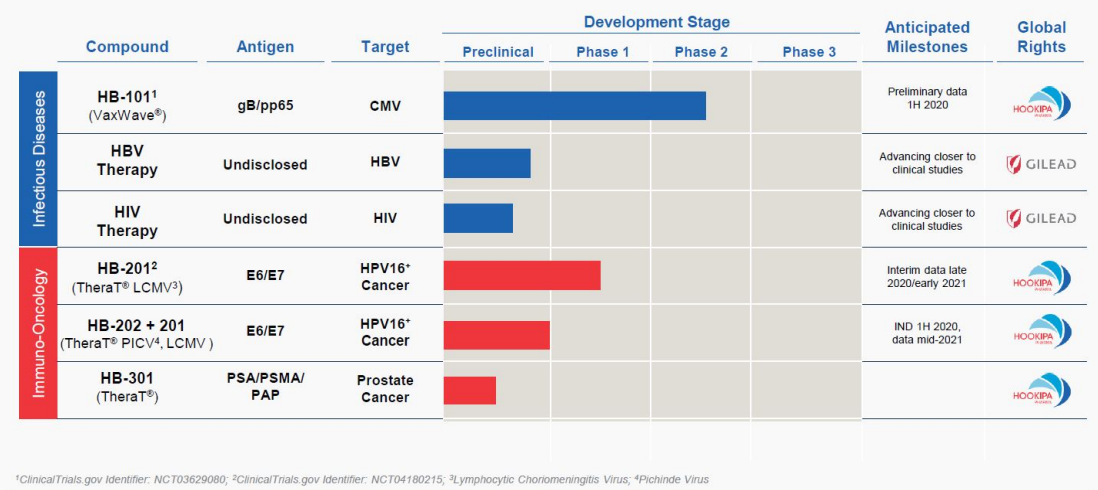
initiated a Phase 1/2 clinical trial for HB-201 in December 2019 to assess its safety and efficacy, both as a monotherapy and in combination with an approved checkpoint inhibitor. Our second planned Phase 1/2 clinical trial will assess the safety and efficacy of the combination of HB-201 and HB-202 in HPV16+ cancers, with or without an approved checkpoint inhibitor. HB-202 is also based on our TheraT technology and similarly targets E6 and E7 of HPV16+ tumors, but uses a different arenavirus than HB-201. We believe that our preclinical studies demonstrate that the combination of HB-201 and HB-202 results in a synergistic increase in E7 immunogenicity as compared to either HB-201 or HB-202 alone. Our goal is to establish the safety of this combination approach and its superiority over monotherapy.

In June 2018, we partnered with Gilead a world leader in innovative therapies against infectious diseases, to develop arenavirus based therapeutics to HBV and HIV infections. We received a one-time upfront payment of $10.0 million upon entering into the agreement. We are also eligible to receive milestone payments based upon the achievement of specified development, regulatory, and commercial milestones potentially amounting to approximately $400 million, as well as tiered royalties ranging from high single-digit to mid-teens percentage on net sales. During 2019, we received $6.0 million in milestone payments from Gilead for the delivery of research vectors and advancing the programs closer to clinical trials. Based on preclinical data generated to date, Gilead committed to preparations to advance the HBV and HIV vectors toward development in December 2019, with the HBV development decision triggering an additional milestone payment of $4.0 million, which we received in February 2020. To enable the development activities and expanded research programs, Gilead agreed to reserve manufacturing capacity and expand the reimbursement for our resources allocated to the Gilead collaboration.

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 infectious diseases and cancers:



We are also pursuing the development "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 issue.

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 non-specific 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 and several immunotherapy products have been approved by the FDA, the European Medicines Agency, or the 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. 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 co-founder, Rolf Zinkernagel, was awarded a Nobel Prize in Physiology or Medicine for his arenavirus-based work on how CD8+ T cells recognize virus-infected cells.

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

- have the ability to induce a robust CD8+ T cell response by directly targeting and activating APCs, such as dendritic cells, which are the most efficient antigen-presenting cells of the body;
- have the ability to induce a robust antibody response to disease-specific target antigens;
- are not neutralized by vector-specific antibodies, thereby allowing for repeat administration that can further boost immune response;
- 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: VaxWave, a replication-defective vector, and TheraT, a replication-competent but attenuated vector.

Our VaxWave and TheraT technologies utilize both lymphocytic choriomeningitis, or LCMV, and Pichinde virus, or 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 non-specific 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.

VaxWave Overview

Our proprietary VaxWave technology disables arenavirus replication by substituting one of its four structural genes with the gene for a desired antigen. The modified, replication-defective 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 dendritic cells in the body.

Advantages of VaxWave

Based on the preclinical and clinical data that we have generated to date, we believe our VaxWave technology supports the benefits of our arenavirus platform approach. Specifically, in preclinical studies and clinical trials VaxWave 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 VaxWave technology is designed to induce a robust CD8+ T cell and pathogen neutralizing response to fight disease. We believe our

technology results in an immunotherapeutic approach with potential for greater potency than existing prophylactic treatments.

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

Lack of Vector-specific Neutralizing Antibodies. Our VaxWave technology does not generate clinically meaningful vector-specific neutralizing antibodies, allowing for repeat administration which can further boost the immune response.

TheraT Overview

Our proprietary TheraT technology is replication-competent but attenuated. The intent of designing a replicating vector was to allow it to retain all of the beneficial properties of VaxWave but to induce an even more robust immune response. Unlike naturally occurring arenaviruses which have two genomic segments, our TheraT 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 attenuated.

Advantages of TheraT

Based on the preclinical data that we have generated to date, we believe our TheraT technology supports the benefits of our arenavirus platform approach. In addition to having the advantages of VaxWave technology, in preclinical studies TheraT has shown the following additional benefits:

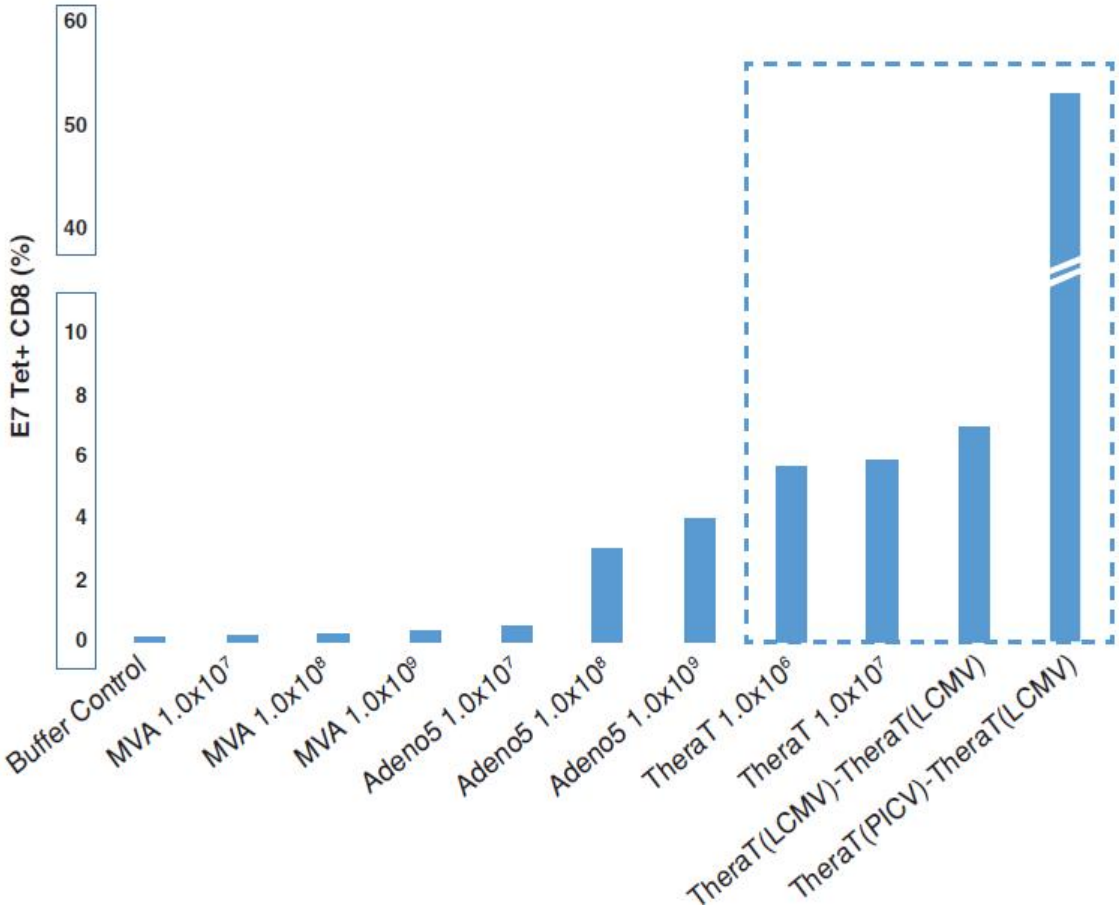
Quantitatively; Even More Robust CD8+ T Cell Response. Our TheraT technology is designed to induce a CD8+ T cell response that directs more than 50% of a body's T cells, which is approximately ten times greater than the response induced by VaxWave, to focus on a single target of choice. We believe our technology results in an immunotherapeutic approach with potential for greater potency than existing therapeutic treatments.

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

The additional benefits of TheraT are attributable to its 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 TheraT-induced CD8+ T cells do not need the addition of commonly used checkpoint inhibitors to function at optimal potency, as they are able to establish long-lasting interactions with their target cells inside solid tissues and kill them.

To demonstrate the superior properties of our approach, we performed a head-to-head comparison in mice of our TheraT LCMV and PICV E7 constructs versus modified vaccinia virus Ankara, or MVA, and adenovirus 5, or Adeno5, each expressing E7 antigens for their ability to induce E7-specific CD8+ T cells. As shown below, our TheraT 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 TheraT(PICV) followed by administration of TheraT(LCMV) 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 TheraT PICV and LCMV constructs to direct up to 50% of a body's T cells to focus on a single target of choice.

VaxWave Preclinical Data

We believe our preclinical data support the development of VaxWave for prophylactic and therapeutic uses for infectious disease.

HIV Model

We conducted a preclinical study in a monkey model of HIV infection using simian immunodeficiency virus, or SIV. We treated ten monkeys using 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-Env prophylactic immunization on its own was shown not to prevent SIV infection. We then boosted the monkeys eight weeks later with an LCMV vector encoding SIV Env. We also treated ten monkeys 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 VaxWave(LCMV)-Env vaccination resulted in over 70% of monkeys being SIV free at the end of the trial, as compared to less than 20% in the null group.

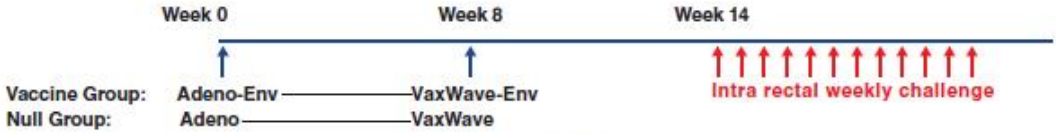


Figure 1

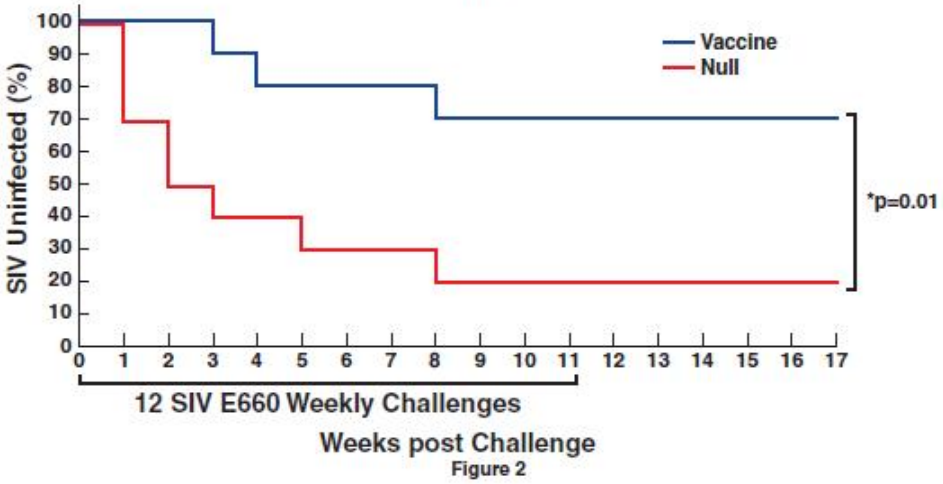


Figure 2

* **A p-value of 0.05 or less represents statistical significance, meaning that there is a less than 1-in-20 likelihood that the observed results occurred by chance. A p-value of 0.01 or less means that there is a less than 1-in-100 likelihood that the observed results occurred by chance.**

HBV Model

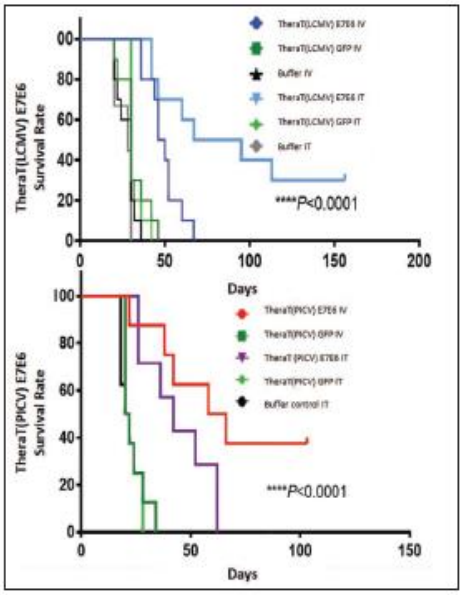
In addition to the HIV model, we explored the ability of our VaxWave vectors to induce immune responses against hepatitis B core, HBc, and hepatitis B surface, HBs, antigens. In our study, we observed that VaxWave(LCMV) expressing both HBc and HBs was able to generate significant CD8+ T cell responses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

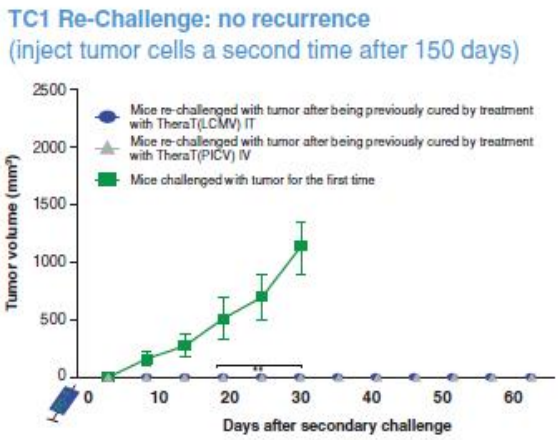
We believe that the combination of our HIV and HBV preclinical and subsequent VaxWave clinical data facilitated our Gilead collaboration.

TheraT Preclinical Data

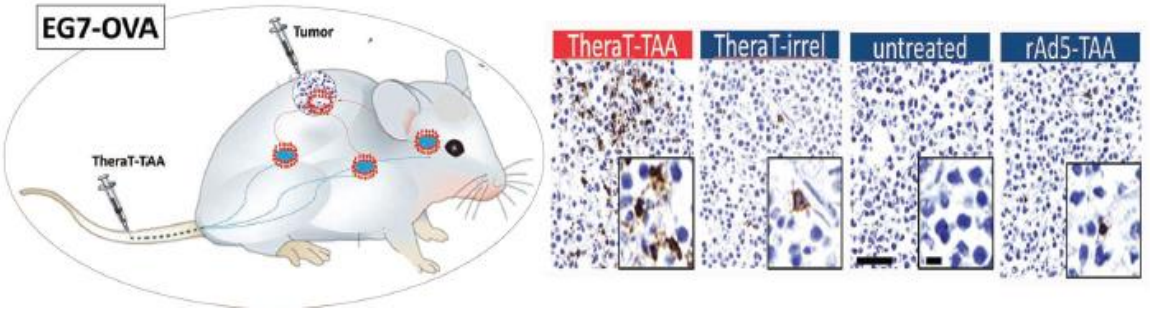
We have conducted several preclinical studies assessing the efficacy of our TheraT technology, for both LCMV and PICV constructs, carrying the HPV specific E7/E6 fusion protein through intravenous, or IV, and intratumoral, or IT, administration. Mice treated with the replication-attenuated TheraT vectors showed no evidence of toxicity. In a mouse model of HPV-induced cancer (TC1), we observed that a single intravenous administration of TheraT(LCMV) significantly suppressed and delayed tumor growth while a single intratumoral administration of TheraT(LCMV) eliminated the tumor in approximately half of the mice (top left panel). Intravenous administration of TheraT(PICV) eliminated the tumor in approximately half of the mice, by the same definition, while intratumoral administration of

TheraT(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, TheraT 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).



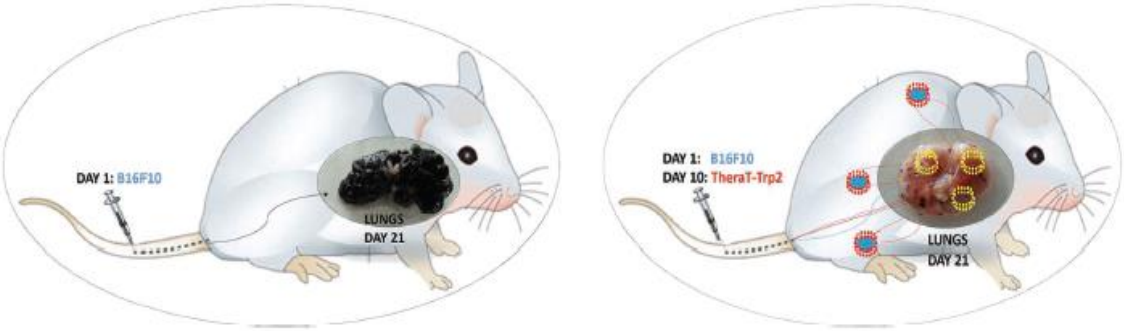


We have also performed "tracking" experiments wherein we observed that while our intravenous TheraT vectors travel to APCs, such as dendritic cells, the reprogrammed antigen CD8+ T cells travel to tumors. We illustrated this in an EG7-OVA model, which analyzed subcutaneous tumors for the presence of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

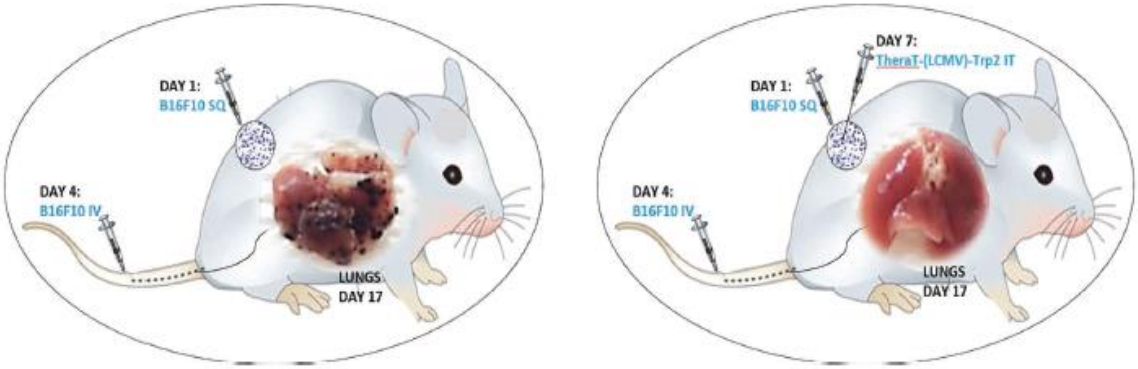


We observed similar results in a more aggressive B16F10 melanoma mouse model. In this experiment B16F10 malignant cells were introduced into the tail vein of mice, resulting in lung metastases within three weeks. Ten days after the introduction of B16F10, a TheraT vector expressing Trp2, a melanoma antigen,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



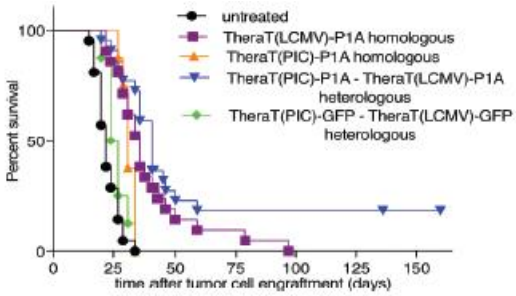
When we combined the above two experiments, by initially introducing B16F10 malignant cells subcutaneously, and then intravenously, we achieved both a localized subcutaneous tumor and metastatic lung lesions. Subsequent administration of our intratumoral TheraT vector demonstrated both a localized response,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

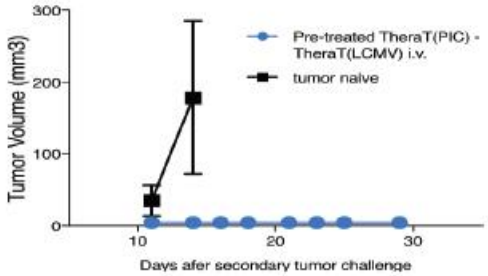


Advantages of sequential administration of TheraT(PICV) and TheraT(LCMV)

We have observed increased anti-tumor activity and survival of animals that received sequential administration of TheraT(PICV) and TheraT(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 TheraT(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 TheraT(PICV) P1A followed by a second dose with a different arenavirus, TheraT(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 re-challenge (right panel below).





Our Product Candidates

HB-101, a Prophylactic Vaccine for Cytomegalovirus

HB-101 is a VaxWave product candidate 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 VaxWave increased in a statistically significant manner. 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 to date, and to gain further insights that will inform Phase 3 trial design, we added a new cohort of CMV-positive recipients awaiting kidney transplantation from CMV-positive or -negative donors to the trial in early 2020. We amended the IND filing accordingly in January 2020. We believe that the addition of CMV-positive patients will also help to expedite trial recruitment. We expect to report on the safety data of approximately one-third of the total 150 patients to be enrolled in the first half of 2020. The safety monitoring period will include the period between the first dose and the date of transplantation. We also expect to report on the immunogenicity data for approximately one-quarter of the total patients to be enrolled in the first half of 2020. Importantly, in addition to surrogate immunogenicity data, we expect to report preliminary data focusing on the effects on viremia in the late second half of 2020. We intend to pursue regulatory approval for HB-101 for the prevention of CMV in all solid organ transplants regardless of CMV status of the recipient. In the future, and in the event of successful proof of concept of HB-101 in the Phase 2 clinical trial, we may pursue additional indications such as stem cell transplantation and congenital CMV infection.

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 lead to reactivation of latent virus. Based on a

recent 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 post-transplant 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 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 VaxWave-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 VaxWave(LCMV)-based vectors:

(i) one vector expresses the gene encoding the CMV 65 kD pp65 protein; and

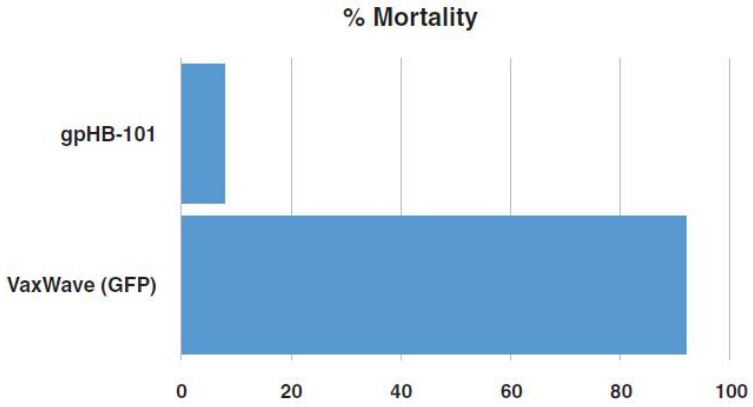
(ii) another vector expresses the gene encoding the CMV gB protein.

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, non-pregnant 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 (gpHB-101) had a statistically significant ($p<0.0001$) lower mortality rate at birth compared to those born to females who had only received a VaxWave carrying an irrelevant antigen, labeled as GFP in the figure below. CMV-positive pups born to mothers that received gpHB-101 vaccination also gained weight more rapidly and had improved survival rates as compared to those born to mothers vaccinated with placebo.



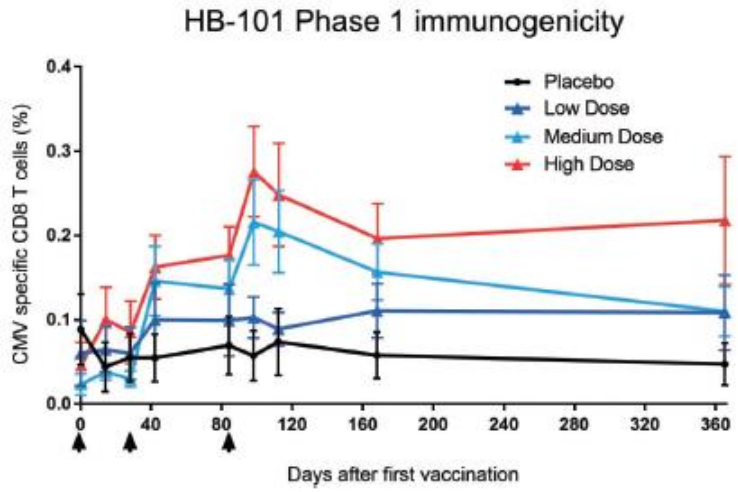
HB-101 Phase 1 (H-100-001) Clinical Results

We conducted a placebo-controlled, randomized double-blinded dose escalating Phase 1 clinical trial of HB-101 to assess the vaccine's safety and immunogenicity. In this trial, 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.

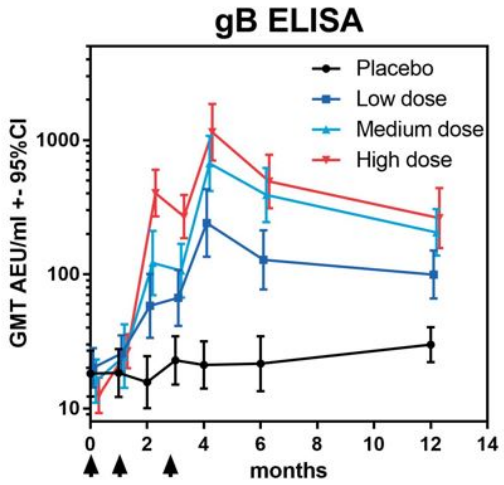
We observed that HB-101 was well-tolerated with no dose limiting toxicities and no serious adverse events. Symptoms by volunteers were of mild to moderate intensity and 93.5% of reported symptoms were of short duration (1-8 days). The maximum duration of any symptom was 10 days. Pain at the injection 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.

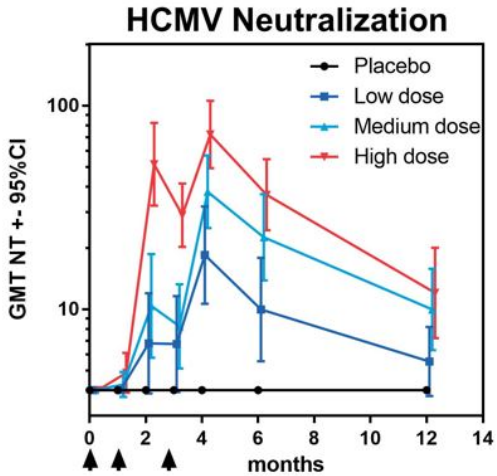
In addition, HB-101 elicited a strong, dose-dependent, and durable response as measured by the frequency of pp65-specific interferon-gamma, or IFNγ, producing CD8+ T cells. Each administration of HB-101, as depicted by the black arrows in the figure below, resulted in an increase in IFNγ producing CD8+ 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 twelve-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 Clinical Development Plan

In the fourth quarter of 2018, pursuant to an IND filed by us with the FDA in July 2018, which we amended in January 2020, we initiated a randomized, double-blinded Phase 2 trial 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 tolerability profile in the target patient population to 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 -negative donors to the trial in early 2020. We believe that the addition of CMV-positive patients will also help to expedite trial recruitment. We expect to report on the tolerability data for approximately one-third of the total 150 patients to be enrolled in the first half of 2020. The immunogenicity data set will contain both CMV specific antibody and CMV specific CD8+ T cell responses. The data analysis has been designed to help us evaluate any interpatient effect (i.e., between those patients that received placebo compared to those that received vaccine) as well as whether there is an intrapatient effect (i.e., an increase over baseline in those patients that receive vaccine). Also, the immunogenicity analysis is designed to determine whether there is a significant vector-neutralizing antibody response that is induced by repeat administration. Importantly, in addition to surrogate immunogenicity data, we expect to report preliminary data focusing on the effects on viremia in the late second half of 2020.

We plan to enroll a total of 150 patients, in three treatment arms.

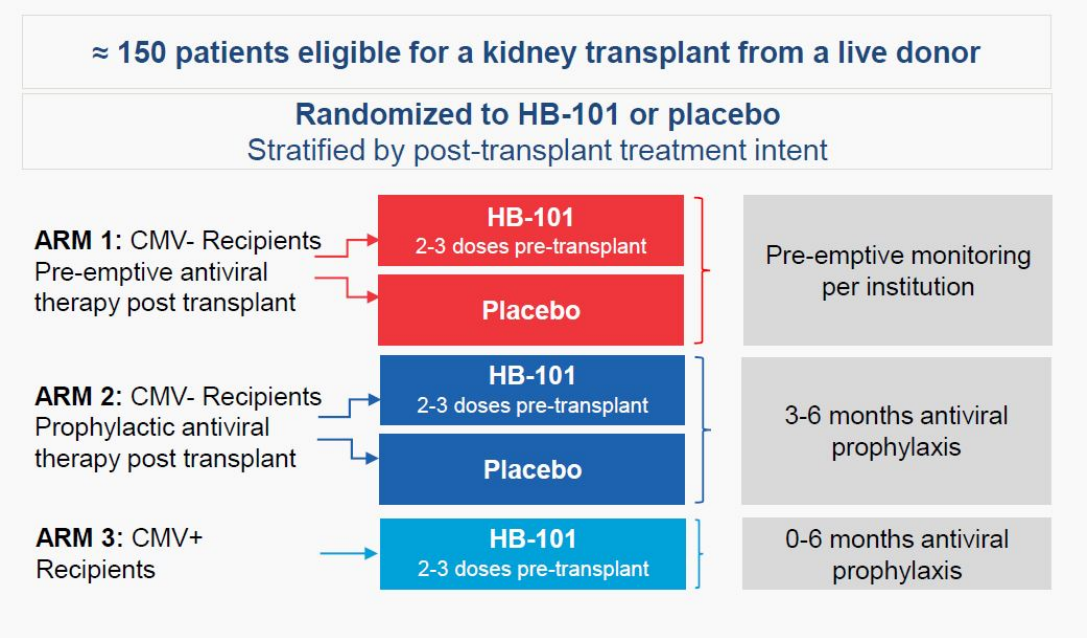
1. Arm 1 (CMV-negative, pre-emptive antivirals): CMV-negative patients are being randomized 2:1 to either receive two to three administrations of HB-101 or placebo prior to transplant and then treated with standard preemptive anti-viral therapy post-transplant.

2. Arm 2 (CMV-negative, prophylactic antivirals): CMV-negative patients are being 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 anti-viral prophylaxis therapy post-transplant.

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

Patients will be 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.



We dosed the first patient in our Phase 2 trial for HB-101 in December 2018.

HB-200 Program for the Treatment of HPV16+ Cancers

We are currently developing two immunotherapeutics targeting HPV16+ cancers.

HB-201 is a TheraT(LCMV)-based product candidate expressing the E6/E7 fusion protein specific to HPV16+ cells and being developed for the treatment of HPV16+ cancers, including head and neck squamous cell carcinoma, or HNSCC, cervical and anal cancer. HB-201 is being studied as both monotherapy and in combination with a checkpoint inhibitor.

HB-202 is a TheraT(PICV)-based product candidate expressing the E6/E7 fusion protein and also being developed for the treatment of HPV16+ cancers, including HNSCC, cervical and anal cancer. HB-202 will be studied in combination with HB-201, both with and without a checkpoint inhibitor. Our preclinical data support the concept that the combination of two different TheraT constructs based on different arenaviruses, but carrying the same tumor antigen, results in an exponentially more robust immune response with potential improvements in anti-tumor activity.

We initiated a Phase 1/2 clinical trial for HB-201 in patients with treatment-refractory HPV16+ cancers in the second half of 2019. We expect preliminary results in late 2020 or early 2021. We will also combine HB-201 with a checkpoint inhibitor and plan to submit an IND for a Phase 1/2 trial combining HB-201 and HB-202, both with and without an approved checkpoint inhibitor, in patients with treatment-refractory HPV16+ cancers in first half 2020.

HPV-Positive Cancers

HPV is estimated to cause about 5% of cancers worldwide, including approximately 99% of cervical cancers, 25% 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 fifth 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 13,700 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 a combination of chemotherapy, radiation and surgery. These treatments are associated with acute and long-term effects including mucositis, swallowing dysfunction, dry mouth, and dental problems. The overall survival rate 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 with high levels of CD8+ T cells in tumors have a much better prognosis. In many cases, the survival rate of these patients is more than double that of patients with lower levels of CD8+ T cells.

We believe that evaluating the potential of our product candidates for the treatment of HPV16+ HNSCC is a rational clinical development strategy as there is precedent data supporting the efficacy of immunotherapy in this patient population. In developed countries, HPV16+ HNSCC accounts for an estimated 13% of the approximately 120,000 annual cases of HPV+ cancers. In contrast, in less developed countries, HPV+ HNSCC accounts for just 1% of 490,000 annual HPV-related cancer cases. 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 TheraT-based product candidates expressing a non-oncogenic but highly antigenic E6/E7 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 monotherapy has the potential to provide therapeutic benefit to patients across the broader HPV16+ cancer setting. We have observed strong immunogenicity and robust anti-tumor activity in mouse models for HB-201 alone as well as for the sequential administration of HB-201 and HB-202.

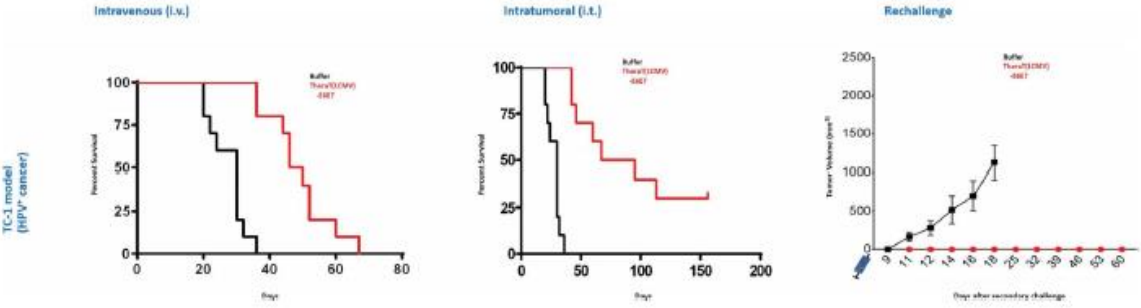
Relevance of E6 and E7 as Tumor Antigens

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.

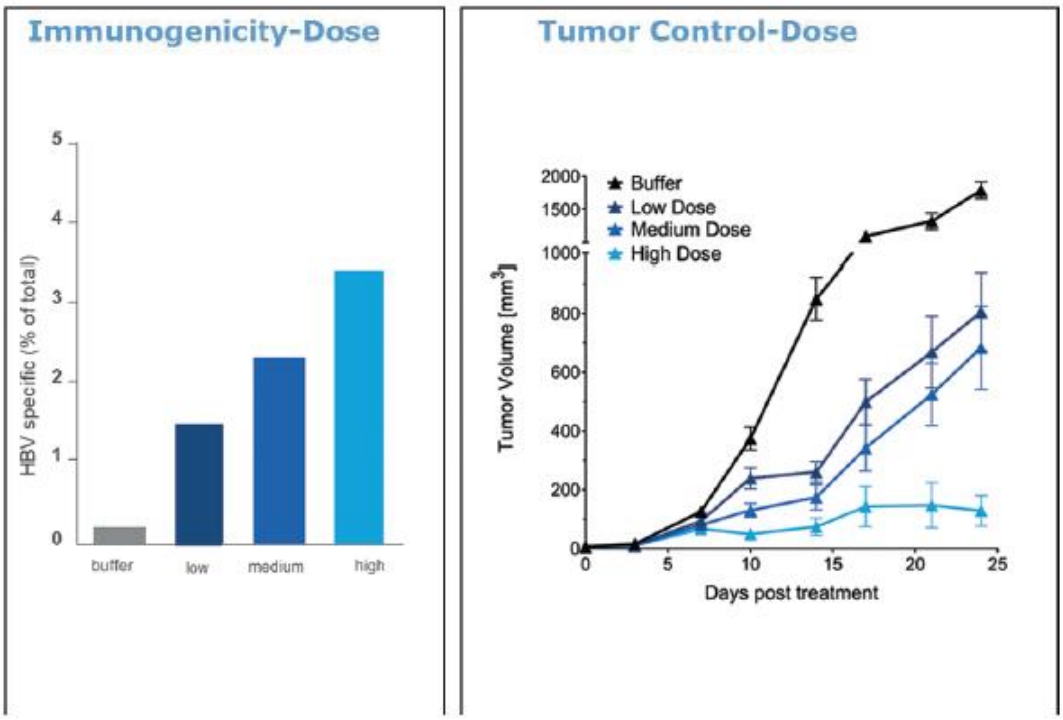
Profiling of immune cells isolated from patients with HPV16+ tumors has identified E6- and E7-specific T cells, indicating that the E6 and E7 proteins are immunogenic, meaning that they trigger antigen-specific CD8+ T cell responses. Because both E6 and E7 are highly expressed in tumor cells and are 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 re-challenged 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 anti-tumor activity, as depicted in the right side of the figure below. We believe that this indicates that anti-tumor activity is directly linked to immunogenicity. Specifically, low doses of HB-201 containing as few as 100 replication-competent virus, or 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-201 Clinical Trial

We initiated and dosed the first patient in an open label, dose escalating Phase 1/2 clinical trial in December 2019 to evaluate HB-201 in HPV16+ cancers, alone and in combination with an approved checkpoint inhibitor.

We expect to enroll 100 patients in total for this trial with 20 patients in each dose escalation and expansion group, respectively. The trial will consist of two dose escalation groups in Phase 1 and three dose expansion groups in Phase 2.

For Phase 1 dose escalation, the patient population will be divided into two groups:

- Group 1 (intravenous, or IV, administration HB-201): patients with HNSCC HPV16+ cancers with tumor progression or recurrence on standard of care therapy, or for whom standard of care therapy is contraindicated.

- Group 2 (intratumoral, or IT, administration of HB-201 followed by IV administration of HB-201): patients with cervical, anal, or other HPV16+ cancers with a safe and accessible tumor site amenable for IT administration who had tumor progression or recurrence on standard of care therapy or for whom standard of care therapy is contraindicated.

For Phase 2 dose expansion, the patient population will be divided into three arms:

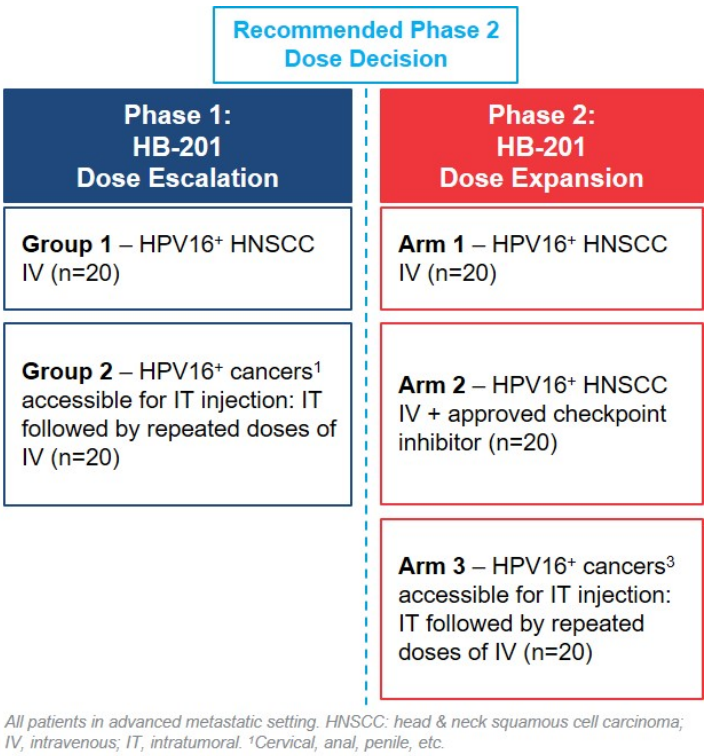
- Arm 1 (IV administration of HB-201): patients with HNSCC HPV16+ cancers with tumor progression or recurrence on standard of care therapy, or for whom standard of care therapy is contraindicated.

- Arm 2 (IV administration of HB-201 with an approved checkpoint inhibitor): patients with HNSCC HPV16+ cancers with tumor progression or recurrence on standard of care therapy, or for whom standard of care therapy is contraindicated.

- Arm 3 (IT administration of HB-201 followed by IV administration of HB-201): patients with cervical, anal, or other HPV16+ cancers with a safe and accessible tumor site amenable for IT administration who had tumor progression or recurrence on standard of care therapy or for whom standard of care therapy is contraindicated.

The primary endpoint of the Phase 1 portion of this trial will be to evaluate safety and tolerability to determine the recommended dose for the Phase 2 portion of the trial. Secondary endpoints will evaluate anti-tumor activity and

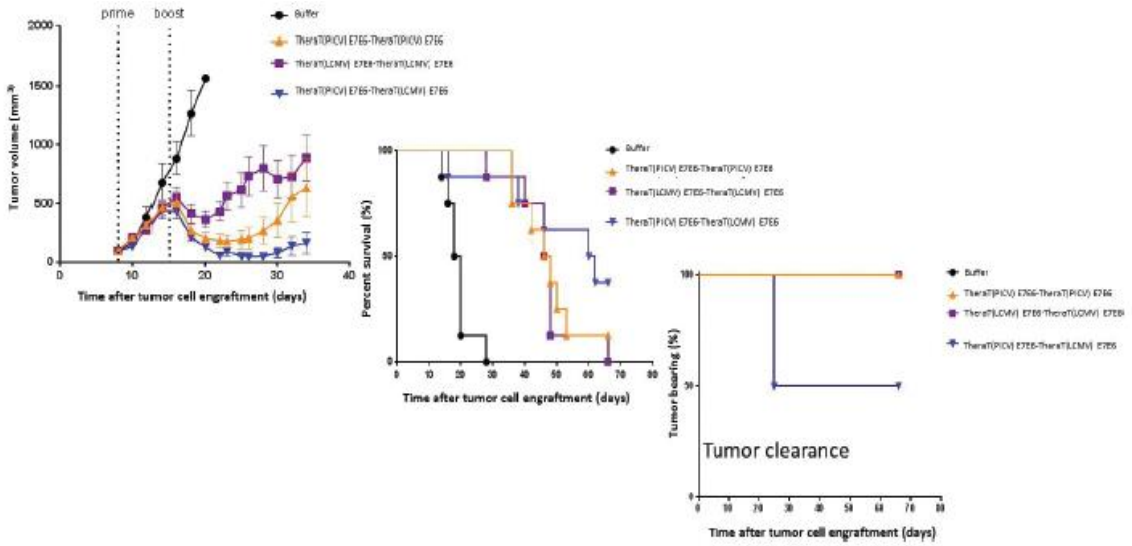
immunogenicity. The Phase 2 groups of the trial will also investigate the efficacy of HB-201 alone and in combination with an approved checkpoint inhibitor. We expect preliminary data to be available in late 2020 or early 2021.



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.



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 the repeat administration of either one alone.

HB-201 and HB-202 Clinical Plans

Based on preclinical data observed with the sequential administration of HB-201 and HB-202, we intend to commence an open label dose escalating Phase 1/2 trial to evaluate the HB-201/HB-202 combination alone and in combination with an approved checkpoint inhibitor. Based on our preclinical experience, we anticipate that this combination approach may deliver significantly more robust anti-tumor activity in patients than an approved checkpoint inhibitor alone. The design of the trial will be the same as that of the single agent trial for HB-201. The primary endpoint of the Phase 1 portion of this trial will be to evaluate safety and tolerability to determine the recommended dose for the Phase 2 portion of the trial. Secondary endpoints will evaluate anti-tumor activity and immunogenicity. We anticipate submitting the IND in first half 2020 with preliminary data expected to be available in mid-2021. Subsequent trials will also investigate the potential of the sequential administration of HB-201 and HB-202 in combination with an approved checkpoint inhibitor.

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 TheraT 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.

Additional Product Opportunities: Tumor Self-Antigens

Our HB-101, HB-201 and HB-202 programs target viral antigens associated with virally-induced tumors. 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, non-viral antigenic proteins that are highly overexpressed in solid tumors or only minimally expressed in normal cells. Because these self-antigens are found in certain normal cells as well as tumor cells, the immune system

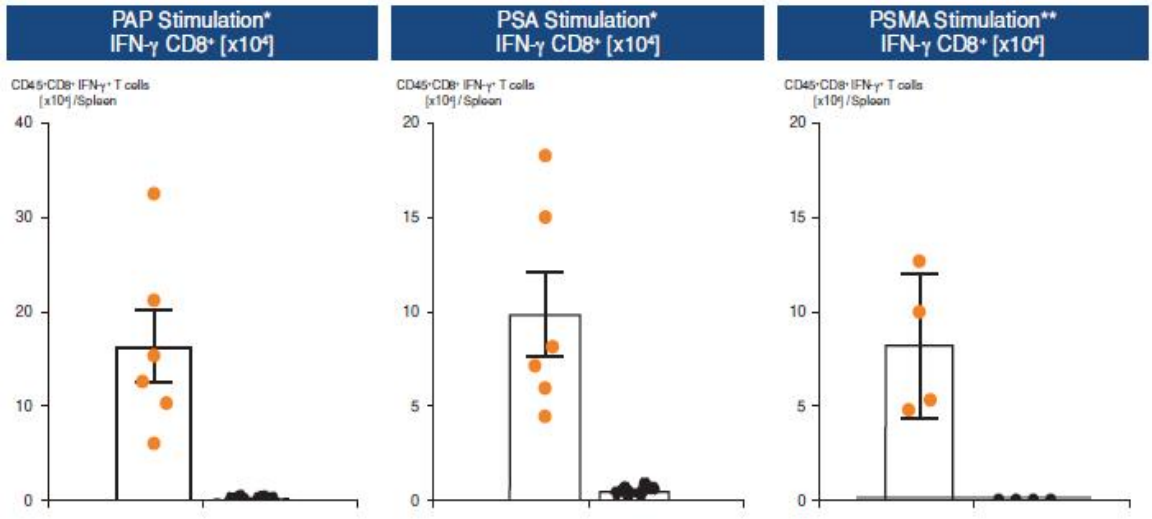
does not typically recognize them as foreign proteins and does not respond to them. This protection of self-antigens from immune system attack is known as immune tolerance. The results obtained by earlier-generation marketed products such as sipuleucel-T, developed as Provenge by Dendreon Pharmaceuticals, 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 anti-tumor response.

HB-301 in Prostate Cancer

We are developing our most advanced self-antigen project in this area, HB-301, as a TheraT product candidate 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-301 targets three of these antigens: prostatic acid phosphatase, or PAP, prostate specific antigen, or PSA, and prostate-specific membrane antigen, or 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 a complex, patient-specific therapeutic manufacturing process involving isolating cells from patients, loading them *ex vivo* with tumor antigens and then re-administering the cells to patients.

Our TheraT technology has been engineered to hold two additional genes compared to the natural form of the arenavirus. This allows us to express multiple antigens in one construct. In HB-301, we are including the coding sequences for PAP, PSA and PSMA antigens. Since it is a TheraT-based product candidate, we can deliver HB-301 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 TheraT 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 TheraT vectors based on both LCMV and PICV in a sequential dosing regimen.



** PSA and PAP specific CD8+ responses in C57BL6 mice after single dose of TheraT*
*** PSMA specific CD8+ responses in Balb/c mice after single dose of TheraT*

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

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 and present full length proteins rather than fragments 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, or 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 neo-epitope-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 NY-ESO-1, 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 two year preclinical 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 anti-tumor 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.

Intellectual Property

Our success depends, in part, on our ability to obtain and maintain intellectual property protection for our product candidates, technology and know-how, to defend and enforce our intellectual property rights, in particular, our patent rights, to preserve the confidentiality of our know-how 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, know-how, 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 December 31, 2019, we are the owner or exclusive licensee to five issued U.S. patents and nine pending U.S. patent applications, and 26 issued foreign patents and approximately 74 foreign patent applications. These patents and patent applications are related to our technologies concerned with the arenavirus-based immunization systems, VaxWave and TheraT, 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.

VaxWave Technology Portfolio

Our patent portfolio related to our VaxWave technology includes a patent family exclusively licensed to us from the University of Zurich. This patent family includes three 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 VaxWave 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 VaxWave technology is being employed or may be employed in one or more of the product candidates or programs described herein.

TheraT Technology Portfolio

We are the owner or exclusive licensee to proprietary patent positions related to our TheraT technology. Our patent portfolio related to our TheraT technology includes a patent family exclusively licensed from the University of Geneva. This patent family includes pending applications in the United States, Europe, Canada, Australia, Japan, India, China and Hong Kong. The second patent family in our TheraT 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 pending applications related to our TheraT 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 TheraT technology is being employed or may be employed in one or more of the product candidates or programs described herein.

Oncology Technology Portfolio

For the application of our VaxWave and TheraT technologies in oncology, we own three patent families. Each of these patent families include pending applications in the United States, Europe, Australia, Canada, China, 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 VaxWave technology. In addition to the VaxWave 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 pending applications in the United States, Europe, Australia, Canada, China, Hong Kong, India and Japan. Excluding the VaxWave 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.

HBV

Our HBV program, co-developed with Gilead, is in the preclinical phase and is being built on either our VaxWave or TheraT technologies. In addition to the VaxWave and TheraT patent portfolios, we own one patent family that relates to the use of our platform technologies for prevention and treatment of HBV. This patent family 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 VaxWave and TheraT patent portfolios, the pending applications related to the HBV program are expected to expire in 2036, not giving effect to any potential patent term

extensions or patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

HIV

Our HIV program, co-developed with Gilead, is in preclinical phase and is being built on either our VaxWave or TheraT technologies. We currently do not own any patents or patent applications that more specifically relate to an HIV program outside of the VaxWave and TheraT patent portfolios.

HB-201 (HPV)

Our HB-201 product candidate relies on our TheraT technology and, depending on its clinical implementation, may relate to one or more applications in our oncology patent portfolio. In addition to the TheraT and oncology patent portfolios, we own one patent family that relates more specifically to our HB-201 product candidate. This patent family includes pending applications in the United States, Europe, Australia, Canada, China, India, Japan and Hong Kong. Excluding the TheraT and oncology patent portfolios, the pending applications specifically related to our HB-201 product candidate are expected to expire in 2036, not giving effect to any potential patent term extensions or patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

HB-202 (HPV)

Our HB-202 product candidate relies on our TheraT technology and, depending on its clinical implementation, may relate to one or more applications in our oncology patent portfolio. In addition to the TheraT and oncology patent portfolios, we own one patent family that relates more specifically to our HB-202 product candidate. This patent family includes pending applications in the United States, Europe, Australia, Canada, China, India, Japan and Hong Kong. Excluding the TheraT and oncology patent portfolios, the pending applications specifically related to our HB-202 product candidate are expected to expire in 2036, not giving effect to any potential patent term extensions or patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

HB-301

Our HB-301 product candidate relies on our TheraT technology and, depending on its clinical implementation, may relate to one or more applications in our oncology patent portfolio. We currently do not own any patents or patent applications that more specifically relate to our HB-301 product candidate outside of the TheraT and oncology patent portfolios.

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

Overview

On June 4, 2018, we entered into a Research Collaboration and License Agreement, or the Collaboration Agreement, with Gilead to collaborate on preclinical research programs to evaluate potential vaccine products using or incorporating our TheraT and Vaxwave technology platforms for the treatment, cure, diagnosis, or prevention of HBV 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 know-how 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 TheraT or Vaxwave technology platforms for expressing one or more HIV or HBV antigens, which foregoing know-how 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 TheraT and Vaxwave technology platforms. Gilead will own all other intellectual property rights conceived or created out of the activities conducted under the Collaboration Agreement.

Governance

The development of the programs governed by the Collaboration Agreement is overseen by a six-member joint steering committee, or the 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 reviewing the research plan for potential amendments, settling disputes arising under the Collaboration Agreement, and approving a Licensed Product as being ready for development. Similarly, the Collaboration Agreement establishes a six-member joint research committee, or the JRC, comprised of three representatives from each of us and Gilead. The JRC will review the research activities conducted by HOOKIPA and Gilead, provide guidance with respect to such research activities, review and discuss the results, status and progress of such research activities, and approve our use of third party subcontractors to perform our tasks under the Collaboration Agreement.

Research on HBV and HIV products

Under the Collaboration Agreement, we are responsible for manufacturing and supplying to Gilead Lymphocytic Choriomeningitis Virus- and Pichinde Virus-based vectors expressing one or more HIV or HBV antigens to the extent necessary for both us and Gilead to carry out our respective research activities under the research plans. HBV antigen-encoding vectors and HIV antigen-carrying vectors used in good laboratory practice, or GLP, studies will be produced at a CMO. We are also responsible during the collaboration term for preparing all non-clinical and chemistry, manufacturing and control, or CMC, reports for inclusion in any IND filing. Pursuant to the Collaboration

Agreement, each party is obligated to use commercially reasonable efforts to perform it obligations under the HBV and HIV research plans. Gilead committed to preparations to advance the HBV and HIV vectors toward clinical entry. To enable the development activities and expanded research programs, Gilead agreed to reserve manufacturing capacity and to expand the reimbursement for our resources allocated to the Gilead collaboration.

Development and Commercialization of HBV and HIV products

Pursuant to the Collaboration Agreement, Gilead is solely responsible for conducting the development activities, including all regulatory filings, at its expense for any product arising from the Collaboration Agreement designated for development by Gilead and approved by the JSC. Gilead is also solely responsible, at its expense, for the manufacture and commercialization of any Licensed Product developed and commercialized under the Collaboration Agreement.

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 HBV or HIV, except for the activities we are expressly permitted to perform under the Collaboration Agreement.

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.

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, 2019 we received $6.0 million in milestone payments for the delivery of research grade vectors. For each of the HBV and the HIV program, Gilead is obligated to pay us a one-time mid seven-digit dollar amount after initiation of the IND-enabling studies for such program and we are eligible for up to $140.0 million in developmental milestone payments for each of the HBV and HIV programs and $50.0 million in commercialization milestone payments for each of the HBV and HIV programs. Upon the commercialization of a Licensed 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 Licensed Product, and royalties of a mid-single-digit to low-teens percentage of worldwide net sales of each HIV Licensed Product. 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 and HIV 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 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 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.

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 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 anti-dilution 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, or the NIH, which was subsequently amended in April 2017 and July 2018, hereinafter referred to as the NIH Agreement. Pursuant to the NIH Agreement, the NIH granted us a worldwide, non-exclusive 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., Merck & Co., GlaxoSmithKline plc and Pfizer Inc.

- In immuno-oncology for HPV+ cancers, companies such as Kite Pharma, a Gilead company, Advaxis, Inc., ISA Pharmaceuticals B.V., in collaboration with Regeneron Pharmaceuticals, Inc. and BioNtech AG;

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, Turnstone Biologics Inc., Adaptimmune PLC, Achilles Therapeutics Ltd., 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 are 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 VaxWave-based and TheraT-based product candidates. For GMP production and testing we rely on 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 immunotherapeutics. 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.

As an intermediate step between utilizing different CMOs for production of clinical trial material, depending on their availability at the required times, and establishing our own manufacturing facility, we have recently entered into an agreement with Valneva Sweden AB, or Valneva, a commercial vaccine manufacturer, by which we gain exclusive access to a dedicated GMP facility including qualified workforce for the manufacture and testing of clinical trial material according to our specifications. We expect that through this agreement, the necessary capacity for manufacture of

Phase 1 and Phase 2 clinical trial material will largely be covered from 2020 onwards. In addition, we will avoid technology transfer activities to different CMOs and will benefit from increases in experience and efficiency with each additional run performed under the Valneva agreement.

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, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of biological products, such as those developed from our VaxWave and TheraT 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, or FDCA, and its implementing regulations and biologics under the FDCA, the Public Health Service Act, or the 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, or 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:

- Completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with GLP requirements;
- Submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- Approval by an Institutional Review Board, or IRB, or independent ethics committee at each clinical trial site before each trial may be initiated;
- Performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, good clinical practice, or GCP, requirements and other clinical trial-related regulations to establish the safety and efficacy of the investigational product for each proposed indication;
- Submission to the FDA of a BLA;
- A determination by the FDA within 60 days of its receipt of a BLA to accept the filing for review;
- Satisfactory completion of an FDA pre-approval 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;

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

- FDA review and approval of the BLA, including 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.

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 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.

Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biologic has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated check points based on access to certain data from the trial. Concurrent with clinical trials, companies usually complete additional animal studies and also must develop additional information about the chemistry and physical characteristics of the biologic as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product and, among other things, companies must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidates do not undergo unacceptable deterioration over their shelf life.

FDA Review Process

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

Under the Prescription Drug User Fee Act, or 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, 2020, the user fee for an application requiring clinical data, such as a BLA, is $2,942,965. The sponsor of an approved BLA is also subject to an annual prescription drug program fee, which for fiscal year 2020 is $325,424. 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 pre-approval 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

The FDA has a fast track program that 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.

Any product submitted to the FDA for marketing, including under a fast track program, may 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, or 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, or 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, or 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, or 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 record-keeping 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, or 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. 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, or 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:

- The federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under the Medicare and Medicaid programs, or other federal healthcare programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;

- The federal civil and criminal false claims laws and civil monetary penalty laws, including the FCA, which prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to, or approval by, the federal government or knowingly making, using or causing to be made or used a false record or statement, including providing inaccurate billing or coding information to customers or promoting a product off-label, material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the federal government. In addition, manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;

- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose, among other things, specified requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities and their business associates. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- The federal legislation commonly referred to as the Physician Payments Sunshine Act, created under the Patient Protection and Affordable Care Act, or ACA, and its implementing regulations, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or

other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

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

- Analogous state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources.

Pricing and rebate programs must comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the ACA. 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.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

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 subjects 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.

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.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and congressional challenges, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since assuming the presidency in January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or TCJA, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018 among other things, amends the ACA, effective January 1, 2019, to reduce the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole."

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 and, due to subsequent legislative amendments to the statute, will remain in effect through 2027 unless additional congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers.

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.

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, or 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, or 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. Although the EU Clinical Trials Directive 2001/20/EC has sought to harmonize the EU clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the EU, the EU member states have transposed and applied the provisions of the Directive differently. This has led to significant variations in the member state regimes. Under the current regime, before a clinical trial can be initiated it must be approved in each of the EU countries where the trial is to be conducted by two distinct bodies: the National Competent Authority, or NCA, and one or more Ethics Committees, or ECs. Under the current regime all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the member state where they occurred.

The EU clinical trials legislation currently is undergoing a transition process mainly aimed at harmonizing and streamlining clinical-trial authorization, simplifying adverse-event reporting procedures, improving the supervision of clinical trials and increasing their transparency. Recently enacted Clinical Trials Regulation EU No 536/2014 ensures that the rules for conducting clinical trials in the EU will be identical.

European Union Drug Review and Approval

In the European Economic Area, or EEA, which is comprised of the 28 member states of the EU and Iceland, Liechtenstein, Norway, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. There are two types of marketing authorizations.

- The Community MA is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the EMA and is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced-therapy medicines such as 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 EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.

- National MAs, which are issued by the competent authorities of the Member States of the EEA 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 EEA, 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 state 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, or RMS. The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics, or SPC, and a draft of the labeling and package leaflet, which are sent to the other member state, referred to as the Member States Concerned, for their approval. If the Member States Concerned raise no objections, based on a potential serious risk to public health, to the assessment, SPC, labeling, or packaging proposed by the RMS, the product is subsequently granted a national MA in all the member states (i.e., in the RMS and the Member States Concerned).

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

European Union Orphan Designation and Exclusivity

In the European Union, the EMA's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in the European Union community (or where it is unlikely that the development of the medicine would generate sufficient return to justify the investment) and for which no satisfactory method of diagnosis, prevention or treatment has been authorized (or, if a method exists, the product would be a significant benefit to those affected).

In the European Union, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity is granted following medicinal product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. Orphan drug designation must be

requested before submitting an application for MA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

European Union Drug Marketing

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 governed by the national anti-bribery laws of European Union member states, such as the U.K. Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment.

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.

European Data Collection

The collection and use of personal health data in the EU is governed by the provisions of the Data Protection Directive, and as of May 2018 the General Data Protection Regulation, or GDPR. This directive imposes several 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 Data Protection Directive and GDPR also impose strict rules on the transfer of personal data out of the EU 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 EU member states may result in fines and other administrative penalties. The GDPR introduces new data protection requirements in the EU and substantial fines for breaches of the data protection rules. 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 the new data protection rules. This may be onerous and adversely affect our business, financial condition, results of operations and prospects.

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.

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, no uniform policy of coverage and reimbursement for drug or biological products exists. 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.

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, or 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, or the 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 co-payments 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 European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

Employees

As of February 28, 2020, we had 85 full-time employees and 19 part-time employees. Of our 104 full and part-time employees, 26, or 25%, have Ph.D. or M.D. degrees and 84, or 81%, 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.

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 December 2018, we entered into a collaboration and manufacturing agreement which included embedded leases of unlimited duration of manufacturing facilities which are located in Solna, Sweden. 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 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, 2018 and 2019, we reported a net loss of $16.2 million and $43.0 million, respectively. As of December 31, 2019, we had an accumulated deficit of $103.0 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 VaxWave and TheraT 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 U.S. Food and Drug Administration, or the FDA, the European Medicines Agency, or 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, 2019, we had approximately $113.6 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, 2019 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 candidate, HB-101, which is currently in a Phase 2 clinical trial, and our HB-201 program, which recently commenced 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 investigational new drug application, or IND, or biologics license application, 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 investigational new drug applications, or 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 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 good clinical practice, or 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 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 and clinical trials 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.

Many 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 are currently repeating the testing of samples from the respective patients. If we are unable to successfully complete these additional tests with respect to HB-101 or establish a validated assay in time with respect to HB-201, we will not be able to include all of the planned immunogenicity data for all of the treated patients in our planned interim and final data analyses, which may negatively affect the timing or completion of our trials.

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.

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

TheraT is an attenuated but replicating viral vector technology. We dosed the first patient in our first clinical trial of our TheraT technology in December 2019, and we have not yet reported any clinical data. If our Phase 1/2 clinical trial for HB-201 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 TheraT 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 VaxWave and TheraT technologies, and our future success depends on the successful development of this therapeutic approach. Our VaxWave and TheraT technologies utilize arenaviruses to activate CD8+ T cells and induce pathogen-neutralizing antibodies. There are no approved products that utilize the arenavirus. Because our VaxWave and TheraT technologies are novel, regulatory agencies may lack experience with product candidates such as HB-101 and HB-201, 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 later-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 institutional review boards, or 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; and

- 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.

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. Large-scale trials would require significant additional financial and management resources and reliance on third-party clinical investigators, contract research organizations, or 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, or CMOs, and their know-how 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 TheraT 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.

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 TheraT-based product candidates will depend in part on public acceptance of the use of cancer immunotherapies. Adverse events in clinical trials of HB-201 or our other TheraT-based product candidates 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 TheraT-based product candidates 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 VaxWave and TheraT 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 VaxWave and TheraT 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 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 human papilloma virus-16 positive, or 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, or 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.

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.

A pandemic, epidemic or outbreak of an infectious disease in the United States or Europe may adversely affect our business.

If a pandemic, epidemic or outbreak of an infectious disease occurs in the United States, Europe or worldwide, our business may be adversely affected. In December 2019, a novel strain of coronavirus, COVID-19, was identified in Wuhan, China. This virus continues to spread globally and, as of March 2020, has spread to over 70 countries, including the United States, and was declared a pandemic by the World Health Organization in March 2020. The spread of COVID-19 has impacted the global economy and may impact our operations, including the potential interruption of our clinical trial activities, regulatory reviews and our supply chain. For example, the COVID-19 outbreak may delay enrollment in our clinical trials due to prioritization of hospital resources toward the outbreak or other factors, and some patients may be unwilling to enroll in our trials or be unable to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services, which would delay our ability to conduct clinical trials or release clinical trial results and could delay our ability to obtain regulatory approval and commercialize our product candidates. Furthermore, the spread of the virus may affect the operations of key governmental agencies, such as the FDA, which may delay the development of our product candidates. The spread of an infectious disease, including COVID-19, may also result in the inability of our suppliers to deliver components or raw materials on a timely basis or at all. In addition, hospitals may reduce staffing and reduce or postpone certain treatments in response to the spread of an infectious disease. Such events may result in a period of business disruption, and in reduced operations, or doctors and medical providers may be unwilling to participate in our clinical trials, any of which could materially affect our business, financial condition and results of operations. The extent to which the coronavirus impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others. A significant outbreak of coronavirus and other infectious diseases could result in a widespread health crisis that could adversely affect the economies and financial markets worldwide, resulting in an economic downturn that could impact our business, financial condition and results of operations.

Continued uncertainty surrounding the implementation and effect of Brexit may cause increased economic volatility, affecting our operations and business.

In March 2017, the United Kingdom served notice to the European Council under Article 50 of the Treaty of Lisbon to withdraw membership from the European Union. Such exit, or Brexit, could cause disruptions to, and create uncertainty surrounding, our business in the United Kingdom and European Union, including affecting our relationships with our existing and future customers, suppliers, and employees. As a result, Brexit could have an adverse effect on our future business, financial results, and operations. The United Kingdom formally left the European Union on January 31, 2020, and is now in a transition period through December 31, 2020. Although the United Kingdom will remain in the European Union single market and customs union during the transition period, the long-term nature of the United Kingdom’s relationship with the European Union is unclear and there is considerable uncertainty any agreement will be reached and implemented. The political and economic instability created by Brexit has caused and may continue to cause

significant volatility in global financial markets and uncertainty regarding the regulation of data protection in the United Kingdom. In particular, although the United Kingdom enacted a Data Protection Act in May 2018 that is consistent with the European Union General Data Protection Regulation, uncertainty remains regarding how data transfers to and from the United Kingdom will be regulated. Brexit could also have the effect of disrupting the free movement of goods, services, and people between the United Kingdom, the European Union, and elsewhere. Brexit could lead to legal uncertainty and potentially divergent national laws and regulations as the United Kingdom determines which European Union laws to replace or replicate. Further, uncertainty around these and related issues could lead to adverse effects on the economy of the United Kingdom and the other economies. There can be no assurance that any or all of these events will not have a material adverse effect on our business operations, results of operations and financial condition.

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 in-house 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 human immunodeficiency virus and hepatitis B virus programs 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 with Gilead, or the Collaboration Agreement, which is focused on researching, developing and commercializing therapies for the treatment, cure, diagnosis and prevention of human immunodeficiency virus, or HIV, and hepatitis B virus, or HBV. Pursuant to the Collaboration Agreement, we granted Gilead a worldwide exclusive license to research, develop, manufacture and commercialize vaccine products for HIV and HBV using our VaxWave and TheraT technologies. The collaboration 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 programs. Our lack of control over the clinical development 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 IND filings in a timely fashion, if at all. Additionally, Gilead has the right to terminate the Collaboration Agreement at any time for convenience. In the event Gilead terminates the Collaboration Agreement, we would be prevented from receiving any milestone payments, royalty payments and other benefits under that agreement, 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 HIV and 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 good clinical

practices, or 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, or 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 expect 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;
- 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.

Each 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 risk evaluation and mitigation strategy, or 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.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA. Among the provisions of the ACA of potential importance to our business and our product candidates are the following:

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription products and biologic products;

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;

- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for products that are inhaled, infused, instilled, implanted or injected;

- expansion of healthcare fraud and abuse laws, including the civil False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance;

- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts, which was increased to 70% by the Bipartisan Budget Act of 2018, off negotiated prices of applicable brand products to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient products to be covered under Medicare Part D;

- extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;

- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;

- new requirements to report certain financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report product samples that manufacturers and distributors provide to physicians;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models.

The ACA, among other things, 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 and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and creates a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% (increased pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Since its 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. Various portions of the ACA are currently undergoing legal and constitutional challenges in the Fifth Circuit Court and the United States Supreme Court, the Trump Administration has issued various Executive Orders eliminating cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices, and Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended. We cannot predict what affect further changes to the ACA would have on our business.

We expect federal, state and national healthcare reform measures that may be adopted in the United States or other foreign jurisdictions in the future may result in more rigorous coverage criteria, increased regulatory burdens and operating costs, decreased net revenue from our pharmaceutical products, decreased potential returns from our development efforts, and in additional downward pressure on the price that we receive for any approved product. 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 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, 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 Drug Designation after receiving the opinion of the EMA Committee for Orphan Medicinal Products on an Orphan Drug Designation application. Orphan Drug 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 not more than 5 in 10,000 persons in Europe 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 drugs 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 drug in Europe would be sufficient to justify the necessary investment in developing the drug. In Europe, Orphan Drug 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 Drug 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 European exclusivity period can be reduced to six years if a drug no longer meets the criteria for Orphan Drug 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. The laws that may affect our ability to operate include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving, providing or paying any remuneration (including any kickback, bribe, or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal

and state healthcare programs such as Medicare and Medicaid. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers and formulary managers, among others, on the other. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act or federal civil money penalties statute;

- the U.S. federal false claims and civil monetary penalties laws, including the civil False Claims Act and federal civil monetary penalty laws, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim or obligation to pay or transmit money to the federal government, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. Manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The False Claims Act also permits a private individual acting as a "whistleblower" to bring qui tam actions on behalf of the federal government alleging violations of the False Claims Act and to share in any monetary recovery;

- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or obtaining by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the pay (e.g., public or private) or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, and as amended again by the Omnibus Rule in 2013, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the Final HIPAA Omnibus Rule, i.e. certain covered health plans, healthcare clearinghouses and healthcare providers, as well as their business associates, those independent contractors or agents of covered entities that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- the U.S. Federal Food, Drug and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;

- the U.S. federal legislation commonly referred to as Physician Payments Sunshine Act, enacted as part of the ACA, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the CMS under the Open Payments Program information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists,

optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners;

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

- analogous state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and local laws that require the licensure of sales representatives; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect; and state laws related to insurance fraud in the case of claims involving private insurers; and

- European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers and data privacy and security laws and regulations that may be more stringent than those in the United States.

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, like 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 General Data Protection Regulation, or 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. Further, the United Kingdom's vote in favor of exiting the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear how data transfers to and from the United Kingdom will be regulated, nor is it clear when Brexit will occur.

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, or DOJ, and the Securities and Exchange Commission, or the 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, or 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, or 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 VaxWave and TheraT 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 VaxWave technology, including our HB-101 product candidate, obtain patent protection with respect to our TheraT technology, including our HB-201, HB-202 and HB-301 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 U.S. Patent and Trademark Office, or 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 VaxWave 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 HB-101 or another product candidate is 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 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 VaxWave and TheraT technologies we may not be able to obtain intellectual property to all uses of VaxWave and TheraT 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 will serve as our Scientific Advisor to the Chief Executive Officer going forward, 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 future 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.

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.

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.

In April 2019, we closed our initial public offering. Prior to that offering, there was no public market for our common stock. Although we completed our initial public offering and shares of our common stock are listed on The Nasdaq Global Select Market, 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.

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, or the 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, or the 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 completes 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.

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.

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 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.

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, or SOX Section 404, we will be required to furnish a report by our management on our internal control over financial reporting beginning with our second filing of an 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 will be required to report upon the effectiveness of our internal control over financial reporting beginning with the annual report for our fiscal year ending December 31, 2020. 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.

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 December 2018, we entered into a collaboration and manufacturing agreement which included embedded leases of unlimited duration of manufacturing facilities which are located in Solna, Sweden. 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.

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

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Certain Information Regarding the Trading of Our Common Stock

Our common stock trades under the symbol “HOOK” on The Nasdaq 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 3, 2020, there were approximately 11 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.

Use of Proceeds from Initial Public Offering

On April 23, 2019, we closed our initial public offering of 6,000,000 shares of our common stock at a public offering price of $14.00 per share for an aggregate offering of $84.0 million.

The offer and sale of all of the shares in the offering were registered under the Securities Act of 1933, as amended, pursuant to registration statement on Form S-1 (File No. 333-230451), which was declared effective by the SEC on April 17, 2019. Merrill Lynch, Pierce, Fenner & Smith Incorporated, SVB Leerink LLC and RBC Capital Markets, LLC acted as joint book-running managers for the offering. The offering commenced on April 17, 2019 and did not terminate until the sale of all of the shares offered.

We received aggregate net proceeds from the offering of $74.6 million, after deducting underwriting discounts and commissions of $5.9 million and estimated offering expenses of $3.5 million payable by us. None of the underwriting discounts and commissions or offering expenses were incurred or paid to directors or officers of ours or their associates or to persons owning 10% or more of our common stock or to any affiliates of ours.

As of December 31, 2019 the net proceeds from the offering have been partially invested in a money market fund and partially deposited in an interest-bearing bank account with an investment grade financial institution. There has

been no material change in our planned use of the net proceeds from the offering as described in our Prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on April 17, 2019.

Issuer Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. Selected Financial Data

We have derived the consolidated statement of operations data for the years ended December 31, 2019, 2018 and 2017 and the consolidated balance sheet data as of December 31, 2019, 2018 and 2017 from our audited consolidated financial statements appearing at the end of this Annual Report on Form 10-K. The balance sheet data as of December 31, 2017 is derived from our audited consolidated financial statements not included in this Annual Report on Form 10-K. Our historical results are not necessarily indicative of the results that may be expected in the future. You should read the following selected consolidated financial data together with our consolidated financial statements and the related notes appearing elsewhere in this Annual Report on Form 10-K and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this Annual Report on Form 10-K. See Note 2 and Note 15 to our consolidated financial statements at the end of this Annual Report on Form 10-K for further details on the calculation of basic and diluted net loss per share attributable to common shareholders and on the calculation of basic and diluted net loss per share attributable to common shareholders.

	Year ended December 31,		
	2019	2018	2017
(in thousands, except share and per share data)			
Consolidated Statements of Operations Data:			
Revenue from collaboration and licensing	$ 11,942	$ 7,629	$ —
Operating expenses:			
Research and development[(1)]	(46,312)	(21,965)	(9,772)
General and administrative(1)	(16,715)	(6,844)	(4,385)
Total operating expenses	(63,027)	(28,809)	(14,157)
Loss from operations	(51,085)	(21,180)	(14,157)
Other income (expense):			
Grant income	6,737	5,612	2,069
Interest income	1,587	0	—
Interest expense	(877)	(778)	(606)
Other income and expenses, net	601	133	(25)
Total other income (expense), net	8,048	4,967	1,438
Net loss before tax	(43,037)	(16,213)	(12,719)
Income tax expense	(0)	(24)	(4)
Net loss	(43,037)	(16,237)	(12,723)
Net loss per share — basic and diluted	$ (2.41)	$ (17.76)	$ (13.95)
Weighted average common shares outstanding—basic and diluted	17,859,935	914,375	911,777

[1] Amounts include stock-based compensation expense, as follows (in thousands):

	Year ended December 31,		
	2019	2018	2017
Research and development expenses	$ 1,981	$ 399	$ 295
General and administrative expenses	3,584	468	475
	$ 5,565	$ 867	$ 770

	As of December 31,		
	2019	2018	2017
		(in thousands)	
Consolidated Balance Sheet Data:			
Cash, cash equivalents and restricted cash	$ 113,575	$ 48,580	$ 61,362
Working capital[1]	113,273	47,616	65,923
Total assets	143,745	68,251	73,732
Redeemable convertible preferred stock	—	104,774	104,774
Accumulated deficit	(103,019)	(59,982)	(43,745)
Total stockholders' equity (deficit)	117,899	(60,375)	(42,656)

[1] We define working capital as current assets less current liabilities

As discussed in Note 2 to the financial statements, we have changed our method of accounting for leases in 2019 due to adoption of Accounting Standards Update No. 2016-02, Leases (Topic 842), using the modified retrospective transition approach.

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 targeting infectious diseases and cancers based on our proprietary arenavirus platform that is designed to reprogram the body's immune system. We are using our "off-the-shelf" technologies, VaxWave and TheraT, to elicit directly within patients a powerful and durable response of antigen-specific killer T cells and antibodies, thereby activating essential immune defenses against infectious diseases and cancers. We believe that our technologies can meaningfully leverage the human immune system for prophylactic and therapeutic purposes by eliciting killer T cell response levels previously not achieved by other published immunotherapy approaches. Our lead infectious disease product candidate, HB-101, is in a randomized, double-blinded Phase 2 clinical trial in patients awaiting kidney transplantation from CMV-positive donors. Our lead oncology product candidates, HB-201 and HB-202, are in development for the treatment of Human Papillomavirus-positive cancers. In December 2019, we initiated the Phase 1/2 clinical trial for HB-201 and expect preliminary results in late 2020 or early 2021. We plan to file an investigational new drug application, or IND, with the U.S. Food and Drug Administration, or FDA, for HB-202 in first half 2020. We have also entered into a strategic partnership with Gilead Sciences, Inc., or Gilead, to develop infectious disease product candidates intended to support functional cures for chronic Hepatitis B virus, or HBV, and human immunodeficiency virus, or HIV, infections. Based on preclinical data generated to date, Gilead has committed to preparations to advance the HBV and HIV candidates toward development.

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 $16.0 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, or 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.

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 product candidate, HB-101, 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 minimize or eliminate our reliance on contract manufacturing organizations, or 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 incur additional legal, accounting and other expenses in operating our business, including the additional 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. Further, we expect to incur additional costs associated with operating as a public company.

We have incurred net losses each year since our inception in 2011, including net losses of $43.0 million for the year ended December 31, 2019 and $16.2 million for the year ended December 31, 2018. As of December 31, 2019, we had an accumulated deficit of $103.0 million and we do not expect positive cash flows from operations in the foreseeable future. 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.

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 TheraT technology and VaxWave 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 and through to December 31, 2019 we received $6.0 million in milestone payments for the delivery of research grade vectors. 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 Collaboration Agreement. We are also eligible to receive up to $140.0 million in developmental milestone payments for each of the HBV and HIV programs and up to $50.0 million in commercialization milestone payments for each of the HBV and HIV programs. Additionally, Gilead is obligated to pay royalties of a high single-digit to low-teens percentage on the worldwide net sales of each HBV product, and royalties of a mid-single-digit to low-teens percentage of worldwide net sales of each HIV product.

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

Since entering into the Collaboration Agreement and through to December 31, 2019, we have received from Gilead the non-refundable upfront payment of $10.0 million and $6.0 million in milestone payments for the delivery of research grade vectors. In addition, we have recognized $6.3 million of cost reimbursements for research and development services performed under the Collaboration Agreement. In January 2020, we announced the achievement of a further milestone under the HBV program, entitling us to a milestone payment of $4.0 million.

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 currently ongoing Phase 2 clinical trial for HB-101 as well as initiating a Phase 1/2 trial for HB-201 and preparing an IND 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, or 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 studies and pursue regulatory approval. The process of conducting the necessary clinical studies to obtain regulatory approval is costly and time-consuming. Clinical studies 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 study 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 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.

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

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 an Austrian government 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.

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, 2019, we had foreign net operating loss carryforwards of $112.3 million with no expiry date, resulting in a deferred tax asset of $29.2 million. We have considered that we will likely not realize the benefits of the deferred tax asset, and accordingly, have established a full valuation allowance as of December 31, 2019.

Results of Operations

Comparison of Years Ended December 31, 2019 and 2018

The following table summarizes our results of operations for the years ended December 31, 2019 and 2018:

	Year ended December 31,		
	2019	2018	2017
Revenue from collaboration and licensing	$ 11,942	$ 7,629	$ —
Operating expenses:			
Research and development	(46,312)	(21,965)	(9,772)
General and administrative	(16,715)	(6,844)	(4,385)
Total operating expenses	(63,027)	(28,809)	(14,157)
Loss from operations	(51,085)	(21,180)	(14,157)
Other income (expense):			
Grant income	6,737	5,612	2,069
Interest income	1,587	0	—
Interest expense	(877)	(778)	(606)
Other income and expenses, net	601	133	(25)
Total other income (expense), net	8,048	4,967	1,438
Net loss before tax	(43,037)	(16,213)	(12,719)
Income tax expense	(0)	(24)	(4)
Net loss	$ (43,037)	$ (16,237)	$ (12,723)

Revenue from collaboration and licensing

Revenue was $11.9 million for the year ended December 31, 2019, compared to $7.6 million for the year ended December 31, 2018.

The increase of $4.3 million for the year ended December 31, 2019 compared to the year ended December 31, 2018 was due to higher recognition of revenue related to the upfront payment and higher cost reimbursements received under the Collaboration Agreement with Gilead. For the year ended December 31, 2019, this revenue included $4.3 million from reimbursement of research and development expenses and $4.4 million from partial recognition of revenue related to the upfront payment of $10.0 million that we received in June 2018. In addition to the recognition of the upfront payment we recognized $3.2 million in milestone payments. For the year ended December 31, 2018, revenue from reimbursement of research and development expenses was $2.0 million, revenue from partial recognition of the upfront payment was $2.8 million, and revenue for the achievement of the first pre-clinical milestone was $2.8 million.

Research and Development Expenses

For the year ended December 31, 2019, our research and development expenses were $46.3 million, compared to $22.0 million, for the year ended December 31, 2018.

The primary drivers of the increase of $24.3 million for the year ended December 31, 2019 compared to the year ended December 31, 2018 were an increase in direct research and development expenses by $19.9 million and an increase in internal research and development expenses of $4.4 million. Direct research and development expenses increased primarily due to the costs for conducting a Phase 2 clinical trial for our HB-101 program, the preparation costs of clinical trials for our HB-201 and HB-202 programs, expansion of earlier stage programs and other direct research and development costs, primarily in connection with securing manufacturing capacity for production of clinical trial material. In addition, costs related to our collaboration with Gilead contributed to the increase in direct expenses. Internal expenses increased mainly due to an increase in personnel-related research and development expenses increased by $3.1 million, primarily a result of our increased research and development headcount and an increase in stock

compensation expenses. In addition, an increase in facility related costs of $0.4 million and in other internal costs of $0.9 million contributed to the overall increase in internal research and development expenses.

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

	Year ended December 31,		
	2019	2018	2017
Direct research and development expenses by program:			
HB-101	$ 5,120	$ 4,287	$ 1,185
HB-201/202	12,931	6,596	1,695
Gilead partnered programs[1]	2,628	715	—
Other and earlier-stage programs	13,365	2,496	1,637
Sub-total direct expenses	34,044	14,094	4,517
Internal research and development expenses:			
Personnel related (including stock-based compensation)	8,518	5,391	3,789
Facility related	1,588	1,181	779
Other internal costs	2,162	1,299	687
Sub-total internal expenses	12,268	7,871	5,255
Total research and development expenses	$ 46,312	$ 21,965	$ 9,772

[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, 2019 were $16.7 million, compared to $6.8 million for the year ended December 31, 2018. The increase of $9.9 million was primarily due to an increase in personnel related expenses of $5.4 million, an increase in professional and consulting fees of $2.5 million and an increase in other general and administrative expenses of $2.0 million. Personnel-related expenses increased mainly due to an increase in stock compensation expenses, an increase in salaries and the growth in headcount in our general and administrative functions. The increase in professional and consulting fees resulted from an increase in accounting, audit and legal fees as well as costs associated with ongoing business activities and costs to operate as a public company.

Grant Income

In the year ended December 31, 2019 we recorded grant income of $6.7 million, compared to $5.6 million in the year ended December 31, 2018 from grants, research incentives and imputed benefits from below market interest rates on loans from governmental agencies. The increase of $1.1 million was primarily due to higher income from Austrian research and development incentives, which was partially offset by the expiry of a grant from the Austrian Research Promotion Agency, or FFG.

Interest Income and Expense

Interest income was $1.6 million for the year ended December 31, 2019, compared to no interest income for the year ended December 31, 2018. The interest income represents interest from cash and cash equivalents held in US dollars resulting from the proceeds from the issuance of Series D Preferred Stock, our IPO, and payments received under our collaboration with Gilead. During the year ended December 31, 2019 our cash, cash equivalents and restricted cash were mainly held in dollars at US investment grade financial institutions or in money market funds. In addition smaller amounts were held in US dollars and euros at our Austrian subsidiary which produced no interest income due 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, 2019, compared to $0.8 million for the year ended December 31, 2018. Interest expense was recorded at the market rate of interest, which exceeded the contractual interest.

Liquidity and Capital Resources

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

We have raised gross proceeds of approximately $142.5 million from the issuance of our convertible preferred stock and $10.0 million from a non-refundable upfront payment pursuant to the Collaboration Agreement with Gilead. On April 23, 2019, we completed our IPO by issuing 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. As of December 31, 2019, the principal amount outstanding under loans from government agencies was $7.3 million and we had cash, cash equivalents and restricted cash of $113.5 million.

We entered into various funding agreements with the FFG. The loans by FFG, or the FFG Loans, were made on a project-by-project basis and bear interest at rates ranging from 0.75% to 1.0% 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.

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, 2019, the unamortized debt discount related to FFG Loans was $2.6 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 product candidates HB-101, HB-201 and HB-202, 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, 2019, we had an accumulated deficit of $103.0 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 the 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 VaxWave and TheraT 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, 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,		
	2019	2018	2017
Net cash used in operating activities	$ (41,731)	$ (14,998)	$ (11,913)
Net cash used in investing activities	(1,999)	(2,150)	(1,297)
Net cash provided by financing activities	109,751	6,873	58,892
Net increase (decrease) in cash and cash equivalents	66,021	(10,275)	45,682

Cash Used in Operating Activities

During the year ended December 31, 2019, cash used in operating activities was $41.7 million, which consisted of a net loss of $43.0 million, adjusted by non-cash charges of $8.7 million and changes in our operating assets and liabilities of $7.4 million. The non-cash charges consisted primarily of stock-based compensation of $5.6 million and depreciation and amortization expense of $3.1 million. The change in our operating assets and liabilities was primarily due to an increase in prepaid expenses and other current assets of $6.0 million, a decrease in deferred revenues of $4.4 million, a decrease of accounts receivable of $3.6 million, and a decrease in operating lease liabilities of $2.4 million, partially offset by an increase in accounts payable of $4.2 million and an increase in accrued expenses and other current liabilities of $4.0 million. Changes in accounts payable, prepaid expenses and other current assets and liabilities in the year ended December 31, 2019 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, 2019 were mainly due to a prepayment related to embedded leases and regular lease payments.

During the year ended December 31, 2018, cash used in operating activities was $15.0 million, which consisted of a net loss of $16.2 million, adjusted by non-cash charges of $1.5 million and cash used by changes in our operating assets and liabilities of $0.3 million. The change in our operating assets and liabilities included $13.5 million in cash as a result of increases in accounts receivables, prepaid expenses and other current assets. These charges were largely offset by an increase in accounts payable and other current liabilities of $4.6 million and an increase in deferred revenues of $8.6 million mainly driven by the unrecognized portion of the $10.0 million upfront payment received pursuant to the Collaboration Agreement.

During the year ended December 31, 2017, cash used in operating activities was $11.9 million, which consisted of a net loss of $12.7 million, adjusted by non-cash charges of $1.1 million and cash used due to changes in our operating assets and liabilities of $0.3 million. The non-cash charges consisted primarily of depreciation and amortization expense of $0.4 million and stock-based compensation of $0.8 million. The change in our operating assets and liabilities was primarily due to a decrease of $1.2 million in accounts payable, partially offset by an increase of accrued expenses and other liabilities of $1.0 million.

Cash Used in Investing Activities

During the years ended December 31, 2019, 2018 and 2017, cash used in investing activities was $2.0 million, $2.2 million, and $1.3 million, respectively, which resulted from capital expenditures in connection with leasehold improvements to expand our laboratory space and for purchase of property and equipment.

Cash Provided by Financing Activities

During the year ended December 31, 2019, cash provided by financing activities was $109.8 million, which consisted of net proceeds of $37.3 million from the issuance of shares of our Series D convertible preferred stock in February 2019 and net proceeds of $74.7 million from our IPO in April 2019, partially offset by an upfront payment for embedded finance lease assets.

During the year ended December 31, 2018, cash provided by financing activities was $6.9 million, which primarily consisted of $6.4 million in net proceeds from the issuance of shares of our Series C convertible preferred stock in December 2017, and of proceeds from borrowings of $0.4 million, received under the FFG Loans.

During the year ended December 31, 2017, cash provided by financing activities was $58.9 million, which primarily consisted of net proceeds from the issuances of shares of our Series C convertible preferred stock of $58.1 million and $0.7 million in loan proceeds from FFG.

Off-Balance Sheet Arrangements

We did not have during the periods presented and we do not currently have any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2019 (in thousands):

	Payments Due by Calendar Year				
	Total	Less Than 1 Year	1 - 3 Years	4 - 5 Years	More than 5 Years
Lease commitments	$ 7,979	$ 1,981	$ 3,922	$ 2,076	$ —
CMO commitments	13,078	10,189	2,889	—	—
Debt obligations	7,305	1,280	3,029	2,996	—
Total	$ 28,362	$ 13,450	$ 9,840	$ 5,072	$ —

The contractual obligations table does not include any potential contingent payments upon the achievement by us of specified clinical, regulatory and commercial events, as applicable, or patent prosecution or royalty payments we may be required to make under license agreements we have entered into because the timing and likelihood of these contingent payments are not known.

We enter into contracts in the normal course of business with CROs for clinical trials, preclinical research studies and testing, manufacturing and other services and products for operating purposes. These contracts generally provide for termination upon notice, and therefore we believe that our non-cancellable obligations under these agreements are not material.

Our IPO provided a change in ownership structure of the Company and, as a consequence, we agreed a change in the due dates of a part of the debt obligations with the Austrian government agency to whom we owe our debt obligations.

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 the year ended December 31, 2019, we recorded $1.9 million in licensing fees from intellectual property licenses as research and development expenses. At December 31, 2019, no payable from sublicensing fees were included in accrued expenses and other current liabilities. In the year ended December 31, 2018, we recorded $0.1 million in

licensing fees from intellectual property licenses as research and development expenses. At December 31, 2018, $0.5 million payable from sublicensing fees were included in accrued expenses and other current liabilities.

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

Critical Accounting Policies

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 since our Prospectus, except for our adoption of the new leasing standards which is discussed below.

Recognition of revenue from contracts with customers

We have entered into the 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, the Company satisfies 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 collaboration and licensing 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 collaboration and licensing 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 collaboration and licensing arrangement 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

Effective January 1, 2019, we adopted ASU No. 2016-02, Leases (Topic 842) as amended from time to time (the new leasing standards) using the modified retrospective transition approach with no restatement of prior periods or

cumulative adjustment to retained earnings. Upon adoption, we elected the package of transition practical expedients, which allowed us to carry forward prior conclusions related to whether any expired or existing contracts are or contain leases, the lease classification for any expired or existing leases and initial direct costs for existing leases. We also elected the practical expedient to not reassess certain land easements and made an accounting policy election to not recognize leases with an initial term of 12 months or less within the consolidated balance sheets and to recognize those lease payments on a straight-line basis in the consolidated statements of operations over the lease term. Upon adoption of the new leasing standards an operating lease asset of $3.3 million and a corresponding operating lease liability of $3.3 million were recorded in our consolidated balance sheets. The adoption of the new leasing standards did not have a material impact on our consolidated statements of operations.

The determination whether an arrangement was qualified as a lease was 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.

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.

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.

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.

Discussion of the year ended December 31, 2018 compared with the year ended December 31, 2017 is included in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our registration statement on Form S-1, as amended, as filed with the Securities Exchange Commission.

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, 2019 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 $113.5 million as of December 31, 2019, 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, 2019, management, with the participation of our Principal Executive Officer and Principal Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act 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 Officer, to allow timely decisions regarding required disclosures.

Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on that evaluation, our Principal Executive Officer and Principal Financial Officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of December 31, 2019.

Management’s Annual Report on Internal Control over Financial Reporting

This annual report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the company's registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

Changes in Internal Control Over Financial Reporting

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 two 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, which we describe below. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company’s annual financial statements will not be prevented or detected on a timely basis.

4. We did not maintain a sufficient complement of resources with an appropriate level of accounting knowledge, experience, and training, which would allow for appropriate monitoring, presentation and disclosure, and

internal control over financial reporting. Specifically, we had not designed and implemented a sufficient level of formal accounting policies and procedures.

5. Additionally, the limited personnel resulted in our inability to consistently establish appropriate authorities and responsibilities in pursuit of our financial reporting objectives, as demonstrated by, amongst other things, our insufficient segregation of duties in their finance and accounting functions.

During 2019 and during the first quarter of 2020 we implemented measures to improve our internal control over financial reporting which we believe remediated the material weaknesses described above. Specifically, in order to remediate such material weaknesses, we:

6. Hired additional finance and accounting staff with financial controls and GAAP reporting experience. Hired additional human resources and IT staff to segregate duties in the areas of payroll and system controls.

7. Engaged third party specialists to support our compliance with internal control requirements.

8. Identified and documented our significant financial reporting risks and mitigating controls.

9. Documented existing internal control over financial reporting s, implemented additional controls and identified remaining deficiencies. Implemented various entity level and governance controls.

10. Developed internal control and risk matrices to monitor controls and continue to improve internal control monitoring.

11. Developed formalized accounting procedures and clearly defined authorities. Initiated the updating of accounting policies to match current control environment.

12. Implemented formal disclosure controls and procedures, including the formalization of a quarterly disclosure committee and requiring management sub-certifications from employees in key functional areas.

13. Reported quarterly to the audit committee on the design of the internal control and disclosure program.

We have implemented a variety of controls to remediate the material weaknesses identified. Those controls include the expanded the use of qualified accounting personnel and segregation of duties. In addition, we formalized the internal controls documentation based on a documented risk assessment process using quantitative and qualitative risk methodology. We documented our key internal controls and expanded the completeness of supporting evidence of oversight controls. Finally, we strengthened supervisory reviews by our management, disclosure committee and audit committee. These additional resources and procedures enable 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 described above.

Other than the applicable remediation efforts as described above, there were no other changes in our internal control over financial reporting (as defined in Rules 13a 15(f) and 15d 15(f) under the Exchange Act) that occurred during the year ended December 31, 2019 that have materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

On December 30, 2019, we entered into Amendment No. 9, or the Amendment, to the Consultancy Agreement between the Company and Daniel Pinschewer, dated November 13, 2011, as amended, together with the Amendment, the Agreement. The Amendment extended the terms of the Agreement from January 1, 2020 to the date in which we file this Annual Report on Form 10-K for the fiscal year ended December 31, 2019. Upon the filing of this Annual Report on March 19, 2020, Dr. Pinschewer’s services have terminated and he will serve as our consultant and, upon execution of an applicable consultancy agreement, as the Scientific Advisor to our Chief Executive Officer.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance

Incorporated by reference from the information in our Proxy Statement for our 2020 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.

Item 11. Executive Compensation

Incorporated by reference from the information in our Proxy Statement for our 2020 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.

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 2020 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.

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

Incorporated by reference from the information in our Proxy Statement for our 2020 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.

Item 14. Principal Accountant’s Fees and Services

Incorporated by reference from the information in our Proxy Statement for our 2020 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.

Part IV

Item 15. Exhibits.

(1) Financial Statements

The following documents are included on pages F-1 through F-[XX] 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 (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed on April 23, 2019 (File No. 001-38869) and incorporated herein by reference)
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	Form 8-K (File No. 001-38869) filed with the SEC on April 23, 2019)
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)

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#*	Consultancy Agreement between Daniel Pinschewer and Hookipa Biotech GmbH, dated as of November 16, 2011, as amended by the First Amendment, dated January 7, 2013, the Second Amendment, dated December 16, 2013, the Third Amendment, dated December 18, 2014, the Fourth Amendment, dated February 25, 2016, the Fifth Amendment, dated December 7, 2016, the Sixth Amendment, dated December 16, 2016, the Seventh Amendment, dated December 4, 2017, the Eighth Amendment dated December 21, 2018 and the Ninth Amendment, dated December 30, 2019
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†*	Collaboration and License Agreement, by and between Hookipa Biotech AG and Gilead Sciences, Inc., dated as of June 4, 2018, as amended on December 22, 2019
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)

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
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)
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 19, 2020

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 Joern Aldag	Chief Executive Officer and Director (Principal Executive Officer)	March 19, 2020
/s/ Reinhard Kandera Reinhard Kandera	Chief Financial Officer and Director (Principal Financial and Accounting Officer)	March 19, 2020
/s/ Jan van de Winkel Jan van de Winkel, Ph.D.	Chairman of the Board	March 19, 2020
/s/ Michael A. Kelly Michael A. Kelly	Director	March 19, 2020
/s/ David Kaufman David Kaufman	Director	March 19, 2020
/s/ Christoph Lengauer Christoph Lengauer, Ph.D.	Director	March 19, 2020
/s/ Julie O'Neill Julie O'Neill	Director	March 19, 2020
/s/ Graziano Seghezzi Graziano Seghezzi	Director	March 19, 2020
/s/ Sander van Deventer Sander van Deventer, M.D., Ph.D.	Director	March 19, 2020

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, 2019 and 2018, and the related consolidated statements of operations and comprehensive loss, of redeemable convertible preferred stock and stockholders' deficit and of cash flows for each of the three years in the period ended December 31, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019 in conformity with accounting principles generally accepted in the United States of America.

Change in Accounting Principle

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for leases in 2019.

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.

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 19, 2020

PwC Wirtschaftsprüfung GmbH
/s/ Alexandra Rester
Austrian Certified Public Accountant

We have served as the Company's, or its predecessors, auditor since 2012, which includes periods before the Company became subject to SEC reporting requirements.

PART I—FINANCIAL INFORMATION

HOOKIPA PHARMA INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except share amounts)

	As of December 31,	
	2019	2018
Assets		
Current assets:		
Cash and cash equivalents	$ 113,151	$ 48,580
Accounts receivable	1,537	4,919
Receivable research incentives	8,190	2,329
Prepaid expenses and other current assets	5,139	6,483
Total current assets	128,017	62,311
Non-current assets:		
Restricted cash	424	—
Property and equipment, net	5,126	4,337
Operating lease right of use assets	7,875	—
Finance lease right of use assets	1,602	—
Other non-current assets	701	1,603
Total non-current assets	15,728	5,940
Total assets	$ 143,745	$ 68,251
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities		
Accounts payable	$ 944	$ 3,656
Deferred revenues	3,591	6,619
Operating lease liabilities, current	1,814	—
Accrued expenses and other current liabilities	8,406	4,420
Total current liabilities	14,755	14,695
Non-current liabilities		
Loans payable, non-current	3,495	4,392
Operating lease liabilities, non-current	5,290	—
Deferred revenues, non-current	72	1,663
Other non-current liabilities	2,234	3,102
Total non-current liabilities	11,091	9,157
Total liabilities	25,846	23,852
Commitments and contingencies (Note 13)		
Redeemable convertible preferred stock (series A, B, C and D), $0.0001 par value; 0 and 1,323,506 shares authorized, issued and outstanding at December 31, 2019 and December 31, 2018, respectively; aggregate liquidation preference of $0.0 million and $99.7 million at December 31, 2019 and December 31, 2018, respectively	—	104,774
Stockholders' equity (deficit):		
Common stock, $0.0001 par value; 100,000,000 and 18,454,860 shares authorized at December 31, 2019 and December 31, 2018, respectively; 21,746,392 shares and 1,006,595 shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively	3	0
Class A common stock, $0.0001 par value; 3,900,000 and 0 shares authorized at December 31, 2019 and December 31, 2018, respectively; 3,819,732 and 0 shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively	0	—
Additional paid-in capital	225,568	3,327
Accumulated other comprehensive loss	(4,653)	(3,720)
Accumulated deficit	(103,019)	(59,982)
Total stockholders' equity (deficit)	117,899	(60,375)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 143,745	$ 68,251

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,		
	2019	2018	2017
Revenue from collaboration and licensing	$ 11,942	$ 7,629	$ —
Operating expenses:			
Research and development	(46,312)	(21,965)	(9,772)
General and administrative	(16,715)	(6,844)	(4,385)
Total operating expenses	(63,027)	(28,809)	(14,157)
Loss from operations	(51,085)	(21,180)	(14,157)
Other income (expense):			
Grant income	$ 6,737	$ 5,612	$ 2,069
Interest income	1,587	0	—
Interest expense	(877)	(778)	(606)
Other income and expenses, net	601	133	(25)
Total other income, net	8,048	4,967	1,438
Net loss before tax	(43,037)	(16,213)	(12,719)
Income tax expense	(0)	(24)	(4)
Net loss	(43,037)	(16,237)	(12,723)
Other comprehensive loss:			
Foreign currency translation gain (loss), net of tax	(933)	(2,358)	1,764
Comprehensive loss	$ (43,970)	$ (18,595)	$ (10,959)
Net loss per share — basic and diluted	$ (2.41)	$ (17.76)	$ (13.95)
Weighted average common shares outstanding — basic and diluted	17,859,935	914,375	911,777

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

HOOKIPA PHARMA INC.

CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT

(In thousands, except share amounts)

	Convertible Preferred Stock		Common Stock				Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
			Common Stock		Class A Common Stock					
	Shares	Amount	Shares	Amount	Shares	Amount				
Balances as of January 1, 2017	547,974	40,189	911,777	—	—	—	1,682	(3,126)	(31,022)	(32,466)
Issuance of Series B preferred stock, net of issuance costs of $0	82,032	5,315	—	—	—	—	—	—	—	—
Issuance of Series C convertible preferred stock, net of issuance costs of $93	693,500	59,270	—	—	—	—	—	—	—	—
Foreign currency translation adjustment	—	—	—	—	—	—	—	1,764	—	1,764
Stock-based compensation expense	—	—	—	—	—	—	769	—	—	769
Net loss	—	—	—	—	—	—	—	—	(12,723)	(12,723)
Balances as of December 31, 2017	**1,323,506**	**104,774**	**911,777**	**—**	**—**	**—**	**2,451**	**(1,362)**	**(43,745)**	**(42,656)**
Issuance of common stock upon exercise of stock options	—	—	94,818	—	—	—	9	—	—	9
Foreign currency translation adjustment (unaudited)	—	—	—	—	—	—	—	(2,358)	—	(2,358)
Stock-based compensation expense	—	—	—	—	—	—	867	—	—	867
Net loss	—	—	—	—	—	—	—	—	(16,237)	(16,237)
Balance as of December 31, 2018	**1,323,506**	**$ 104,774**	**1,006,595**	**$ —**	**—**	**$ —**	**$ 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 $9,386	—	—	6,000,000	1	—	—	74,614	—	—	74,615
Conversion of Series A, B, C and D preferred stock into common stock upon initial public offering	(1,580,506)	(142,048)	14,582,161	2	3,819,732	—	142,046	—	—	142,048
Issuance of common stock upon exercise of stock options	—	—	157,636	—	—	—	16	—	—	16
Foreign currency translation adjustment, net of tax	—	—	—	—	—	—	—	(933)	—	(933)
Stock-based compensation	—	—	—	—	—	—	5,565	—	—	5,565
Net loss	—	—	—	—	—	—	—	—	(43,037)	(43,037)
Balance as of December 31, 2019	**—**	**$ —**	21,746,392	$ 3	3,819,732	$ —	$ 225,568	$ (4,653)	$ (103,019)	$ 117,899

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, 2019	2018	2017
Operating activities:			
Net loss	$ (43,037)	$ (16,237)	$ (12,723)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	5,565	867	770
Depreciation expense	1,443	640	398
Non-cash operating lease expense	1,624	—	—
Other non-cash items	52	7	(45)
Changes in operating assets and liabilities:			
Accounts receivable	(3,619)	(4,991)	—
Prepaid expenses and other current assets	(6,005)	(7,049)	(67)
Other non-current assets	869	(1,465)	(83)
Accounts payable	4,203	3,413	(1,172)
Deferred revenues	(4,442)	8,587	—
Operating lease liabilities	(2,396)	—	—
Accrued expenses and other liabilities	4,012	1,230	1,009
Net cash used in operating activities	(41,731)	(14,998)	(11,913)
Investing activities:			
Purchases of property and equipment	(1,999)	(2,150)	(1,297)
Net cash used in investing activities	(1,999)	(2,150)	(1,297)
Financing activities:			
Payments related to finance leases	(1,437)	—	—
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	37,274	6,439	58,145
Proceeds from issuance of common stock, net of issuance costs	74,756	9	—
Proceeds from borrowings	—	425	747
Repayments of borrowings	(842)	—	—
Net cash provided by financing activities	109,751	6,873	58,892
Net increase (decrease) in cash, cash equivalents and restricted cash	66,021	(10,275)	45,682
Cash, cash equivalents and restricted cash at beginning of period	48,580	61,362	13,186
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(1,026)	(2,507)	2,494
Cash, cash equivalents and restricted cash at end of period	$ 113,575	$ 48,580	$ 61,362
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ (64)	$ (71)	1 (60)
Cash paid for income taxes	$ —	$ (24)	$ (4)
Supplemental disclosure of non-cash financing activities:			
Due from shareholder for issuance of redeemable convertible preferred stock	$ —	$ —	$ 6,520
Conversion of redeemable preferred shares upon the IPO	$ 142,048	$ —	$ —
Property and equipment additions in accounts payable and accrued expenses	$ (10)	$ 545	$ (533)

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 targeting infectious diseases and cancers 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.

Stock split

On April 5, 2019, the Company effected a 11.643-for-one stock split of its issued and outstanding shares of common stock. The par value of the common stock was not adjusted as a result of the split. All issued and outstanding share and per share amounts of common stock and options included in the accompanying consolidated financial statements have been adjusted to reflect this stock split for all periods presented. The conversion ratios for each series of the Company's redeemable convertible preferred stock (see Note 9) have been adjusted proportionally.

Transaction between entities under common control

In June 2018, the Company acquired all of the shares of its parent company, Hookipa Biotech AG, against issuance of 78,311 shares of common stock and 1,323,506 shares of redeemable convertible preferred stock to the shareholders of Hookipa Biotech AG, who became the sole shareholders of the Company. The transaction was recorded as a transaction between entities under common control that led to a change in the reporting entity. In the accompanying consolidated financial statements, the assets and liabilities and relating operations of the transferring entity are retrospectively presented at their carrying amounts without a change in the basis for all periods during which the

transferring entity was under common control. The share capital as well as the share and per share information included in the accompanying consolidated financial statements have been retrospectively adjusted to reflect the share capital of the Company after the transaction. Differences in the par value of common stock between the transferring and the receiving entity were reflected by adjustments to redeemable convertible preferred stock and additional paid-in capital.

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, 2019, the Company has funded its operations with proceeds from sales of common stock in the IPO, sales of redeemable convertible preferred stock, collaboration and licensing agreements, grants and borrowings under various agreements with foreign public funding agencies. Since inception, the Company has incurred recurring losses, including net losses of $43.0 million, $16.2 million and $12.7 million for the years ended December 31, 2019, 2018 and 2017, respectively. As of December 31, 2019, the Company had an accumulated deficit of $103.0 million. The Company expects to continue to generate operating losses in the foreseeable future. As of March 19, 2020, the filing date of this Annual Report on Form 10-K, the Company expected that its cash and cash equivalents 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.

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, the present value of lease right of use assets and corresponding liabilities, the valuation of common and preferred stock, the valuation of stock-based awards and the valuation of liabilities. 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. 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.

HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

Assets and liabilities of Hookipa Biotech GmbH are translated into United States dollars at the exchange rate in effect on the balance sheet date. Income items and expenses are translated at the average exchange rate in effect during the period. Unrealized translation gains and losses are recorded as a cumulative translation adjustment, which is included in the Consolidated Statements of Convertible Preferred Stock and Stockholders' 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.

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. The net proceeds from the Company's offerings in the year ended December 31, 2019 have been deposited in interest-bearing bank accounts with investment grade US financial institutions and have been partially invested in a money market fund. The money market fund, held in U.S. dollar, is primarily invested in U.S. and foreign short-term debt obligations. As of December 31, 2018 and December 31, 2019, 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.

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, 2019 cash equivalents consisted of money market funds. As of December 31, 2018, the Company had no cash equivalents.

Deferred offering costs

The Company capitalized certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs in prepaid expenses and other current assets 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 generated as a result of the offering. Should the in-process equity financing be abandoned, the deferred offering costs would be expensed immediately as a charge to operating expenses in the consolidated statements of operations and comprehensive loss. Total offering costs of $9.4 million recorded in stockholders' equity in the year ended December 31, 2019 included $1.4 million of cost incurred in previous periods, which were initially recorded as deferred offering costs as of December 31, 2018.

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

HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1 - Quoted prices in active markets for identical assets or liabilities.
- Level 2 - Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's cash equivalents are carried at fair value, determined according to the fair value hierarchy described above (see Note 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[(1)]	5 years
Laboratory equipment	3 - 10 years
Furniture and fixtures	3 - 10 years
Computer equipment and software	3 - 4 years

[(1)] In the course of the application of ASC 842, the estimated useful life of the leasehold improvements was adjusted to the shorter period of economic useful life of the asset and lease term.

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.

Leases

The Company adopted the new leasing standards as of January 1, 2019. The new leasing standards were adopted using the modified retrospective transition approach, as of January 1, 2019, with no restatement of prior periods or cumulative adjustment to retained earnings. Upon adoption, the Company elected the package of transition practical expedients, which allowed the Company to carry forward prior conclusions related to whether any expired or existing contracts are or contain leases, the lease classification for any expired or existing leases and initial direct costs for existing leases. The Company also elected the practical expedient to not reassess certain land easements, elected to use hindsight in determining the lease term and made an accounting policy election to not recognize leases with an initial term of 12 months or less within the consolidated balance sheets and to recognize those lease payments on a straight-line basis in the consolidated statements of operations over the lease term. Upon adoption of the new leasing standards an operating lease asset of $3.3 million and a corresponding operating lease liability of $3.3 million were recorded in the consolidated balance sheets. The adoption of the new leasing standards did not have a material impact on the Company's consolidated statements of operations.

The determination whether an arrangement was qualified as a lease was made at contract inception. Operating lease assets represent the Company's right to use an underlying asset for the lease term and operating lease liabilities

represent its obligation to make lease payments arising from the lease. 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, 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 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. In addition, certain of the Company’s arrangements contain lease and non-lease components. The Company elected to generally separate lease payments from non-lease payments but applied an accounting choice to not separate lease payments from certain non-lease payments for its office and laboratory space leases and its car leases. Operating leases are reflected in operating lease assets, in accrued expenses and other current liabilities and in non-current operating lease liabilities in the consolidated balance sheets. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. The right-of-use asset is tested for impairment in accordance with ASC 360.

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, 2019 and 2018.

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.

Revenue recognition from contracts with customers

The Company has entered into a collaboration and license agreement (the "Gilead Agreement") with Gilead Sciences, Inc. ("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 Accounting Standards Codification (ASC) 606. 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 collaboration and licensing 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 collaboration and license 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 collaboration and licensing arrangement also includes certain sales-based milestone and royalty payments upon successful commercialization of a licensed product. In accordance with ASC 606-10-55-65, 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.

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.

HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

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.

Redeemable convertible preferred stock

Upon the closing of the Company's IPO on April 23, 2019, the Company's outstanding redeemable convertible preferred stock automatically converted into shares of common stock or Class A common stock. Prior to the conversion, the Company has applied the guidance in ASC 480-10-S99-3A, SEC Staff Announcement: Classification and Measurement of Redeemable Securities and had therefore classified the Series A, Series B, Series C and Series D redeemable convertible preferred stock as mezzanine equity. The redeemable convertible preferred stock was recorded outside of stockholders' equity because, in the event of certain deemed liquidation events considered not solely within the Company's control, such as a merger, acquisition and sale of all or substantially all of the Company's assets, the convertible preferred stock would have become redeemable at the option of the holders. In the event of a change of control of the Company, proceeds received from the sale of such shares would have been distributed in accordance with the liquidation preferences set forth in the Company's Preferred Stock agreements. The Company has determined not to adjust the carrying values of the redeemable convertible preferred stock to the liquidation preferences of such shares because of the uncertainty of whether or when such an event would occur.

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 years ended December 31, 2019 and 2018, comprehensive loss included $0.9 million and $2.4 million of foreign currency translation loss adjustments, respectively. For the year ended December 31, 2017 comprehensive loss included $1.8 million of foreign currency translation gain.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

Net loss per share

Prior to the closing of its IPO, the Company calculated the basic net loss per share by dividing the net loss by the weighted-average number of shares of common stock outstanding or deemed outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share was the same as basic net loss per share, since the effects of potentially dilutive securities are antidilutive given the net loss for each period presented.

Subsequent to the closing of its IPO, basic net loss per share is computed by dividing the net loss by the weighted average number of shares of 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. 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.

In April 2019, upon the closing of the IPO, all outstanding shares of the Company’s redeemable convertible preferred stock automatically converted into 14,582,161 shares of the Company’s common stock and 3,819,732 of the Company’s class A common stock.

The Company reported a net loss attributable to common stockholders for the years ended December 31, 2019, 2018 and 2017.

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.

HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

Adopted as of current period

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (Topic 842) ("ASU 2016-02"), which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e., lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether cost of the lease is recognized based on an effective interest method or on a straight-line basis over the term of the lease. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification.

The FASB subsequently issued the following amendments to ASU 2016-02 that have the same effective date and transition date: ASU No. 2018-01, Leases (Topic 842): Land Easement Practical Expedient for Transition to Topic 842, ASU No. 2018-10, Codification Improvements to Topic 842, Leases, ASU No. 2018-11, Leases (Topic 842): Targeted Improvements, ASU No. 2018-20, Narrow-Scope Improvement for Lessors, and ASU No. 2019-01, Leases (Topic 842): Codification Improvements. The Company adopted these amendments with ASU 2016-02 (collectively, the new leasing standards) effective January 1, 2019. The new leasing standards were adopted using the modified retrospective transition approach, as of January 1, 2019, with no restatement of prior periods or cumulative adjustment to retained earnings. Upon adoption, the Company elected the package of transition practical expedients, which allowed the Company to carry forward prior conclusions related to whether any expired or existing contracts are or contain leases, the lease classification for any expired or existing leases and initial direct costs for existing leases. The Company also elected the practical expedient to not reassess certain land easements, elected to use hindsight in determining the lease term and made an accounting policy election to not recognize leases with an initial term of 12 months or less within the consolidated balance sheets and to recognize those lease payments on a straight-line basis in the consolidated statements of operations over the lease term. Upon adoption of the new leasing standards an operating lease asset of $3.3 million and a corresponding operating lease liability of $3.3 million were recorded in the consolidated balance sheets. The adoption of the new leasing standards did not have a material impact on the Company’s consolidated statements of operations.

The determination whether an arrangement was qualified as a lease was made at contract inception. Operating lease assets represent the Company’s right to use an underlying asset for the lease term and operating lease liabilities represent its obligation to make lease payments arising from the lease. 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, 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 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. In addition, certain of the Company’s arrangements contain lease and non-lease components. The Company elected to generally separate lease payments from non-lease payments but applied an accounting choice to not separate lease payments from certain non-lease payments for its office and laboratory space leases and its car leases. Operating leases are reflected in operating lease assets, in accrued expenses and other current liabilities and in non-current operating lease liabilities in the consolidated balance sheets. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term.

In July 2017, the FASB issued ASU No. 2017-11, Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815) I. Accounting for Certain Financial Instruments with Down Round Features II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception

HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

("ASU 2018-11"). Part I applies to entities that issue financial instruments such as warrants, convertible debt or convertible preferred stock that contain down-round features. Part II replaces the indefinite deferral for certain mandatorily redeemable noncontrolling interests and mandatorily redeemable financial instruments of nonpublic entities contained within ASC Topic 480 with a scope exception and does not impact the accounting for these mandatorily redeemable instruments. For public entities, this guidance is required to be adopted for annual periods beginning after December 15, 2018, including interim periods within those fiscal years. The Company adopted ASU 2017-11 as of January 1, 2019. The adoption of this ASU did not have a material impact on its consolidated loss from operations or cash flows.

Recently Issued Accounting Pronouncements

In August 2018, the FASB issued ASU 2018-15, Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract. The amendments in this update align the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). The accounting for the service element of a hosting arrangement that is a service contract is not affected by the amendments in this update. For public entities, this guidance is required to be adopted for annual periods beginning January 1, 2020 and early adoption is permitted. The amendments in this update should be applied either retrospectively or prospectively to all implementation costs incurred after the date of adoption. The Company adopted ASU 2018-15 as of January 1, 2020 using the prospective approach. The Company does not expect the adoption of this ASU to have a material impact on its consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, Financial Instruments-Credit Losses which was clarified and amended by the issuances of ASUs 2018-19, 2019-04, 2019-05 and 2019-11 in November 2018, April 2019, May 2019 and November 2019, respectively. The new standard requires that expected credit losses relating to financial assets measured on an amortized cost basis are measured using an expected-loss model, replacing the current incurred-loss model, and recorded through an allowance for credit losses. The guidance also establishes a new impairment model for available-for-sale debt securities. The Company adopted the new standard and the related amendments on January 1, 2020 using a modified retrospective approach. The adoption of this ASU did not have a material impact on its consolidated financial statements.

In November 2018, the FASB issued ASU 2018-18, Clarifying the Interaction Between Topic 808 and Topic 606, which clarifies when transactions between participants in a collaborative arrangement are within the scope of the FASB's revenue standard, Topic 606. This ASU becomes effective for the Company in the year ending December 31, 2020 and early adoption is permitted. The Company is currently assessing the impact that this ASU will have on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement, ("ASU 2018-13"). The new standard removes certain disclosures, modifies certain disclosures and adds additional disclosures related to fair value measurement. The new standard will be effective beginning January 1, 2020 and early adoption is permitted. The Company is currently evaluating the impact that the adoption of ASU 2018-13 will have on its consolidated financial statements.

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes (ASU 2019-12), which eliminates certain exceptions related to the general principles in ASC 740 and makes amendments to other areas with the intention of simplifying various aspects related to accounting for income taxes. The pronouncement is effective for fiscal years, and for interim periods within those fiscal years,

beginning after December 15, 2020, with early adoption permitted. The Company is currently evaluating the potential impact of the adoption of these updates on its consolidated financial statements.

3. Collaboration and Licensing Agreements

Gilead Collaboration and License Agreement

In June 2018, the Company has entered into a collaboration and license agreement (the "Gilead Agreement") with Gilead Sciences, Inc. ("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).

Under the Gilead Agreement, the Company granted Gilead an exclusive, royalty-bearing license to the Company's technology platforms. In June 2018, the Company has received a non-refundable $10.0 million upfront payment from Gilead of which $4.4 million was recorded as revenue from collaboration and licensing in the year ended December 31, 2019 and $2.6 million was included as a liability in deferred revenues, current and non-current, as of December 31, 2019. In addition deferred revenues as of December 31, 2019 include a prepayment received from Gilead related to ordered manufacturing services of $1.0 million. Approximately 97% of the upfront payment included in deferred revenue as of December 31, 2019 is expected to be recognized in 2020 and the remaining 3% in 2021. 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 a total of $280 million. The commercial milestones amount to a total of $100 million. Additionally, Gilead is obligated to pay royalties on net sales for each program. All payments from Gilead have a 60 days payment term. In addition to the $4.4 million recognition of the upfront payment, the Company recognized $4.3 million revenue from cost reimbursements for research and development services and $3.2 million in milestone payments in the year ended December 31, 2019. For the year ended December 31, 2018, revenue from reimbursement of research and development expenses was $2.0 million, revenue from partial recognition of the upfront payment was $2.8 million, and revenue for the achievement of the first pre-clinical milestone was $2.8 million.

Sublicense fees payable to certain licensors of technologies upon the receipt of the non-refundable upfront payment, 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, 2019, the contract asset relating to the sublicense payment was $0.3 million. As of December 31, 2018, the liability and the contract asset relating to the sublicense payment were $0.5 million and $0.4 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, 2019 Using			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 35,132	$ —	$ —	$ 35,132
Total	$ 35,132	$ —	$ —	$ 35,132

The Company did not have any money market funds as of December 31, 2018.

During the year ended December 31, 2019, there were no transfers between Level 1, Level 2 and Level 3.

HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

5. Property and equipment, net

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

	Year ended December 31, 2019	2018
Leasehold improvements	$ 1,919	$ 1,885
Finance lease right of use assets	1,967	—
Construction in progress	286	—
Laboratory equipment	4,555	3,443
Furniture and fixtures	524	352
Computer equipment and software	923	723
Property and equipment, gross	10,174	6,403
Less: Accumulated depreciation	(3,446)	(2,066)
Property and equipment, net	$ 6,728	$ 4,337

Depreciation expense for the years ended December 31, 2019, 2018 and 2017 was $1.4 million, $0.6 million and $0.4 million, respectively. Construction-in-progress as of December 31, 2019 related to leasehold improvements in connection with the expansion of laboratories in the Company's leased facilities. The table presented above consists of the balance sheet items property and equipment and finance lease right of use assets.

6. 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 1 years 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, 2019.

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, 2019
Assets		
Operating lease assets, net	Operating lease right of use assets	$ 7,875
Finance lease assets, net	Finance lease right of use assets	1,602
Total lease assets		9,477
Liabilities		
Current operating lease liability	Operating lease liabilities, current	1,814
Current finance lease liability	Accrued expenses and other current liabilities	159
Total current lease liabilities		1,973
Non-current operating lease liability	Operating lease liabilities, non-current	5,290
Non-current finance lease liability	Other non-current liabilities	367
Total non-current lease liabilities		5,657
Total lease liabilities		$ 7,630

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

In the year ended December 31, 2019 the Company terminated a lease of office space and derecognized the relating right of use asset and the lease liability of $0.2 million.

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, 2019
Operating lease expenses	Research and development expenses	$ 1,108
	General and administrative expenses	712
Finance lease amortization expenses	Research and development expenses	350
	General and administrative expenses	14
Interest on finance lease liabilities	Interest expenses	9
Sublease income	Other income (expense)	(128)
Net lease expense		$ 2,065

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

	December 31, 2019		
	Operating lease	Finance lease	Total
2020	1,826	155	1,981
2021	1,832	138	1,970
2022	1,830	122	1,952
2023	1,818	120	1,938
2024	128	10	138
Thereafter	—	—	—
Total lease payments	7,434	545	7,979
Less: interest	330	19	349
Present value of lease liabilities	$ 7,104	$ 526	$ 7,630

Under the prior lease guidance minimum rental commitments under non-cancelable leases for each of the next five years and total thereafter as of December 31, 2018, were as follows (in thousands):

Year ending December 31	Amount
2019	$ 520
2020	278
2021	43
2022	43
2023	11
Thereafter	—
Total	$ 895

Rent expense under operating leases for the years ended December 31, 2018 and 2017 was $1.1 million and $0.6 million, respectively.

These annual minimum lease payments did not include the embedded lease obligations under service agreements, which commenced in the year ended December 2019.

HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

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

	December 31, 2019
Weighted average remaining lease term in years	4.1
Weighted average discount rate [1]	2.3 %

[1] The majority of the contracts are concluded 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, 2019
Weighted average remaining lease term in years	3.9
Weighted average discount rate [1]	1.7 %

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

The Company subleases certain of its leased real estate that it does not currently utilize to a third party. The sublease has a remaining lease terms of 1.2 years without an option to renew and has been qualified as an operating lease. The Company recognizes sublease income in its consolidated statements of operations and comprehensive loss. The Company continued to account for the head lease as it did before sublease commencement.

7. Accrued expenses and other current liabilities

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

	December 31, 2019	December 31, 2018
Consulting fees	$ 724	$ 1,764
Salaries and bonuses	2,640	1,404
Social security contributions	177	121
Unearned grant income (current)	725	833
Loans	1,224	—
Invoices not yet received	2,673	—
Finance lease liabilities	159	—
Other accruals and liabilities	84	298
	$ 8,406	$ 4,420

HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

8. Loans payable

As of December 31, 2019 and December 31, 2018, loans payable consisted of the following (in thousands):

	Year ended December 31, 2019	2018
Loans from FFG	$ 7,305	$ 8,316
Unamortized debt discount	(2,586)	(3,924)
Total Loans payable, net	$ 4,719	$ 4,392

Note: The short-term portion of the loans are included in other current liabilities.

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 rates ranging from 0.75% to 1.0% per annum and mature at various dates between March 2020 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 $0.5 million during the years ended December 31, 2019, 2018 and 2017, 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, $0.8 million and $0.7 million as of December 31, 2019, 2018 and 2017, respectively, and unearned income (non-current) presented under loans payable non-current related to such benefit was $1.9 million, $3.0 million and $3.8 million as of December 31, 2019, 2018 and 2017, 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, 2019 and 2018, the unamortized debt discount related to FFG Loans was $2.6 million and $3.9 million, respectively.

The Company recognized interest expense of $0.9 million, $0.8 million and $0.6 million during the years ended December 31, 2019, 2018 and 2017, 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 $0.5 million during the years ended December 31, 2019, 2018 and 2017, respectively. A principal payment of $0.8 million was made in the year ended December 31, 2019. There were no principal payments due or paid under the FFG Loans during the year ended December 31, 2018.

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.

HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

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 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, 2019, the aggregate minimum future principal payments due in connection with the FFG Loans are summarized as follows (in thousands):

Year ending December 31,	Amount
2020	1,280
2021	—
2022	3,029
2023	1,806
2024	1,190
Thereafter	—
Total	$ 7,305

9. Redeemable convertible preferred stock

Redeemable convertible preferred stock

The Company previously issued Series A redeemable convertible preferred stock (the "Series A Preferred Stock"), Series B redeemable convertible preferred stock (the "Series B Preferred Stock"), Series C redeemable convertible preferred stock (the "Series C Preferred Stock") and Series D redeemable convertible preferred stock (the "Series D Preferred Stock"). Upon the closing of the Company’s IPO in April 2019, the Company’s outstanding redeemable convertible preferred stock automatically converted into shares of common stock or, if elected by the holder, into Class A common stock. Prior to conversion, the Preferred Stock had certain contingent redemption features based upon the occurrence of events that were not solely within the control of the Company and was therefore classified as mezzanine equity.

In December 2017, the Company issued and sold 693,500 shares of Series C Preferred Stock at an average price of $85.60 per share for gross proceeds of $59.4 million. An amount of $6.5 million of the gross proceeds from the issuance of Series C Preferred Stock was received on January 4, 2018. The Company incurred issuance costs in connection with the Series C Preferred Stock of $0.1 million.

In February 2019, the Company issued and sold 257,000 shares of Series D Preferred Stock at an average price of $145.65 per share for gross proceeds of $37.4 million. The Company incurred issuance costs in connection with the Series D Preferred Stock of $0.2 million.

Upon issuance of each class of Preferred Stock, the Company assessed the embedded conversion and liquidation features of the shares and determined that such features did not require the Company to separately account for these features. The Company also concluded that no beneficial conversion feature existed on the issuance date of each class of Preferred Stock.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

Upon the closing of the Company's IPO, on April 23, 2019, all 1,580,506 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. The related carrying value of $142.0 million was reclassified to common stock and additional paid-in capital.

As of December 31, 2019, the Company had no shares of Preferred Stock outstanding. The Company is authorized to issue 10,000,000 shares of undesignated preferred stock.

Prior to the IPO, the shares of Preferred Stock consisted of the following (in thousands, except share amounts):

	Preferred shares authorized	Preferred shares issued and outstanding	Carrying value	Common stock issuable upon conversion
Series A Preferred Stock	137,814	137,814	$ 0.014	1,604,574
Series B Preferred Stock	492,192	492,192	0.049	5,730,612
Series C Preferred Stock	693,500	693,500	0.069	8,074,447
Series D Preferred Stock	257,000	257,000	0.026	2,992,260
	1,580,506	1,580,506	$ 0.158	18,401,893

As of December 31, 2018, the outstanding shares of Preferred Stock consisted of the following (in thousands, except share amounts):

	Preferred shares authorized	Preferred shares issued and outstanding	Carrying value	Common stock issuable upon conversion
Series A Preferred Stock	137,814	137,814	$ 0.014	1,604,574
Series B Preferred Stock	492,192	492,192	0.049	5,730,612
Series C Preferred Stock	693,500	693,500	0.069	8,074,447
	1,323,506	1,323,506	$ 0.132	15,409,633

Prior to the conversion of the Preferred Stock upon closing of the IPO, the rights, preferences, and privileges of the Preferred Stock were as follows:

Conversion

Each share of Preferred Stock was convertible, at the option of the holder, at any time, and without the payment of additional consideration, into 11.643 fully paid and non-assessable shares of common stock or non-voting Class A common stock as determined by dividing the original issue price paid for such Preferred Shares by the applicable conversion price in effect at the time of conversion.

Liquidation

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company or certain deemed liquidation events, the holders of Preferred Shares had a right to receive, certain amounts in preference to any distribution to the holders of common stock.

10. Common stock and Class A common stock

In June 2018 the Company became the reporting entity in a transaction between entities under common control. In the accompanying consolidated financial statements and notes, the common stock is retrospectively presented as if the

HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

Company had been the reporting entity for all periods during which the previous reporting entity was under common control.

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.

As of December 31, 2018, the Company was authorized to issue 18,454,860 shares of common stock and had 1,006,595 shares of common stock outstanding and issued.

As of December 31, 2019, the Company was authorized to issue 100,000,000 shares of common stock and 3,900,000 shares of Class A common stock and had 21,746,392 shares of common stock and 3,819,732 shares of Class A common stock outstanding and issued.

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 are not entitled to vote, except as required by law. 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.

The holders of common stock and Class A common stock do not have any cumulative voting rights. Subject to any preferential dividend rights of any outstanding preferred stock, 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. 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 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, subject to the preferences that may be applicable to any outstanding shares of preferred 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 retrospectively presented as if such options had been issued and outstanding under the 2018 Stock Option and Grant Plan for all periods during which the previous reporting entity was under common control.

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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

quarterly installments following the first anniversary of the grant date, provided the option holder continues to have an employment or service relationship with the Company on each vesting date. The options expire on the 10th anniversary of the grant date. As of December 31, 2019, 1,357,764 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 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 2,608,042, 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 10th anniversary of the grant date. For each option the beneficiary is entitled to receive one share of common stock upon the exercise of the option.

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 of 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:

	Year ended December 31,		
	2019	2018	2017
Risk-free interest rate	2.21 %	2.78 %	(0.67)%
Expected term (in years)	6.1	5.1	2.8
Expected volatility	74.2 %	72.1 %	66.1 %
Expected dividends	— %	— %	— %

For option grants in 2017, the Company used AAA-rated euro area central government bond yields as the basis for the risk-free interest rate in the Black-Scholes model. For 2018 and 2019 option grants, following the change of incorporation to the United States, the Company used a risk-free interest rate based on the U.S. Treasury yield curve in

HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

effect at the time of grant. For the 2019 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, 2019 (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, 2018	1,606,325	$ 1.95	8.0	$ 13,466
Granted	1,661,200	12.34		
Exercised	(157,636)	0.10		
Forfeited	(110,605)	6.72		
Outstanding as of December 31, 2019	2,999,284	$ 7.63	8.1	$ 15,840
Options exercisable as of December 31, 2019	836,105	$ 0.88	6.1	$ 9,488
Options unvested as of December 31, 2019	2,163,179	$ 10.23	8.9	$ 6,352

The aggregate intrinsic value of stock options was calculated as the difference between the exercise price of the stock options and the estimated 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 estimated fair value per common stock used for calculating the intrinsic values as of December 31, 2019 and December 31, 2018, was $12.23 and $10.33, respectively.

The aggregate intrinsic value of options exercised during the years ended December 31, 2019 and 2018 was $1.4 million and $1.0 million, respectively. There were no options exercised during the year ended December 31, 2017.

The weighted average grant-date fair value per share of stock options granted during the years ended December 31, 2019 and 2018 was $7.92 and $2.55, respectively.

Cash received from option exercise under share-based payment arrangements for the years ended December 31, 2019 and 2018 was $16 thousand and $9 thousand, respectively. No cash from option exercise was received in the year ended December 31, 2017.

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,		
	2019	2018	2017
Research and development expenses	$ 1,981	$ 399	$ 295
General and administrative expenses	3,584	468	475
	$ 5,565	$ 867	$ 770

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

In the year ended December 31, 2018, the terms of 2,000 outstanding stock options were modified to increase the exercise price from $1.17 to $34.12. The Company determined that the fair value of the modified award on the effective date of the modification was smaller than the fair value of the original award immediately before the modification. Therefore, the modification did not lead to recognition of additional compensation cost or a change in unrecognized compensation cost.

As of December 31, 2019 and 2018, total unrecognized compensation cost related to the unvested stock-based awards was $9.3 million and $2.2 million, respectively, which is expected to be recognized over weighted average periods of 1.8 and 1.7 years, respectively.

12. Income taxes

During the years ended December 31, 2019, 2018 and 2017, 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, 2019, 2018 and 2017 consisted of the following (in thousands):

	Year ended December 31,		
	2019	2018	2017
United States	$ (7,886)	$ (604)	$ (121)
Foreign (Austria)	(35,151)	(15,609)	(12,598)
Net loss before tax	$ (43,037)	$ (16,213)	$ (12,719)

The Company's worldwide effective tax rate for the years ended December 31, 2019, 2018 and 2017 was 0.0%, (0.1)% 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

HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

21% for the years ended December 31, 2019 and 2018 and 35% for the year ended December 31, 2017 and the effective tax rate:

	Year ended December 31,		
	2019	2018	2017
U.S. federal statutory income tax rate	(21.0)%	(21.0)%	(35.0)%
State income taxes, net of federal benefit	—	—	—
Foreign tax rate differential[1]	(4.0)	(4.0)	10.0
Not taxable government grants[2]	(5.4)	(7.5)	(3.0)
Stock-based compensation[3]	(0.3)	(4.6)	(3.5)
other	(0.3)	(0.5)	—
Change in deferred tax asset valuation allowance[4]	31.0	37.5	31.5
Effective income tax rate	— %	(0.1)%	— %

[1] The 4% increase for the years ended December 31, 2019 and 2018, respectively, and the 10% reduction for the year ended December 31, 2017 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, 2019, 2018 and 2017, 5.4%, 7.5% and 3.0% increase, respectively, resulted from non-taxable research subsidies received from Austrian government agencies.

[3] For the years ended December 31, 2019, 2018 and 2017, 0.3% increase, 4.6% increase and 3.5% increase, respectively, resulted from non-taxable Stock-based compensation expense.

[4] For the years ended December 31, 2019, 2018 and 2017, 31.0% reduction, 37.5% reduction and 31.5% 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.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

Components of the net deferred tax assets or liabilities as of the years ended December 31, 2019 and 2018 consisted of the following (in thousands):

	Year ended December 31,	
	2019	2018
Deferred tax assets:		
Net operating loss carryforwards	$ 29,180	$ 19,011
Credit carryforwards	180	—
Accrued expenses and other	669	94
Stock-based compensation	2,717	51
Operating lease liabilities	1,740	—
Other liabilities	132	—
Total deferred tax assets	34,618	19,156
Valuation allowance	(32,583)	(19,156)
Total deferred tax assets	2,035	—
Deferred tax liabilities:		
Operating lease right of use asset	(1,808)	—
Finance lease right of use asset	(227)	—
Total deferred tax liabilities	(2,035)	—
Net deferred tax assets	$ —	$ —

As of December 31, 2019, 2018 and 2017, the Company had Austrian net operating loss carryforwards of $112.3 million, $76.0 million and $55.2 million, respectively, 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, 2019, 2018 and 2017. 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. As of December 31, 2019, there were no pending income tax examinations.

Changes in the valuation allowance for deferred tax assets during the years ended December 31, 2019, 2018 and 2017 related primarily to the increases in net operating loss carryforwards as follows (in thousands):

	Year ended December 31,		
	2019	2018	2017
Valuation allowance at beginning of period	$ (19,156)	$ (13,789)	$ (8,378)
Increases	(13,427)	(5,367)	(5,411)
Valuation allowance at end of period	$ (32,583)	$ (19,156)	$ (13,789)

On December 22, 2017, the United States enacted the Tax Cuts and Jobs Act ("Tax Reform Legislation" or "TCJA"), which made significant changes to U.S. federal income tax code, including a reduction of the statutory corporate tax rate from 35% to 21%, effective on January 1, 2018. This new legislation also eliminated or reduced

certain corporate income tax deductions as well as introduced new provisions that taxed certain foreign income not previously taxed in the United States. The TCJA also includes a provision for a tax on all previously undistributed earnings of U.S. companies located in foreign jurisdictions. Undistributed earnings in the form of cash and cash equivalents is taxed at a rate of 15.5% and all other earnings are taxed at a rate of 8.0%. This tax is payable over 8 years and will not accrue interest.

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.

Due to its loss making situation, the Company has established a full valuation allowance against its deferred tax assets as of December 31, 2019, 2018 and 2017 and the changes under the Tax Reform Legislation therefore did not have an effect on its deferred tax assets and liabilities and deferred tax asset valuation allowances in the period the tax regimen change was enacted.

The Company files income tax returns in the U.S. federal jurisdiction as well as in New York. The tax year 2018 remains open to examination by the jurisdictions in which the Company is subject to tax. Furthermore, the Company files income tax returns in Austria. The tax years 2015 to 2018 remain open to examination by the jurisdictions in which the Company is subject to tax.

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, 2019, 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, 2019, the Company’s total non-cancellable obligations under contracts with CMOs, excluding embedded lease liabilities, were $13.1 million, of which $10.2 million relate to 2020 deliverables, $2.9 million relate to 2021 deliverables and no payments relate to 2022 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 2021. 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.

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, 2019 and 2018, the Company recorded $1.9 million and $0.1 million, respectively, in licensing fees from 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, 2019 and December 31, 2018.

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. 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 any asserted or un-asserted legal claims or proceedings, individually or in the aggregate, will have a material adverse effect on the Company. The Company expenses the costs related to 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, 2019, 2018 and 2017, 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,		
	2019	2018	2017
Numerator:			
Net loss	$ (43,037)	$ (16,237)	$ (12,723)
Denominator:			
Weighted-average common shares outstanding, basic and diluted	17,859,935	914,375	911,777
Net loss per share, basic and diluted	$ (2.41)	$ (17.76)	$ (13.95)

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

	Year ended December 31,		
	2019	2018	2017
Series A Preferred Stock	—	1,604,574	1,604,574
Series B Preferred Stock	—	5,730,612	5,730,612
Series C Preferred Stock	—	8,074,447	8,074,447
Series D Preferred Stock	—	—	—
Options issued and outstanding	2,999,284	1,606,325	1,434,150
Total	2,999,284	17,015,958	16,843,783

16. Related parties

The Company is party to research and service arrangements with the University of Basel. The Company's Chief Scientific Officer and his spouse are employees of the University of Basel and both involved in providing the services under these arrangements. In the years ended December 31, 2019, 2018 and 2017, the Company recorded $0.3 million, $0.4 million and $0.3 million, respectively, in research and development expenses for service fees paid to the University of Basel. 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 Chief Scientific Officer in the course of his consulting services to the Company. In the years ended December 31, 2019, 2018 and 2017, no royalties were paid pursuant to the terms of this arrangement.

During the year ended December 31, 2019, the Company issued 50,670 shares of Series D Preferred Stock for total gross proceeds of $7.4 million and 1,303,750 shares of common stock for total gross proceeds of $18.3 million to certain stockholders that were related parties as part of the IPO.

During the year ended December 31, 2018, the Company issued no shares to stockholders that were related parties.

HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

During the year ended December 31, 2017, the Company issued 61,524 shares of Series B Preferred Stock for total proceeds of $4.0 million and 147,712 shares of Series C Preferred Stock for total proceeds of $12.6 million to certain stockholders that were related parties. The due from shareholder amount of $6.5 million as of December 31, 2017 is from one of these related parties.

17. Selected Quarterly Financial Information (Unaudited)

The following information has been derived from unaudited condensed consolidated financial statements that, in the opinion of management, include all recurring adjustments necessary for a fair statement of such information (in thousands except per share data) for the years ended December 31, 2019 and 2018 are as follows:

	2019 Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
Revenue	$ 2,235	$ 4,051	$ 2,038	$ 3,618
Operating expenses	(12,890)	(17,680)	(15,614)	(16,843)
Net loss	(9,329)	(12,079)	(11,385)	(10,244)
Net loss per share - basic and diluted	$ (9.27)	$ (0.63)	$ (0.45)	$ (0.40)

	2018 Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
Revenue	$ —	$ 649	$ 1,900	$ 5,080
Operating expenses	(6,449)	(7,624)	(7,452)	(7,284)
Net loss	(4,573)	(5,819)	(3,953)	(1,892)
Net loss per share - basic and diluted	$ (5.02)	$ (6.38)	$ (4.34)	$ (2.05)

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").

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.

No 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.

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.

CONSULTANCY AGREEMENT

This consultancy agreement (the "**Agreement**") is made among and between:

1. **HOOKIPA Biotech GmbH, FN 365895g,** c/o Julius-Raab-Platz 4, 1010 Vienna (after the change of corporate form "HOOKIPA Biotech AG")

(the "**Company**")

and

2. Daniel D. Pinschewer, 17 chemin de Planta, 1223 Cologny

(the "**Consultant**")

(each of them being also designated as a "**Party**" and together the "**Parties**")

Preamble

WHEREAS

A. The Company is active in the biotechnological / pharmaceutical industry;

B. The Company intends to hire the Consultant to perform certain consultancy services as defined in Section 1 below.

C. The Consultant will have access to confidential and proprietary information, trade secrets, inventions and know-how, including confidential information relating to the business or interests of the Company and of persons and entities with whom the Company may have commercial, technical or scientific relationships, in particular information relating to the Company's research and development programs and technology platforms;

D. The Parties desire to further specify the terms and conditions of the Consultant's functions, in particular his rights and obligations towards the Company;

NOW, THEREFORE, THE PARTIES HEREBY AGREE AS FOLLOWS:

1. Services

The Consultant agrees to perform the consultancy services agreed in the Schedules of Work attached hereto as Exhibit A (the "**Services**"), within the Consulting Service Term of this Agreement, as stipulated in Section 15. For the purposes of this Agreement, the expected level of effort for provision of consultancy services will be 20% of his time on average (i.e. one day/8 hours per week in average) while the Consultant is not bound to any fixed working hours and is free to choose his place of work. Each Schedule of Work defines the scope of the Services and other details (delivery schedule, etc.) for a separate project. The Company may at any time in liaison with the Consultant decide to assign further projects to the Consultant by establishing further Schedules of Work, it being understood that the terms and conditions of this Agreement will apply to such additional Services. The Company agrees that the Consultant shall have reasonable access to the Company's representatives as necessary and on a timely manner to perform the Services as per this Agreement.

2. Payment for Services

As consideration for the performance of the Services defined in the Schedules of Work (Exhibit A), the Company agrees to pay the Consultant, as follows

2.1 **Fees.** Fees for services provided within the Consulting Service Term of this Agreement, as stipulated in Section 15, will be a lump sum of EUR 50,000.—(Fifty thousand euros), VAT ("*Umsatzsteuer*"), if applicable, included. Such lump sum shall be paid by the Company to Consultant in 4 installments (EUR 12,500.—each installment) on the last day of March 2012, June 2012, September 2012 and December 2012, upon receiving an invoice and work report from the Consultant.

2.2 **Reimbursable Expenses.** In addition to the payments outlined in Section 2.1 of this Agreement, the Company will reimburse Consultant for all reasonable travel costs incurred while traveling to and from the Consultant's place of business and the location specified by the Company. These costs include airfare, train, lodging, food, rental automobile, taxis, parking, other ground transportation. In addition, Company will reimburse Consultant for all reasonable costs associated with the **services** provided to the Company at his place of business and when traveling, proportionate to the level of effort specified in Section 1 (one day/8 hours per week in average), including telephone, fax, and internet charges, postage and courier charges, and office supplies. Receipts for these expenses will be attached to invoices submitted to the Company for reimbursement.

3. Payment Terms

The Consultant shall send quarterly invoices for the Services rendered and for reimbursable expenses in accordance with this Agreement. The Company agrees that all invoiced fees and expenses payable under this Agreement shall be paid to the Consultant within thirty (30) business days of receipt of said invoice. Payments shall be made in Euros by wire transfer to the Consultant's designated bank account.

All taxes and fees relating to amounts payable under this Agreement shall be deducted and transferred by Consultant to the competent authority.

4. Reporting

The Consultant shall give to the Company such information regarding the performance and results of the Services as required by the Company. He is not obliged to comply with any instructions of the Company. The Company shall, however, be entitled to more closely specify the scope of work of the Consultant and to suspend or terminate the Consultant services for one or more projects.

5. Subcontractors

The Consultant may, in providing the Services to the Company, engage the services of professionals (e.g., subcontractors and associates). At least one week prior to such engagement, the Consultant shall notify the Company in writing and shall abstain from the engagement in case that the Company objects to the engagement due to substantive concerns against the person of the professional.

6. Work equipment, use of premises

The Consultant will use his own work equipment when providing the Services to the Company.

The Consultant will not use Company facilities as his place of business, except for occasional meetings.

7. Confidentiality

"**Information**" shall mean all confidential information relating to the Company, including without limitation its products, business, operations, ideas, formulas, compositions, generally, including without limitation financial, technical, medical, biological, legal and commercial information, know-how, manufacturing and production processes, techniques, research and development information and trade secrets relating to the Company which may be disclosed to the Consultant for the purpose of providing the Services. The failure to identify the information as being confidential shall not relieve the Consultant from the obligations of confidentiality with respect to such information.

The Consultant hereby undertakes to keep the Information confidential and to use the Information solely for the purposes of providing the Services and not to disclose or reveal the Information to any third party, following the receipt of the Information.

Exclusions - Information shall not be deemed confidential and Consultant shall have no obligation with respect to any information which:

(i) at the time of the disclosure, is rightfully in the public domain;
(ii) subsequently becomes available to the public other than by a breach of this Agreement;
(iii) is rightfully in the possession of the Consultant at the time such information is disclosed by the Company, without any limitation on use or disclosure prior to its receipt from the Consultant, as shown by documents or other tangible evidence in the Consultant's possession;

(iv) has been fully received by the Consultant from a third party, who did not obtain the same from the Company, directly or indirectly;
(v) has been independently developed by the Consultant without assistance, application or use of the Information, as evidenced by written records of the Consultant; or
(vi) has been approved for release by a written authorization of the Company.

The Consultant undertakes to use the Information only for the purpose of providing the Services and not for any other purposes.

Following receipt of a written request from the Company, the Consultant must deliver to the Company, all tangible materials containing or embodying the Information within thirty (30) working days following the receipt of such request. The Information shall be sent by registered mail or by courier and the Consultant shall retain proof of such mailing.

The Parties acknowledge that the disclosure of the Information, without the express written consent of the Company, may cause damages to the Company. It is understood and agreed that money damages would not be a sufficient remedy for any breach of this Agreement by the Consultant and that the Company shall be entitled to seek other relief, including injunction or order of a competent court or administrative agencies and specific performance, as a remedy of such breach.

The Consultant will use the Information for the sole purpose of rendering the Services. The Information will be disclosed to the Consultant with the express understanding that neither the Consultant nor the Company will be obligated to enter into any further agreement relating to the Information.

It is understood and agreed that any and all proprietary rights, including, but not limited to, patent rights, trademarks and proprietary rights, in and to the Information disclosed to the Consultant shall be and remain in the possession of the Company and the Consultant shall have no right, title or interest in or to any of the Information.

The Article shall apply for the full term of this Agreement and for an unlimited time period after termination of this Agreement.

8. Intellectual Property

8.1 **Definition of "Proprietary Information".** Consultant understands that the Company possesses and will possess Proprietary Information, which is important to its business. For purposes of this Agreement, "Proprietary Information" is all information, whether or not in writing or other tangible form, that was or will be developed, created, or discovered by or on behalf of the Company, or which became or will become known by, or was or is conveyed to the Company, and which has commercial value to the Company. "Proprietary Information" includes, but is not limited to, information about trade secrets, designs, methodologies, technology, know-how, processes, data, ideas, techniques, inventions (whether patentable or not), trademarks, registered designs, features and modes of operation, internal documentation, works of authorship, technical, business, financial, client, marketing, and product development plans, forecasts, the salaries and terms of compensation of employees, client and supplier lists, contacts and other information concerning the Company's actual or anticipated products or services, business, research or development, or any information which is received in confidence by or for the Company from any other person.

8.2 **Consultant's obligations**. The Consultant acknowledges that, because of the nature of the Consultant's duties and the particular responsibilities arising as a result of such duties, the Consultant owes to the Company an obligation to further the interests of the Company.

The Consultant shall promptly disclose to the Company any idea or invention created or developed by the Consultant or his subcontractors and ensuing from the Services performed by the Consultant or his subcontractors during the term of this Agreement, which is actually or potentially relevant to the business of the Company.

The Consultant acknowledges that any Proprietary Information whether in existence now or coming into existence at any time in the future, on creation either during the normal course of Service or by using materials, tools or knowledge made available through Service to the Company shall vest in and be the exclusive property of the Company which the Company shall nominate and, if required to do so (whether before or after the termination of this Agreement), the Consultant will execute all instruments and do all things necessary to vest ownership in the above rights in the Company as sole beneficial owner. The Consultant may not, without the Company's written consent, disclose, multiply, use, manufacture, bring on the market or sell, lease, deliver or otherwise trade, offer, or register the results of his Services.

The Consultant appoints the Company to be the Consultant's attorney in the Consultant's name and on the Consultant's behalf to execute any such instrument or do any such thing necessary for the purpose of giving to the Company or its nominee the full benefit of the provisions of this clause 8. It is a condition of the Service that the Consultant executes as a deed the Power of Attorney attached as Exhibit B to this Agreement. Upon the Company's request, the Consultant shall issue further powers of attorney to the Company within the same scope of the Power of Attorney Exhibit B, in particular if the Company requires a special Power of Attorney or a Power of Attorney with certain form requirements.

All information including, but not limited to notes, memoranda, computer discs, data sticks, software, databases, spreadsheets, files, reports, minutes, plans and records concerning the business of the Company or any of its, or their suppliers, agents, distributors, clients or customers which are received or made by the Consultant in the course of Service will be the property of the Company and must be surrendered by the Consultant to the Company at any time and in any event on the termination of Agreement.

The provisions of this clause 8 shall survive termination of this Agreement insofar as they relate to discoveries, inventions, secret processes, and improvements in procedure, trademarks, registered designs, design rights, copyright, database rights and all other intellectual property rights which were created before the termination of this Agreement.

The Company shall have the right to file applications for intellectual property rights containing the Consultant's name. The Company will acknowledge the Consultant's role as an inventor on patent applications, according to applicable rules of inventorship.

Insofar as rights that are mentioned above and are related to the intellectual property rights, are not vested in the Company by operation of law or based on this Agreement, the Consultant covenants that he will transfer and hereby transfers to the Company such rights provided, however, that the Company may at its sole discretion renounce such transfer or transfer back to the Consultant any such intellectual property rights at any time. If a transfer should not be possible under the applicable law, then the Consultant shall grant to the Company a perpetual, transferable, royalty-free license to use such Intellectual Property.

The Consultant acknowledges that his consultancy fees under Section 2.1 include reasonable compensation for the loss of intellectual property rights.

The Company is entitled to transfer the intellectual property rights in full or in part to any third party. Subject to mandatory applicable law, the Company and such third parties are not obliged to mention the Consultant as the author if they publish any inventions, computer programs or other works. They are free to make any modifications, translations and/or other adaptations and/or can refrain from making any publications.

With regard to intellectual property that cannot be entirely transferred to the Company, in particular intellectual property under the Austrian Copyright Act (*Urheberrechtsgesetz*) the Consultant shall transfer, upon the Company's request, any and all rights that can be derived from such intellectual property rights (in particular rights to use the intellectual property / *Werknutzungsrechte*) to the Company.

9. Vacation

The Consultant is not entitled to any paid vacation.

10. Non-Competition and Non-Solicitation Undertaking

During the term of this Agreement and for a period of 10 years after termination hereof, the Consultant shall not act as a consultant for any competitor of the Company, that uses a recombinant arenavirus vector as a vaccine candidate. In particular, Consultant shall not directly or indirectly support the development, improvement and manufacture of any product of any competitor of the Company that uses a recombinant arenavirus vector as a vaccine candidate or support the distribution of such product. In addition, during the term of this Agreement and for a period of 3 years after termination hereof, the Consultant shall not act as a consultant for any competitor of the Company that is developing a vaccine against the Company's targets, cytomegalovirus and/or others (to be defined).

Nothing in this Agreement shall be construed to restrict Consultant's activity as a professor in the Department of Pathology and Immunology and the W.H.O. Collaborating Centre for Vaccine Immunology of the University of Geneva or in any other mere scientific and non-commercial activity, or his ability to enter into new agreements; provided that (a) Consultant's new agreements in the field of vaccines shall be disclosed in advance and in writing to the Company; (b) in carrying out any such activities, Consultant shall at all times adhere to his confidentiality obligations and non-competition clauses of this Agreement; (c) the totality of such outside activities shall not affect the time committed by the Consultant to Company under this Agreement (1 days per week) unless with the prior consent of the Company; and (c) Consultant shall be bound by any confidentiality agreements pertaining to such outside activities and will not disclose confidential information of third parties to the Company.

11. Approval

The Consultant declares that this Agreement has been notified to the Consultant's employer(s) and that his employer(s) have approved of this Agreement. Should the Consultant be obliged under applicable laws and regulations or employment contracts to pay any portion of the remuneration under this Agreement to his or her employer or any other third party, the Consultant shall be solely responsible for such payments.

12. Independent Contractors

It is the express intention of the parties that Consultant is an independent contractor, and is classified by the Company as such for all tax and employee benefit purposes, and is not an employee, agent, or partner of the Company. Nothing in this Agreement shall be construed as granting to the Consultant any license or right under any patent rights or as representing any commitment by either Party to enter into any license or other agreement by implication or otherwise.

Consultant acknowledges and agrees that Consultant is obligated to report as income all compensation received by Consultant pursuant to this Agreement and that Consultant is solely responsible for all taxes, withholdings, and other similar statutory obligations including, but not limited to, self-employment tax and social security. In the event that Consultant, employs assistants or subcontractors to aid in the performance of the Services, the parties agree that such assistants or subcontractors are employed or retained solely by Consultant, and that Consultant alone is responsible for providing workers' compensation insurance for, paying the compensation, salaries and wages of, and ensuring that all required tax withholdings are made for such assistants or subcontractors. Consultant agrees to ensure that any such assistants or subcontractors shall abide by all of the terms of this Agreement. Consultant agrees to defend, indemnify and hold the Company harmless from any and all claims made by any entity on account of an alleged failure by Consultant to satisfy any tax or withholding obligations of Consultant.

13. Entire Agreement

This Agreement and the Exhibits hereto, contain the entire Agreement between the Parties hereto with respect to the matters covered herein. No other agreements, representations, warranties, or other matters, oral or written, purportedly agreed to or represented by or on behalf of the Consultant, shall be deemed to bind the Parties hereto with respect to the subject matter hereof. The Company acknowledges that it is entering into this Agreement solely on the basis of representations contained herein. In the event of a conflict in the provisions of the Exhibits hereto and the provisions set forth in the Agreement, the provisions of the Exhibits shall prevail.

14. Applicable Law and competent jurisdiction

This Agreement is subject to Austrian law and the competent court in the First district of the City of Vienna, Austria, shall have exclusive jurisdiction for all disputes between the parties arising out of or in connection with this Agreement.

15. Term and Termination

The Agreements shall be effective from January 1st, 2012 (Effective Date) and shall remain in force for a period of One year until December 31st, 2012 (Consulting Service Term) unless earlier terminated by the Consultant in case the University of Geneva would in the future withdraw its consent to this side activity of the Consultant for the Company. The extension of this Agreement shall be subject to mutual written agreement by both Parties and the Parties shall review the services to be provided and determine whether the level of effort specified in Section 1 and the scope of work require changes to reflect the on-going needs of the Company.

This Agreement may be terminated by either Party at any time on cause (*aus wichtigem Grund*) with immediate effect as well as without cause upon a thirty (30) day written notice delivered to the other Party. In the event a notice of termination is issued, the Company shall promptly pay to the Consultant any monies due and owing to the Consultant in relation to any Services performed by the Consultant prior to the date of such termination and any costs associated with the termination itself and the Consultant will promptly return to the Company all tangible materials containing or embodying the Information.

16. Severability

The illegality, invalidity or unenforceability in any jurisdiction of any provision of this Agreement shall not affect the validity or enforceability of any other provision of this Agreement in that or any other jurisdiction. The Parties undertake to negotiate in good faith to replace the relevant provision by another provision reflecting as closely as possible the original intention and purpose of the Parties.

17. Disclaimer

Each party to this agreement hereby disclaims any and all warranties, either express or implied, including without limitation any warranties of merchantability, fitness for a particular purpose, and non-infringement. Without limiting the foregoing, Consultant hereby disclaims any and all representations pertaining to (a) the efficacy, safety, market potential and/or other characteristics or qualities of any product developed in the course of the services provided and/or (b) whether any product can be designed, developed, marketed or sold without infringing any third party intellectual property rights.

18. Indemnification

18.1 **Indemnification by Consultant.** Unless otherwise provided herein, Consultant agrees to indemnify, hold harmless, and defend the Company, its affiliates, and any of their respective directors, officers, employees, and agents (collectively, the "Company Indemnitees") from and against any and all liability, damages, loss, cost or expense (including reasonable attorneys' fees) ("Losses") arising out of third party claims, actions, proceedings, or suits ("Claims"), to the extent resulting from: a breach by Consultant of an obligation set forth in this Agreement; or the willful misconduct of the Consultant or and of his employees or subcontractors. Such indemnity shall not apply if the Company fails to comply with the indemnification procedures set forth in Section 18.2 or to the extent that a Loss results from (i) breach by Company of its obligations under this Agreement; or (ii) the negligence, recklessness or willful misconduct of any Company Indemnitee.

18.2 **Indemnification by Company.** Unless otherwise provided herein, the Company agrees to indemnify, hold harmless, and defend Consultant and his employees, and subcontractors if any (collectively, the "Assignor Indemnitees") from and against any and all Losses arising out of Claims, to the extent resulting from: (a) research, development, manufacture, possession, storage, transport, importation, use, sale, marketing, or distribution of products arising out of the services provided by the Consultant in the territory by Company or its affiliates or licensees; (b) breach by the Company of any obligation set forth in this Agreement; or (c) the willful misconduct of the Company, any of its affiliates, or any of their respective employees or agents. Such indemnity shall not apply if the Consultant fails to comply with the indemnification procedures set forth in Section 18.1 or to the extent that a Loss results from (i) a breach by Consultant of any obligation of this Agreement; or (ii) the negligence, recklessness or willful misconduct of the Consultant or any of his employees or subcontractors (if any)

18.3 **Control of Defense.** Any entity entitled to indemnification under this Article 18 shall give written notice to the indemnifying Party of any Claims that may be subject to indemnification, promptly after learning of such Claim. Within a reasonable time after receiving such notice, the indemnifying Party shall assume the defense of such Claim with counsel reasonably satisfactory to the indemnified Party. The indemnified Party shall cooperate with the indemnifying Party in such defense. The indemnified Party may, at his or its option and expense, be represented by counsel of his or its choice in any action or proceeding with respect to such Claim. The indemnifying Party shall not be liable for any litigation costs or expenses incurred by the indemnified Party without the indemnifying Party's written consent, such consent not to be unreasonably withheld. The indemnifying Party shall not settle any such Claim if such settlement (a) does not fully and unconditionally release the indemnified Party from all liability relating thereto or (b) adversely impacts the rights granted to the indemnified Party under this Agreement, unless the indemnified Party otherwise agrees in writing.

19. Notices

Any notice in connection with this Agreement shall be sent by registered mail, delivery or fax as follows:

Company:
CEO
HOOKIPA Biotech GmbH

c/o Julius-Raab-Platz 4
1010 Vienna

Consultant:
Daniel Pinschewer
17 chemin de Planta
1223 Cologny
Switzerland

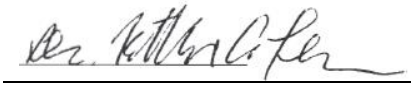
or to such other address or facsimile number as is notified in writing from time to time by any Party to this Agreement to the other Party hereto.

20. Assignment

A Party may not assign this Agreement without the prior written consent of the other Party.

IN WITNESS WHEREOF, the Parties hereto have signed this Agreement.

Company:
Hookipa Biotech GmbH
Dr. Katherine Cohen

Signature 

Date Nov 13, 2011

Consultant:
Daniel Pinschewer

Signature 

Date Nov 16th 2011

EXHIBIT A

Schedules of Work

The Consultant will in particular report to Dr Katherine Cohen, CEO who will monitor the Services provided to the Company.

Scope of the Services:

- Provide consultancy to the development plan with respect to:
- Vector production strategy;
- Choice of target diseases / antigens.
- Specialized expertise on the arenavirus vector platform
- Consult Company’s IP strategy
- Provide technology advice on Company’s wetlab activities
- Advise company on international funding opportunities provided by organizations such as the Gates Foundation and NIH.

3. General Tasks:

- Supporting the Project Teams
- Participate in Project Meetings/teleconferences
- Undertake specific project tasks, as specified and agreed
- Consulting on timelines and budgets
- Serve as the Company’s scientific advisor (for example as member of SAB)
- Providing consultation to manufacturing and vector design

EXHIBIT B

POWER OF ATTORNEY

By this Power of Attorney **Daniel Pinschewer, 17 chemin de Planta, 1223 Cologny, Switzerland,** in accordance with the terms of my Consultancy Agreement with *Hookiba Biotech GmbH* (the "**Company**") dated today (the "**Consultancy Agreement**") **HEREBY APPOINT** the Company to act as my attorney with authority in my name and on my behalf:

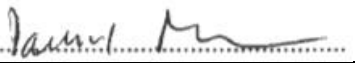
(a) during my service or after it has terminated, to do anything and sign or execute any document and generally to use my name for the purpose of giving to the Company or its or their nominee(s) the full benefit of clauses 8; and

(b) to appoint any substitute and to delegate to that substitute all or any powers conferred by this Power of Attorney.

I declare that this Power of Attorney, having been given by me to secure my obligations under clause 8 of the Consultancy Agreement, shall be irrevocable in accordance with Section 1002 following of the Austrian Civil Code (as amended from time to time).

Hookiba Biotech GmbH ("the **Company**") is released from the restrictions regarding self-contracting and also entitled to multiple representations *(Doppelvertretung)*.

IN WITNESS whereof this Power of Attorney has been duly executed.
EXECUTED as a deed by:

Signature 

Date Nov 16th 2011

Witness

Signature 

Name: Doron Merkler

Address: Route De Valleiry 28A

1284 Chancy CH

Date: 16 Nov 2011

AMENDMENT TO THE AGREEMENT

between

1. **HOOKIPA Biotech GmbH, FN 365895g,** Helmut-Qualtinger-Gasse 2, 1030 Vienna, Austria ("HOOKIPA Biotech AG")

(the "**Company**")

and

2. Daniel D. Pinschewer, 17 chemin de Planta, 1223 Cologny

(the "**Consultant**")

(each of them being also designated as a "**Party**" and together the "**Parties**")

RECITALS

WHEREAS, the Parties entered into a Consultancy Agreement signed by the Company on November 13, 2011 and by the Consultant on November 16, 2011, (the "**Agreement**") whereby the Company hired Daniel Pinschewer as Consultant.

WHEREAS, the Parties now wish to extend the Agreement in accordance with the terms and conditions of this amendment (the "**Amendment**").

NOW THEREFORE THE PARTIES HEREBY AGREE AS FOLLOWS:

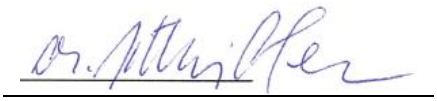
1. The Agreement is hereby extended for one more year from January 1, 2013 to December 31, 2013 ("**Extension Period**").

2. The Consultant confirms that he has received all Fees and Reimbursable Expenses governed in Section 2 of the Agreement for January 1, 2012 to December 31, 2012. The Payment dates specified in Section 2 of the Agreement will be changed to the corresponding dates for Extension Period for the service during such period.

3. All terms and conditions in Agreement remain in force for the Amendment.

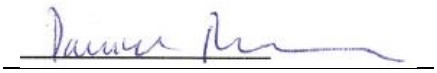
IN WITNESS WHEREOF, the Parties hereto have signed this Agreement.

Company:
Hookipa Biotech AG
Dr. Katherine Cohen, CEO

Signature 

Date 7 Jan 2013

Consultant:
Dr. Daniel Pinschewer

Signature 

Date 7 January 2013

AMENDMENT NO. 2 TO THE CONSULTANCY AGREEMENT

between

1. **HOOKIPA Biotech AG, FN 365895g,** Helmut-Qualtinger-Gasse 2, 1030 Vienna, Austria

(the "**Company**")

and

2. **Prof. Dr. Daniel Pinschewer,** Im Zehntenfrei 21 A, 4102 Binningen, Switzerland

(the "**Consultant**")

(each of them being also designated as a "**Party**" and together the "**Parties**")

RECITALS

WHEREAS, the Parties entered into a Consultancy Agreement signed by the Company on November 13, 2011 and by the Consultant on November 16, 2011 (the "**Agreement**") whereby the Company hired Daniel Pinschewer as Consultant. The Parties signed an amendment (the "**Amendment No. 1**") to the Agreement on January 7, 2013.

WHEREAS, the Parties now wish to extend the Agreement in accordance with the terms and conditions of this amendment (the "**Amendment No. 2**").

NOW THEREFORE THE PARTIES HEREBY AGREE AS FOLLOWS:

1. The Agreement is hereby extended for one year from January 1, 2014 to December 31, 2014 (the "**Extension Period**").

2. The address of the Consultant shall be amended to: Im Zehntenfrei 21A, 4102 Binningen, Switzerland

3. The Payment dates specified in Section 2 of the Agreement will be changed to the corresponding dates for the Extension Period for the Consultant's service during such period.

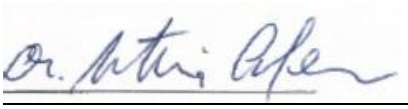
4. In Section 10 of the Agreement the words "Department of Pathology and Immunology and the W.H.O. Collaborating Centre for Vaccine Immunology of the University of Geneva" shall be deleted and replaced by "Department of Biomedicine of the University of Basel." All other texts in Section 10 remain unchanged.

5. The first sentence of Section 11 of the Agreement ("Approval") shall be amended to read: "The Consultant declares that this Agreement is notified to the Consultant's employer, the University of Basel, in accordance with the latter institutions regulations."

6. All other terms and conditions in the Agreement remain in force for the Amendment No. 2.

IN WITNESS WHEREOF, the Parties hereto have signed this Agreement.

Company:
Hookipa Biotech AG
Dr. Katherine Cohen, CEO

Signature 

Date Dec 13, 2013

Consultant:
Prof. Dr. Daniel Pinschewer

Signature 

Date Dec.16th 2013

AMENDMENT NO. 3 TO THE CONSULTANCY AGREEMENT

between

1. **HOOKIPA Biotech AG, FN 365895g,** Helmut-Qualtinger-Gasse 2, 1030 Vienna, Austria

(the "**Company**")

and

2. **Prof. Dr. Daniel Pinschewer,** Im Zehntenfrei 21A, 4102 Binningen, Switzerland

(the "**Consultant**")

(each of them being also designated as a "**Party**" and together the "**Parties**")

RECITALS

WHEREAS, the Parties entered into a Consultancy Agreement signed by the Company on November 13, 2011 and by the Consultant on November 16, 2011 (the "**Agreement**") whereby the Company hired Daniel Pinschewer as Consultant. The Parties signed an amendment (the "**Amendment No. 1**") to the Agreement on January 7, 2013 and a further amendment (the "**Amendment No. 2**") on December 13th, 2013 and December 16th, 2013, respectively.

WHEREAS, the Parties now wish to extend the Agreement, as amended, in accordance with the terms and conditions of this amendment (the "**Amendment No. 3**").

NOW THEREFORE THE PARTIES HEREBY AGREE AS FOLLOWS:

1. The Agreement, as amended, is hereby extended for one year from January 1, 2015 to December 31, 2015 (the "**Extension Period**").

2. The Payment dates specified in Section 2 of the Agreement, as amended, will be changed to the corresponding dates for the Extension Period for the Consultant's service during such period.

3. All other terms and conditions in the Agreement, as amended, remain in force for the Amendment No. 3.

IN WITNESS WHEREOF, the Parties hereto have signed this Agreement.

Company:		**Consultant:**	
Hookipa Biotech AG		**Prof. Dr. Daniel Pinschewer**	
Dr. Katherine Cohen, CEO			
Signature		Signature	
Date	December 18, 2014	Date	December 15th 2014

AMENDMENT NO. 4 TO THE CONSULTANCY AGREEMENT

between

1. **HOOKIPA Biotech AG, FN 365895g,** Helmut-Qualtinger-Gasse 2, 1030 Vienna, Austria

(the "**Company**")

and

2. **Prof. Dr. Daniel Pinschewer,** Im Zehntenfrei 21A, 4102 Binningen, Switzerland

(the "**Consultant**")

(each of them being also designated as a "**Party**" and together the **"Parties**")

RECITALS

WHEREAS, the Parties entered into a Consultancy Agreement signed by the Company on November 13, 2011 and by the Consultant on November 16, 2011 (the "**Agreement**") whereby the Company hired Daniel Pinschewer as Consultant. The Parties signed an amendment (the "**Amendment No. 1**") to the Agreement on January 7, 2013, a further amendment (the "**Amendment No. 2**") on December 13, 2013 and December 16, 2013. and a further amendment (the "**Amendment No. 3**") on December 15, 2014 and December 18, 2014, respectively.

WHEREAS, the Parties now wish to extend the Agreement, as amended, in accordance with the terms and conditions of this amendment (the "**Amendment No. 4**").

NOW THEREFORE THE PARTIES HEREBY AGREE AS FOLLOWS:

1. The Agreement, as amended, is hereby extended for one year from January 1, 2016 to December 31, 2016 (the "**Extension Period**").

2. The Payment dates specified in Section 2 of the Agreement, as amended, will be changed to the corresponding dates for the Extension Period for the Consultant's service during such period.

3. All other terms and conditions in the Agreement, as amended, remain in force for the Amendment No. 4.

IN WITNESS WHEREOF, the Parties hereto have signed this Agreement.

Company: **Hookipa Biotech AG** Dr. Katherine Cohen, CEO	**Consultant:** **Prof. Dr. Daniel Pinschewer**
Signature 	Signature 
Date Feb 25, 2016	Date Feb 24th 2016

AMENDMENT NO. 5 TO THE CONSULTANCY AGREEMENT

between

1. **HOOKIPA Biotech AG, EN 365895g,** Helmut-Qualtinger-Gasse 2, 1030 Vienna, Austria

(the "**Company**")

and

2. **Prof. Dr. Daniel Pinschewer,** Im Zehntenfrei 5, 4102 Binningen, Switzerland

(the "**Consultant**")

(each of them being also designated as a "**Party**" and together the "**Parties**")

RECITALS

WHEREAS, the Parties entered into a Consultancy Agreement signed by the Company on November 13, 2011 and by the Consultant on November 16, 2011 (the "**Agreement**") whereby the Company hired Daniel Pinschewer as Consultant. The Parties signed an amendment (the "**Amendment No. 1**") to the Agreement on January 7, 2013, a further amendment (the "**Amendment No. 2**") on December 13, 2013 and December 16, 2013, a further amendment (the "**Amendment No. 3**") on December 15, 2014 and December 18, 2014, and a further amendment (the "**Amendment No. 4**") on February 24, 2016 and February 25, 2016, respectively.

WHEREAS, the Parties now wish to extend the Agreement, as amended, in accordance with the terms and conditions of this amendment (the "**Amendment No. 5**").

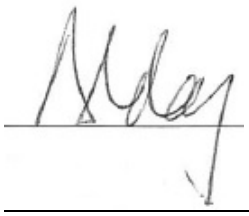
NOW THEREFORE THE PARTIES HEREBY AGREE AS FOLLOWS:

1. The Agreement, as amended, is hereby extended for one year from January 1, 2017 to December 31, 2017 (the "**Extension Period**").

2. The Payment dates specified in Section 2 of the Agreement, as amended, will be changed to the corresponding dates for the Extension Period for the Consultant's service during such period.

3. All other terms and conditions in the Agreement, as amended, remain in force for this Amendment No. 5.

IN WITNESS WHEREOF, the Parties hereto have signed this Agreement.

Company: **Hookipa Biotech AG** Jörn Aldag, CEO	**Consultant:** **Prof. Dr. Daniel Pinschewer**
Signature 	Signature 
Date 7.12.16	Date 7.12.2016

AMENDMENT NO. 6 TO THE CONSULTANCY AGREEMENT

between

1. **HOOKIPA Biotech AG, FN 365895g,** Helmut-Qualtinger-Gasse 2, 1030 Vienna, Austria

(the "**Company**")

and

2. **Prof. Dr. Daniel Pinschewer,** Im Zehntenfrei 5, 4102 Binningen, Switzerland

(the "**Consultant**")

(each of them being also designated as a "**Party**" and together the "**Parties**")

RECITALS

WHEREAS, the Parties entered into a Consultancy Agreement signed by the Company on November 13, 2011 and by the Consultant on November 16, 2011 (the "**Agreement**") whereby the Company hired Daniel Pinschewer as Consultant. The Parties signed an amendment (the "**Amendment No. 1**") to the Agreement on January 7, 2013, a further amendment (the "**Amendment No. 2**") on December 13, 2013 and December 16, 2013, a further amendment (the "**Amendment No. 3**") on December 15, 2014 and December 18, 2014, a further amendment (the "**Amendment No. 4**") on February 24, 2016 and February 25, 2016, and a further amendment (the "**Amendment No. 5**") on December 7, 2016, respectively.

WHEREAS, the Parties now wish to extend the Agreement, as amended, in accordance with the terms and conditions of this amendment (the "**Amendment No. 6**").

NOW THEREFORE THE PARTIES HEREBY AGREE AS FOLLOWS:

1. The Agreement, as amended, is hereby extended for one year from January 1, 2017 to December 31, 2017 (the "**Extension Period**").

2. Section 2 of the Agreement shall be amended such that the fees for the Services provided within the Extension Period defined above, will be a lump sum of EUR 60,000 (sixty thousand euros), VAT, if applicable, included. Such lump sum shall be paid by the Company to Consultant in 4 installments (EUR 15,000 each installment) on the last day of March 2017, June 2017, September 2017 and December 2017, upon receiving an invoice and work report from the Consultant.

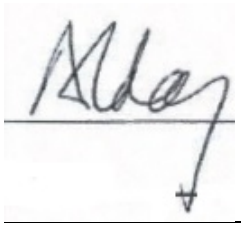
3. The Schedules of Work as defined in Exhibit A of the Agreement, shall be changed so that the Consultant shall now report to Jörn Aldag, CEO of the Company. General tasks defined in Exhibit A of the Agreement, shall be amended to also include the « representation of the Company, including presentation of Company technologies, in meetings with investors and/or potential business partners of Company ».

4. In consideration of the amended Schedules of Work as defined above the parties agree that the Consultant shall hold the title of CSO (Chief Scientific Officer) of the Company when representing the Company in meetings with third parties.

5. The Consultant shall further be granted 6375 stock options of the Company, subject to the terms and conditions of the Company's stock option plan 2016.

6. All other terms and conditions in the Agreement, as amended, remain in force for this Amendment No. 6.

IN WITNESS WHEREOF, the Parties hereto have signed this Agreement.

Company:	**Consultant:**
Hookipa Biotech AG	**Prof. Dr. Daniel Pinschewer**
Jörn Aldag, CEO	
Signature 	Signature 
December 14, 2016	Date 16.Dec.2016

AMENDMENT NO. 7 TO THE CONSULTANCY AGREEMENT

between

1. **HOOKIPA Biotech AG, FN 365895g,** Helmut-Qualtinger-Gasse 2, 1030 Vienna, Austria

(the "**Company**")

and

2. **Prof. Dr. Daniel Pinschewer,** Im Zehntenfrei 5, 4102 Binningen, Switzerland

(the "**Consultant**")

(each of them being also designated as a "**Party**" and together the "**Parties**")

RECITALS

WHEREAS, the Parties entered into a Consultancy Agreement signed by the Company on November 13, 2011 and by the Consultant on November 16, 2011 (the "**Agreement**") whereby the Company hired Daniel Pinschewer as Consultant. The Parties signed an amendment (the "**Amendment No. 1**") to the Agreement on January 7, 2013, a further amendment (the "**Amendment No. 2**") on December 13, 2013 and December 16, 2013, a further amendment (the "**Amendment No. 3**") on December 15, 2014 and December 18, 2014, a further amendment (the "**Amendment No. 4**") on February 24, 2016 and February 25, 2016, a further amendment (the "**Amendment No. 5**") on December 7, 2016, and a further amendment (the "**Amendment No. 6**") on December 14, 2016 and December 16, 2016, respectively.

WHEREAS, the Parties now wish to extend the Agreement, as amended, in accordance with the terms and conditions of this amendment (the "**Amendment No. 7**").

NOW THEREFORE THE PARTIES HEREBY AGREE AS FOLLOWS:

1. The Agreement, as amended, is hereby extended for one year from January 1, 2018 to December 31, 2018 (the "**Extension Period**").

2. The Payment dates specified in Section 2 of the Agreement, as amended, will be changed to the corresponding dates for the Extension Period for the Consultant's service during such period.

3. All other terms and conditions in the Agreement, as amended, remain in force for this Amendment No. 7.

IN WITNESS WHEREOF, the Parties hereto have signed this Agreement.

Company:
Hookipa Biotech AG
Jörn Aldag, CEO

Signature 

Date: 4-Dec-2017

Consultant:
Prof. Dr. Daniel Pinschewer

Signature 

Date 4.12.2017

AMENDMENT NO. 8 TO THE CONSULTANCY AGREEMENT

between

1. **HOOKIPA Biotech GmbH** (**previously HOOKIPA Biotech AG**), Helmut-Qualtinger-Gasse 2, 1030 Vienna, Austria
(the "**Company**") and

2. **Prof. Dr. Daniel Pioschewer**, Im Zehntenfrei 5, 4102 Binningen, Switzerland
(the "**Consultant**")

(each of them being also designated as a "**Party**" and together the ("**Parties**")

RECITALS

WHEREAS, the Parties entered into a Consultancy Agreement signed by the Company on November 13, 2011 and by the Consultant on November 16, 2011 (the "**Agreement**") whereby the Company hired Daniel Pinschewer as Consultant. The Parties signed an amendment (the "**Amendment No. 1**") to the Agreement on January 7, 2013, a further amendment (the "**Amendment No. 2**") on December 13, 2013 and December 16, 2013, a further amendment (the "**Amendment No. 3**") on December 15, 2014 and December 18, 2014, a further amendment (the "**Amendment No. 4**") on February 24, 2016 and February 25, 2016, a further amendment (the "**Amendment No. 5**") on December 7, 2016, a further amendment (the "**Amendment No. 6**") on December 14, 2016 and December 16, 2016, respectively, and a further amendment on December 17, 2017 ("**Amendment No. 7**").

WHEREAS, the Parties now wish to extend and amend the Agreement, as amended, in accordance with the terms and conditions of this amendment (the "**Amendment No. 8**").

NOW THEREFORE THE PARTIES HEREBY AGREE AS FOLLOWS:

1. The definition of Company in the Agreement shall be amended to "Hookipa Biotech GmbH, FN 491551 w".
2. The Agreement, as amended, is hereby extended for one year from January 1, 2019 to December 31, 2019 (the "**Extension Period**").

3. Section 2 of the Agreement shall be amended such that the fees for the Services provided within the Extension Period defined above will be;

    a. a lump sum of EUR 64,000 (sixty four thousand Euros), VAT, if applicable, included. Such lump sum shall be paid by the Company to Consultant in 4 installments (EUR 16,000 each installment) on the last day of March 2019, June 2019, September 2019 and December 2019, upon receiving an invoice and work report from the Consultant; and

    b. a discretionary bonus in the amount of 40% of the gross cash payment in accordance with the Company's bonus policy and based solely on the achievement of Company goals.

4. All other terms and conditions in the Agreement, as amended, remain in force for this Amendment No. 8.

IN WITNESS WHEREOF, the Parties hereto have signed this Agreement

Company: **Hookipa Biotech GmbH** Jörn Aldag, CEO	**Consultant:** **Prof. Dr. Daniel Pinschewer**
Signature: /s/ Jörn Aldag	Signature: /s/ Daniel Pinschewer
Date: December 21, 2018	Date: December 21, 2018

AMENDMENT NO. 9 TO THE CONSULTANCY AGREEMENT

between

1. **HOOKIPA Biotech GmbH (previously HOOKIPA Biotech AG),** Helmut-Qualtinger Gasse 2, 1030 Vienna, Austria

(the **"Company")** and

2. **Prof. Dr. Daniel Pinschewer,** Im Zehntenfrei 5, 4102 Binningen, Switzerland

(the **"Consultant")**

(each of them being also designated as a **"Party"** and together the **"Parties")**

RECITALS

WHEREAS, the Parties entered into a Consultancy Agreement signed by the Company on November 13, 2011 and by the Consultant on November 16, 2011 (the **"Agreement")** whereby the Company hired Daniel Pinschewer as Consultant. The Parties signed an amendment (the **"Amendment No. 1")** to the Agreement on January 7, 2013, a further amendment (the **"Amendment No. 2")** on December 13, 2013 and December 16, 2013, a further amendment (the**"Amendment No. 3")** on December 15, 2014 and December 18, 2014, a further amendment (the**"Amendment No. 4")** on February 24, 2016 and February 25, 2016, a further amendment (the **"Amendment No. 5")** on December 7, 2016, a further amendment (the **"Amendment No. 6")** on December 14, 2016 and December 16, 2016, a further amendment **("Amendment No. 7")** on December 17, 2017 and a further amendment **("Amendment No. 8")** on December 21, 2018.

WHEREAS, the Parties now wish to extend and amend the Agreement, as amended, in accordance with the terms and conditions of this amendment (the **"Amendment No. 9").**

NOW THEREFORE THE PARTIES HEREBY AGREE AS FOLLOWS:

1. The Agreement, as amended, is hereby extended from January 1, 2020 to the day the Company files its Annual Report on Form 10-K for the fiscal year ended December 31, 2019 (the **"Extension Period").**

2. All other terms and conditions in the Agreement, as amended, remain in force for this Amendment No. 9.

IN WITNESS WHEREOF, the Parties hereto have signed this Agreement

Company:
Hookipa Biotech GmbH
Joern Aldag, CEO

/s/ Joern Aldag

December 30, 2019

Daniel Pinschewer

/s/ Daniel Pinschewer

December 30, 2019

CONFIDENTIAL TREATMENT REQUESTED. INFORMATION FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED IS OMITTED AND MARKED WITH "[***]". AN UNREDACTED VERSION OF THE DOCUMENT HAS ALSO BEEN FURNISHED SEPARATELY TO THE SECURITIES AND EXCHANGE COMMISSION AS REQUIRED BY RULE 406 UNDER THE SECURITIES ACT OF 1933, AS AMENDED.

RESEARCH COLLABORATION AND LICENSE AGREEMENT

BY AND BETWEEN

GILEAD SCIENCES, INC.

AND

HOOKIPA BIOTECH AG

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CONFIDENTIAL TREATMENT REQUESTED. INFORMATION FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED IS OMITTED AND MARKED WITH "[***]". AN UNREDACTED VERSION OF THE DOCUMENT HAS ALSO BEEN FURNISHED SEPARATELY TO THE SECURITIES AND EXCHANGE COMMISSION AS REQUIRED BY RULE 406 UNDER THE SECURITIES ACT OF 1933, AS AMENDED.

LIST OF EXHIBITS AND SCHEDULES

Exhibits

Schedules

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RESEARCH COLLABORATION AND LICENSE AGREEMENT

This RESEARCH COLLABORATION AND LICENSE AGREEMENT (this "**Agreement**") is made as of June 4, 2018 (the "**Effective Date**"), by and between Gilead Sciences, Inc., a Delaware corporation having an office at 333 Lakeside Drive, Foster City, CA 94404 ("**Gilead**") and Hookipa Biotech AG, an Austrian corporation (*Aktiengesellschaft*) having an office at St Marx Vienna Bio Center: Helmut-Qualtinger-Gasse 2, 1030 Vienna, Austria ("**Hookipa**"). Gilead and Hookipa are each referred to individually as a "**Party**" and together as the "**Parties**."

RECITALS

WHEREAS, Gilead and its Affiliates are in the business of Researching, Developing, Manufacturing, and Commercializing (each, as defined below) pharmaceutical and biological products and therapies;

WHEREAS, Hookipa Controls the Licensed Technology (each, as defined below);

WHEREAS, Gilead and Hookipa are parties to the Preliminary Funding Letter Agreement (as defined below), pursuant to which the Parties are currently collaborating on certain preclinical research;

WHEREAS, Gilead and Hookipa wish to further collaborate with respect to certain preclinical research programs to evaluate potential vaccine products using or incorporating the Hookipa Technologies for the treatment, cure, diagnosis, or prevention of HBV or HIV (each, as defined below);

WHEREAS, Gilead wishes to obtain, and Hookipa wishes to grant, an exclusive license under the Licensed Technology on the terms and conditions of this Agreement; and

WHEREAS, subject to the terms and conditions of this Agreement, the Parties' overall collaboration under this Agreement is contemplated to consist of: (i) the HBV Program during the HBV Collaboration Term, and the HTV Program during the HIV Collaboration Term; and (ii) on a Licensed Product-by-Licensed Product basis, the Development, Manufacture, and Commercialization of such Licensed Product by or on behalf of Gilead, its Affiliates, or its sublicensees in the Field.

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained, the Parties agree as follows:

1. DEFINITIONS AND INTERPRETATION

1.1 Definitions.

Unless the context otherwise requires, the terms in this Agreement with initial letters capitalized shall have the meanings set forth below, or the meaning as designated in the indicated places throughout this Agreement.

"**ACA**" means the Patient Protection and Affordable Care Act.

"**Accounting Standards**" means, with respect to Gilead, U.S. GAAP and, with respect to Hookipa, Austrian GAAP.

"**Affiliate**" means, with respect to a Person, any entity or person that controls, is controlled by, or is under common control with that Person, For the purpose of this definition, "control" or "controlled" means, direct or indirect, ownership of more than fifty percent (50%) of the shares of stock entitled to vote for the election of directors in the case of a corporation or more than fifty percent (50%) of the equity interest in the case of any other type of legal entity; status as a general partner in any partnership; or any other arrangement whereby the entity or person controls or has the right to control the board of directors or equivalent governing body of a corporation or other entity or the ability to cause the direction of the management or policies of a corporation or other entity. The Parties acknowledge that in the case of entities organized under the laws of certain countries where the maximum percentage ownership permitted by Applicable Law for a foreign investor is less than fifty percent (50%), such lower percentage shall be substituted in the preceding sentence; provided, that such foreign investor has the power to direct the management and policies of such entity.

"**Affordable Basis**" means the sale or other disposition of a Licensed Product at cost or with a [***] of the fully-burdened Manufacturing/acquisition cost of such Licensed Product.

"**Agreement**" shall have the meaning set forth in the first and opening paragraph of this Agreement.

"**Alliance Manager**" shall have the meaning set forth in Section 4.5.

"**Antigen**" means an HBV Antigen or an HIV Antigen, as the context requires.

"**Applicable Law**" means, individually and collectively, any federal, state, local, national, and supra-national laws, treaties, statutes, ordinances, rules, and regulations, including any rules, regulations, guidance, guidelines, or requirements having the binding effect of law of national securities exchanges, automated quotation systems, or securities listing organizations, Regulatory Authorities, courts, tribunals, agencies other than Regulatory Authorities, legislative bodies, and commissions that are in effect from time to time during the Term and applicable to a particular activity hereunder. Applicable Law includes Data Protection Law.

"**Audited Party**" shall have the meaning set forth in Section 10.6(b).

"**Auditing Party**" shall have the meaning set forth in Section 10.6(b).

"**Auditor**" shall have the meaning set forth in Section 10.6(b).

"**Austrian GAAP**" means Austrian generally accepted accounting principles, as consistently applied.

"**Base Exchange Rate**" means the exchange rate of [***] USD per Euro.

"**Biosimilar**" means a biological medicine or biological product for human use which: (a) is highly similar to a reference biological medicine or biological product that has Regulatory Approval in the country or jurisdiction in question; (b) has no clinically meaningful differences from such reference product as determined by Applicable Laws or any applicable Regulatory Authority; and (c) is approved for use (i) in the U.S., as a biosimilar biologic product (as defined in the ACA) pursuant to an abbreviated regulatory approval process established under the ACA, (ii) in the EU, as a similar biological medicine pursuant to Directive 2001/83/EC or Regulation (EC) No 726/2004 (as applicable), or (iii) in any other country or jurisdiction, pursuant to an equivalent regime in such county or jurisdiction.

"**BLA**" means a Biologics License Application filed with the FDA in the United States with respect to a Licensed Product, as defined in Title 21 of the U.S. Code of Federal Regulations, Section 601.2 et seq.

"**Breaching Party**" shall have the meaning set forth in Section 13.2.

"**Brief**" shall have the meaning set forth in Section 18.5(b).

"**Business Day**" means a day that is not: (a) a Saturday, Sunday, a day on which banking institutions in San Francisco, California or Vienna, Austria are required by Applicable Law to remain closed or otherwise generally closed; or (b) December 26 through December 31.

"**Calendar Quarter**" means each successive period of three (3) calendar months commencing on January 1, April 1, July 1, and October 1, except that the first Calendar Quarter of the Term shall commence on the Effective Date and end on the day immediately prior to the first to occur of January 1, April 1, July 1, or October 1 after the Effective Date, and the last Calendar Quarter shall end on the last day of the Term.

"**Calendar Year**" means each successive period of twelve (12) calendar months commencing on January 1 and ending on December 31, except that the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the year in which the Effective Date occurs and the last Calendar Year of the Term shall commence on January 1 of the year in which the Term ends and end on the last day of the Term.

"**Claims**" shall have the meaning set forth in Section 16.1.

"**CMC**" means chemistry, manufacturing, and controls portion of a Regulatory Filing.

"**Code**" shall have the meaning set forth in Section 13.3.

"**Collaboration Term**" means the HBV Collaboration Term or the HIV Collaboration Term, as the context requires.

"**Combination Product**" means any product, [***], that combines: (a) [***] (the "**Vaccine Product**"); and (b) one (1) or more [***] (each, an "**Other Product**"), whether [***].

"**Commercialize**" means to market, promote, distribute, import, export, offer to sell, or sell a pharmaceutical or biological product or conduct other commercialization activities, and "**Commercialization**" means marketing, promoting, distributing, importing, exporting, offering for sale, selling or other commercialization activities with respect to a pharmaceutical or biological product. For clarity, "Commercialization" does not include Development or Manufacturing.

"**Commercially Reasonable Efforts**" means: (a) with respect to [***]; and (b) with respect to [***].

"**Competing Infringement**" has the meaning set forth in Section 11.3(a).

"**Confidential Information**" means any non-public, proprietary, scientific, technical, business, or other information of a Party or of any of its Affiliates which is disclosed to or otherwise received by the other Party in context of the performance of this Agreement on or after the Effective Date, whether in writing, orally or in graphic form, whether by hard copy or by electronic data transfer, whether explicitly marked as confidential or not, in particular information relating to corporate status, intellectual property rights, know-how, trade and business secrets, products, development activities, commercial and licensing relationships, business status and strategies as well as marketing plans, technical or non-technical data, scientific data, analysis, studies and results, chemical structures and sequences, financial and commercial data, financial plans, or lists of actual or potential partners, customers or, suppliers, and including any information that would be apparent to a reasonable Person, familiar with the Parties' business or industry, to be of a confidential or proprietary nature, as well as any other information deemed Confidential Information as expressly provided in this Agreement. For clarity, subject to Section 12.2: (a) any Know-How provided or otherwise made available by Gilead for use in a Program (including Antigens), shall be deemed Gilead's Confidential Information; and (b) any Know-How provided or otherwise made available by Hookipa for use in a Program shall be deemed Hookipa's Confidential Information.

"**Control**" or "**Controlled**" means, with respect to any Patent Rights, Know-How, material, or other intellectual property rights, or any proprietary or trade secret information, that a Party or any of its Affiliates: (a) owns such Patent Right, Know-How, material, or other intellectual property right, or proprietary or trade secret information; or (b) has a license to or a right to use such Patent Right, Know-How, material, or other intellectual property right, or proprietary or trade secret information and, in each case of (a) or (b), possesses the right (other than by operation of this Agreement), whether directly or indirectly, to grant the other Party access, a right to use, or a license or sublicense, as applicable, to or under such Patent Rights, Know-How, material, or other intellectual property rights, or proprietary or trade secret information, as provided herein, without: (i) violating the terms of any agreement with or obligation to any Third Party in existence as of the time such Party or any Affiliates of such Party would first be required hereunder to grant the other Party such access, right to use, license, or sublicense; or (ii) incurring any financial or other material obligation towards any Third Party that assigned or licensed such Patent Rights, Know-How, material, or other intellectual property rights, or disclosed such proprietary or trade secret information to such first Party or any Affiliates of such first Party that become due in connection with the other Party's use thereof hereunder, unless, with respect to (ii): (A) such other Party agrees in writing to pay any sums arising from such financial obligations pursuant to Section 9.5(a); or (B) such financial obligations are triggered pursuant to a Hookipa Third Party Agreement set forth on Schedule 9.5(a).

"**Data Protection Law**" means the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) as well as, if applicable, any other data protection laws of the United States and any data protection laws applicable to either Party in connection with this Agreement. "Personal Data" as used in this Agreement shall mean any information relating to an identified or identifiable natural person as defined in the General Data Protection Regulation.

"**Default**" means: (a) any breach, violation, or default; (b) the existence of circumstances or the occurrence of an event that with the passage of time or the giving of notice or both would constitute a breach, violation, or default; or (c) the existence of circumstances or the occurrence of an event that, with or without the passage of time or the giving of notice or both, would give rise to a right of termination, renegotiation, acceleration, or material change of terms.

"**Develop**" or "**Development**" means drug or vaccine development activities relating to pharmaceutical or biological products, including test method development, process development and stability testing, assay and audit development, toxicology, formulation, quality assurance and quality control development, statistical analysis, clinical trials, and regulatory affairs, and the preparation, filing, and prosecution of MAAs and other Regulatory Approvals. For clarity, "Development" does not include Research, Manufacturing, or Commercialization.

"**Development-Ready**" shall have the meaning set forth in Section 2.3.

"**Disclosing Party**" shall have the meaning set forth in Section 12.1.

"**Dispute**" shall have the meaning set forth in Section 18.5(a).

"**Effective Date**" shall have the meaning set forth in the first and opening paragraph of this Agreement.

"**EMA**" means the European Medicines Agency or any successor entity thereto.

"**Encumbrance**" means any claim, charge, equitable interest, hypothecation, lien, mortgage, pledge, option, license, assignment to a Third Party, power of sale, retention of title by a Third Party, right of pre-emption, right of first refusal, or security interest of any kind.

"**EU**" means the European Union, as its membership may be constituted from time to time and any successor thereto.

"**EU Major Market Countries**" means France, Germany, Italy, Spain, and the United Kingdom.

"**EU Regulatory Approval**" means achievement of both: (a) receipt of written notice from EMA of approval by EMA of an MAA submitted by Gilead, its Affiliates, or its sublicensees for a Licensed Product; and (b) either (i) receipt of written notice from the applicable Regulatory Authorities of Pricing Approval for such Licensed Product in [***] EU Major Market Countries, or (ii) First Commercial Sale (disregarding any requirements for Pricing Approvals) of such Licensed Product in [***] EU Major Market Countries.

"**FDA**" means the United States Food and Drug Administration or any successor entity thereto.

"**FDCA**" shall have the meaning set forth in Section 6.6.

"**Field**" means all uses, including treatment, cure diagnosis, or prevention, in the indications HIV or HBV [***].

"**First Commercial Sale**" means, with respect to a Licensed Product, the first sale or other disposition for value of such Licensed Product to a Third Party by Gilead or its Affiliates or sublicensees in a country in the Territory following applicable Regulatory Approval of such Licensed Product in such country. Dispositions of Licensed Product, or use of Licensed Product in, clinical trials or other scientific testing, as free samples, or under named patient use, compassionate use, patient assistance, charitable purposes, on an Affordable Basis, or test marketing programs or other similar programs or studies shall not be considered a First Commercial Sale.

"[***]" means [***].

"**FTE**" shall have the meaning set forth in the definition of "**FTE Rate**."

"**FTE Rate**" means a rate of [***] per annum based on the yearly time for a full-time equivalent scientific employee during the applicable Collaboration Term, consisting of a total of [***] hours per annum ("**FTE**"), to be pro-rated on a [***] basis if necessary (per annum amount to be divided by [***] to produce the rate per whole day consisting of at least [***] hours); such rate to be: (a) restricted to scientific work and managerial activities related directly to the applicable Program(s); and (b) increased at the start of each Calendar Year by [***] during the Collaboration Term, commencing on January 1, 2019; provided, that the increase as of January 1, 2019 shall be based on [***]. For the avoidance of doubt: (i) such rate includes [***]; and (ii) in no event shall any one (1) individual be counted as more than one (1) FTE.

"**GCP**" means the then-current standards, practices, and procedures: (a) promulgated or endorsed by the FDA as set forth in the guidelines entitled, "Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance," including related regulatory requirements imposed by the FDA; (b) set forth in Directive 2001/20/EC of the European Parliament and of the Council of April 4, 2001 and Commission Directive 2005/28/EC of April 8, 2005; (c) ICH Guideline for Good Clinical Practice E6; (d) analogous Applicable Laws of an applicable Regulatory Authority; and (e) all additional Regulatory Authority documents or regulations that replace, amend, modify, supplant, or complement any of the foregoing.

"**Generic Version**" means, with respect to a Licensed Product, a product (including a "biogeneric," "follow-on biologic," "follow-on biological medicine or product," "follow-on protein product," "similar biological medicine or product," or "biosimilar product") that: (a) within the U.S., is "biosimilar" or "interchangeable," with respect to such Licensed Product as evaluated by the FDA or otherwise determined by Applicable Law; or (b) in the ROW, is determined by the applicable Regulatory Authority or by Applicable Law to be "similar," "comparable," "interchangeable," "bioequivalent," or "biosimilar" to such Licensed Product. For clarity, a Biosimilar of a Licensed Product shall constitute a Generic Version of such Licensed Product.

"**Gilead**" shall have the meaning set forth in the first and opening paragraph of this Agreement.

"**Gilead Background Intellectual Property**" means any and all Patent Rights, Know-How, and other intellectual property rights: (a) in existence and owned or otherwise Controlled by Gilead or its Affiliates as of the Effective Date; or (b) that arise outside of this Agreement and are owned or otherwise Controlled by Gilead or its Affiliates after the Effective Date.

"**Gilead Improvements**" mean any and all Improvements other than Hookipa Technologies Improvements.

"**Gilead Indemnitees**" shall have the meaning set forth in Section 16.1.

"**GLP**" means the then-current good laboratory practice standards promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58, as such regulations may be amended from time to time, and analogous Applicable Laws of an applicable Regulatory Authority and all additional Regulatory Authority documents or regulations that replace, amend, modify, supplant, or complement any of the foregoing.

"**GMP**" means then-current standards for the Manufacture of pharmaceutical products, pursuant to: (a) the FDCA (21 U.S.C. § 321 et seq.); (b) relevant United States regulations in Title 21 of the United States Code of Federal Regulations (including Parts 11, 210, and 211); (c) European Community Directives 2003/94 and 91/356/EC; (d) the European Community Guide to Good Manufacturing Practice for Medicinal Intermediate Products; (e) ICH Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients; (f) analogous Applicable Laws of an applicable Regulatory Authority at the time of Manufacture; and (g) all additional Regulatory Authority documents or regulations that replace, amend, modify, supplant, or complement any of the foregoing.

"**HBV**" means hepatitis B virus.

"**HBV Antigen**" means any [***] that is intended to stimulate an immune response in humans against HBV.

"**HBV Collaboration Term**" means the period of time commencing on the Effective Date and concluding upon the earlier of: (a) the completion of all activities set forth in the HBV Research Plan; or (b) the termination of the HBV Program in accordance with Section 13.4(a)(ii).

"**HBV Licensed Product**" means any product containing, incorporating, or otherwise including an HBV Licensed Vaccine, in any dosage strength, formulation, or method of administration.

"**HBV Licensed Vaccine**" means any vaccine developed under *this* Agreement, which vaccine was developed from or otherwise uses the Hookipa Technologies to express one (1) or more HBV Antigens.

"**HBV Program**" means all Research activities conducted solely or jointly by the Parties during the HBV Collaboration Term pursuant to the HBV Research Plan.

"**HBV Research Budget**" shall have the meaning set forth in the definition of "HBV Research Plan."

"**HBV Research Plan**" means the research plan attached as Exhibit A and any amendments thereto, including the integrated budget (the "**HBV Research Budget**"), research goals, activities (including IND-Enabling Studies), timelines, deliverables, allocation of responsibilities between the Parties, and the commitment of resources by the respective Parties with respect to the HBV Program.

"**HBV Royalty Term**" shall have the meaning set forth in Section 9.3(b)(i).

"**HIV**" means human immunodeficiency virus.

"**HIV Antigen**" means any [***] that is intended to stimulate an immune response in humans against HIV.

"**HIV Collaboration Term**" means the period of time commencing on the Effective Date and concluding upon the earlier of: (a) the completion of all activities set forth in the HIV Research Plan; or (b) the termination of the HIV Program in accordance with Section 13.4(a)(i),

"**HIV Licensed Product**" means any product containing, incorporating, or otherwise including an HIV Licensed Vaccine, in any dosage strength, formulation, or method of administration.

"**HIV Licensed Vaccine**" means any vaccine developed under this Agreement, which vaccine was developed from or otherwise uses the Hookipa Technologies to express one (1) or more HIV Antigens.

"**HIV Program**" means all Research activities conducted solely or jointly by the Parties during the HIV Collaboration Term pursuant to the HIV Research Plan.

"**HIV Research Budget**" shall have the meaning set forth in the definition of "**HIV Research Plan**."

"**HIV Research Plan**" means the research plan attached as Exhibit B and any amendments thereto, including the integrated budget (the "**HIV Research Budget**"), research goals, activities (including IND-Enabling Studies), timelines, deliverables, allocation of responsibilities between the Parties, and the commitment of resources by the respective Parties with respect to the HIV Program.

"**Hookipa**" shall have the meaning set forth in the first and opening paragraph of this Agreement.

"**Hookipa Background Intellectual Property**" means any and all Patent Rights, Know-How, and other intellectual property rights: (a) in existence and owned or otherwise Controlled by Hookipa or its Affiliates as of the Effective Date; or (b) that arise outside of this Agreement and are owned or otherwise Controlled by Hookipa or its Affiliates after the Effective Date.

"**Hookipa Indemnitees**" shall have the meaning set forth in Section 16.2.

"**Hookipa Know-How**" means any and all Know-How owned or otherwise Controlled by Hookipa or its Affiliates as of the Effective Date or at any time during the Term which is necessary or reasonably useful for Researching, Developing, Manufacturing, or Commercializing Licensed Products.

"**Hookipa Patent Rights**" means any and all Patent Rights owned or otherwise Controlled by Hookipa or its Affiliates as of the Effective Date or at any time during the Term which are necessary or reasonably useful for Researching, Developing, Manufacturing, or Commercializing Licensed Products. Exhibit C sets forth a complete and accurate list of all Hookipa Patent Rights as of the Effective Date. Hookipa shall update Exhibit C as necessary from time to time to reflect the then-current Hookipa Patent Rights.

"**Hookipa Technologies**" means the TheraT Technology Platform and the Vaxwave Technology Platform,

"**Hookipa Technologies Improvements**" mean any Improvements that specifically relate to the Hookipa Technologies. For the avoidance of doubt, an [***].

"**Hookipa Third Party Agreement**" means any agreement between Hookipa or an Affiliate thereof, on the one hand, and a Third Party, on the other hand: (a) which is set forth on Schedule 9.5(a); or (b) which Gilead accepts pursuant to Section 9.5(a).

"**ICC Rules**" shall have the meaning set forth in Section 18.5(b).

"**Improvements**" means: (a) any and all Know-How, compounds, sequences, molecules, data, derivatives, designs, developments, discoveries, enhancements, inventions, materials, modifications, new uses, processes, products, research results, techniques, writings, or other technology rights, whether or not patentable, in each case, that are invented, conceived, reduced to practice, or otherwise developed in the course of performance of this Agreement, whether solely by or on behalf of each of the Parties or jointly by or on behalf of both Parties; and (b) any and all Patent Rights and other intellectual property rights in any of the foregoing.

"**IND**" means an Investigational New Drug application in the U.S. filed with the FDA or the corresponding application for the investigation of Licensed Products in any other country or group of countries, as defined in the Applicable Laws and filed with the Regulatory Authority of the relevant country or group of countries.

"**IND-Enabling Studies**" means studies that are reasonably required to meet the requirements for filing an IND with a Regulatory Authority, including GLP toxicology and safety studies, or studies required for the preparation of the CMC section of such IND, including studies relating to analytical methods and purity analysis, and formulation and manufacturing development studies, and which also includes ADME (absorption, distribution, metabolism, and excretion) information, all as necessary to obtain the permission of the Regulatory Authority in the relevant jurisdiction to begin human clinical testing, which, for the avoidance of doubt, include the studies and activities identified in each of the HBV Research Plan or the HIV Research Plan as IND-Enabling Studies.

"**Indemnification Claim Notice**" shall have the meaning set forth in Section 16.3(b).

"**Indemnified Party**" shall have the meaning set forth in Section 16.3(b).

"**Indemnifying Party**" shall have the meaning set forth in Section 16.3(b).

"**Indemnitee**" means a Gilead Indemnitee or a Hookipa Indemnitee, as the context requires.

"**Joint Committee**" means the JRC or the JSC, as the context requires.

"**Joint Committee Co-Chairs**" means the JRC Co-Chairs or the JSC Co-Chairs, as the context requires.

"**Joint Research Committee**" or "**JRC**" shall have the meaning set forth in Section 4.2(a).

"**Joint Steering Committee**" or "**JSC**" shall have the meaning set forth in Section 4.1(a).

"**JRC Co-Chair**" shall have the meaning set forth in Section 4.2(b).

"**JSC Co-Chair**" shall have the meaning set forth in Section 4.1(b).

"**Know-How**" means all tangible and intangible scientific or technical information, know-how, and data of any type whatsoever, whether or not patentable, including inventions, discoveries, trade secrets, specifications, instructions, processes, formulae, materials, expertise and other technology applicable to compounds, sequences, molecules, formulations, compositions, products or to their manufacture, development, registration, use or commercialization or methods of assaying or testing them or processes for their manufacture, formulations containing them, compositions incorporating or comprising them and including all biological, chemical, pharmacological, biochemical, toxicological, pharmaceutical, physical, and analytical, safety, quality control, manufacturing, preclinical, and clinical data, instructions, processes, formulae, expertise, and information, Regulatory Filings, and copies thereof, relevant to the development, manufacture, use, or commercialization of, or which may be useful in studying, testing, development, production, or formulation of, products, or intermediates for the synthesis thereof,

"**Knowledge**" means, with respect to any Person, the [***] knowledge of such Person's executive officers, including, with respect to each Party, its Senior Officer, after [***]. [***].

"**Licensed Product**" means an HBV Licensed Product or an HIV Licensed Product, as the context requires.

"**Licensed Technology**" means all Hookipa Patent Rights and Hookipa Know-How.

"**Licensed Vaccine**" means an HBV Licensed Vaccine or an HIV Licensed Vaccine, as the context requires.

"**Loss of Market Exclusivity**" means, with respect to any Licensed Product in any country or jurisdiction in the Territory, that: (a) [***] Generic Versions of such Licensed Product has been sold by any Third Party (other than a permitted sublicensee of Gilead) in such country or jurisdiction; and (b) units of such Generic Version(s) sold in that country or jurisdiction during any [***] represent at least [***] of the sum of: (i) units of such Generic Version(s) and (ii) units of such Licensed Product, sold in that country or jurisdiction during such [***].

"**Losses**" shall have the meaning set forth in Section 16.1.

"**MAA**" means an application for the authorization to market a Licensed Product in any country or group of countries, as defined in the Applicable Laws, and filed with the Regulatory Authority of a given country or group of countries, including a BLA.

"**Manufacture**" means all activities related to manufacturing, packaging, in-process and finished product testing, release of product or any component or ingredient thereof, quality assurance and quality control activities related to manufacturing and release of product, ongoing stability tests, storage, shipment, and regulatory activities related to any of the foregoing. For clarity, "Manufacture" does not include Research, Development, or Commercialization.

"**Measurement Date**" shall have the meaning set forth in Section 10.2(b).

"**Milestone Payments**" means the payments to be made by Gilead to Hookipa upon the achievement of the corresponding Milestones as set forth in Section 9.2,

"**Milestones**" means the milestone events relating to the Licensed Products as set forth in Section 9.2.

"**Net Sales**" means, with respect to a Licensed Product, the gross amount invoiced or billed on sales of such Licensed Product in the Territory by a Selling Party to any Third Party in bona-fide, arms'-length transactions, less [***]:

(a) normal and customary trade, cash, and quantity discounts, allowances, and credits allowed or paid, in the form of deductions actually allowed with respect to sales of such Licensed Product (to the extent not already reflected in the amount invoiced and excluding commissions for Commercialization);

(b) retroactive price reductions, allowances, or credits actually granted upon rejections or returns of Licensed Product, including for recalls or damaged good and billing errors;

(c) discounts, chargeback payments, rebates, and reimbursements granted to wholesalers and other distributors, pharmacies and other retailers, managed care organizations, group purchasing organizations, or other buying groups, pharmacy benefit management companies, health maintenance organizations, federal, state/provincial, local, or other governments, and any other providers of health insurance coverage, health care organizations, or other health care institutions (including hospitals), health care administrators, or patient assistance or other similar programs;

(d) compulsory payments and cash rebates related to the sales of such Licensed Product paid to a governmental authority (or agent thereof) pursuant to governmental regulations by reason of any national or local health insurance program or similar program, including required chargebacks and retroactive price reductions, to the extent allowed and taken; including government levied fees as a result of healthcare reform policies, to the extent such fees are specifically allocated to sales of such Licensed Product as a percentage of Gilead's entire pharmaceutical product sales;

(e) reasonable and customary freight, shipping insurance and other transportation expenses to the extent they are separately itemized and included in the gross amount invoiced and charged to the buyer;

(f) tariffs; duties; import, export, excise, sales, use, turnover, value-added, and other similar taxes (other than taxes based on income); customs duties; or other government charges, in each case imposed on the sale of Licensed Product to the extent included in the price and separately itemized on the invoice, including VAT, but only to the extent that such VAT are not reimbursable or refundable;

(g) amounts invoiced for sales of Licensed Product that are written off as uncollectible after reasonable collection efforts, in accordance with standard practices of the applicable party; provided, that any recovery of such amounts shall be deemed a sale for the purposes of calculating Net Sales; and

(h) any other specifically identifiable amounts included in gross amounts invoiced or billed for the Licensed Products, to the extent such amounts are customary deductions from net sales calculations in the pharmaceutical or biotechnology industries in the applicable country or countries for reasons substantially equivalent to those listed above.

Such amounts shall be determined from the books and records of the Selling Party, maintained in accordance with Accounting Standards. With respect to Net Sales not denominated in USD, Gilead shall convert such Net Sales from the applicable foreign currency into USD in accordance with Section 10.2.

Net Sales shall include the cash consideration received on a sale and the fair market value of all non-cash consideration. Dispositions of Licensed Product for, or use of Licensed Product in, clinical trials or other scientific testing, as free samples, or under named patient use, compassionate use, patient assistance, charitable purposes, on an Affordable Basis, or test marketing programs or other similar programs or studies shall not result in any Net Sales.

In order to determine Net Sales of a Licensed Product that is a Combination Product, the Net Sales applicable to such Combination Product in a country shall be determined by [***].

If [***], then Net Sales shall be calculated by [***].

If [***], then Net Sales shall be calculated by [***].

If [***], the adjustment to Net Sales shall be determined by [***].

"**Non-Breaching Party**" shall have the meaning set forth in Section 13.2.

"**Other Product**" shall have the meaning set forth in the definition of "**Combination Product**."

"**Out-of-Pocket Costs**" means, with respect to certain activities hereunder, direct expenses actually paid by a Party or its Affiliates to Third Parties and specifically identifiable and incurred to conduct such activities, but excluding (with respect to Hookipa's Research activities) any costs included in the FTE Rate.

"**Party**" and "**Parties**" shall have the meaning set forth in the first and opening paragraph of this Agreement.

"**Patent Rights**" means all rights, title, and interests in and to: (a) all national, regional, and international patents and patent applications filed in any country of the world, including provisional patent applications and all supplementary protection certificates; (b) all patent applications filed either from such patents, patent applications, or provisional applications or from an application claiming priority to any of the foregoing, including any continuation, continuation-in-part, divisional, provisional, converted provisional, and continued prosecution application, or any substitute application; (c) any patent issued with respect to or in the future issued from any such patent applications, including utility models, petty patents, design patents, and certificates of invention; and (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, reexaminations, and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications.

"**Patent Term Extensions**" shall have the meaning set forth in Section 11.9.

"**Payment Floor**" shall have the meaning set forth in Section 9.5(c).

"**Permitted Recipient**" has the meaning set forth in Section 12.3(e).

"**Person**" means any individual, partnership, limited liability company, firm, corporation, association, trust, unincorporated organization, or other entity.

"**Personal Data**" shall have the meaning set forth in the definition of "**Data Protection Law**."

"**Phase 1 Clinical Trial**" means a human clinical trial which provides for the first introduction into humans of a product, conducted in normal volunteers or patients to get information on product safety, tolerability, immunogenicity, pharmacological activity, or pharmacokinetics, as more fully defined in 21 C.F.R. § 312.21(a) (or the foreign equivalent thereof).

"**Phase 1b Clinical Trial**" means a Phase 1 Clinical Trial in the target patient population that is designed to establish safety and immunogenicity, which may also be designed to establish an initial indication of efficacy.

"**Phase 2 Clinical Trial**" means a human clinical trial, the principal purposes of which are the evaluation of the efficacy of such product for a particular indication in the target patient population and a determination of the common side-effects and risks associated with the product in the dosage range to be prescribed and to obtain sufficient information about the efficacy for such pharmaceutical product in the disease or condition being studied to permit the design and dose of such product in a Registrational Clinical Trial. Phase 2 Clinical Trial shall exclude in all cases any combined Phase 1 Clinical Trial/Phase 2 Clinical Trial.

"**PPI**" means the Producer Price Index published by EuroStat.

"**Preliminary Funding Letter Agreement**" means that certain Letter Agreement Re: Funding of Early Research Activities, by and between Gilead and Hookipa, dated [***].

"**Pricing Approval**" means any approval, agreement, determination, or decision establishing prices that can be charged to consumers for a pharmaceutical product or that shall be reimbursed by governmental authorities for a pharmaceutical product, in each case, in a country where governmental authorities approve or determine pricing for pharmaceutical products for reimbursement or otherwise.

"**Prior CDA**" means the Mutual Confidential Disclosure Agreement between the Parties, dated [***].

"**Product Marks**" shall have the meaning set forth in Section 11.6.

"**Program**" means the HBV Program or the HIV Program, as the context requires.

"**Proof of Concept Clinical Trial**" means a human clinical trial of a Licensed Product, which may be [***], and which is intended to [***].

"**Prosecution and Maintenance**" or "**Prosecute and Maintain**" means, with respect to a Patent Right, the preparation, filing, prosecution, and maintenance of such Patent Right, as well as reexaminations, reissues, appeals, and requests for patent term adjustments and patent term extensions with respect to such Patent Right, together with the initiation or defense of interferences, the initiation or defense of oppositions, and other similar proceedings with respect to the particular Patent Right, and any appeals therefrom. For clarity, "Prosecution and Maintenance" or "Prosecute and Maintain" shall not include any other enforcement actions taken with respect to a Patent Right.

"**Recipient Party**" shall have the meaning set forth in Section 12.1.

"**Reference Exchange Rate**" has the meaning set forth in Section 10.2(b).

"**Registrational Clinical Trial**" means a human clinical trial of a Licensed Product that: (a) would satisfy the requirements of 21 C.F.R. § 312.21(c) or corresponding foreign regulations; or (b) that if successful would provide sufficient efficacy data to support the filing of an MAA for such Licensed Product in such country.

"**Regulatory Approval**" means any and all approvals (including any applicable Pricing Approvals), licenses, registrations, or authorizations of any government agency or authority that are necessary for the marketing and sale of a Licensed Product in the relevant country or group of countries in the Territory.

"**Regulatory Authority**" means any governmental agency or authority responsible for evaluating or granting Regulatory Approvals for Licensed Products, including the FDA, the EMA, the European Commission, and any corresponding national or regional regulatory authorities, as applicable.

"**Regulatory Exclusivity**" means the ability to exclude Third Parties from Commercializing a Licensed Product in a country, either through data exclusivity rights, orphan drug designation, or such other rights conferred by Applicable Laws or a Regulatory Authority in such country or jurisdiction, in each case, other than through Patent Rights.

"**Regulatory Filings**" means any submission to a Regulatory Authority of any appropriate regulatory application, including any submission to a regulatory advisory board, marketing authorization application, and any supplement or amendment thereto. For the avoidance of doubt, Regulatory Filings shall include any IND or MAA.

"**Research**" means activities related to the characterization, design, discovery, generation, identification, non-clinical or pre-clinical studies, pre-clinical development, process development, optimization, production, or profiling of vaccine candidates or products. For clarity, "Research" does not include Development or Manufacturing.

"**Research Budget**" means the HBV Research Budget or the HIV Research Budget, as the context requires.

"**Research Plan**" means the HBV Research Plan or the HIV Research Plan, as the context requires.

"**Response**" shall have the meaning set forth in Section 18.5(b).

"**ROW**" means all countries and territories of the world in the Territory other than the U.S.

"**ROW HIV Royalty Term**" shall have the meaning set forth in Section 9.3(b)(iii).

"**Royalty Term**" shall have the meaning set forth in Section 9.3(b)(iii).

"**Selected Dispute**" shall have the meaning set forth in Section 18.5(a).

"**Selling Party**" means Gilead, its Affiliates, or its sublicensees, in each case, expressly excluding distributors.

"**Senior Officers**" means, with respect to Gilead, [***] or his designee, and, with respect to Hookipa, [***] or his designee.

"**Sublicense Payments**" shall have the meaning set forth in Section 9.5(a).

"**Term**" shall have the meaning set forth in Section 13.1.

"**Terminated Licensed Product**" means, with respect to: (a) the termination of this Agreement with respect to a Licensed Product pursuant to Sections 13.2 or 13.4(b), the Licensed Product subject to such termination; (b) the termination of this Agreement with respect to a country in the Territory pursuant to Sections 13.2 or 13.4(b), all Licensed Products in the country in the Territory subject to such termination; (c) the termination of this Agreement with respect to a Program pursuant to Section 13.4(a), all Licensed Products in the Territory included in the Program subject to such termination (provided, that any Development-Ready Licensed Product shall not be deemed to be "included in the Program"); and (d) the termination of this Agreement in its entirety, all Licensed Products in all countries in the Territory.

"**Territory**" means all countries and territories of the world.

"**TheraT Technology Platform**" means [***].

"**Third Party**" means any Person other than a Party or an Affiliate of a Party.

"**Third Party Infringement**" has the meaning set forth in Section 11.4.

"**U.S. GAAP**" means United States generally accepted accounting principles, as consistently applied.

"**U.S. HIV Royalty Term**" shall have the meaning set forth in Section 9.3(b)(ii).

"**United States**" or "**U.S.**" means the United States of America, its territories, and its possessions.

"**USD**" or "**$**" means United States Dollars, the lawful currency of the United States.

"**Vaccine Product**" shall have the meaning set forth in the definition of "**Combination Product**."

"**Valid Claim**" means a claim in: (a) an issued and unexpired patent which has not been revoked or held unenforceable or invalid by a decision of a court, patent office, or other governmental agency of competent jurisdiction from which no appeal can be or has been taken within the time allowed for appeal, and which has not been disclaimed, donated to the public or admitted to be invalid or unenforceable through reissue, re-examination, disclaimer, or otherwise; (b) an issued and unexpired supplementary protection certificate or equivalent instrument, solely to the extent that any such certificate or instrument is requested to be obtained by Gilead pursuant to Section 11.9; or [***].

"**Vaxwave Technology Platform**" means [***].

1.2 Interpretation. Headings used herein are for convenience only and shall not in any way affect the construction of or be taken into consideration in interpreting this Agreement. The terms of this Agreement represent the results of negotiations between the Parties and their representatives, each of which has been represented by counsel of its own choosing, and neither of which has acted under duress or compulsion, whether legal, economic, or otherwise. Accordingly, the terms of this Agreement shall be interpreted and construed in accordance with the definitions for such terms provided herein or, if no such definitions arc provided, with their usual and customary meanings, and each of the Parties hereby waives the application in connection with the interpretation and construction of this Agreement of any rule of Applicable Laws to the effect that ambiguous or conflicting terms or provisions contained in this Agreement shall be interpreted or construed against the Party whose attorney prepared the executed draft or any earlier draft of this Agreement. Any reference in this Agreement to an Article, Section, subsection, paragraph, clause, Exhibit, or Schedule shall be deemed to be a reference to any Article, Section, subsection, paragraph, clause, Exhibit, or Schedule, of or to, as the case may be, this Agreement. Except where the context otherwise requires: (a) any definition of or reference to any agreement, instrument, or other document refers to such agreement, instrument, other document as from time to time amended, supplemented, or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein); (b) any reference to any Applicable Laws refers to such Applicable Laws as from time to time enacted, repealed, or amended; (c) the words "herein", "hereof", and "hereunder", and words of similar import, refer to this Agreement in its entirety and not to any particular provision hereof; (d) the words "include", "includes", and "including" shall be deemed to be followed by the phrase "but not limited to", "without limitation", or words of similar import; (e) the word "or" is used in the inclusive sense (and/or), unless explicitly indicated otherwise by the term "either/or"; (f) the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders; (g) a "Party" includes its permitted assignees or the respective successors in title to substantially the whole of its undertaking; and (h) the Exhibits and Schedules to this Agreement form part of the operative provision of this Agreement, and references to this Agreement shall, unless the context otherwise requires, include references to the Exhibits and Schedules.

2. PROGRAMS

2.1 Goals.

(a) HBV Program. The objective of the HBV Program, as provided in the HBV Research Plan, shall be to utilize the Hookipa Technologies to Research Lymphocytic Choriomeningitis Virus- and Pichinde Virus-based vectors suitable for the Development, Manufacture, and Commercialization by Gilead, its Affiliates, or its sublicensees as HBV Licensed Products for the treatment, cure, diagnosis, or prevention of HBV.

(b) HIV Program. The objective of the HIV Program, as provided in the HIV Research Plan, shall be to utilize the Hookipa Technologies to Research Lymphocytic Choriomeningitis Virus- and Pichinde Virus-based vectors suitable for the Development, Manufacture, and Commercialization by Gilead, its Affiliates, or its sublicensees as HIV Licensed Products for the treatment, cure, diagnosis, or prevention of HIV.

(c) Application of Vectors to Antigens. The Programs shall include the application of certain Antigens to Lymphocytic Choriomeningitis Virus- and Pichinde Virus-based vectors.

2.2 Research Plans; Records; Reports; Payments.

(a) Research Plans. During the Collaboration Term for each Program, each Party shall use Commercially Reasonable Efforts to perform its obligations under the Research Plan for such Program. From time to time during the Collaboration Term for a Program, and on at least an annual basis, the JSC shall review the then-current Research Plan for such Program for potential amendments. Each Party's JSC representatives shall consider in good faith all such amendments proposed by the other Party's JSC representatives. Each JSC-approved amended Research Plan shall become effective only upon approval by both Parties. Each Research Plan shall be consistent with the terms of this Agreement and shall form a part of this Agreement, In the event of an inconsistency between a Research Plan and this Agreement, the terms of this Agreement shall prevail. Each Research Plan shall be deemed the Confidential Information of each Party.

(b) Records. Each Party shall prepare and maintain complete and accurate written records of all activities performed as well as results and data obtained pursuant to its efforts under each Research Plan, in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes. In addition to the reporting obligations set forth herein, upon reasonable request of the other Party, each Party shall grant to the other Party and its Affiliates reasonable, secured access (e.g., by remote web-access secured by end-user identity and authentication solutions or by other means providing a comparable, sufficient level of data security) to all data (including all primary data and data contained in laboratory notebooks) that is generated in the course of performance of the Programs. Gilead and its Affiliates shall also have the right, at reasonable intervals and upon reasonable notice to Hookipa, to have copies of such records made to use and transfer as permitted hereunder. Any data not otherwise contained in laboratory notebooks and relevant to the Programs or to Licensed Technology shall be provided to Gilead upon reasonable request in a format mutually agreed by the Parties. All such records shall be deemed the Confidential Information of each Party,

(c) Reporting. Each Party shall keep the other Party reasonably informed on the status, progress, and results of its activities under each Research Plan through the regularly-scheduled JRC meetings described in Section 4.3(a), At least [***] Business Days before each regularly-scheduled JRC meeting, each Party shall submit to the JRC a written summary (in the form of a slide deck or as otherwise reasonably determined by such Party) of the status, progress, and results of its activities under each Research Plan since its prior report. The JRC shall review and discuss the status, progress, and results of each Program. In addition, Hookipa shall provide Gilead with a final written report within [***] days following the expiration or termination of each of the HBV Collaboration Term and the HIV Collaboration Term, which reports shall summarize the Research activities undertaken and all accomplishments achieved under the applicable Research Plan and contain a copy of all results generated by Hookipa in the performance of such Research Plan. All such summaries and reports shall be deemed the Confidential Information of each Party.

(d) Payments. Gilead shall reimburse Hookipa for certain costs and expenses relating to Hookipa's performance under the Research Plans in accordance with Section 9.6.

2.3 Transition to Development of Licensed Product. Without limiting any other rights of Gilead under this Agreement, Gilead may, at any time during the Collaboration Term for a Program, notify the JSC of its desire to initiate Development of a Licensed Product in the Field in the Territory. Effective upon the JSC's approval thereof, such Licensed Product shall be considered "**Development-Ready**" and shall thereafter be outside the scope of the applicable Program and subject to Development, Manufacture, and Commercialization by or on behalf of Gilead, its Affiliates, or its sublicensees in accordance with this Agreement. Upon expiration or termination of the Collaboration Term of a Program, all Licensed Products arising out of such Program shall be considered Development-Ready, irrespective of whether the JSC has formally approved such Licensed Products as such.

2.4 Termination of Preliminary Funding Letter Agreement. Pursuant to Section 6 of the Preliminary Funding Letter Agreement, the Preliminary Funding Letter Agreement shall terminate effective upon the Effective Date; provided, that Sections 2, 3, 5, and 7 of the Preliminary Funding Letter Agreement shall survive such termination solely with respect to the research activities covered by the Preliminary Funding Letter Agreement and performed prior to its termination.

3. LICENSES; EXCLUSIVITY

3.1 License Grants.

(a) Subject to the terms and conditions of this Agreement, Hookipa hereby grants to Gilead, during the Term, a milestone- and royalty-bearing, transferrable (pursuant to Section 18.1) sublicensable (pursuant to Section 3.2(a)) license, under the Licensed Technology, to: (i) perform its activities under the Research Plans; and (ii) Research, Develop, Manufacture, and Commercialize Licensed Products in the Field in the Territory. Without limiting the generality of the foregoing, the license granted by Hookipa to Gilead pursuant to this Section 3.1(a) shall, as applicable, be: (A) exclusive (even as to Hookipa and its Affiliates) with respect to Licensed Technology owned by Hookipa or any of its Affiliates; (B) exclusive (even as to Hookipa and its Affiliates) with respect to Licensed Technology that has been in-licensed by Hookipa or any of its Affiliates from a Third Party on an exclusive basis; and (C) non-exclusive (but exclusive as between Hookipa and its Affiliates, on the one hand, and Gilead, on the other hand) with respect to Licensed Technology which has been in-licensed by Hookipa or any of its Affiliates from a Third Party on a non-exclusive basis. Following expiration of the last-to-expire Royalty Term for a Licensed Product in a country, the licenses granted to Gilead under this Section 3.1(a) with respect to such Licensed Product in such country shall continue in effect, but shall become fully paid-up, royalty-free, perpetual, and irrevocable.

(b) Subject to the terms and conditions of this Agreement, Gilead hereby grants to Hookipa, during each Collaboration Term, a non-exclusive, royalty-free, transferable (pursuant to Section 18.1) sublicensable (pursuant to Section 3.2(c)) sublicense, under the Licensed Technology, and license under: (i) the Gilead Background Intellectual Property; and (ii) the Gilead Improvements, in each case, solely to perform Hookipa's activities under the applicable Research Plan.

3.2 Sublicensing and Subcontracting Rights.

(a) Subject to Section 3.6, Gilead may sublicense the rights granted by Hookipa under Section 3.1(a) (including in multiple tiers) at any time to any Affiliates or Third Parties at its sole discretion and without approval of Hookipa; provided, that: (i) where any such rights are in-licensed by Hookipa from a Third Party licensor and sublicensed hereunder, the grant of such sublicense is permitted under the terms and conditions of the applicable Hookipa Third Party Agreement(s); (ii) Gilead shall ensure that each of its Affiliates or any Third Party is bound by a written agreement that is consistent with and subject to the applicable terms and conditions of this Agreement; (iii) Gilead shall remain responsible for the performance of this Agreement and shall cause any such Affiliate or Third Party to comply with all applicable terms and conditions of this Agreement; and (iv) promptly following the full execution of each sublicense agreement with a Third Party, Gilead shall provide Hookipa with a copy of each such sublicense agreement, which copy may be redacted in order to prevent the disclosure of any information not reasonably necessary to confirm compliance with this Agreement.

(b) Gilead may subcontract, to Affiliates or Third Parties the performance of tasks and obligations reasonably related to Gilead's Research, Development, Manufacture, and Commercialization of Licensed Products hereunder as Gilead deems reasonably appropriate, which subcontract may include a sublicense of rights necessary for the performance of the subcontract as reasonably required; provided, that Gilead shall remain responsible for the performance of this Agreement and shall cause any such subcontractor to comply with all applicable terms and conditions of this Agreement.

(c) Hookipa may not subcontract to Third Parties the performance of Hookipa's tasks and obligations under this Agreement or the Research Plans without first obtaining, in each case, the JRC's prior approval. Any subcontract contemplated by this Section 3.2(c) may include a sublicense of rights necessary for the performance of the subcontract as reasonably required; provided, that Hookipa shall remain responsible for the performance of this Agreement and shall cause any such subcontractor to comply with all applicable terms and conditions of this Agreement.

3.3 Right of First Negotiation.

(a) (Subject to the terms and conditions of this Agreement, Hookipa hereby grants Gilead a right of first negotiation to extend the license grant by Hookipa to Gilead under the Licensed Technology pursuant to Section 3.1(a) to all fields outside of the Field.

(b) In the event that Hookipa elects to offer to one (1) or more Third Parties a license or other rights under the Licensed Technology, which license or other rights would include the right to Research, Develop, Manufacture, or Commercialize any Licensed Product in [***], then Hookipa shall provide Gilead with written notice thereof. Gilead may, within [***] days after receipt of such notice, notify Hookipa in writing either that: (i) Gilead is interested in negotiating for such rights; or (ii) Gilead has no such interest and therefore rejects such negotiation opportunity at such time. If Gilead notifies Hookipa within such [***]-day period that Gilead is interested in negotiating with Hookipa for such rights, the Parties shall negotiate in good faith for up to [***] days from such notification by Gilead regarding the terms pursuant to which Hookipa would license or otherwise grant such rights to Gilead. Failure by Gilead to give notice of its interest or lack of interest in negotiating for such rights within the [***]-day period after receipt of the written notice from Hookipa as described in the first sentence of this Section 3.3(b) shall be deemed to constitute a waiver by Gilead of its right of first negotiation for such rights. If Gilead waives or otherwise fails to exercise its right of first negotiation for such rights as provided in this Section 3.3, or if the Parties fail to agree on the terms pursuant to which Hookipa would license or otherwise grant such rights to Gilead within such [***]-day negotiation period, then Hookipa shall be free to offer such rights to a Third Party and enter into an agreement with a Third Party with respect thereto; provided, however, that for a period of [***] months following the conclusion of the [***]-day negotiation period, Hookipa may not offer such rights to a Third Party on substantive terms which are more favorable than those last offered to Gilead, unless such terms are first offered to Gilead and Gilead either: (x) declines in writing to accept such terms; or (y) fails to accept such terms within [***] days of such offer. Such period of [***] months shall be extended by [***] months to [***] months if, within [***] Business Days prior to the end of such [***]-month period, Hookipa provides written notice to Gilead in reasonable detail demonstrating that Hookipa and such Third Party are in active, bona fide negotiations on an agreement for such rights. If Hookipa does not, for any reason, enter into an agreement with a Third Party with respect to such rights within such [***]-month or, as the case may be, [***]-month period, then Hookipa shall not be permitted to enter into any such agreement without again complying with this Section 3.3.

(c) The right of first negotiation of Gilead pursuant to this Section 3.3 shall commence on the Effective Date and terminate ten (10) years after the Effective Date.

3.4 No Other Rights. Each Party expressly reserves and retains all Patent Rights, Know-How, or other intellectual property rights not expressly granted herein, and no right or license under any Patent Rights, Know-How, or other intellectual property rights of either Party is granted or shall be granted by implication. Except as otherwise expressly provided in this Agreement, neither Party shall receive any rights under this Agreement to own, use, or access the Patent Rights, Know-How, or other intellectual property rights .of the other Party. For clarity, and notwithstanding any other provision of this Agreement, except as expressly provided in Section 3.1(b), in no event shall Hookipa receive any right or license with respect to any Antigens provided or otherwise made available by Gilead for use in the Programs.

3.5 Exclusivity. During the Term, Hookipa shall not itself, or with or through any of its Affiliates or any Third Party, directly or indirectly, conduct, participate in, or fund any Research, Development, Manufacture, or Commercialization of or with respect to products utilizing arenavirus-based vectors (including the Hookipa Technologies) for the treatment, cure, diagnosis, or prevention of HBV or HIV, except in accordance with the performance of activities expressly permitted under this Agreement.

3.6 Certain Terms of Hookipa Third Party Agreements. To the extent that the license grant by Hookipa to Gilead under the Licensed Technology pursuant to Section 3.1(a) constitutes the grant of a sublicense to Gilead of certain Licensed Technology that is not owned by Hookipa or any of its Affiliates, but that is in-licensed by Hookipa or any such Affiliate from a Third Party licensor on the basis of a Hookipa Third Party Agreement, then:

(a) Gilead acknowledges that the rights and licenses under, or with respect to, the Licensed Technology granted by Hookipa to Gilead under this Agreement shall be no greater in scope than those granted by such Third Party to Hookipa;

(b) Gilead shall comply, and shall cause its Affiliates and sublicensees to comply, with the specific obligations applicable to sublicensees under such Hookipa Third Party Agreement listed on Schedule 9.5(a), as such Schedule 9.5(a) may be amended from time to time: (i) in the event that any Hookipa Third Party Agreement is accepted by Gilead pursuant to Section 9.5(a): or (ii) upon mutual agreement of the Parties to address any reasonable comments received from a Third Party licensor under any such Hookipa Third Party Agreement (including any reasonable comments concerning the specific listing of obligations applicable to sublicensees under the relevant Hookipa Third Party Agreement on Schedule 9.5(a));

(c) With respect to the Hookipa Third Party Agreements listed on Schedule 9.5(a) as of the Effective Date, Hookipa shall initiate discussions with each Third Party licensor within [***] days of the Effective Date, and otherwise use commercially reasonable efforts to collaborate with Gilead and each such Third Party licensor, in each case, to amend as soon as practicable such Hookipa Third Party Agreement, in a form reasonably acceptable to Gilead and Hookipa, to provide that, if such Hookipa Third Party Agreement, or any license granted by such Third Party licensor to Hookipa under the Licensed Technology pursuant to such Hookipa Third Party Agreement which Hookipa sublicenses to Gilead hereunder, terminates for any reason, Gilead shall receive a direct license from such Third Party licensor to the Licensed Technology sublicensed by Hookipa to Gilead hereunder on terms consistent with those set forth in this Agreement; and

(d) With respect to the Hookipa Third Party Agreement listed on Schedule 9.5(a) as of the Effective Date between Hookipa and [***], if requested by Gilead, Hookipa shall initiate discussions with [***] within [***] days of such request, and otherwise use commercially reasonable efforts to collaborate with Gilead and [***], in each case, to amend as soon as practicable such Hookipa Third Party Agreement, in a form reasonably acceptable to Gilead and Hookipa, to provide that, as between Hookipa and [***], Hookipa shall have the first right to take and control legal action against a Third Party for infringement.

4. GOVERNANCE

4.1 Joint Steering Committee.

(a) Formation. Promptly after the Effective Date, the Parties shall establish a joint steering committee (the "**Joint Steering Committee**" or "**JSC**"), which JSC shall oversee the Programs and have such other responsibilities as set forth in this Section 4.1 and elsewhere in this Agreement.

(b) Membership. The JSC shall consist of three (3) representatives from each of the Parties, each with the requisite experience and seniority to enable such person to make decisions on behalf of such Party with respect to the issues falling within the jurisdiction of the JSC. From time to time, each Party may substitute one (1) or more of its representatives on the JSC upon written notice to the other Party. Gilead shall designate one (1) of its JSC representatives as one (1) of the co-chairpersons of the JSC, and Hookipa shall designate one (1) of its representatives as the other co-chairperson of the JSC (each, a "**JSC Co-Chair**"). The JSC Co-Chairs, in consultation with the Alliance Managers, shall have the following roles and responsibilities: (i) to call meetings, send notice of each such meeting, and designate the time, date, and place of each such meeting; (ii) to convene or poll the representatives by other permitted means; and (iii) to sign and date the final minutes of any meeting of the JSC.

(c) Specific Responsibilities. During the Collaboration Term with respect to a Program, the JSC shall oversee such Program, and shall in particular: (i) be responsible for resolving any disputes that arise in connection with the performance of the Research Plan for such Program; (ii) consider any amendments to the Research Plan for such Program, including any increase in the Research Budget, in accordance with Section 2.2(a); (iii) approve a Licensed Product as Development-Ready, in accordance with Section 2.3; (iv) discuss the entry by Gilead into any agreement for rights to intellectual property owned or otherwise Controlled by a Third Party which are necessary or useful in order to Research, Develop, Manufacture, or Commercialize a Licensed Product, in accordance with Section 9.5(c); and (v) discuss whether an adjusted allocation of the payments for the various components of Licensed Technology is advisable, in accordance with Section 9.9(c). Notwithstanding the foregoing, the JSC shall have no decision-making authority with respect to any Licensed Product that is Development-Ready.

(d) Post-Collaboration Term. Upon expiration or termination of the Collaboration Term of a Program, the JSC's authority with respect to such Program and Licensed Products arising therefrom shall terminate; provided, that, until the First Commercial Sale of the first Licensed Product with respect to such Program (or at any earlier time, upon Gilead's election in its sole discretion), the JSC shall, upon Gilead's request, continue to meet on a [***] basis (or more or less frequently, if mutually agreed by the Parties) solely to serve as a forum for sharing and discussing information, as requested from time to time by Gilead, which is relevant to the further Research, Development, Manufacture, and Commercialization of Licensed Products for such Program. For clarity, during such period: (i) the JSC shall have no decision-making authority with respect to such Program or Licensed Products; and (ii) Gilead may disband the JSC in its sole discretion.

(e) Post-First Commercial Sale. Unless earlier disbanded in accordance with Section 4.1(d), following the First Commercial Sale of the first Licensed Product with respect to a Program, the JSC shall immediately be disbanded with respect to such Program.

4.2 Joint Research Committee.

(a) Formation. Promptly after the Effective Date, the Parties shall establish a joint research committee (the "**Joint Research Committee**" or "**JRC**"), which JRC shall have the responsibilities as set forth in this Section 4.2 and elsewhere in this Agreement.

(b) Membership. The JRC shall consist of three (3) representatives from each of the Parties, each with the requisite experience and seniority to enable such person to make decisions on behalf of such Party with respect to the issues falling within the jurisdiction of the JRC. From time to time, each Party may substitute one (1) or more of its representatives on the JRC upon written notice to the other Party. Gilead shall designate one (1) of its JRC representatives as one (1) of the co-chairpersons of the JRC, and Hookipa shall designate one (1) of its representatives as the other co-chairperson of the JRC (each, a "**JRC Co-Chair**"). The JRC Co-Chairs, in consultation with the Alliance Managers, shall have the following roles and responsibilities: (i) to call meetings, send notice of each such meeting, and designate the time, date, and place of each such meeting; (ii) to convene or poll the representatives by other permitted means; and (iii) to sign and date the final minutes of any meeting of the JRC.

(c) Specific Responsibilities. During the Collaboration Term with respect to a Program, the JRC shall: (i) review the Parties' Research activities under such Program; (ii) provide guidance with respect to such Program; (iii) review and discuss the results, status, and progress of such Program, in accordance with Section 2.2(c); and (iv) approve Hookipa's use of Third Party subcontractors, in accordance with Section 3.2(c).

(d) Post-Collaboration Term. From and after the end of the Collaboration Term with respect to a Program, the JRC shall immediately be disbanded with respect to such Program.

4.3 Joint Committee General Provisions.

(a) Meetings and Minutes. Unless otherwise agreed by the Parties, during the Collaboration Term for each Program, the JSC shall meet [***] and the JRC shall meet [***] to address matters within its jurisdiction with respect to such Program. Meetings of any Joint Committee may be held in person or by audio or video teleconference; provided, that unless otherwise agreed by the Parties, the location of any such in-person meetings shall alternate between locations designated by Gilead and locations designated by Hookipa. The applicable Joint Committee Co-Chairs shall be responsible for scheduling meetings and setting agendas based on the input of each Party. The applicable Joint Committee Co-Chairs shall prepare and circulate for review and approval of the Parties minutes of each meeting promptly after the meeting. The Parties shall agree on the minutes of each meeting promptly, but in no event later than the next meeting of the applicable Joint Committee.

(b) Procedural Rules. Each Joint Committee shall have the right to adopt such standing rules as shall be necessary for its work to the extent that such rules are not inconsistent with this Agreement. A quorum of a Joint Committee shall exist whenever there is present at a meeting at least two (2) representatives appointed by each Party. Each Joint Committee shall take action by consensus of the representatives present at a meeting at which a quorum exists, with each Party having a single vote irrespective of the number of representatives of such Party in attendance, or by a written resolution signed by at least two (2) representatives appointed by each Party. Employees or consultants of either Party that are not representatives of the Parties on a Joint Committee may attend meetings of such Joint Committee; provided, however, that such attendees: (i) shall not vote or otherwise participate in the decision-making process of the Joint Committee; (ii) shall not be counted when determining whether a quorum exists at any such meeting; and (iii) shall be bound by obligations of confidentiality and non-disclosure equivalent to those set forth in Article 12. A Party's representative on the JSC may also serve as such Party's representative on the JRC and *vice versa;* provided, that such representative has the requisite experience and seniority to enable such person to make decisions on behalf of such Party with respect to the issues falling within the jurisdiction of the relevant Joint Committee.

4.4 Dispute Resolution.

(a) JSC. If after reasonable discussion and good fair consideration of each Party's view on a particular matter before the JSC and within the scope of its authority, the representatives of the Parties on the JSC cannot reach consensus as to such matter in accordance with Section 4.3(b) within [***] Business Days after such matter was brought to the JSC for resolution or after such matter has been referred to the JSC in accordance with Section 4.4(b), then either Party may refer such disagreement to the Senior Officers for resolution. If the Senior Officers cannot resolve such matter within [***] Business Days after such matter has been referred to them in accordance with this Section 4.4(a) then [***]. Notwithstanding the foregoing, [***] shall have the final decision-making authority, during [***], with respect to [***]; provided, that [***]. If the Parties are unable to reach such mutual agreement within [***] days after the Parties initiate discussions, then either Party may escalate the matter to the Parties' Senior Officers for resolution in accordance with Section 18.5(a). If the Senior Officers cannot resolve such matter in accordance with Section 18.5(a), then [***]. For clarity, each supply agreement entered into pursuant to Section 7.2 shall detail the Parties' respective final decision-making authority with respect to all matters that specifically relate to Manufacturing of any applicable Licensed Product(s) covered by such supply agreement.

(b) JRC. If, after reasonable discussion and good faith consideration of each Party's view on a particular matter before the JRC and within the scope of its authority, the representatives of the Parties on the JRC cannot reach consensus as to such matter in accordance with Section 4.3(b) within [***] Business Days after such matter was brought to the JRC for resolution, then such disagreement shall be referred to the JSC for resolution pursuant to Section 4.4(a).

(c) Limitations on Authority. Each Party shall retain the rights, powers, and discretion granted to it under this Agreement, and no such rights, powers, or discretion shall be delegated to or vested in a Joint Committee unless such delegation or vesting of rights, powers, or discretion is expressly provided for in this Agreement or the Parties expressly so agree in writing. No Joint Committee shall have the power to amend, modify, or waive compliance with this Agreement, which may only be amended, modified, or waived as provided in Section 18.7.

4.5 Alliance Managers. Promptly following the Effective Date, each Party shall appoint (and notify the other Party of the identity thereof in writing) one (1) senior representative having a general understanding of vaccine Research, Development, and Commercialization to act as its alliance manager under this Agreement (each, an "**Alliance Manager**"). The Alliance Managers shall serve as the contact point between the Parties and will be primarily responsible for facilitating the flow of information and otherwise promoting communication, coordination, and collaboration between the Parties, including: (a) facilitating periodic communications between the Parties in connection with the Parties' reporting requirements; (b) providing single-point communication for seeking

consensus both internally within the respective Party's organization and together regarding key global strategy and planning issues, as appropriate, including facilitating review of external corporate communications; (c) raising cross-Party or cross-functional disputes in a timely manner; and (d) consulting with: (i) the JSC Co-Chairs, in accordance with Section 4.1(b), and (ii) the JRC Co-Chairs, in accordance with Section 4.2(b). Each Alliance Manager may be member of a Joint Committee and *vice versa;* provided, that such Alliance Manager has the requisite experience and seniority to enable such person to make decisions on behalf of such Party with respect to the issues falling within the jurisdiction of the relevant Joint Committee. From time to time, each Party may substitute its Alliance Manager at any time upon written notice to the other Party.

4.6 Costs of Governance. The Parties agree that the costs incurred by each Party in connection with its participation at any meetings under this Article 4 shall be borne solely by such Party.

5. TECHNOLOGY TRANSFERS

5.1 Disclosure of Know-How. To the extent not already provided prior to the Effective Date, each Party shall promptly provide to the other Party access to all documents and materials containing the Hookipa Know-How and Know-How included within the Gilead Background Intellectual Property or Gilead Improvements as shall be reasonably requested by the other Party and as necessary or useful to exercise its rights or fulfill its obligations under this Agreement, including to undertake the activities assigned to it under the Research Plan and the activities of Gilead in connection with the Development, Manufacture, and Commercialization of Licensed Products, except for any Hookipa Know-How relating to the Manufacture of Licensed Products and addressed in Section 7.5.

5.2 Consultation and Assistance. Unless otherwise agreed by the Parties, the Party granting such access pursuant to Section 5.1 shall further provide reasonable consultation and assistance to the other Party for the purpose of transferring the respective Know-How to the other Party to the extent necessary or useful for the purposes set forth in Section 5.1. The Parties agree that each Party shall provide such reasonable consultation and assistance to the other Party free of charge, it being understood that such free consultation and assistance provided by one (1) Party to the other Party shall not exceed a total amount of [***] hours of work. Any consultation and assistance exceeding such cap amount of hours shall be charged by the Party providing such consultation and assistance to the other Party at the FTE Rate (in the case of Hookipa providing consultation and assistance) or in accordance with its standard intercompany rates (in the case of Gilead providing consultation and assistance). Any consultation and assistance to be provided, if provided in person at the other Party's facilities or any other place as may be mutually agreed by the Parties, shall be provided subject to the payment of reasonable and documented travel and living expenses associated with the provision of such consultation and assistance by the Party granting such access.

5.3 Materials Transfer. From time to time during the Term, at the reasonable request of Gilead, Hookipa shall provide to Gilead or its designated Affiliate reasonable quantities of any biological materials generated by use of the Licensed Technology in Hookipa's possession and Control as required by Gilead in connection with activities under this Agreement. Gilead shall reimburse Hookipa at the FTE Rate for the documented costs of any FTEs and Out-of-Pocket Costs reasonably incurred by Hookipa for the manufacturing or supply of such biological materials by Hookipa within [***] days after Gilead's receipt of an invoice therefor from Hookipa.

5.4 Regulatory Transfer. On a Development-Ready Licensed Product-by-Development-Ready Licensed Product basis, promptly following the JSC's approval of such Licensed Product as Development-Ready in accordance with Section 2.3, Hookipa shall, and hereby does, assign and transfer to Gilead (or Gilead's designee) all of Hookipa's right, title, and interest in and to all Regulatory Approvals, Regulatory Filings, and related submissions, if any, owned by Hookipa or its Affiliates that relate to such Development-Ready Licensed Product, including any IND filed by Hookipa with respect to such Development-Ready Licensed Product, as well as copies of all results generated by or on behalf of Hookipa during its performance of the applicable Program relating to such Development-Ready Licensed Product. Gilead shall reimburse Hookipa and its Affiliates for their reasonable Out-of-Pocket Costs attributable to such assignment and transfer. Hookipa's obligation to disclose and transfer such Development and regulatory data is limited to the disclosure of the data, information, and reports in the form, format, and quality as reasonably available to Hookipa; in no event shall Hookipa be obliged to translate, summarize, re-arrange, re-format, compile, correct, enhance, evaluate, interpret, or otherwise undertake secondary review of any such Development or regulatory data and any such activities, if required for the Development, Manufacture, or Commercialization of Licensed Products in the Field in the Territory, shall be the sole responsibility of Gilead. If Hookipa, upon request of Gilead, agrees to perform such activities, Hookipa shall be reimbursed for the internal costs thereof by Gilead at the FTE Rate.

6. DEVELOPMENT AND REGULATORY MATTERS

6.1 Development. From and after the date that a Licensed Product becomes Development-Ready, Gilead shall be solely responsible for conducting all Development activities with respect to such Licensed Product, [***].

6.2 Development Reports. From and after the date that a Licensed Product becomes Development-Ready, Gilead shall provide to Hookipa within [***] days after the end of each Calendar Year a written report which summarizes [***]. Each report shall be compiled and reported in English and shall be the Confidential Information of Gilead. If, within [***] days of Hookipa's receipt of a written report pursuant to this Section 6.2. Hookipa provides Gilead written notice that it wishes to discuss such written report, then Gilead shall make available to Hookipa, [***].

6.3 Development Diligence.

(a) HBV Licensed Products. Beginning at such time as the first HBV Licensed Product becomes Development-Ready, Gilead shall itself, or through its Affiliates or sublicensees, use Commercially Reasonable Efforts to Develop for purposes of achieving Regulatory Approval [***] HBV Licensed Product in: [***].

(b) HIV Licensed Products. Beginning at such time as the first HIV Licensed Product becomes Development-Ready, Gilead shall itself, or through its Affiliates or sublicensees, use Commercially Reasonable Efforts to Develop for purposes of achieving Regulatory Approval [***] HIV Licensed Product in: [***].

(c) Gilead's Discretion. For clarity, subject to compliance with the foregoing in this Section 6.3, the Development of Licensed Products shall be in Gilead's sole discretion.

6.4 Regulatory.

(a) General Responsibility, From and after the Effective Date, as between the Parties, Gilead shall be responsible for: (i) preparing and submitting to applicable Regulatory Authorities all Regulatory Documentation, including INDs, for Licensed Products; (ii) obtaining and maintaining all Regulatory Approvals for Licensed Products; and (iii) conducting communications with the Regulatory Authorities for the Licensed Products.

(b) Support by Hookipa. As between the Parties, during each Collaboration Term, Hookipa shall be responsible for preparing all non-clinical and CMC reports, in each case, as reasonably required by Gilead for inclusion in any IND filing for a Licensed Product arising from each Program. Hookipa shall prepare all such reports, and provide Gilead with copies of any such reports, in each case, in a timely manner to permit Gilead to make such IND filings without delay. Without limiting the foregoing, Hookipa shall support Gilead as may be reasonably necessary in connection with Gilead's preparation of Regulatory Documentation under each Program during the applicable Collaboration Term. Gilead shall reimburse Hookipa for the documented costs of any FTEs (at the FTE Rate) and Out-of-Pocket Costs reasonably incurred by Hookipa in carrying out such preparation and support activities pursuant to and in accordance with Sections 9.6(a) or 9.6(b), as applicable.

(c) Ownership. Subject to Section 14.1(g), all Regulatory Documentation generated under this Agreement, including in the course of the Programs, shall be owned by and held in the name of Gilead or its designee.

(d) Communication with Regulatory Authorities. Gilead shall have the exclusive right to correspond or communicate with Regulatory Authorities regarding the Licensed Products and other regulatory matters under this Agreement. Unless required by Applicable Law, Hookipa, its Affiliates, and its permitted subcontractors shall not correspond or communicate with Regulatory Authorities regarding any Licensed Product without first, in each case, obtaining Gilead's prior written consent, either during or after the applicable Collaboration Term for a Program; provided, that, upon Gilead's request, Hookipa or its Affiliates shall attend any meeting with a Regulatory Authority regarding any Licensed Product. If Hookipa, its Affiliates, or its permitted subcontractors receive any correspondence or other communication from a Regulatory Authority regarding a Licensed Product, Hookipa shall provide Gilead with access to or copies of all such material written or electronic correspondence promptly after its receipt.

6.5 Pharmacovigilance. Prior to the [***], the Parties shall agree upon and implement a procedure for the mutual exchange of adverse event reports and safety information associated with the Licensed Products. Details of the operating procedure respecting such adverse event reports and safety information exchange shall be the subject of a mutually-agreed written pharmacovigilance agreement between the Parties which shall be entered into within the same period.

6.6 Compliance. Each Party agrees that in performing its obligations under this Agreement, it: (a) shall comply with all Applicable Law, including applicable current international regulatory standards, such as GMP, GLP, GCP, and other rules, regulations, and requirements; and (b) shall not employ or use any person that has been debarred under Sections 306(a) or 306(b) of the U.S. Federal Food, Drug and Cosmetic Act (the "**FDCA**").

6.7 Regulatory Notices. In the event that: (a) based on the results of an audit or inspection by a Regulatory Authority of any facility of a Party (including its CRO or CMO, subject to the terms of such Party's contract with such CRO or CMO) involved in the Research, Development, or Manufacture of a Licensed Product, a Regulatory Authority notifies such Party in writing of a finding; or (b) a Regulatory Authority takes, or gives notice in writing of its intent to take, any regulatory action with respect to any activity of a Party, in each case ((a) or (b)), which finding or action would reasonably be expected to have a material adverse effect on, with respect to Hookipa, its activities under any Research Plan or Manufacture of a Licensed Product or, with respect to Gilead, any activities under any Research Plan or the Research, Development, Manufacture, or Commercialization of a Licensed Product, such Party shall promptly notify the other Party thereof and provide a copy of such notice or summary of such action taken, as applicable. Such notice, finding, action, and all information related thereto shall constitute the Confidential Information of the disclosing Party. Notwithstanding the foregoing: (i) if such Party determines that it may be required by Applicable Law to make a public disclosure of such notice, finding, or action, then the disclosure obligations under this Section 6.7 shall be tolled until such public announcement has been made or such Party determines that such a public disclosure is not required; and (ii) this Section 6.7 shall terminate and be of no further force or effect, on a Licensed Product-by-Licensed Product basis, following First Commercial Sale of such Licensed Product.

7. MANUFACTURING

7.1 Hookipa Supply. Hookipa shall, directly or through a contract manufacturing organization reasonably acceptable to Gilead, Manufacture and supply Lymphocytic Choriomeningitis Virus- and Pichinde Vims-based vectors and each Licensed Vaccine to the extent necessary for the Parties to carry out their respective Research activities under the Research Plans.

7.2 Supply Agreement; Initial Manufacturing Technology Transfer. Prior to the initiation of IND-Enabling Studies with respect to any Licensed Product, the Parties shall conduct good-faith discussions regarding the terms of a supply agreement (and a corresponding quality agreement with customary terms and conditions) pursuant to which Hookipa would supply such Licensed Product [***] (which shall not also be subject to Gilead's reimbursement obligations set forth in Section 9.6) to Gilead for use in Gilead's post-IND Development activities hereunder through completion of the first Proof of Concept Clinical Trial for such Licensed Product.

7.3 Manufacturing. Subject to Sections 7.1 and 7.2 and the Parties' rights and responsibilities in connection with the Programs as provided in the Research Plans, Gilead and its Affiliates or its designated sublicensees shall be solely responsible, [***], for the Manufacture of the Licensed Products being Developed or Commercialized under this Agreement.

7.4 Manufacturing Know-How and Assistance. In addition to its obligations under Section 7.2, during the Term, Hookipa shall fully cooperate with and provide assistance to Gilead or its designee, through documentation, consultation, and face-to-face meetings, to enable Gilead or its designee, in an efficient and timely manner, to proceed with Manufacturing of the Licensed Products and to obtain all appropriate Regulatory Approvals for Manufacturing of Licensed Products. Gilead shall reimburse Hookipa at the FTE Rate for the documented costs of any FTEs and Out-of-Pocket Costs reasonably incurred by Hookipa in carrying out such support activities and assistance within [***] days after Gilead's receipt of an invoice therefor from Hookipa.

7.5 Subsequent Manufacturing Technology Transfer. No later than [***] months prior to the completion of the first Proof of Concept Clinical Trial for a Licensed Product (or earlier, at Gilead's option), Hookipa shall: (a) provide access to Gilead or its designee to copies of all Hookipa Know-How and other Know-How as of the date of transfer that is necessary or reasonably useful for Gilead, or its designee, to Manufacture such Licensed Product; and (b) assign (to the extent requested by Gilead) to Gilead any contract manufacturing agreements with any Third Party contract manufacturer relating to such Licensed Product; provided, that, to the extent the services provided under any contract manufacturing agreements existing and in effect as of the Effective Date are also for products other than such Licensed Product, Hookipa shall use commercially reasonable efforts to promptly amend or otherwise

modify such agreements so that such agreements can be assigned to Gilead as contemplated hereunder. In addition, upon written request of Gilead, Hookipa shall provide to Gilead or its designee consultation and technical assistance as reasonably requested for Gilead to Manufacture, itself or through a Third Party, such Licensed Product. Gilead shall reimburse Hookipa at the FTE Rate for the documented costs of any FTEs and Out-of-Pocket Costs reasonably incurred by Hookipa in carrying out such transfer(s), consultation, and assistance within [***] days after Gilead's receipt of an invoice therefore from Hookipa.

8. COMMERCIALIZATION

8.1 Commercialization. From and after the Effective Date, Gilead shall be solely responsible for Commercializing Licensed Products, [***].

8.2 Commercialization Diligence.

(a) HBV Licensed Products. Gilead shall itself, or through its Affiliates or sublicensees, use Commercially Reasonable Efforts to Commercialize following Regulatory Approval [***] HBV Licensed Product in the Field in: [***].

(b) HIV Licensed Products. Gilead shall itself, or through its Affiliates or sublicensees, use Commercially Reasonable Efforts to Commercialize following Regulatory Approval [***] HIV Licensed Product in the Field in: [***].

(c) Gilead's Discretion. For clarity, subject to compliance with the foregoing in this Section 8.2, the Commercialization of the Licensed Products shall be in Gilead's sole discretion.

9. FINANCIAL PROVISIONS

9.1 Upfront Payment. In consideration of the licenses and rights granted to Gilead hereunder, Gilead shall pay to Hookipa a non-refundable, non-creditable, one (1)-time upfront payment of Ten Million USD ($10,000,000) within [***] days after the Effective Date.

9.2 Milestone Payments. In further consideration of the Research activities performed by or on behalf of Hookipa (Sections 9.2(a) and 9.2(b)) and the licenses and rights granted to Gilead hereunder (Sections 9.2(c) and 9.2(d), subject to the allocation set forth in Section 9.9), the following Milestone Payments shall become due and payable by Gilead to Hookipa in accordance with the following terms and conditions. All payments to be made pursuant to this Section 9.2 shall be made as provided in Article 10.

(a) HBV Pre-Clinical Milestones.

(i) Following Hookipa's delivery to Gilead of [***], in each case, in compliance with the HBV Research Plan, Gilead shall pay Hookipa a one (1)-time payment of [***] for each [***]. The HBV Research Plan shall detail: (A) [***]; and (B) [***], each of which (both (A) and (B)) must be delivered as a package by Hookipa to Gilead in order for Gilead's Milestone Payment obligation under this Section 9.2(a)(i) to become due and payable. For clarity, the HBV Research Plan may provide for [***] to be delivered by Hookipa to Gilead in accordance with this Section 9.2(a)(i) and, in such case, Gilead's Milestone Payment obligation under this Section 9.2(a)(i) shall apply to each such package.

(ii) Gilead shall pay Hookipa a one (1)-time payment of [***] after [***]. The HBV Research Plan shall detail the [***] in order for Gilead's Milestone Payment obligation under this Section 9.2(a)(ii) to be become due and payable.

(b) HIV Pre-Clinical Milestones.

(i) Following Hookipa's delivery to Gilead of [***], in each case, in compliance with the HIV Research Plan, Gilead shall pay Hookipa a one (1)-time payment of Two Hundred Thousand USD ($200,000) for each [***]. The FIIV Research Plan shall detail: (A) [***]; and (B) [***], each of which (both (A) and (B)) must be delivered as a package by Hookipa to Gilead in order for Gilead's Milestone Payment obligation under this Section 9.2(b)(i) to become due and payable. For clarity, the HIV Research Plan may provide for [***] to be delivered by Hookipa to Gilead in accordance with this Section 9.2(b)(i) and, in such case, Gilead's Milestone Payment obligation under this Section 9.2(b)(i) shall apply to each such package.

(ii) Gilead shall pay Hookipa a one (1)-time payment of [***] after [***]. The HIV Research Plan shall detail the [***] in order for Gilead's Milestone Payment obligation under this Section 9.2(b)(ii) to be become due and payable.

(c) Development Milestones. Gilead shall pay Hookipa the following one (l)-time Milestone Payments under this Section 9.2(c) upon the first achievement of the corresponding development milestone event for: (i) the first HBV Licensed Product to achieve the corresponding development milestone event; and (ii) the first HIV Licensed Product to achieve the corresponding development milestone event. For avoidance of doubt, the total Milestone Payments that may become due and payable under this Section 9.2(c) shall not exceed Two Hundred Eighty Million USD ($280,000,000).

(i) *HBV Licensed Product.*

Development Milestone Event	**Milestone Payment**
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

(ii) *HIV Licensed Product.*

Development Milestone Event	**Milestone Payment**
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

(d) Commercial Milestones. Gilead shall pay Hookipa the following one (l)-time Milestone Payments under this Section 9.2(d) upon the first achievement of the corresponding commercial milestone event for the first HBV Licensed Product and for the first HIV Licensed Product. For avoidance of doubt, the total Milestone Payments that may become due and payable under this Section 9.2(d) shall not exceed One Hundred Million USD ($100,000,000).

(i) *HBV Licensed Product.*

Commercial Milestone Event	**Milestone Payment**
Annual Net Sales of an HBV Licensed Product > [***]	[***]
Annual Net Sales of an HBV Licensed Product > [***]	[***]

(ii) *HIV Licensed Product.*

Commercial Milestone Event	**Milestone Payment**
Annual Net Sales of an HIV Licensed Product > [***]	[***]
Annual Net Sales of an HIV Licensed Product > [***]	[***]

9.3 Royalty Payments.

(a) Royalty Rates. In further consideration of the licenses and rights to Gilead hereunder, during each applicable Royalty Term, Gilead shall make the following royalty payments under this Section 9.3 to Hookipa, on a Licensed Product-by-Licensed Product basis, based on the aggregate annual Net Sales of such Licensed Product in the Territory. For clarity, the royalty payments: (i) shall be calculated separately with respect to each Licensed Product; and (ii) shall be payable only once with respect to the same unit of Licensed Product. All payments made pursuant to this Section 9.3 shall be made as provided in Article 10.

(i) *HBV Licensed Product*.

Portion of Annual Net Sales in the Following Range	Royalty Rate
[***] up to [***]	[***]
[***] up to [***]	[***]
[***] up to [***]	[***]
[***] and greater	[***]

(ii) *HIV Licensed Product*.

Portion of Annual Net Sales in the Following Range	Royalty Rate
[***] up to [***]	[***]
[***] up to [***]	[***]
[***] and greater	[***]

(b) Royalty Terms.

(i) The royalty payments described in this Section 9.3 with respect to HBV Licensed Products sold in the Territory shall be payable on an HBV Licensed Product-by-HBV Licensed Product and country-by-country basis, commencing upon the First Commercial Sale of an HBV Licensed Product in a country in the Territory and expiring upon the latest of: (A) [***] years after the First Commercial Sale of such HBV Licensed Product in such country; (B) the expiration of the last-to-expire Valid Claim of a Patent Right within the Licensed Technology in such country that would be infringed by the sale of such HBV Licensed Product in such country in the absence of the licenses granted to Gilead under this Agreement; or (C) the expiration of any Regulatory Exclusivity in such country with respect to such HBV Licensed Product (the "**HBV Royalty Term**").

(ii) The royalty payments described in this Section 9.3 with respect to HIV Licensed Products sold in the U.S. shall be payable, on an HIV Licensed Product-by-HIV Licensed Product basis, commencing upon the First Commercial Sale of an HIV Licensed Product in the U.S. and expiring upon the latest of: (A) [***] years after the First Commercial Sale of such HIV Licensed Product in the U.S.; (B) the expiration of the last-to-expire Valid Claim of a Patent Right within the Licensed Technology in the U.S. that would be infringed by the sale of such HIV Licensed Product in the U.S. in the absence of the licenses granted to Gilead under this Agreement; or (C) the expiration of any Regulatory Exclusivity in the U.S. with respect to such HIV Licensed Product (the "**U.S. HIV Royalty Term**").

(iii) The royalty payments described in this Section 9.3 with respect to HIV Licensed Products sold in a country in the ROW shall be payable, on an HIV Licensed Product-by-HIV Licensed Product and country-by-country basis, commencing upon the First Commercial Sale of a HIV Licensed Product in a country in the ROW and expiring upon the latest of: (A) [***] years after the First Commercial Sale of such HIV Licensed Product in such country; (B) the expiration of the last-to-expire Valid Claim of a Patent Right within the Licensed Technology in such country that would be infringed by the sale of such HIV Licensed Product in such country in the absence of the licenses granted to Gilead under this Agreement; or (C) the expiration of any Regulatory Exclusivity in such country with respect to such HIV Licensed Product (the "**ROW HIV Royalty Term**") (each of the HBV Royalty Term, the U.S. HIV Royalty Term, and the ROW HIV Royalty Term, a "**Royalty Term**" and, collectively, the "**Royalty Terms**").

9.4 Royalty Step-Down.

(a) U.S.

(i) For any period during the applicable Royalty Term, if such Royalty Term continues in the U.S.: (A) with respect to the HBV Royalty Term, solely by virtue of Section 9.3(b)(i)(A) or Section 9.3(b)(i)(C); or (B) with respect to the U.S. HIV Royalty Term, solely by virtue of Section 9.3(b)(ii)(A) or Section 9.3(b)(ii)(C), then the royalty rates under Section 9.3 applicable to Net Sales of such Licensed Product in the U.S. during such period shall be reduced by an amount equal to [***] of such royalty rates under Section 9.3.

(ii) If, during the applicable Royalty Term, Loss of Market Exclusivity with respect to a Licensed Product occurs in the U.S., then the royalty rates under Section 9.3 applicable to Net Sales of such Licensed Product in the U.S. for the remainder of the applicable Royalty Term, as may be adjusted by Section 9.4(a)(i) shall be reduced by an amount equal to [***] of the royalty rates under Section 9.3.

(b) ROW. For any period during the applicable Royalty Term, if such Royalty Term continues in any country in the ROW: (i) (A) with respect to the HBV Royalty Term, solely by virtue of Section 9.3(b)(i)(A) or Section 9.3(b)(i)(C); or (B) with respect to the ROW HIV Royalty Term, solely by virtue of Section 9.3(b)(iii)(A) or Section 9.3(b)(iii)(C); and (ii) Loss of Market Exclusivity with respect, to a Licensed Product occurs in such country, then the royalty rates under Section 9.3 applicable to Net Sales of such Licensed Product in such country for the remainder of the applicable Royalty Term shall be reduced by [***] of such royalty rates under Section 9.3, [***].

9.5 Third Party Obligations.

(a) Subject to Section 9.5(c) in the event that Hookipa enters into an agreement with a Third Party after the Effective Date pursuant to which Hookipa in-licenses or otherwise acquires Control of Patent Rights, Know-How, or other intellectual property rights that would constitute Licensed Technology for purposes of this Agreement, then Hookipa shall promptly provide Gilead with notice and a copy of the applicable license or other agreement with the Third Party, together with a schedule of obligations under any such Hookipa Third Party Agreement applicable to sublicensees, including any payment obligations: (A) specifically attributable to the grant of a sublicense to Gilead to the Patent Rights, Know-How, or other intellectual property rights that would constitute Licensed Technology for purposes of this Agreement; or (B) arising thereunder solely as a result of Gilead's activities under this Agreement in its capacity as a sublicensee of Hookipa under such Hookipa Third Party Agreement (such payment obligations pursuant to (A) and (B), collectively the "**Sublicense Payments**"). Within [***] days following receipt of such notice, Gilead shall decide, in its sole discretion, whether or not to accept such Patent Rights, Know-How, or other intellectual property as Licensed Technology licensed under this Agreement and provide Hookipa written notice of such decision. In the event of acceptance: (i) such Patent Rights, Know-How, or other intellectual property shall constitute Licensed Technology licensed to Gilead under this Agreement; (ii) such agreement shall thereafter be included within the definition of Hookipa Third Party Agreements; (iii) Gilead shall be responsible for all Sublicense Payments; and (iv) Schedule 9.5(a) shall be deemed amended to add such schedule of obligations applicable to sublicensees and Gilead, in its capacity as a sublicensee, shall be obligated to comply with such obligations. In the event that Gilead does not accept such Third Party agreement as a Hookipa Third Party Agreement (including by failing to respond within such [***]-day period): (x) Gilead and its Affiliates shall have no obligations with respect to such Third Party agreement; and (y) Hookipa shall have no obligation to grant any rights to Gilead under such Third Party agreement.

(b) Notwithstanding Section 9.5(a), Hookipa shall remain solely responsible for the payment of royalties, milestones, and other payment obligations under the Hookipa Third Party Agreements set forth on Schedule 9.5(a), as in effect on the Effective Date. All such payments shall be made promptly by Hookipa in accordance with the terms of the applicable Hookipa Third Party Agreement.

(c) In the event that Gilead reasonably determines that any Patent Rights, Know-How, or other intellectual, property rights owned or otherwise Controlled by a Third Party are necessary or useful in order to Develop, Manufacture, or Commercialize a Licensed Product, then [***]. Following such discussion, Gilead shall have the right to enter into a license agreement or otherwise acquire rights to such Patent Rights, Know-How, or other intellectual property (including by way of settlement of litigation) and to deduct from [***] due to Hookipa on such Licensed Product under this Agreement pursuant to Section 9.3, with respect to a given [***] of any and all payments actually paid by Gilead to such Third Party with respect to such Licensed Product. Gilead shall keep Hookipa reasonably informed with respect to Gilead's negotiations for such license with such Third Party licensor and shall use good-faith efforts to [***]. Notwithstanding the foregoing, including in the event that Gilead enters into multiple licenses with multiple Third Party licensors, in no event shall any royalty payments pursuant to Section 9.3 due to Hookipa on such Licensed Product in a [***] be reduced, taking into account also any reductions pursuant to Section 9.4, by more than [***] of the amount that would otherwise be due hereunder (the "**Payment Floor**"). Any such amounts payable for a license to Patent Rights, Know-How, or other intellectual property [***] which are not fully recovered in a [***] in accordance with this Section 9.5(c) as a result of the application of the Payment Floor or otherwise may be carried forward, and Gilead may deduct such carried-forward amount from subsequent [***] due to Hookipa with respect to the applicable Licensed Product until the full amount that Gilead was entitled to deduct is deducted. For clarity, no deductions from [***] due to Hookipa on any Licensed Products under this Agreement pursuant to Section 9.3 shall be made pursuant to this Section 9.5(c) with respect to any amounts payable by Gilead for licenses granted by a Third Party to Gilead for any Patent Rights, Know-How, or other intellectual property rights owned or otherwise Controlled by a Third Party that have been concluded on or prior to the Effective Date.

9.6 Research Funding.

(a) During each Collaboration Term and in connection with any wind-down activities contemplated by Section 13.4. Gilead shall reimburse Hookipa for all Out-of-Pocket Costs actually incurred (with no markup) by Hookipa in connection with the applicable Program, to the extent specifically contemplated in the applicable Research Plan and in accordance with the applicable Research Budget. Gilead shall reimburse the undisputed amount of such Out-of-Pocket Costs incurred in a [***] within [***] days after receipt from Hookipa of an invoice therefor issued within [***] days after the end of such [***].

(b) During each Collaboration Term for a Program, Gilead shall reimburse Hookipa at the FTE Rate for the costs of any FTEs (not to exceed the number of FTEs specified in the applicable Research Plan for such Program for any period without first obtaining, in each case, Gilead's prior written consent) actually performing activities allocated to Hookipa under such Research Plan. Hookipa shall provide to Gilead, within [***] days after the end of each [***] during each Collaboration Term, a report indicating the number of FTEs actually provided by Hookipa with respect to each Program during such [***], Hookipa shall use standard industry systems and processes to record the number of hours and FTEs actually applied to each Program, which systems and processes shall be consistently and equitably applied to all Hookipa research programs with Third Parties. Gilead shall reimburse Hookipa the undisputed amount for such FTE costs incurred in a [***] within [***] days after receipt from Hookipa of an invoice therefor issued within [***] days after the end of each [***].

(c) For clarity, Gilead shall not be obligated to reimburse Hookipa for any costs or expenses incurred by Hookipa in the course of its activities under the Programs, other than: (i) those costs and expenses expressly identified in this Section 9.6 or elsewhere in this Agreement; (ii) reimbursement for the supply of Licensed Products to Gilead in accordance with the terms of any supply agreement entered into by the Parties pursuant to Section 7.2; or (iii) any other costs and expenses approved by Gilead in writing in advance.

9.7 No Projections. Each of Hookipa and Gilead hereby acknowledges and agrees that nothing in this Agreement shall be construed as representing an estimate or projection of anticipated sales of any Licensed Product, and that the Milestones and Net Sales levels set forth above or elsewhere in this Agreement or that have otherwise been discussed by the Parties are merely intended to define the Milestone Payments and royalty obligations to Hookipa in the event such Milestones or Net Sales levels are achieved, NEITHER HOOKIPA NOR GILEAD MAKES ANY REPRESENTATION OR WARRANTY, EITHER EXPRESS OR IMPLIED, THAT IT WILL BE ABLE TO SUCCESSFULLY DEVELOP, OBTAIN REGULATORY APPROVAL FOR, OR COMMERCIALIZE ANY LICENSED PRODUCT OR, IF COMMERCIALIZED, THAT ANY PARTICULAR NET SALES LEVEL OF SUCH LICENSED PRODUCT WILL BE ACHIEVED.

9.8 Non-Refundable and Non-Creditable Payments. Notwithstanding the non-refundable or non-creditable nature of any payments hereunder, but subject to the limitations set forth in Section 16.5 nothing in this Agreement shall limit either Party's rights to assert or obtain damages for breach of this Agreement, including damages calculated based on the payments made under this Agreement.

9.9 Allocation of Payment Values.

(a) The Parties agree and acknowledge that: (i) the Licensed Technology comprises Patent Rights, Know-How, and other intellectual property rights both owned by Hookipa and in-licensed by Hookipa from Third Parties under the Hookipa Third Party Agreements set forth in Schedule 9.5(a), as in effect on the Effective Date; and (ii) Hookipa has certain payment obligations to Third Parties under such Hookipa Third Party Agreements based on amounts payable by Gilead to Hookipa under this Agreement in consideration for Hookipa's grant of a respective sublicense to Gilead in accordance with Section 3.1(a).

(b) To enable Hookipa to correctly calculate the payments due to its Third Party licensors under the Hookipa Third Party Agreements and solely for this purpose, and in acknowledgement that the payments set forth in Sections 9.1, 9.2(c), 9.2(d), and 9.3 are paid in consideration of a license or, as applicable, sublicense to Gilead under the Licensed Technology in its entirety, the Parties agree that the payments set forth in Sections 9.1, 9.2(c), 9.2(d), and 9.3 shall be allocated to the various components of Licensed Technology as follows: (i) [***].

(c) Notwithstanding Sections 9.9(a) and 9.9(b), the Parties agree and acknowledge that one (1) or more of the intellectual property rights comprised by the Licensed Technology may become irrelevant for a given Licensed Product in course of the Research, Development, Manufacture, or Commercialization undertaken under this Agreement. The Parties shall discuss from time to time at the JSC whether any Patent Rights, Know-How, or other intellectual property rights comprised by the Licensed

Technology are no longer relevant for further Research, Development, Manufacture, or Commercialization of a Licensed Product, including whether an adjusted allocation of the payments set forth in Sections 9.1, 9.2(c), 9.2(d), and 9.3 to the various components of Licensed Technology is advisable. Upon the Parties' mutual agreement, if any, on such adjusted allocation, Hookipa will calculate the participation payments due to its Third Party licensors in accordance with such adjusted allocation.

(d) For the avoidance of doubt, the Parties further confirm that the payments set forth in Sections 9.2(a), 9.2(b), and 9.6 are paid as reimbursement of costs and expenses as well as in consideration of the Research work performed and results achieved by Hookipa, and not in consideration of a (sub)license grant.

10. REPORTS AND PAYMENT TERMS

10.1 Reports; Payment Terms.

(a) Gilead shall furnish to Hookipa a written notice of the achievement by Gilead, its Affiliates, or its sublicensees of a Milestone (other than a commercial milestone set forth in Section 9.2(d)) within [***] days after such Milestone has been achieved. After the receipt of any such notice, Hookipa shall submit an invoice to Gilead with respect to the corresponding Milestone Payment. Gilead shall pay such Milestone Payment within [***] days after receipt of such invoice.

(b) During the period from the First Commercial Sale of any Licensed Product until the end of the last-to-expire Royalty Term, Gilead shall, within [***] days following the end of each [***] for which royalties are due: (i) furnish to Hookipa a written report, showing: (A) the aggregate Net Sales of each Licensed Product sold in each country during the relevant [***] in USD; (B) the royalties and, as the case may be, commercial milestones set forth in Section 9.2(d) which shall have accrued hereunder in respect of Net Sales; and (C) the exchange rates used in determining the amounts payable in USD; and (ii) pay such royalties and commercial milestones with respect to such [***] as set forth in such written report.

(c) All payments shall be made by wire transfer to the credit of such bank account as may be designated by Hookipa in this Agreement or in writing to Gilead. Any payment which falls due on a date which is not a Business Day may be made on the next succeeding Business Day.

10.2 Currency; Adjustments to Payment Amounts.

(a) All payments under this Agreement shall be payable in USD (including, for clarity, all payments based on amounts defined herein in currencies other than USD). With respect to sales of a Licensed Product and other amounts received or to be paid to a Third Party in a currency other than USD, such amounts and amounts payable shall be converted to USD using the exchange rate mechanism generally applied by Gilead in preparing its audited financial statements for the applicable [***], subject to Section 10.2(b); provided, that such mechanism is in compliance with Accounting Standards. Gilead shall inform Hookipa of any changes to its standard worldwide currency conversion methodology prior to any such changes becoming effective.

(b) In the event that the exchange rate of USD to Euro as calculated in accordance with Section 10.2(a) (such exchange rate, the "**Reference Exchange Rate**") is greater than [***] of the Base Exchange Rate or less than [***] of the Base Exchange Rate as of the last day of the [***] immediately preceding the reimbursement date for any FTEs or Out-of-Pocket Costs in accordance with this Agreement (the "**Measurement Date**"), the calculation for which is based on or requires, in whole or in part, the Reference Exchange Rate, such reimbursement shall be adjusted up or down, as applicable, to reflect the Reference Exchange Rate in effect on the Measurement Date. Gilead shall notify Hookipa of the Reference Exchange Rate as of the applicable Measurement Date by written notice delivered prior to or contemporaneously with delivery of such reimbursement.

10.3 Blocked Currency. If at any time legal restrictions in the Territory prevent the prompt remittance of any payments with respect to sales therein, Gilead shall have the right and option to make such payments by depositing the amount thereof in local currency to Hookipa's account in a bank or depository designated by Hookipa in the Territory.

10.4 Taxes. Hookipa shall pay any and all taxes levied on account of any payments made to Hookipa under this Agreement. If any taxes are required to be withheld by Gilead, Gilead shall: (a) deduct such taxes from the payment made to Hookipa; (b) timely pay such taxes to the proper taxing authority; (c) send proof of payment to Hookipa; and (d) reasonably assist Hookipa in its efforts to obtain a credit for such tax payment. Each Party agrees to reasonably assist the other Party in lawfully claiming exemptions from or minimizing such deductions or withholdings under double taxation laws or similar circumstances.

10.5 Late Payments. Any amount owed by a Party to the other Party under this Agreement that is not paid within the applicable time period set forth herein shall accrue interest at the rate per annum equal to the [***] as quoted on [***] (or if it no longer exists, a similarly authoritative source) plus rate per annum of [***] calculated on a [***] basis, or, if lower, the highest rate permitted under Applicable Law.

10.6 Records and Audit Rights.

(a) Each Party shall keep complete, true, and accurate books and records in accordance with its Accounting Standards in relation to this Agreement, including, with respect to Gilead, its Affiliates, and its sublicensees, in relation to Net Sales, royalties, and Milestone Payments, and with respect to Hookipa, in relation to FTE efforts expended and Out-of-Pocket Costs incurred under the Programs or otherwise which Gilead is obligated to reimburse under this Agreement. Each Party or other selling entity shall keep such books and records for at least [***] years following the Calendar Year to which they pertain or for such longer period of time as required under any Applicable Law.

(b) Each Party (the "**Auditing Party**") shall have the right, once per [***] and at its own expense, to have an internationally recognized, independent, certified public accounting firm (the "**Auditor**"), selected by the Auditing Party and reasonably acceptable to the other Party (the "**Audited Party**"), review any such records of such other Party (either directly by the Auditing Party or through the Audited Party) in the location(s) where such records are maintained by the Audited Party upon reasonable written notice (which shall be no less than [***] days' prior written notice) and during regular business hours and under obligations of strict confidence secured through a confidentiality agreement between the Auditor and the Audited Party, for the sole purpose of verifying the basis and accuracy of payments made and deductions taken within the [***] period preceding the date of the request for review. Records for any particular period may be audited only once.

(c) In the event such audit leads to the discovery of a discrepancy to the Auditing Party's detriment, the Audited Party shall, within [***] days after receipt of such report from the Auditor, pay any undisputed amount of the discrepancy. The Auditing Party shall pay the full cost of the audit unless the underpayment of amounts due or overpayment of amounts payable by the Auditing Party is greater than [***] of the amount due for the entire period being examined, in which case the Audited Party shall pay the reasonable cost charged by the Auditor for such review. Any undisputed overpayments by the Audited Party revealed by an examination shall be paid by the Auditing Party at the Audited Party's discretion either: (i) as a credit against future payments owed; or (ii) within [***] days of the Auditing Party's receipt of the applicable report.

(d) Any disagreement regarding the results of any audit conducted under this Section 10.6 shall be [***].

11. INTELLECTUAL PROPERTY RIGHTS

11.1 Ownership.

(a) Background Intellectual Property. As between the Parties, and subject to the licenses granted under this Agreement, each Party retains all rights, tide, and interests in and to all Patent Rights, Know-How, and other intellectual property rights that such Party owns or otherwise Controls as of the Effective Date or that it develops or otherwise acquires after the Effective Date outside the performance of the activities under this Agreement, Without limiting the generality of the foregoing, as between the Parties, Gilead shall own all rights, title, and interests in and to the Gilead Background Intellectual Property, and Hookipa shall own all rights, title, and interest in and to the Hookipa Background Intellectual Property.

(b) Improvements. As between the Parties, Gilead shall own all rights, title, and interests in and to the Gilead Improvements, and Hookipa shall own all rights, title, and interests in and to the Hookipa Technologies Improvements. Each Party shall and hereby does assign to the other Party any right, title, and interest it may have in any Improvement that is to be owned by the other Party pursuant to this Section 11.1, and agrees to execute such documents and take such other actions reasonably requested by the other Party to the extent necessary to give effect to the ownership allocation set forth in this Section 11.1.

(c) Invention Protection. Each Party shall ensure that the employees, officers and independent contractors (excluding any sublicensees or subcontractors, each of whom are subject to Section 3.2) of such Party or its respective Affiliates performing activities under this Agreement shall, prior to commencing such work, be bound by written invention assignment obligations requiring: (i) prompt reporting of any Patent Rights, Know-How, or other intellectual property rights arising from such work; (ii) assignment to the applicable Party or Affiliate all of his or her rights, tide, and interests in and to any Patent Rights, Know-How, or other intellectual property rights arising from such work; (iii) cooperation in the Prosecution and Maintenance and enforcement of any Patent Right that is required to be assigned under this Agreement; and (iv) performance of all acts and signing, executing, acknowledging, and delivering any and all documents required for effecting the obligations and purposes of this Agreement.

11.2 Prosecution and Maintenance.

(a) Background Intellectual Property. Gilead shall be solely responsible for the Prosecution and Maintenance of the Gilead Background Intellectual Property at Gilead's sole cost and expense, and Hookipa shall be solely responsible for the Prosecution and Maintenance of the Hookipa Background Intellectual Property at Hookipa's sole cost and expense.

(b) Improvements; Licensed Technology.

(i) Gilead shall be solely responsible for the Prosecution and Maintenance of the Patent Rights claiming or directed to the Gilead Improvements at Gilead's sole cost and expense.

(ii) Subject to Section 3.6, Hookipa shall, in consultation with Gilead, be responsible for Prosecution and Maintenance of Hookipa Patent Rights at Hookipa's cost and expense. Hookipa shall use Commercially Reasonable Efforts to obtain appropriate patent protection with respect to claimed inventions that are supported by the relevant specification of each Hookipa Patent Right. Gilead shall reasonably cooperate with Hookipa in connection with the Prosecution and Maintenance of the Hookipa Patent Rights to the extent reasonably requested by Hookipa, including by providing reasonable access to relevant persons and executing all documentation reasonably requested by Hookipa. Hookipa shall consult with Gilead and keep Gilead reasonably informed of the status of such Hookipa Patent Rights, and provide copies of all relevant documents in a timely manner for Gilead's review and comment, including any material reduction in scope, and shall reasonably consider and use reasonable efforts to incorporate any Gilead comments in good faith; provided, however, that Hookipa shall have the authority to make, in good faith, all final decisions relating to such matters.

(c) Hookipa shall notify Gilead in writing of any decision not to file applications for, to cease Prosecution and Maintenance of, or to not continue to pay the expenses of Prosecution and Maintenance of, any Hookipa Patent Right, including any decision to abandon any pending patent application or issued patent within the Hookipa Patent Rights. Hookipa shall provide such notice at least [***] days prior to any relevant filing or payment due date, or any other due date that requires action, in connection with such Hookipa Patent Right or claim thereof. In such event, Hookipa shall permit Gilead, at Gilead's sole discretion, cost, and expense, to file or to continue Prosecution and Maintenance of such Hookipa Patent Right, and if Gilead continues to prosecute and maintain such Hookipa Patent Right, the following shall apply, subject to Section 3.6:

(i) Such Hookipa Patent Right shall remain in the ownership or otherwise in the Control of Hookipa and shall remain included in the definition of Hookipa Patent Rights for the purpose of this Agreement; provided, however, that, for purposes of this Agreement, all Valid Claims of such Hookipa Patent Right shall be deemed to have expired;

(ii) Hookipa shall fully cooperate with Gilead in connection with the Prosecution and Maintenance of such Hookipa Patent Right to the extent reasonably requested by Gilead, including by providing reasonable access to relevant persons and executing all documentation reasonably requested by Gilead; and

(iii) Gilead shall keep Hookipa reasonably informed of the status of such Hookipa Patent Right and shall notify Hookipa in writing at least [***] days prior to any relevant filing or payment due date of any decision not to file applications for, to cease Prosecution and Maintenance of, or to not continue to pay the expenses of Prosecution and Maintenance of, such Hookipa Patent Right, including any decision to abandon any pending patent application or issued patent within such Hookipa Patent Right, in which case Hookipa shall be entitled to re-assume the sole right for the Prosecution and Maintenance of such Hookipa Patent Right at its sole discretion, cost and expense.

11.3 Enforcement.

(a) Each Party shall promptly notify the other Party of any infringement, misappropriation, or other violation by a Third Party of any of the Licensed Technology of which it becomes aware, including any declaratory judgment, opposition, or similar action alleging the invalidity, unenforceability, or non-infringement with respect to the Licensed Technology (collectively, **"Competing Infringement").**

(b) Subject to Section 3.6, to the extent such Competing Infringement is related to Licensed Technology primarily related to HBV or HIV, Gilead shall have the first right (but not the obligation) to bring and control any legal action in connection with the Competing Infringement at its own expense as it reasonably determines appropriate, and Hookipa shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. If Gilead does not wish to bring an action or proceeding with respect to, or to otherwise terminate, any such infringement of any Licensed Technology, then it shall provide written notice thereof to Hookipa: (i) within [***] following the notice of alleged Competing Infringement; or (ii) prior to [***] months before the time limit, if any, specified under Applicable Laws for the filing of such actions, whichever comes first, then, upon receipt of such notice (or, if no such notice is provided by Gilead, upon the earlier of (i) and (ii)), Hookipa shall have the right (but not the obligation) to bring and control any such action at its own expense and by counsel of its own choice, and Gilead shall have the right, at its own expense, to be represented in any such action by counsel of its own choice; provided, however, that if Gilead notifies Hookipa in writing prior to [***] days before such time limit for the filing of any such action that Gilead intends to the such action before the time limit, then Gilead shall be obligated to the such action before the time limit and to reimburse Hookipa for its reasonable and documented costs and expenses (including reasonable attorneys' and professional fees) incurred in connection with Hookipa's preparation of such action, and Hookipa shall not have the right to bring and control such action.

(c) At the request and expense of the Party prosecuting the relevant action pursuant to Section 11.3(b), the other Party shall provide reasonable assistance in connection therewith, including by executing reasonably appropriate documents, cooperating in discovery, and joining as a party to the action if required.

(d) In connection with any proceeding pursuant to Section 11.3(b), the Party bringing and controlling an enforcement action shall not enter into any settlement admitting the invalidity of, or otherwise impairing the other Party's rights in, the Licensed Technology without first obtaining, in each case, the prior written consent of the other Party, which shall not be unreasonably withheld, conditioned, or delayed.

(e) To the extent such Competing Infringement is related to Licensed Technology not primarily related to HBV or HIV, Hookipa shall have the first right (but not the obligation) to bring and control any legal action in connection with the Competing Infringement at its own expense as it reasonably determines appropriate, and Gilead shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. If Hookipa fails to bring an action or proceeding with respect to, or to otherwise terminate, any such infringement of any Licensed Technology: (i) within [***] days following the notice of alleged Competing Infringement; or (ii) prior to [***] months before the time limit, if any, specified under Applicable Laws for the filing of such actions, whichever comes first, Gilead shall have the right (but not the obligation) to bring and control any such action at its own expense and by counsel of its own choice, and Hookipa shall have the right, at its own expense, to be represented in any such action by counsel of its own choice; provided, however, that if Hookipa notifies Gilead in writing prior to [***] days before such time limit for the filing of any such action that Hookipa intends to file such action before the time limit, then Hookipa shall be obligated to file such action before the time limit and to reimburse Gilead for its reasonable and documented costs and expenses (including reasonable attorneys' and professional fees) incurred in connection with Gilead's preparation of such action, and Gilead shall not have the right to bring and control such action.

11.4 Defense.

(a) Each Party shall promptly notify the other Party of any actual or potential claim alleging that the Research, Development, Manufacture, or Commercialization of any Licensed Product infringes, misappropriates, or otherwise violates any Patent Rights, Know-How, or other intellectual property rights of any Third Party ("**Third Party Infringement**"). In any such instance, the Parties shall as soon as practicable thereafter discuss in good faith the best response to such notice of Third Party Infringement, and, subject to Section 3.6, Gilead shall have the first right (but not the obligation) to defend any such claim of Third Party Infringement, at Gilead's sole discretion, cost, and expense, and Hookipa shall have the right to be represented in any such action by counsel of its own choice at Hookipa's sole cost and expense.

(b) If Gilead declines or fails to assert its intention to defend any such claim of Third Party Infringement within [***] days following receipt or, as applicable, sending of a notice pursuant to Section 11.4(a), then Hookipa shall have the right (but not the obligation) to defend such claim of Third Party Infringement at Hookipa's sole discretion, cost and expense, and Gilead shall have the right to be represented in any such action by counsel of its own choice at Gilead's sole cost and expense.

(c) In no event shall either Party settle or otherwise compromise any Third Party Infringement by admitting that any Patent Right included within the Licensed Technology is invalid or unenforceable, unless explicitly approved by the other Party in writing. In the event that Gilead, subject to Hookipa's prior approval, enters into any settlement with respect to any actual or potential claim of Third Party Infringement which includes the acceptance of any license to Patent Rights, Know-How, or other intellectual property rights owned or otherwise Controlled by any Third Party and necessary or useful for the Research, Development, Manufacture, or Commercialization of any Licensed Product, such settlement shall further be subject to Section 9.5(c).

11.5 Recovery. Subject to Section 3.6, any recovery received as a result of any action under Sections 11.3 or 11.4 shall be used in the following order: (a) to reimburse the Party taking legal action for the costs and expenses (including attorneys' and professional fees) incurred in connection with such action (and not previously reimbursed); (b) to reimburse the Party not taking the lead in a legal action but which joins such legal action as provided herein, for the costs and expenses (including attorneys' and professional fees) incurred in connection with such action (and not previously reimbursed); and (c) the remainder of the recovery shall be [***] and each such share shall be paid to or retained by a Party.

11.6 Trademarks. Gilead shall have the right to brand the Licensed Products using Gilead-related trademarks and any other trademarks and trade names it determines appropriate for each Licensed Product, which may vary by country or within a country (the "**Product Marks**"). Gilead shall own all rights, tide, and interests in and to the Product Marks and register and maintain the Product Marks in the countries and regions it determines reasonably necessary.

11.7 Patent Marking. To the extent commercially feasible and consistent with prevailing business and legal practices, Gilead shall mark, and shall cause its Affiliates and sublicensees to mark, all Licensed Products that are Manufactured or Commercialized under this Agreement with the number of each issued Hookipa Patent Right that specifically claims such Licensed Products.

11.8 Licensed Product Listings. With respect to filings in the FDA's Orange Book or Purple Book or other similar filings or listings as may be applicable to a biologic or drug (and foreign equivalents) for issued patents for a Licensed Product, upon request by Gilead, Hookipa shall provide reasonable cooperation to Gilead in filing and maintaining any such listing and filings.

11.9 Patent Term Extensions. Subject to Section 3.6, upon Gilead's request, Hookipa shall: (a) with respect to requests solely applicable to one (1) or more Licensed Products, cooperate in obtaining, but only to the extent such Patent Term Extensions do not impact Hookipa's ability to obtain Patent Term Extensions based on approvals for any products other than the Licensed Products; and (b) with respect to all other request, consider in good-faith whether to obtain, in each case, patent term restoration (including under the Drug Price Competition and Patent Term Restoration Act), supplemental protection certificates or their equivalents, and patent term extensions (collectively, "**Patent Term Extensions**") with respect to the Hookipa Patent Rights in any country or region within the Territory, where applicable, at Gilead's sole cost and expense. Gilead acknowledges that Hookipa's internal patent strategies and business considerations and obligations under any applicable Hookipa Third Party Agreements will be taken into account. If the Parties agree on a Patent Term Extension for a given Hookipa Patent Right, Hookipa shall provide all reasonable assistance requested by Gilead, including permitting Gilead to proceed with applications for such in the name of Hookipa or the Third Party licensor under the applicable Hookipa Third Party Agreement, if deemed appropriate by Gilead, and executing documents and providing any relevant information and assistance to Gilead.

12. CONFIDENTIALITY

12.1 Duty of Confidence. Subject to the other provisions of this Article 12, all Confidential Information disclosed by a Party or any of its Affiliates (the "**Disclosing Party**") to the other Party or any of its Affiliates (the "**Recipient Party**") under this Agreement shall be maintained in confidence and otherwise safeguarded by the Recipient Party. The Recipient Party may only use Confidential Information of the Disclosing Party for the purposes of this Agreement and pursuant to the rights granted to the Recipient Party under this Agreement. Subject to the other provisions of this Article 12, the Recipient Party shall hold as confidential such Confidential Information of the Disclosing Party in the same manner and with the same protection as such Recipient Party maintains its own Confidential Information, but in any event with no less than reasonable protections.

12.2 Exceptions. The obligations under this Article 12 shall not apply to any Confidential Information to the extent that such Confidential Information:

(a) is (at the time of disclosure) or becomes (after the time of disclosure) known to the public or part of the public domain through no breach of this Agreement by the Recipient Party;

(b) was known to, or was otherwise in the possession of, the Recipient Party, as evidenced by its written records, prior to the time of disclosure by the Disclosing Party;

(c) is disclosed to the Recipient Party on a non-confidential basis by a Third Party lawfully in possession thereof who is entitled to disclose it without breaching any confidentiality obligation to the Disclosing Party; or

(d) is independently developed by or on behalf of the Recipient Party, as evidenced by its written records, without reference to the Confidential Information disclosed by the Disclosing Party under this Agreement.

12.3 Authorized Disclosures. In addition to disclosures allowed under Section 12.2, Section 12.6, or Article 17 and those mutually agreed to by the Parties in writing, solely to the extent that it is reasonably necessary or appropriate to fulfill its obligations or exercise its rights under this Agreement, the Recipient Party and Permitted Recipients may disclose Confidential Information of the Disclosing Party in the following instances:

(a) in connection with Prosecution and Maintenance of Patent Rights as permitted by this Agreement;

(b) in connection with Regulatory Filings for Licensed Products made pursuant to this Agreement;

(c) prosecuting or defending litigation as permitted by this Agreement;

(d) subject to Sections 12.4 and 12.5, complying with Applicable Laws (including the rules and regulations of the Securities and Exchange Commission or any national securities exchange) and with judicial process, if such disclosure is necessary for such compliance; and

(e) to the Recipient Party's: (i) officers, directors, and employees; (ii) sublicensees; and (iii) agents, contractors (including consultants and clinical investigators), advisers, and other Third Parties, in the case of each of clauses (i)-(iii), solely to the extent reasonably necessary for the purposes of, and for those matters undertaken pursuant to, this Agreement; provided, that in the case of disclosures to Persons set forth in clauses (ii) and (iii), such Persons are bound by written obligations of confidentiality and non-use no less restrictive than the obligations set forth in this Article 12 (each a "**Permitted Recipient**"); provided, further, that the Recipient Party shall remain responsible for any failure by any Permitted Recipient who receives Confidential Information pursuant to this Article 12 to treat such Confidential Information as required under this Article 12.

If and whenever any Confidential Information is disclosed in accordance with this Section 12.3, such disclosure shall not cause any such information to cease to be Confidential Information except to the extent that such permitted disclosure results in a public disclosure of such information (otherwise than by breach of this Agreement). Where reasonably possible and subject to Sections 12.4 and 12.5, the Recipient Party shall, or cause its Permitted Recipients, if applicable, to notify the Disclosing Party of the Recipient Party's or its Permitted Recipient's, as applicable, intent to make such disclosure pursuant to paragraphs (c) or (d) of this Section 12.3 sufficiently prior to making such disclosure so as to allow the Disclosing Party adequate time to take whatever action it may deem appropriate to protect the confidentiality of the information.

12.4 Required Disclosure. A Recipient Party may disclose Confidential Information pursuant to interrogatories, requests for information or documents, subpoena, civil investigative demand issued by a court or governmental agency, or as otherwise required by Applicable Law; provided, that the Recipient Party shall notify the Disclosing Party promptly upon any receipt thereof, using commercially reasonable efforts to provide the Disclosing Party sufficient advance notice to permit it to oppose, limit, or seek confidential treatment for such disclosure, and to file for patent protection if relevant; provided, further, that the Recipient Party shall furnish only that portion of the Confidential Information which it is advised by counsel is legally required, whether or not a protective order or other similar order is obtained by the Disclosing Party.

12.5 Securities Filings. In the event either Party or any of its Affiliates proposes to file with the Securities and Exchange Commission or the securities regulators of any state or other jurisdiction a registration statement or any other disclosure document which describes, refers to, or provides a copy of this Agreement under the Securities Act of 1933, the Securities Exchange Act of 1934, or any other Applicable Law, the Party shall, and shall, if applicable, cause its Affiliate to, notify the other Party of such intention and shall provide such other Party with a copy of relevant portions of the proposed filing not less than [***] Business Days prior to such filing (and any revisions to such portions of the proposed filing a reasonable time prior to the filing thereof), including any exhibits thereto relating to this Agreement, and shall use reasonable efforts to obtain confidential treatment of any information concerning this Agreement that such other Party requests be kept confidential, and shall only disclose Confidential Information which it is advised by counsel is legally required to be disclosed. No such notice shall be required under this Section 12.5 if the substance of the description of or reference to this Agreement contained in the proposed filing has been included in any previous filing made by either Party or its Affiliates hereunder or otherwise has been approved by the other Party.

12.6 Terms of Agreement. The existence and the terms and conditions of this Agreement that the Parties have not specifically agreed to disclose pursuant to Section 12.3 or Article 17 shall be considered Confidential Information of both Parties. Either Party and its Affiliates may disclose such terms and conditions of this Agreement on a need-to-know basis to [***], licensor (including, in the case of Hookipa, any Third Party licensor under a Hookipa Third Party Agreement), [***], consultant, advisor, sublicensee, or an acquirer of rights to a Licensed Product, and their attorneys and agents; provided, that each such Person to whom such information is to be disclosed: (a) is informed of the confidential nature of such information; (b) has entered into a written agreement with the Party, or is otherwise bound by professional rules, requiring such Person to maintain the confidentiality of such Confidential Information; and (c) is obliged to maintain the confidentiality in a manner consistent with the confidentiality provisions of this Agreement, provided, however, that the foregoing clause (c) shall not apply with respect to the Third Party licensors under the Hookipa Third Party Agreements. To the extent that Hookipa is obliged under any Hookipa Third Party Agreement to disclose to its Third Party licensor any progress or financial reports from Gilead that are related to the Development or Commercialization of Licensed Products as described in detail in Schedule 9.5(a). Hookipa may undertake such disclosure and any such disclosure shall not constitute a breach of this Article 12.

12.7 Ongoing Obligation for Confidentiality. Upon early termination of this Agreement in its entirety for any reason, each Party and its Permitted Recipients shall immediately return to the other Party or destroy any Confidential Information disclosed by or on behalf of the other Party, except for one (1) copy which may be retained in its confidential files for archive purposes.

13. TERM AND TERMINATION

13.1 Term. The term of this Agreement shall commence upon the Effective Date and continue, unless earlier terminated as permitted by this Agreement, until the expiration of the last-to-expire Royalty Term (the "**Term**").

13.2 Termination for Material Breach. If a Party (the "**Non-Breaching Party**") reasonably believes that the other Party (the "**Breaching Party**") is in breach of any material obligation hereunder, the Non-Breaching Party may give written notice to the Breaching Party specifying the breach in reasonable detail. In the event such breach is not cured within the relevant time period specified below after such notice, the Non-Breaching Party shall have the right thereafter to terminate this Agreement immediately, in its entirety, with the consequences as set forth in Sections 14.1 or 14.2, as applicable, by giving written notice to the Breaching Party to such effect. The Breaching Party shall have [***] following receipt of the Non-Breaching Party's written notice to either cure such breach or, if cure cannot be reasonably effected within such [***] period, to deliver to the Non-Breaching Party a plan for curing such breach which is reasonably sufficient to effect a cure within a reasonable period not to exceed [***] following receipt of such plan by the Non-Breaching Party. Following delivery of such plan, the Breaching Party shall use Commercially Reasonable Efforts to carry out the plan and cure the breach. Notwithstanding the foregoing, the right to terminate in accordance with this Section 13.2 may be exercised on a Licensed Product-by-Licensed Product or country-by-country basis.

13.3 Termination for Insolvency. Either Party may terminate this Agreement at any time during the Term upon the other Party's filing or institution of bankruptcy, reorganization, liquidation, or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; provided, however, that in the case of any involuntary bankruptcy proceeding, such right to terminate shall only become effective if the Party consents to the involuntary bankruptcy or such proceeding is not dismissed within [***] days after the filing thereof, In addition, Gilead may terminate this Agreement in the event that Hookipa rejects this Agreement under Section 365 of the United States Bankruptcy Code, 11 U.S.C. §§ 101 et seq. (the "**Code**").

13.4 Termination by Gilead for Convenience.

(a) Termination of Program by Gilead for Convenience.

(i) During the HBV Collaboration Term, Gilead shall have the right to terminate this Agreement with respect to the HBV Program for convenience upon [***] prior written notice to Hookipa, Upon the termination of this Agreement with respect to the HBV Program in accordance with this Section 13.4(a)(i). Gilead shall reimburse Hookipa in accordance with Section 9.6 at the FTE Rate for the documented costs of any FTEs and Out-of-Pocket Costs reasonably incurred and directly arising from of Hookipa's prompt wind-down of the HBV Program for a reasonable period following the effective date of such termination to be mutually agreed between the Parties; provided, that: (i) such period does not exceed [***] months; and (ii) such costs do not exceed the expenses budgeted for the HBV Program in such period in accordance with the HBV Research Plan.

(ii) During the HIV Collaboration Term, Gilead shall have the right to terminate this Agreement with respect to the HIV Program for convenience upon [***] prior written notice to Hookipa. Upon the termination of this Agreement with respect to the HIV Program in accordance with this Section 13.4(a)(ii). Gilead shall reimburse Hookipa in accordance with Section 9.6 at the FTE Rate for the documented costs of any FTEs and Out-of-Pocket Costs reasonably incurred and directly arising from of Hookipa's prompt wind-down of the HIV Program for a reasonable period following the effective date of such termination to be mutually agreed between the Parties; provided, that: (i) such period does not exceed [***] months; and (ii) such costs do not exceed the expenses budgeted for the HBV Program in such period in accordance with the HIV Research Plan.

(iii) For clarity, the termination of a Program in accordance with this Section 13.4(a) shall not constitute a termination of this Agreement with respect to any Development-Ready HBV Licensed Product or Development-Ready HIV Licensed Product, as applicable.

(b) Termination of Agreement by Gilead for Convenience. At any time during the Term, Gilead shall have the right to terminate this Agreement in its entirety or on a Licensed Product-by-Licensed Product or a country-by-country basis for convenience upon [***] prior written notice to Hookipa.

13.5 Rights in Bankruptcy.

(a) The Parties agree that this Agreement constitutes an executory contract under Section 365 of the Code for the license of "intellectual property" as defined under Section 101 of the Code and constitutes a license of "intellectual property" for purposes of any similar Applicable Laws in any other country in the Territory. The Parties further agree that Gilead, as licensee of such rights under this Agreement, shall retain and may fully exercise all of its protections, rights, and elections under the Code, including under Section 365(n) of the Code, and any similar Applicable Laws in any other country in the Territory.

(b) All rights, powers, and remedies of Gilead provided for in this Section 13.5 are in addition to and not in substitution for any and all other rights, powers, and remedies now or hereafter existing at law or in equity (including under the Code and any similar Applicable Laws in any other country in the Territory). Gilead, in addition to the rights, power, and remedies expressly provided herein, shall be entitled to exercise all other such rights and powers and resort to all other such remedies as may now or hereafter exist at law or in equity, including under the Code. The Parties agree that they intend the following Gilead rights to extend to the maximum extent permitted by law, including for purposes of the Code, and the Hookipa Third Party Agreements: (i) the right of access to any Licensed Technology (including all embodiments thereof), or any Third Party with whom Hookipa contracts to perform an obligation of Hookipa under this Agreement which is necessary for the Research, Development, Manufacture, or Commercialization of Licensed Products in the Field in the Territory; (ii) the right to contract directly with any Third Party described in paragraph (i) to complete the contracted work; and (iii) the right to cure any breach of or default under any such agreement with a Third Party and set off or recoup the costs thereof against amounts payable to Hookipa under this Agreement.

14. EFFECT OF TERMINATION

14.1 Termination by Gilead Without Cause or by Hookipa for Material Breach by or Insolvency of Gilead. Upon termination of this Agreement by Gilead pursuant to Section 13.4 or termination of this Agreement by Hookipa pursuant to Section 13.2 or Section 13.3 the following shall apply, but, in the case of termination by Gilead pursuant to Section 13.4 or any other partial termination of this Agreement, solely with respect to the applicable Terminated Licensed Products:

(a) all licenses granted by Hookipa to Gilead hereunder, including under Section 3.1(a) shall terminate;

(b) all licenses granted by Gilead to Hookipa hereunder, including under Section 3.1(b) shall terminate;

(c) Gilead shall be released from its Development and Commercialization obligations;

(d) the provisions of Article 11 (other than Section 11.1) shall be terminated;

(e) upon receipt by Gilead from Hookipa of written notice within [***] of the effective date of termination, the Parties shall enter into good-faith negotiations with respect to the grant by Gilead to Hookipa of [***] license, under the Gilead Improvements, solely to Research, Develop, Manufacture, and Commercialize any Licensed Products currently under Development or Commercialization pursuant to this Agreement as of the effective date of termination. In the event that the Parties do not reach a definitive agreement with respect to such a license within [***] days of receipt by Gilead from Hookipa of the written notice contemplated by this Section 14.1(e), then the terms and conditions of such license shall be determined [***];

(f) Gilead shall reasonably cooperate with Hookipa or its Affiliates or any of their designees to facilitate an orderly and prompt transition of the Research, Development, Manufacturing, and Commercialization activities with respect to the Licensed Products currently under Development or Commercialization pursuant to this Agreement as of the effective date of termination;

(g) Gilead shall, upon written request of Hookipa and subject to Hookipa assuming legal responsibility for any clinical trials of the Licensed Products then ongoing as of the effective date of termination, transfer to Hookipa all Regulatory Filings and other regulatory documentation, including regulatory dossiers, and Regulatory Approvals prepared or obtained by or on behalf of Gilead, in each case, relating solely to any Licensed Products under Development or Commercialization pursuant to this Agreement prior to the date of such termination, to the extent transferable;

(h) Gilead, its Affiliates, or its sublicensees shall cease all Commercialization of Licensed Products in a prompt manner and in accordance with Applicable Laws; provided, however, that Gilead, its Affiliates, or its sublicensees shall be entitled, during the [***]-month period following the effective date of a termination, to sell any commercial inventory of Licensed Products which remains on hand as of the effective date of the termination; provided, that Gilead pays to Hookipa the royalties and, if applicable, commercial Milestones applicable to said subsequent sales in accordance with the terms and conditions set forth in this Agreement. Any commercial inventory remaining following such [***]-month period shall be offered for sale to Hookipa, at a price to be mutually agreed upon between the Parties in good faith;

(i) solely in the case of termination of this Agreement in its entirety or with respect to the last Terminated Licensed Product, Gilead shall return to Hookipa or, on Hookipa's request, destroy all records and materials in its possession or control that contain or comprise Hookipa Know-How or other Confidential Information of Hookipa and, if Hookipa does not timely provide notice to Gilead pursuant to Section 14.1(e), Hookipa shall return to Gilead or, on Gilead's request, destroy all records and materials in its possession or control that contain or comprise Gilead Know-How or other Confidential Information of Gilead; and

(j) solely in the case of termination of this Agreement in its entirety, any and all sublicense agreements entered into by Gilead or any of its Affiliates with a sublicensee pursuant to this Agreement shall survive the termination of this Agreement, except to the extent that any such sublicensee under any sublicense is in material breach of this Agreement or such sublicense or Hookipa elects to grant such sublicensee a direct license of the sublicensed rights on the same terms applicable to Gilead under this Agreement. Gilead shall, at the request of Hookipa, assign any such sublicense (to the extent not terminated pursuant to the preceding sentence) to Hookipa or its Affiliates and, upon such assignment, Hookipa or its Affiliates, as applicable, shall assume such sublicense. For clarity, any sublicense agreement entered into by Gilead with any of its Affiliates shall terminate upon the termination of this Agreement.

14.2 Termination by Gilead for Material Breach by or Insolvency of Hookipa. Upon termination of this Agreement by Gilead pursuant to Section 13.2 or Section 13.3 the following shall apply, but, in the case of a partial termination of this Agreement, solely with respect to the applicable Terminated Licensed Products:

(a) all rights and licenses granted by Gilead to Hookipa hereunder, including under Section 3.1(b), shall terminate;

(b) Gilead shall be released from its Development and Commercialization obligations;

(c) the license granted to Gilead under Section 3.1(a) shall remain in effect and shall become perpetual and all payment obligations under Article 9 shall remain in effect; provided, that with respect to royalties and Milestones arising after the effective date of termination, Gilead shall only be obligated to pay to Hookipa [***] of the amounts otherwise payable under Sections 9.2 and 9.3 as they become due;

(d) Gilead's rights and Hookipa's obligations pursuant to Sections 11.2, 11.3, and 11.4 shall survive;

(e) solely in the case of termination of this Agreement in its entirety or with respect to the last Terminated Licensed Product, Hookipa shall return to Gilead or, on Gilead's request, destroy all records and materials in its possession or control that contain or comprise Gilead Know-How or other Confidential Information of Gilead; and

(f) upon Gilead's request, Hookipa shall use commercially reasonable efforts to facilitate and otherwise assist Gilead in any negotiations for a direct license to the Licensed Technology licensed under any of the Hookipa Third Party Agreements.

14.3 Survival. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. Without limiting the foregoing, the provisions of Articles 1, 10, 14 and 18, Sections 2.4, 3.1(a) (with respect to the last sentence thereof), 3.4, 3.5 (in the case of termination by Gilead pursuant to Sections 13.2 or 13.3), 9.7, 9.8, 11.1, 13.5 (in the case of termination for an insolvency event of Hookipa), 15.5, 16.1, 16.2, 16.3, 16.4, 16,5, 16.6, and 17.2, and any other obligations and rights which are expressly intended to survive, shall survive expiration or termination of this Agreement. The provisions of Article 12 shall survive the termination or expiration of this Agreement for a period of [***] years.

14.4 Termination Not Sole Remedy. Termination is not the sole remedy under this Agreement and, whether or not termination is effected and notwithstanding anything contained in this Agreement to the contrary, all other remedies shall remain available except as agreed to otherwise herein.

15. REPRESENTATIONS, WARRANTIES, AND COVENANTS

15.1 Representations and Warranties by Each Party. Each Party represents and warrants to the other Party, as of the Effective Date, that:

(a) it is a corporation duly organized, validly existing, and, in the case of Gilead, in good standing under the laws of its jurisdiction of formation;

(b) it has full corporate power and authority to execute, deliver, and perform this Agreement, and has taken all corporate action required by Applicable Law and its organizational documents to authorize the execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement;

(c) this Agreement constitutes a valid and binding agreement enforceable against it in accordance with its terms;

(d) all consents, approvals, and authorizations from all governmental authorities or other Third Parties required to be obtained by such Party in connection with the execution and delivery of this Agreement have been obtained; and

(e) the execution and delivery of this Agreement and all other instruments and documents required to be executed pursuant to this Agreement do not and shall not: (i) conflict with or result in a breach of any provision of its organizational documents; (ii) result in a breach of any agreement to which it is a party (including, in the case of Hookipa, any Hookipa Third Party Agreement); or (iii) violate any Applicable Law.

15.2 Representations and Warranties by Hookipa. Hookipa represents and warrants to Gilead as of the Effective Date that:

(a) Exhibit C sets forth a complete and accurate list of all Hookipa Patent Rights as of tire Effective Date (including whether such Hookipa Patent Rights are owned or otherwise Controlled by Hookipa) and, in the case of licensed Hookipa Patent Rights, a reference to the relevant Hookipa Third Party Agreement set forth in Schedule 9.5(a);

(b) Hookipa directly, or through its wholly-owned subsidiaries, is the sole and exclusive owner or otherwise Controls all of the Hookipa Patent Rights set forth on Exhibit C, and, with respect to all owned Hookipa Patent Rights, is listed in the appropriate patent registries as the sole and exclusive owner of record for each registration, grant, and application set forth on Exhibit C and such owned Hookipa Patent Rights are free from Encumbrances;

(c) each named inventor with respect to all of the Hookipa Patent Rights set forth on Exhibit C has properly assigned his or her invention(s) to Hookipa or the applicable Third Party licensor under the applicable Hookipa Third Party Agreement;

(d) Hookipa has the right to grant to Gilead and its Affiliates the licenses under the Licensed Technology that it purports to grant hereunder;

(e) Hookipa has the right to use and disclose and to enable Gilead and its Affiliates to use and disclose (in each case, under appropriate conditions of confidentiality) the Hookipa Know-How to be licensed to Gilead as provided under this Agreement;

(f) to the Knowledge of Hookipa, the issued Hookipa Patent Rights set forth on Exhibit C are valid and enforceable without any claims, challenges, oppositions, interference, or other similar proceedings, pending or threatened;

(g) Hookipa has Prosecuted and Maintained patent applications within the Hookipa Patent Rights set forth on Exhibit C in good faith and complied with all duties of disclosure with respect thereto;

(h) each of Hookipa and, to the Knowledge of Hookipa, the Third Party licensors under the Hookipa Third Party Agreements, have not committed any act, or omitted to commit any act, that may cause the Hookipa Patent Rights set forth on Exhibit C to expire prematurely or be declared invalid or unenforceable;

(i) all application, registration, maintenance, and renewal fees due as of the Effective Date with respect to all Hookipa Patent Rights set forth on Exhibit C have been paid and all necessary documents and certificates have been filed with the relevant patent registries for the purpose of maintaining such Hookipa Patent Rights;

(j) Hookipa has not granted to any Third Party any rights to the Licensed Technology that would interfere or be inconsistent with rights granted to Gilead hereunder;

(k) to the Knowledge of Hookipa, the exploitation of the Licensed Technology for the purpose of: (i) the Research, Development, and Manufacture of Licensed Products as contemplated by the Research Plans (as in effect on the Effective Date); and (ii) the Commercialization of Licensed Products contemplated to arise therefrom, will not infringe the Patent Rights or misappropriate the trade secrets or proprietary rights of any Third Party; Hookipa makes no representation or warranty under this paragraph (k) with respect to any [***] owned or otherwise Controlled by any Third Parties;

(l) to the Knowledge of Hookipa, no Third Party is infringing or misappropriating any of the Licensed Technology, nor has Hookipa received any written notice regarding such infringement, violation, or misappropriation;

(m) Hookipa has not entered into a government funding relationship that would result in rights to any Licensed Technology residing in the U.S. Government, National Institutes of Health, National Institute for Drug Abuse, or other agency, and the licenses granted hereunder are not subject to overriding obligations to the U.S. Government as set forth in Public Law 96-517 (35 U.S.C. 200-204), or any similar obligations under the laws of any other country;

(n) Schedule 9.5(a) sets forth a complete and accurate list of all agreements by and between, on the one hand, Hookipa or any of its Affiliates and, on the other hand, a Third Party, pursuant to which Hookipa or its Affiliates in-licensed Licensed Technology that is sublicensed to Gilead hereunder. Hookipa has provided Gilead true, correct, and complete copies of each Hookipa Third Party Agreement which is set forth in Schedule 9.5(a). Each such Hookipa Third Party Agreement is in full force and effect, and there has been no Default of or under any such Hookipa Third Party Agreement as a result of any action or omission of Hookipa or its Affiliates or, to the Knowledge of Hookipa, the actions or omissions of any Third Party. Hookipa has not waived any of its rights under any such Hookipa Third Party Agreement to which it is party;

(o) all of Hookipa's employees, officers, and consultants who have been involved with the development of Licensed Technology have executed agreements or have existing obligations under Applicable Laws requiring assignment to Hookipa of all inventions made during the course of and as the result of their association with Hookipa, free from Encumbrances, and obligating the individual to maintain as confidential Hookipa's Confidential Information as well as the confidential information of other parties (including the Confidential Information of Gilead and its Affiliates) which such individual has received prior to the Effective Date;

(p) (i) neither Hookipa nor, to the Knowledge of Hookipa, any employee, agent, or subcontractor of Hookipa involved or to be involved in the Research of the Licensed Products has been debarred under subsection (a) or (b) of Section 306 of the FDCA; (ii) no Person who is known by Hookipa to have been debarred under subsection (a) or (b) of Section 306 of the FDCA shall be employed by Hookipa in the performance of any activities hereunder; and (iii) to the Knowledge of Hookipa, no Person on any of the FDA clinical investigator enforcement lists (including the (1) Disqualified/Totally Restricted List, (2) Restricted List, and (3) Adequate Assurances List) shall participate in the performance of any activities hereunder;

(q) Hookipa has maintained intellectual property protection guidelines within its organization and, to the Knowledge of Hookipa, there has not been any unauthorized disclosure of intellectual property rights, including Know-How, to any Third Party;

(r) all activities conducted by or on behalf of Hookipa with respect to the Licensed Technology have been conducted in accordance with Applicable Laws and regulations, including GLP, GCP, and GMP, as applicable; and

(s) Hookipa has responded in good faith to all of Gilead's written requests for materials and information in connection with Gilead's due diligence efforts with respect to this Agreement, and it has no Knowledge of any failure to disclose to Gilead any fact or circumstance known to Hookipa and relating to any of the Licensed Technology that would be reasonably expected to be material to Gilead in connection with this Agreement or the transactions contemplated herein.

15.3 Covenants of Hookipa. Hookipa covenants and agrees that:

(a) it shall not grant any interest in the Licensed Technology which is inconsistent with the terms and conditions of this Agreement, nor shall it assign any of its rights, title, or interests in or to the Licensed Technology to any Third Party except as permitted in Section 18.1;

(b) it shall: (i) maintain Control of all Licensed Technology licensed or sublicensed to Gilead under each Hookipa Third Party Agreement; and (ii) not terminate, breach, or otherwise Default under any Hookipa Third Party Agreement in a manner that would permit the counterparty thereto to terminate such Hookipa Third Party Agreement or otherwise diminish the scope or exclusivity of the licenses granted to Gilead under any Licensed Technology;

(c) if Hookipa receives notice of an alleged Default by Hookipa or its Affiliates under any such Hookipa Third Party Agreement, where termination of such Hookipa Third Party Agreement or any diminishment of the scope or exclusivity of the licenses granted to Gilead under the Licensed Technology is being or could be sought by the counterparty or result from such Default, then Hookipa shall promptly, but in no event less than [***] Business Days thereafter, provide written notice thereof to Gilead and grant Gilead the right (but not the obligation) to: (i) cure such alleged breach; and (ii) offset any costs or expenses incurred in connection therewith against any payments due or that may become due under this Agreement;

(d) it shall not modify, amend, or terminate any Hookipa Third Party Agreement, or exercise, waive, release, or assign any rights or claims thereunder, without first obtaining, in each case, Gilead's prior written consent;

(e) all of Hookipa's employees, officers, and consultants who shall perform activities under this Agreement have executed or will execute agreements or have existing obligations under Applicable Laws requiring assignment to Hookipa of all inventions made during the course of and as the result of their association with Hookipa, free from Encumbrances, and obligating the individual to maintain as confidential Hookipa's Confidential Information as well as the confidential information of other parties (including the Confidential Information of Gilead and its Affiliates) which such individual may receive, to the extent required to support Hookipa's obligations under this Agreement;

(f) if, at any time after execution of this Agreement, Hookipa becomes aware that it or any employee, agent, or subcontractor of Hookipa who participated, or is participating, in the performance of any activities hereunder is on, or is being added to, the FDA Debarment List, it shall provide written notice of this to Gilead within [***] Business Days of its becoming aware of this fact;

(g) it shall perform all activities under this Agreement in compliance with all Applicable Laws and regulations, including GCP, GLP, or GMP, where applicable, and those relating to the conduct of human clinical trials, animal testing, biotechnological research, and the handling and containment of biohazardous materials, and Applicable Laws relating to health, safety, and the environment, fair labor practices, and unlawful discrimination; and

(h) it shall maintain sufficient security systems and intellectual property protection guidelines within its organization equivalent to international industry standards and qualified to avoid any unauthorized disclosure of intellectual property rights, including Know-How, to any Third Party, as more specifically agreed with Gilead hereunder.

15.4 Further Representations, Warranties, and Covenants of Gilead. Gilead further represents, warrants, and covenants to Hookipa:

(a) at any time during the Term, Gilead shall maintain sufficient security systems and intellectual property protection guidelines within its organization equivalent to international industry standards and qualified to avoid any unauthorized disclosure of intellectual property rights, including Know-How, to any Third Party;

(b) (i) as of the Effective Date and at any time during the Collaboration Term for a Program, all of its employees and officers who shall perform activities under the applicable Research Plan; and (ii) during the Collaboration Term for a Program, Gilead shall use Commercially Reasonable Efforts to ensure that all of its consultants who shall perform activities under the applicable Research Plan, in each case ((i) and (ii)), have executed or will execute agreements or have existing obligations under Applicable Laws requiring assignment to Gilead of all inventions made during the course of and as the result of their association with Gilead, free from Encumbrances, and obligating the individual to maintain as confidential Gilead's Confidential Information as well as the confidential information of other parties (including the Confidential Information of Hookipa and its Affiliates) which such individual may receive, to the extent required to support Gilead's obligations under this Agreement; and

(c) as of the Effective Date and at any time during the Term, Gilead shall perform all activities under this Agreement in compliance with all Applicable Laws and regulations, including GCP, GLP, GMP, and those relating to the conduct of human clinical trials, animal testing, biotechnological research, and the handling and containment of biohazardous materials, and Applicable Laws relating to health, safety, and the environment, fair labor practices, and unlawful discrimination.

15.5 No Other Warranties. EXCEPT AS EXPRESSLY STATED IN THIS ARTICLE 15: (A) NO REPRESENTATION, CONDITION, OR WARRANTY WHATSOEVER IS MADE OR GIVEN BY OR ON BEHALF OF GILEAD OR HOOKIPA; AND (B) ALL OTHER CONDITIONS AND WARRANTIES WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE ARE HEREBY EXPRESSLY EXCLUDED, INCLUDING ANY CONDITIONS AND WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR NON-INFRINGEMENT.

16. INDEMNIFICATION; LIABILITY

16.1 Indemnification by Hookipa. Hookipa shall indemnify and hold Gilead, its Affiliates, and their respective officers, directors, and employees (the "**Gilead Indemnitees**") harmless from and against any and all liability, damage, loss, cost, or expense of any nature (including reasonable attorney's fees and litigation expenses) ("**Losses**") incurred by or imposed upon the Gilead Indemnitees or any of them in connection with any claim, suit, action, demand, proceeding, cause of action, or judgment resulting from a Third Party claim ("**Claims**"), in each case, to the extent arising or resulting from:

(a) Hookipa's, or any of its Affiliates' or contractors' activities in connection with: (i) the Programs; (ii) the Manufacture of Licensed Products; or (iii) other activities under this Agreement;

(b) the negligence or willful misconduct of Hookipa or any of its Affiliates or contractors; or

(c) the breach of any of the obligations, covenants, representations, or warranties made by Hookipa to Gilead under this Agreement;

provided, however, that Hookipa shall not be obliged to so indemnify and hold harmless the Gilead Indemnitees for any Claims to the extent Gilead has an obligation to indemnify Hookipa Indemnitees pursuant to Section 16.2 or to the extent that such Claims arise from the breach, negligence, or willful misconduct of Gilead or any Gilead Indemnitee.

16.2 Indemnification by Gilead. Gilead shall indemnify and hold Hookipa, its Affiliates, and their respective officers, directors, and employees (the "**Hookipa Indemnitees**") harmless from and against any and all Losses incurred by or imposed upon the Hookipa Indemnitees or any of them in connection with any Claims, in each case, to the extent arising or resulting from:

(a) Gilead's, or any of its Affiliates', sublicensees', or contractors' activities in connection with the: (i) Programs; (ii) Development, Manufacture, or Commercialization of the Licensed Products in the Field in the Territory; or (iii) other activities under this Agreement;

(b) the negligence or willful misconduct of Gilead or any of its Affiliates or sublicensees or contractors; or

(c) the breach of any of the obligations, covenants, representations, or warranties made by Gilead to Hookipa under this Agreement;

provided, however, that Gilead shall not be obliged to so indemnify and hold harmless the Hookipa Indemnitees for any Claims to the extent Hookipa has an obligation to indemnify Gilead Indemnitees pursuant to Section 16.1 or to the extent that such Claims arise from the breach, negligence, or willful misconduct of Hookipa or any Hookipa Indemnitee.

16.3 Indemnification Procedure.

(a) For the avoidance of doubt, all indemnification claims in respect of a Gilead Indemnitee or a Hookipa Indemnitee shall be made solely by Gilead or Hookipa, respectively.

(b) A Party seeking indemnification hereunder (the "**Indemnified Party**") shall notify the other Party (the "**Indemnifying Party**") in writing reasonably promptly after the assertion against the Indemnified Party of any Claim or fact in respect of which the Indemnified Party intends to base a claim for indemnification hereunder (each, an "**Indemnification Claim Notice**"); provided, that the failure or delay to so notify the Indemnifying Party shall not relieve the Indemnifying Party of any obligation or liability that it may have to the Indemnified Party, except to the extent that the Indemnifying Party demonstrates that its ability to defend or resolve such Claim is adversely affected thereby. The Indemnification Claim Notice shall contain a description of the Claim and the nature and amount of the Claim (to the extent that the nature and amount of such Claim is known at such time). Upon the request of the Indemnifying Party, the Indemnified Party shall furnish promptly to the Indemnifying Party copies of all correspondence, communications and official documents (including court documents) received or sent in respect of such Claim.

(c) Subject to Sections 16.3(d) and 16.3(e), the Indemnifying Party shall have the right, upon written notice given to the Indemnified Party within [***] days after receipt of the Indemnification Claim Notice, to assume the defense and handling of such Claim, at the Indemnifying Party's sole expense, in which case the provisions of Section 16.3(d) below shall govern; provided, that any such Claim is only for monetary damages. The assumption of the defense of a Claim by the Indemnifying Party shall not be construed as acknowledgement that the Indemnifying Party is liable to indemnify any Indemnitee in respect of the Claim, nor shall it constitute a waiver by the Indemnifying Party of any defenses it may assert against any Indemnified Party's claim for indemnification. In the event that it is ultimately decided that the Indemnifying Party is not obligated to indemnify or hold an Indemnitee harmless from and against the Claim, the Indemnified Party shall reimburse the Indemnifying Party for any and all reasonable costs and expenses (including reasonable attorneys' fees and costs of suit) and any losses incurred by the Indemnifying Party in its defense of the Claim. If the Indemnifying Party does not give written notice to the Indemnified Party, within [***] days after receipt of the Indemnification Claim Notice, of the Indemnifying Party's election to assume the defense and handling of such Claim, the provisions of Section 16.3(e) shall govern.

(d) Upon assumption of the defense of a Claim by the Indemnifying Party: (i) the Indemnifying Party shall have the right to and shall assume sole control and responsibility for dealing with the Claim; (ii) the Indemnifying Party may, at its own cost, appoint as counsel in connection with conducting the defense and handling of such Claim any law firm or counsel reasonably selected by the Indemnifying Party; (iii) the Indemnifying Party shall keep the Indemnified Party informed of the status of

such Claim; and (iv) the Indemnifying Party shall have the right to settle the Claim on any terms the Indemnifying Party chooses; provided, however, that it shall not, without the prior written consent of the Indemnified Party (such consent not to be unreasonably withheld, conditioned, or delayed), agree to a settlement of any Claim which could lead to liability or create any financial or other obligation on the part of the Indemnified Party for which the Indemnified Party is not entitled to indemnification hereunder or which admits any wrongdoing or responsibility for the claim on behalf of the Indemnified Party. The Indemnified Party shall cooperate with the Indemnifying Party and shall be entitled to participate in, but not control, the defense of such Claim with its own counsel and at its own expense. In particular, the Indemnified Party shall furnish such records, information, and testimony, provide witnesses, and attend such conferences, discovery proceedings, hearings, trials, and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours by the Indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Claim, and making the Indemnified Party, the Indemnitees and its and their employees and agents available on a mutually convenient basis to provide additional information and explanation of any records or information provided.

(e) If the Indemnifying Party does not give written notice to the Indemnified Party as set forth in Section 16.3(c) or fails to conduct the defense and handling of any Claim in good faith after having assumed such, the Indemnified Party may, at the Indemnifying Party's expense, select counsel reasonably acceptable to the Indemnifying Party in connection with conducting the defense and handling of such Claim and defend or handle such Claim in such manner as it may deem appropriate. In such event, the Indemnified Party shall keep the Indemnifying Party timely apprised of the status of such Claim and shall not settle such Claim without the prior written consent of the Indemnifying Party, which consent shall not be unreasonably withheld, conditioned, or delayed. If the Indemnified Party defends or handles such Claim, the Indemnifying Party shall cooperate with the Indemnified Party, at the Indemnified Party's request but at no expense to the Indemnified Party, and shall be entitled to participate in the defense and handling of such Claim with its own counsel and at its own expense.

16.4 Mitigation of Loss. Each Indemnified Party shall take and shall procure that its Affiliates take all such reasonable steps and action as are necessary or as the Indemnifying Party may reasonably require in order to mitigate any Claims (or potential losses or damages) under this Article 16. Nothing in this Agreement shall or shall be deemed to relieve any Party of any common law or other duty to mitigate any losses incurred by it.

16.5 Special, Indirect and Other Losses. NEITHER PARTY NOR ANY OF ITS AFFILIATES SHALL BE LIABLE IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY, OR OTHERWISE FOR ANY SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE, OR CONSEQUENTIAL DAMAGES OR FOR ANY LOSS OF PROFITS SUFFERED BY THE OTHER PARTY, EXCEPT TO THE EXTENT ANY SUCH DAMAGES ARE: [***].

16.6 No Exclusion. Neither Party excludes any liability for death or personal injury caused by its negligence or willful misconduct or that of its officers, directors, employees, agents, sublicensees, or sub-contractors.

16.7 Insurance. Each Party shall maintain, at its cost, insurance against liability and other risks associated with its activities and obligations under this Agreement, in such amounts and on such terms as are customary for a company such as the respective Party for the activities to be conducted by it under this Agreement. Each Party shall furnish to the other Party evidence of such insurance upon request. It is understood that such insurance shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this Article 16.

17. PUBLICATIONS AND PUBLICITY

17.1 Publications.

(a) Except to the extent made in accordance with the provisions of Article 12 or Section 17.2, any proposed public disclosure (whether written, electronic, oral, or otherwise) by Hookipa or any of its Affiliates relating to the Licensed Products shall require, in each case, the prior written consent of Gilead (such consent not to be unreasonably withheld, conditioned, or delayed).

(b) For the avoidance of doubt, Gilead or any of its Affiliates shall have the sole right, without any required consents from Hookipa, but, to the extent practicable, with at least [***] days' prior written notice to Hookipa, to publish or have published information about clinical trials related to the Licensed Products, including the results of such clinical trials, or other activities under this Agreement. This Section 17.1(b) shall not affect the rights or obligations of the Parties pursuant to Article 12.

17.2 Publicity.

(a) Use of Name. Unless otherwise provided in this Agreement, neither Party shall use the name, symbol, trademark, trade name, or logo of the other Party or its Affiliates in any press release, publication, or other form of public disclosure without, in each case, first obtaining the prior written consent of the other Party (such consent not to be unreasonably withheld, conditioned, or delayed).

(b) Press Releases. On or promptly after the Effective Date, the Parties shall issue a public announcement of the execution of this Agreement in the form attached hereto as Schedule 17.2(b). Except as provided in this Section 17.2(b) or in Article 12 each Party agrees not to issue any press release or other public statement, whether written, electronic, oral, or otherwise, disclosing the existence of this Agreement, the terms of this Agreement, or any information relating to this Agreement without, in each case, first obtaining the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned, or delayed; provided, however, that: (i) Gilead may issue press releases and other public statements as it deems reasonably appropriate in connection with the Research, Development, Manufacture, or Commercialization of Licensed Products under this Agreement without such consent, but, to the extent practicable, with at least [***] Business Days' prior written notice to Hookipa; (ii) Hookipa and any of its Affiliates may issue press releases and other public statements as it deems reasonably appropriate to communicate the receipt of Regulatory Approval for any Licensed Product or the receipt of any Milestone Payment or royalty payments from Gilead pursuant to Section 9.2 or Section 9.3, including the corresponding triggering event, without such consent, but, to the extent practicable, with at least [***] Business Days' prior written notice to Gilead; provided, that such press release or statement by Hookipa or its Affiliates shall not disclose the amount of such Milestone Payment or royalty payment; and (iii) without limiting the foregoing clauses (i) and (ii), the Parties shall discuss in good faith from time to time the advisability of joint or individual press releases with respect to any material progress of a Program or the Research, Development, Manufacture, or Commercialization of Licensed Products under this Agreement; provided, that the issuance and substance of any such press release contemplated by this clause (iii) shall be subject to mutual agreement of the Parties.

(c) Re-Publication. Nothing in Article 12 or this Article 17 (but subject to the Parties' other obligations under this Agreement) shall prohibit either Party or its Affiliates from including, in future publications or press releases, any information that was previously publicly disclosed by the other Party or its Affiliates (other than by breach of this Agreement). Any authorization by a Party for information to be publicly disclosed in any publication or press release of the other Party or its Affiliates shall be valid for [***] days.

18. GENERAL PROVISIONS

18.1 Assignment. This Agreement may not be assigned or otherwise transferred by either Party without the prior written consent of the other Party; provided, however, that either Party may assign this Agreement or individual rights or obligations thereunder without the consent of the other Party: (a) to any of its Affiliates; or (b) to a successor to all or substantially all of its business or assets to which this Agreement relates. Any purported assignment in contravention of this Section 18.1 shall be null and void and of no effect. No assignment shall release either Party from responsibility for the performance of its accrued obligations under this Agreement and upon any such assignment, the assigning Party shall remain liable for the performance of this Agreement and for any acts or omissions of its assignee or its successor constituting a breach of this Agreement. This Agreement shall be binding upon and enforceable against the successor to or any permitted assignees from either of the Parties.

18.2 Extension to Affiliates. Gilead shall have the right to extend the rights, immunities, and obligations granted in this Agreement to one (1) or more of its Affiliates. All applicable terms and provisions of this Agreement shall apply to any such Affiliate to which this Agreement has been extended to the same extent as such terms and provisions apply to Gilead. Gilead shall remain primarily liable for any acts or omissions of its Affiliates.

18.3 Severability. To the extent permitted under any Applicable Laws, each provision of this Agreement shall be interpreted in such manner as to be effective and valid under Applicable Laws, but should one (1) or more of the provisions of this Agreement become void or unenforceable as a matter of law, then such provision(s) shall be void and unenforceable only to the extent of such invalidity or unenforceability, without invaliding the remainder of this Agreement. In such case, this Agreement shall be construed as if such provision(s) were not contained herein and the remainder of this Agreement shall be in full force and effect, and the Parties shall use their commercially reasonable efforts to substitute for the invalid or unenforceable provision a valid and enforceable provision which conforms as nearly as possible with the original intent of the Parties.

18.4 Governing Law and Waiver of Jury Trial.

(a) This Agreement and any dispute arising from the performance or breach hereof shall be governed by and interpreted in accordance with the laws of the State of New York, without giving effect to the application of any conflict of laws principles that would require application of the laws of another jurisdiction. The provisions of the United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement or any subject matter hereof.

(b) THE PARTIES HEREBY WAIVE, AND COVENANT THAT THEY SHALL NOT ASSERT (WHETHER AS PLAINTIFF, DEFENDANT, OR OTHERWISE), ANY RIGHT TO TRIAL BY JURY IN ANY ACTION ARISING IN WHOLE OR IN PART UNDER OR IN CONNECTION WITH THIS AGREEMENT, WHETHER NOW EXISTING OR HEREAFTER ARISING, AND WHETHER SOUNDING IN CONTRACT, TORT, OR OTHERWISE. THE PARTIES AGREE THAT ANY OF THEM MAY FILE A COPY OF THIS PARAGRAPH WITH ANY COURT AS WRITTEN EVIDENCE OF THE KNOWING, VOLUNTARY, AND BARGAINED-FOR AGREEMENT AMONG THE PARTIES IRREVOCABLY TO WAIVE ITS RIGHT TO TRIAL BY JURY IN ANY PROCEEDING WHATSOEVER BETWEEN THEM RELATING TO THIS AGREEMENT SHALL INSTEAD BE TRIED IN A COURT OF COMPETENT JURISDICTION BY A JUDGE SITTING WITHOUT A JURY.

18.5 Dispute Resolution; Rules of Arbitration.

(a) Initial Dispute Resolution Process. Except as otherwise set forth in this Agreement, in the event of an unresolved matter, dispute, or issue which relates to the breach or alleged breach or interpretation of this Agreement (each, a "**Dispute**") or which this Agreement expressly provides shall be resolved in accordance with this Section 18.5 (each, a "**Selected Dispute**"), the Parties shall refer the Dispute or Selected Dispute to the Alliance Managers for discussion and resolution. If the Alliance Managers are unable to resolve such Dispute or Selected Dispute within [***] days of the Dispute or Selected Dispute being referred to them by either Party in writing, either Party may require that the Parties forward the matter to the Senior Officers (or designees with similar authority to resolve such dispute), who shall attempt in good faith to resolve such Dispute or Selected Dispute. If the Senior Officers cannot resolve such Dispute or Selected Dispute within [***] days of the matter being referred to them in writing, then the Dispute or Selected Dispute shall be resolved as provided in Sections 18.5(b), 18.5(c), or 18.5(e) as applicable.

(b) Arbitration. Any unresolved Dispute or Selected Dispute between the Parties arising out of or in connection with this Agreement shall be resolved by final and binding arbitration. Whenever a Party decides to institute arbitration proceedings, it shall give written notice to that effect to the other Party. Arbitration shall be held in New York, New York, according to the Rules of Arbitration of the International Chamber of Commerce ("**ICC Rules**") in effect at the Effective Date, except as they may be modified herein or by mutual agreement of the Parties. All arbitration proceedings shall be conducted by three (3) arbitrators unless otherwise mutually agreed by the Parties. The claimant and the respondent shall each nominate an arbitrator in accordance with the ICC Rules, and the third arbitrator, who shall be the president of the arbitral tribunal, shall be appointed by the two (2) Party-appointed arbitrators in consultation with the Parties. The arbitrators shall: (i) be disinterested, neutral, and independent from both Parties and all of their respective Affiliates; and (ii) have the requisite experience and expertise in licensing and partnering agreements in the pharmaceutical and biotechnology industries, shall have appropriate experience with respect to the subject matter(s) to be arbitrated, and shall have some experience in mediating or arbitrating issues relating to such agreements. In the case of any Dispute involving an alleged failure to use Commercially Reasonable Efforts, the arbitrators shall in addition be an individual with experience and expertise in the worldwide development and commercialization of pharmaceuticals and the business, legal and scientific considerations related thereto. The Arbitrators shall have the authority to engage additional experts as necessary in order to facilitate resolution of the Dispute or Selected Dispute, as applicable.

(c) Selected Dispute Arbitration. Within [***] days after the arbitrators for a Selected Dispute are nominated or appointed pursuant to Section 18.5(b), each Party shall provide the arbitrators a proposal and written memorandum in support of its position regarding the Selected Dispute, including its specific proposal to resolve the Selected Dispute, as well as any documentary evidence it wishes to provide in support thereof (each, a "**Brief**"), and the arbitrators shall provide each Party's Brief to the other Party after it receives a Brief from each Party. Within [***] days after a Party submits its Brief, the other Party shall have the right to respond thereto. The response and any material in support thereof (each, a "**Response**") will be provided to the arbitrators and the other Party. The arbitrators shall have the right to meet with the Parties as necessary to inform the arbitrators' determination and to perform independent research and analysis. Within [***] days of the receipt by the arbitrators of both Parties' Responses (or expiration of the [***]-day period if any Party fails to submit a Response), the arbitrators shall deliver their decision regarding the Selected Dispute in writing; provided, that the arbitrators shall select one (1) of the resolutions proposed by the Parties which corresponds with, or comes closer to, the determination of the arbitrators.

(d) Confidentiality; Awards. The Parties undertake to maintain confidentiality in accordance with Article 12 as to the existence of the arbitration proceedings and as to all submissions, correspondence, evidence, and findings relating to the arbitration proceedings. Sections 18.5(b) and 18.5(c) shall survive the termination of the arbitral proceedings. No arbitrator (nor any arbitral tribunal) shall have the power to award punitive damages under this Agreement, and such award is expressly prohibited. Decisions of the arbitrator(s) shall be final and binding on the Parties, Judgment on the award so rendered may be entered in any court of competent jurisdiction. The costs of the arbitration shall be shared by the Parties during the course of such arbitration, as assessed by the International Chamber of Commerce, and shall be borne as determined by the arbitrator(s).

(e) Preliminary Injunctive Relief. Notwithstanding anything to the contrary, either Party may at any time seek to obtain preliminary injunctive relief or other applicable provisional relief from a court of competent jurisdiction with respect to an issue arising under this Agreement if the rights of such Party would be prejudiced absent such relief. A request by a Party to a court of competent jurisdiction for interim measures necessary to preserve the Party's rights, including attachments or injunctions, shall not be deemed incompatible with, or a waiver of, the agreement to mediate or arbitrate contained in this Section 18.5, or the availability of interim measures of protection under the ICC Rules. Notwithstanding anything to the contrary in this Section 18.5, any disputes regarding the scope, validity, enforceability, or inventorship of any Patent Rights shall be submitted for final resolution by a court of competent jurisdiction.

18.6 Force Majeure. Neither Party shall be responsible to the other for any failure or delay in performing any of its obligations under this Agreement or for other nonperformance hereunder if such delay or nonperformance is caused by strike, stoppage of labor, lockout or other labor trouble, earthquake, fire, flood, accident, war, act of terrorism, act of God or of the government of any country or of any local government, or by any other cause unavoidable or beyond the control of any Party. In such event, the Party affected shall provide the other Party with written notice of the full particulars of the force majeure event as soon as it becomes aware thereof, including its best estimate of the likely extent and duration of the interference with its activities, and shall use Commercially Reasonable Efforts to resume performance of its obligations as soon as practicable.

18.7 Waivers and Amendments. The failure of any Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other Party. No waiver shall be effective unless it has been given in writing and signed by the Party giving such waiver. No provision of this Agreement may be amended or modified other than by a written document signed by authorized representatives of each Party.

18.8 Relationship of the Parties. Nothing contained in this Agreement shall be deemed to constitute a partnership, joint venture, agency, employee-employer relationship, or legal entity of any type between Hookipa and Gilead, or to constitute one as the agent of the other. Each Party agrees not to construe this Agreement, or any of the transactions contemplated hereby, as a partnership for any tax purposes. Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give any Party the power or authority to act for, bind, or commit the other.

18.9 Notices. All notices and other communications between the Parties shall be in writing and shall be deemed to have been duly given: (a) when delivered in person; or (b) when delivered by FedEx or other internationally recognized overnight delivery service, addressed as follows:

If to Gilead:

Gilead Sciences, Inc.
333 Lakeside Drive
Foster City, CA 94404
USA
Attention: General Counsel

with copies (which shall not constitute notice) to:

Hogan Lovells US LLP
875 Third Avenue
New York, NY 10022
USA
Attention: Adam H. Golden

If to Hookipa:

Hookipa Biotech AG
St Marx Vienna Bio Center: Helmut-Qualtinger-Gasse 2
1030 Vienna
Austria
Attention: Joern Aldag, Chief Executive Officer

with copies (which shall not constitute notice) to:

McDermott Will & Emery Rechtsanwalte Steuerberater LLP
Feldbergstraβe 35
60323 Frankfurt a. M.
Germany
Attention: Dr. Rüdiger Herrmann

or to such other address or addresses as the parties may from time to time designate in writing.

18.10 Further Assurances. Gilead and Hookipa hereby covenant and agree without the necessity of any further consideration, to execute, acknowledge, and deliver any and all such other documents and take any such other action as may be reasonably necessary to carry out the intent and purposes of this Agreement.

18.11 Compliance with Law. Each Party shall perform its obligations under this Agreement in accordance with all Applicable Laws. No Party shall, or shall be required to, undertake any activity under or in connection with this Agreement which violates, or which it believes in good faith may violate, any Applicable Law.

18.12 No Third Party Beneficiary Rights. The provisions of this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and they shall not be construed as conferring any rights to any Third Party (including any third party beneficiary rights), except for the indemnification rights of the Gilead Indemnitees pursuant to Sections 16.1 and 16.3 and the indemnification rights of the Hookipa Indemnitees pursuant to Sections 16.2 and 16.3.

18.13 English Language. This Agreement is written and executed in the English language. Any translation into any other language shall not be an official version of this Agreement and in the event of any conflict in interpretation between the English version and such translation, the English version shall prevail.

18.14 Expenses. Except as otherwise expressly provided in this Agreement, each Party shall pay the fees and expenses of its respective lawyers and other experts and all other expenses and costs incurred by such Party incidental to the negotiation, preparation, execution, and delivery of this Agreement.

18.15 Entire Agreement. This Agreement, together with its Exhibits and Schedules, and [***] sets forth the entire agreement and understanding of the Parties as to the subject matter hereof and supersedes all proposals, oral or written, and all other prior communications between the Parties with respect to such subject matter other than the Prior CDA; provided, that, as of the Effective Date, the Prior CDA shall not apply to the disclosure of any Confidential Information under this Agreement, which disclosure shall be governed by Article 12. In the event of any conflict between a substantive provision of this Agreement and any Exhibit or Schedule hereto, the substantive provisions of this Agreement shall prevail.

18.16 Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one (1) and the same instrument. Counterparts and any other document required to be executed and delivered hereunder may be delivered via electronic mail (including .pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000 (e.g., www.docusign.com)) or other transmission method and any counterpart or such document so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

18.17 Cumulative Remedies. No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

[*Signature Page Follows*]

CONFIDENTIAL TREATMENT REQUESTED. INFORMATION FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED IS OMITTED AND MARKED WITH "[***]". AN UNREDACTED VERSION OF THE DOCUMENT HAS ALSO BEEN FURNISHED SEPARATELY TO THE SECURITIES AND EXCHANGE COMMISSION AS REQUIRED BY RULE 406 UNDER THE SECURITIES ACT OF 1933, AS AMENDED.

IN WITNESS WHEREOF, the Parties intending to be bound have caused this Agreement to be executed by their duly authorized representatives.

GILEAD SCIENCES, INC.

By: _____

Name: John F. Milligan

Title: President and CEO

HOOKIPA BIOTECH AG

By: _____

Name: ALDAG

Title: CEO

[*Signature Page to Research Collaboration and License Agreement*]

EXHIBIT A

[***]

Attached.

[***]

[***]

a) [***]

i) [***]

[***]

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Table 1: [***]

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Table 2: [***]

[***]	[***]	[***]
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[***]

ii) [***]

Table 3: [***]

[***]	**[***]**	**[***]**
[***]	[***]	[***]
[***]	[***]	[***]

b) [***]

i) [***]

ii) [***]

Table 4: **[***]**

[***]	[***]	[***]	[***]	[***]
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[***]

iii) [***]

Table 5: **[***]**

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iv) [***]

Table 6: **[***]**

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Table 7: [***]

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c) [***]

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Table 8: **[***]**

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Table 9: **[***]**

[***]	**[***]**	**[***]**	**[***]**
[***]	[***]	[***]	[***]

d) [***]

i) [***]

[***]

ii) [***]

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Table 10: **[***]**

[***]	**[***]**	**[***]**	**[***]**
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[***]	**[***]**	**[***]**	**[***]**
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iii) [***]

[***]

iv) [***]

[***]

CONFIDENTIAL TREATMENT REQUESTED. INFORMATION FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED IS OMITTED AND MARKED WITH "[***]". AN UNREDACTED VERSION OF THE DOCUMENT HAS ALSO BEEN FURNISHED SEPARATELY TO THE SECURITIES AND EXCHANGE COMMISSION AS REQUIRED BY RULE 406 UNDER THE SECURITIES ACT OF 1933, AS AMENDED.

Table 11: **[***]**

[***]	**[***]**	**[***]**	**[***]**
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EXHIBIT B

[***]

Attached.

[***]

[***]

a) [***]
b) [***]
c) [***]
d) [***]
e) [***]

a) [***]

i) [***]

[***]

Table 1: [***]

[***]	**[***]**	**[***]**
[***]	[***]	[***]
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Table 2: [***]

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ii) [***]

Table 3: [***]

[***]	**[***]**	**[***]**
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b) [***]

i) [***]

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ii) [***]

Table 4: [***]

[***]	**[***]**	**[***]**	**[***]**	**[***]**
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[***]	[***]	[***]	[***]	[***]

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iii) [***]

Table 5: [***]

[***]	**[***]**	**[***]**	**[***]**
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iv) [***]

Table 6: [***]

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Table 7: [***]

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c) [***]

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Table 8: [***]

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d) [***]

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Table 9: **[***]**

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ii) [***]

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Table 10: **[***]**

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iii) [***]

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iv) [***]

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Table 11: **[***]**

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EXHIBIT C

[***]

Attached.

EXHIBIT C

[***]

[***]

CONFIDENTIAL TREATMENT REQUESTED. INFORMATION FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED IS OMITTED AND MARKED WITH “[***]”. AN UNREDACTED VERSION OF THE DOCUMENT HAS ALSO BEEN FURNISHED SEPARATELY TO THE SECURITIES AND EXCHANGE COMMISSION AS REQUIRED BY RULE 406 UNDER THE SECURITIES ACT OF 1933, AS AMENDED.

Exhibit C: Hookipa Patent Rights

[***]	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**
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CONFIDENTIAL TREATMENT REQUESTED. INFORMATION FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED IS OMITTED AND MARKED WITH "[***]". AN UNREDACTED VERSION OF THE DOCUMENT HAS ALSO BEEN FURNISHED SEPARATELY TO THE SECURITIES AND EXCHANGE COMMISSION AS REQUIRED BY RULE 406 UNDER THE SECURITIES ACT OF 1933, AS AMENDED.

Exhibit C: Other Patent Rights

[***]	[***]	[***]					[***]
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CONFIDENTIAL TREATMENT REQUESTED. INFORMATION FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED IS OMITTED AND MARKED WITH "[***]". AN UNREDACTED VERSION OF THE DOCUMENT HAS ALSO BEEN FURNISHED SEPARATELY TO THE SECURITIES AND EXCHANGE COMMISSION AS REQUIRED BY RULE 406 UNDER THE SECURITIES ACT OF 1933, AS AMENDED.

SCHEDULE 9.5(a)

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1. [***]

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3. [***]

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A. [***]

B. [***]

C. [***]

SCHEDULE 17.2(b)

DRAFT PRESS RELEASE

Attached.

Schedule 17.2(b)-1

CONFIDENTIAL TREATMENT REQUESTED. INFORMATION FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED IS OMITTED AND MARKED WITH "[***]". AN UNREDACTED VERSION OF THE DOCUMENT HAS ALSO BEEN FURNISHED SEPARATELY TO THE SECURITIES AND EXCHANGE COMMISSION AS REQUIRED BY RULE 406 UNDER THE SECURITIES ACT OF 1933, AS AMENDED.

Hookipa and Gilead Enter into a Collaboration and License Agreement to Develop Immunotherapies Against HIV and Hepatitis B

- Hookipa and Gilead will jointly develop therapeutics against HIV and Hepatitis B infections
- Hookipa and Gilead will jointly research and Hookipa wilt manufacture arenavirus-based vectors for clinical development by Gilead
- The deal expands the relationship between Hookipa and Gilead following Gilead's participation in Hookipa's Series C financing in December 2017
- Total potential deal value exceeds $400 million, including upfront and milestone payments, plus research and development funding

Vienna, Austria and Foster City, CA, 5 June 2018 - Hookipa Biotech AG ("Hookipa"), a clinical-stage biotech company pioneering an innovative class of active immunization therapies for oncology and infectious diseases and Gilead Sciences, Inc., ("Gilead"), a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet medical need, today announced that they have entered into a research collaboration and license agreement that grants Gilead exclusive rights to Hookipa's TheraT® and Vaxwave® arenavirus vector-based immunization technologies for two major chronic infectious disease indications, hepatitis B virus (HBV) and human immunodeficiency virus (HIV).

Under the terms of the agreement, Gilead will provide an upfront payment of $10 million. Additionally, Hookipa will be eligible to receive milestone payments based upon the achievement of specified development, regulatory, and commercial milestones up to a total of more than $400 million. Gilead will fund all research and development activities. Hookipa will also be eligible to receive tiered royalties on net sales.

"Gilead, a world leader in innovative therapies against major viral diseases, is the ideal partner for us to drive our pipeline development in this area for the benefit of patients in need. This partnership is strong recognition of our unique immunization technology, and helps us concentrate our own energy and resources on immuno-oncology," commented Joern Aldag, Chief Executive Officer of Hookipa. "The collaborative HIV and HBV programs nicely complement our significant efforts in the infectious disease area with an exciting proprietary prophylactic CMV vaccine."

"Gilead is committed to advancing innovative approaches directed at functional cures against HIV and HBV," said Bill Lee, PhD, Executive Vice President of Research, Gilead. "We are convinced that Hookipa's unique therapeutic vaccine technology, which has demonstrated excellent safety and immunogenicity in Phase 1 clinical studies, has strong potential to have synergistic effect with other Gilead cure efforts in both of these diseases areas. Our ultimate long-term goal is to eliminate the need for life-long antiviral therapy for millions of patients around the world."

-END-

CONFIDENTIAL TREATMENT REQUESTED. INFORMATION FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED IS OMITTED AND MARKED WITH "[***]". AN UNREDACTED VERSION OF THE DOCUMENT HAS ALSO BEEN FURNISHED SEPARATELY TO THE SECURITIES AND EXCHANGE COMMISSION AS REQUIRED BY RULE 406 UNDER THE SECURITIES ACT OF 1933, AS AMENDED.

About Gilead Sciences, Inc.

Gilead Sciences, Inc. is a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet medical need. The company strives to transform and simplify care for people with life-threatening illnesses around the world. Gilead has operations in more than 35 countries worldwide, with headquarters in Foster City, California.

About Hookipa Biotech

Hookipa Biotech is a clinical stage company developing next-generation immunotherapies for infectious diseases and cancer using novel proprietary arenavirus vector platforms.

Hookipa's Vaxwave® technology presents a completely new replication-defective viral vector platform designed to overcome the limitations of current technologies. Vaxwave® is based on lymphocytic choriomeningitis virus (LCMV). In this vector the gene encoding the LCMV envelope protein, normally responsible for virus entry into target cells, has been deleted and replaced with an antigen of interest. The resulting vectors infect dendritic cells and stimulate very potent and long-lasting immune response, however they cannot replicate and are therefore non-pathogenic and inherently safe.

Hookipa's TheraT® platform is based on an attenuated replicating arenavirus and is capable of eliciting the most potent T cell responses - a crucial step in treating patients with aggressive cancers. Significant pre-clinical data demonstrates that TheraT is a powerful modality capable of turning "cold tumors hot" which should result in an additional layer of efficacy in the fight against solid tumors. Specifically, TheraT® has proven to be safe in animals as well as capable of eliciting uniquely potent antigen-specific CD8+ cytotoxic T cell responses and strong tumor control in mice. The first clinical trial with HB-201 targeting human papilloma virus-induced head and neck cancer is currently being prepared. This immuno-oncology technology is further being leveraged to target tumor self-antigens or shared neoantigens.

Find out more about Hookipa online at http://hookipabiotech.com/.

Gilead Forward-Looking Statements

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks, uncertainties and other factors, including the risk that the parties may not realize the potential benefits of this collaboration. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. These and other risks are described in detail in Gilead's Annual Report on Form 10-K for the year ended December 31, 2017, as filed with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to Gilead, and Gilead assumes no obligation to update any such forward-looking statements.

Issued for and on behalf of Hookipa Biotech AG by Instinctif Partners. For further information please contact:

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Hookipa Biotech AG
ialdag@hookipabiotech.com

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or
Media
Amy Flood, +1-650-522-5643

CERTAIN IDENTIFIED INFORMATION MARKED BY [*] HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED

CONFIDENTIAL

22 December 2019

Hookipa Biotech GmbH St Marx Vienna BioCenter
Helmut-Qualtinger-Gasse 2
1030 Vienna, Austria

Re: Amendment to the Research Collaboration and License Agreement

Dear Ladies and Gentlemen:

Reference is hereby made to the Research Collaboration and License Agreement, dated as of June 4, 2018, by and between Gilead Sciences, Inc. ("**Gilead**") and Hookipa Biotech GmbH (formerly Hookipa Biotech AG) ("**Hookipa**," and each of Gilead and Hookipa, a "**Party**" and, collectively, the "**Parties**"), as amended from time to time (the "**Agreement**"). The Parties desire to amend the Agreement effective as of date hereof as set forth herein. Capitalized terms used herein, but not defined herein, have the meanings set forth in the Agreement.

1. HBV Research Plan.

The Parties acknowledge and agree that the [*]. Further, the Parties acknowledge and agree that some or all of [*] are no longer necessary to include in the HBV Research Plan. In addition, the Parties agree to update (i) Table 2 ([*]) of the HBV Research Plan to reflect [*], (ii) Table 3 ([*]) of the HBV Research Plan to reflect [*], (iii) Table 8 ([*]) of the HBV Research Plan to delete reference to HBV-Study 4, and (iv) Table 9 ([*]) of the HBV Research Plan to amend the scope of Platform- HBV-Study 1, and to amend the wording in sections c) and d) of the HBV Research Plan. Accordingly, the HBV Research Plan shall be amended and restated in its entirety in the form of Exhibit A attached hereto.

2. HBV Pre-Clinical Milestone.

a. Notwithstanding anything to the contrary in Section 9.2(a)(i) of the Agreement, including anything that would require a different or additional payment amount from Gilead, following Hookipa's delivery to Gilead of [*] and [*], in each case, in compliance with the HBV Research Plan, Gilead shall pay Hookipa a one (1)-time payment of [*] for [*].

b. Section 9.2(a)(ii) of the Agreement is hereby amended by deleting such section in its entirety and replacing such section with the following:

> "(ii) Gilead shall pay Hookipa a one (1)-time payment of Four Million USD ($4,000,000) after [*]. Gilead shall notify Hookipa in writing promptly after [*]."

3. Termination for Convenience.

a. Sections 13.4(a)(i) and 13.4(a)(ii) of the Agreement are each hereby amended by deleting "to be mutually agreed between the Parties" from the second sentence of each section.

b. Section 13.4(b) of the Agreement is hereby amended and restated as follows:

> "Termination of Agreement by Gilead for Convenience. On a Program-by-Program basis (including, for clarity, any new program(s) that may be included in the Agreement after the date hereof by mutual agreement of the Parties), at any time after the expiration or termination of the Collaboration Term for such Program, Gilead shall have the right to terminate this Agreement with respect to such Program or on a Licensed Product-by- Licensed Product or a country-by-country basis with respect to such Program for convenience upon thirty (30) days' prior written notice to Hookipa."

4. Funding of [*] and GMP Manufacturingring.

Subsequent to the execution of this letter agreement ("**Letter Agreement**"), the Parties intend to enter into amendments to the HBV Research Plan and HIV Research Plan and certain other terms of the Agreement (the "**Amendments**") to accelerate and expand the HBV Program and the HIV Program towards Phase 1 Clinical Trials. The Parties desire to progress the HBV Program and the HIV Program during the time needed by the Parties to further discuss, negotiate and, subject to agreement by both Parties, reach definitive agreement on such Amendments ("**Negotiation Period**"). The Parties herewith agree as follows irrespective of whether the subsequent execution of these Amendments occur:

a. *Preliminary Development and Manufacturing Activities*. During the Negotiation Period, Hookipa shall continue to perform the envisaged activities set forth in the non-exhaustive list on Exhibit B attached hereto and such other activities which are not described in the current HBV Research Plan or HIV Research Plan but which have been approved by Gilead in writing (including email) shall be performed solely by Hookipa or jointly by the Parties during such period ("**Preliminary Activities**"). Hookipa may engage certain contract manufacturing organizations to perform such Preliminary Activities solely to the extent expressly set forth on Exhibit B or expressly approved by Gilead in writing (including email).

b. *Expense Reimbursement*. Gilead agrees to reimburse Hookipa (i) for all Out-of-Pocket Costs actually incurred (with no markup) by Hookipa and (ii) at the FTE Rate for the costs of any FTEs actually performing activities, in each case, in the performance of such Preliminary Activities provided that (A) such Out-of-Pocket Costs and FTE costs are listed in Exhibit B or (B) for any such Out-of-Pocket Costs and FTE costs not listed in Exhibit B, any single item of such costs does not exceed [*] (collectively, the "**Reimbursable Expenses**"). Gilead shall not be responsible for any Out-of-Pocket Costs or FTE costs not listed in Exhibit B and incurred by Hookipa in connection with the Preliminary Activities in excess of such caps unless Gilead has approved such costs in writing (including email) prior to Hookipa's incurrence of such costs. The invoicing and payment of the Reimbursable Expenses shall be in accordance with the terms of the Agreement.

c. *Term*. Gilead's obligations of payment for Reimbursable Expenses under this Section 4 of this Letter Agreement will expire automatically upon (i) execution of the Amendments, or (ii) termination by the Parties of the Preliminary Activities following good faith negotiations. Execution of the Amendments pursuant to clause (i) and termination of the Preliminary Activities for any reason pursuant to clause (ii) shall not relieve the Parties of any liability or obligation which accrued hereunder prior to the effective date of such execution or termination unless otherwise addressed in the Amendments.

5. General.

Except as expressly set forth in this Letter Agreement, the Agreement shall remain unchanged and in full force and effect in accordance with its terms; provided, however, that to the extent that any of the terms and conditions of this Letter Agreement are inconsistent with the terms and conditions of the Agreement, the terms of this Letter Agreement will govern. This Letter Agreement, including the exhibits attached hereto, constitutes the entire agreement between the Parties regarding the subject matter hereof and supersedes all prior and contemporaneous agreements and understandings between the Parties related to the subject matter set forth herein. The invalidity or unenforceability of any term or provision of this Letter Agreement shall not affect the validity or enforceability of any term or provision of the Agreement. This Letter Agreement may not be amended or supplemented in any way except in writing, signed by authorized representatives of both Parties. This Letter Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all which together shall constitute one and the same instrument. Signatures to this Letter Agreement transmitted by facsimile, by electronic mail in "portable document format" (".pdf"), or by any other electronic means shall have the same effect as physical delivery of the paper document bearing the original signature.

[*signature page follows*]

Sincerely,

Gilead Sciences, Inc.

By: /s/ William Lee

Name: William Lee

Title: EVP, Research

Agreed and acknowledged:

Hookipa Biotech GmbH

By: /s/ Joern Aldag

Name: Joern Aldag

Title: CEO

[*]

Exhibit 10.24

Project no. 849137 /33388 SCK/SAI

Funding Contract

concluded between

The Austrian Research Promotion Agency (FFG)

as Funding Agency

and

HOOKIPA Biotech AG
Helmut-Qualtinger-Gasse 2
1030 Vienna

Commercial register no. FN 365895g

as Funding Recipient.

Sec. 1 Granting funds

1.1 On the basis of the grant application "Development of innovative cancer immunotherapies based on Hookipa's Vaxwave® technology," which was received via eCall on 10/01/2014, and on the basis of the expert decision of the advisory board in the 12/03/2014 meeting, funding will be granted for the following project:

Project number: **849137**

eCall number: **5040485**

Project name (subject-matter of Contract):

Development of innovative cancer immunotherapies based on Hookipa's Vaxwave® technology

Program: General Program

Österreichische	Tel +43 (0)5 7755 — 0	UniCredit Bank Austria AG
Forschungsförderungsgesellschaft mbH	Fax +43 (0)5 7755 — 97900	Account no. 10216727200, Routing no. 12000
Sensengasse 1	www.ffg.at, office@ffg.at	IBAN AT66 1200 0102 1672 7200
1090 Vienna	FN 252263a Commercial Court Vienna	SWIFT BKAUATWW

Sec. 2 Project duration

2.1 The overall project duration starts on 10/01/2014 and ends on 03/31/2018.

2.2 FFG funding of the entire project depends on the results made apparent from the submitted reports, on further fulfilment of the evaluation and decision criteria, on the budget available to the Funding Agency, and on a renewed positive funding decision.

Sec. 3 Funding period

3.1 The funding period of this project begins on the approval date **10/01/2014** and ends on **09/30/2015.**

Sec. 4 Funding nature and amount

4.1 Funding will be provided in the following form for the funding period specified in Sec. 3:

Type of funding		Amount up to max.
FFG subsidy	**EUR**	**581,100**
FFG loan	**EUR**	**548,800**

Loan conditions

Interest rate	0.75% p.a. on a current-account basis
Repayment date:	on 03/31/2023
Repayment sum:	EUR 548,800
Interest and loan collection:	as direct debit payments
Interest payment request:	semi-annually in arrears or at loan due dates

4.2 The subsidized financing of the project amounts to 70% of the verifiable and eligible project costs. Remaining funding of the project costs shall be carried out by the Funding Recipient. Based on the planning data, the cash value of the grant is EUR 689,208 or 42.7% of the eligible project costs in accordance with Section 5.1.

4.3 The maximum eligible cash value under the applicable Community framework for State aid for R&D is 45%.

4.4 If the eligible project costs fall short, it will result in an aliquot reduction in funding.

4.5 The eligible project costs pursuant to Sec. 5 and the costs reported by way of interim or final accounts do not constitute an acknowledgement of costs on the part of FFG prior to their verification. The final amount of the total recognizable project costs and the funding will only be determined after project completion in the course of invoice verification.

Sec. 5 Eligible costs

5.1 The following eligible project costs form the basis of the funding:

Personnel expenses	EUR	401,700
R&D infrastructure use	EUR	15,500
Material costs	EUR	171,200
Third-party services	EUR	1,009,900
Travel expenses	EUR	16,000
Total eligible costs	**EUR**	**1,614,300**

5.2 Eligible costs are all expenses and expenditures attributable to the project that are incurred directly, actually, and in addition to conventional operating expenses for the duration of the funded research activity. Additional supplementary provisions regarding eligible costs may be found in the FFG Guidelines for SMEs, the Cost Guidelines and Guide for Individual Projects of Experimental Development.

5.3 Significant changes to the cost structure require the FFG’s prior written approval.

5.4 The value added tax on the costs of the eligible service is not eligible for funding. If, however, it can be shown that this value added tax is borne verifiably in actual fact and without recourse by the Funding Recipient, thereby not making the Funding Recipient entitled to deduct input tax, it will be taken into account as an eligible cost component. The value added tax that can be reclaimed in whatever way is not eligible for funding even if the Funding Recipient does not actually get it back. Should a grant not be regarded as a grant by the tax office but as a contractual consideration because of the existence of a taxable service of the Funding Recipient to the Funding Agency that is liable to tax under the Value Added Tax Act 1994, Federal Law Gazette No. 663, and the Funding Recipient has to pay value added tax to the tax office in return, the contractual consideration shall be regarded as a gross remuneration. Additional, separate compensation of the value added tax—for whatever legal reason—is thus excluded.

5.5 If the amortization period of an item (Sec. 285 of the Austrian Civil Code, or ABGB) that was purchased for implementing the project exceeds the funding period, the depreciation costs can be funded in accordance with the method laid down in the Guide for Individual Projects of Experimental Development, and in the Cost Guidelines.

5.6 Funds of the Funding Agency may not be used to form reserves or provisions according to the Income Tax Act 1988, Federal Law Gazette No. 400. The funds are to be used only for the services and objectives described in the grant application.

5.7 Eligible costs that can be recognized in new applications are those incurred after receipt of the grant application. For renewal applications, the earliest date for cost recognition shall be the start of the funding period specified in Sec. 3.

5.8 The costs incurred by the Funding Recipient or its affiliates for preparing the Contract or bank transfer charges must be borne by it/them and are not eligible costs.

5.9 The Funding Agency reserves the right to postpone, reduce, or suspend the payment of a grant if and as long as circumstances exist that do not appear to guarantee the proper implementation of the funded project (e.g. proof of costs is not provided to the extent planned).

Sec. 6 Project-specific conditions and requirements

6.1 Project-specific special conditions and requirements

1. The funding of further application possibilities of the Vaxwave technology platform is only provided after at least one field of application (infectious diseases or oncology) has been successfully completed.

2. The costs for R&D infrastructure acquired before the funding period are included in the overhead of the personnel cost surcharge rate.

Sec. 7 Fund payment

7.1 The 1st instalment in the amount of 50% of the pledged funds will be paid after the Funding Contract has been concluded and the conditions and requirements agreed in Sec. 6 have been fulfilled.

The second instalment in the amount of 30% is paid after approval of an interim report and an interim statement, in which 50% of the approved total costs must be proved, and after the conditions and requirements under Sec. 6 have been fulfilled.

The final instalment in the amount of 20% of the total pledged funds will only be paid after all conditions and requirements (final accounting, final reports, etc.) have been fulfilled and after the FFG has verified and approved the where-used list.

7.2 The money will be transferred to the Funding Recipient’s account:

Account holder:	HOOKIPA Biotech AG
Bank name:	RAIFFEISENLANDESBANK NIEDERÖSTERREICH-WIEN AG
IBAN:	AT61 3200 0000 1511 6726
BIC/SWIFT:	RLNWATWW

Sec. 8 Reporting obligation

8.1 According to clause 3 of the General Funding Conditions, the Funding Recipient must report to the FFG on the implementation of the funded project by submitting technical reports (interim and final reports) and billing statements. Reports and statements must be sent via eCall (https://ecall.ffg.at). Using the forms stored in eCall is mandatory. Further documents must be submitted to FFG upon request.

8.2 Where prototypes are funded, the Funding Recipient must report to FFG on the whereabouts or further use of the prototype.

Sec. 9 Amendments to the Contract

9.1 Amendments to this Contract may only be made expressly and in writing. This shall also apply to any departure from this provision.

9.2 Subsequent amendments to the agreed conditions and requirements may, if necessary, under special circumstances, be made by mutual agreement in the form of written additional agreements after a new advisory board decision has been taken.

Sec. 10 Liability

10.1 The Funding Recipient shall be unconditionally liable to the FFG for compliance with all contractual provisions. The Funding Recipient shall also be liable for the conduct of third parties for which it is responsible (e.g. owners, corporate officers, etc.). The Funding Recipient shall indemnify and hold FFG harmless against third-party claims.

Sec. 11 Severability clause

11.1 Should any provision of this Funding Contract be invalid, it shall not affect the validity of the remaining provisions of the Funding Contract. The contracting parties undertakes to replace an ineffective provision with one that comes closest to the purpose of this Funding Contract.

Sec. 12 Applicable law

12.1 This Contract and all of its Appendices shall be governed by Austrian law to the exclusion of the reference standards of the Austrian Private International Law (IPRG).

Sec. 13 Place of jurisdiction

13.1 The place of jurisdiction for all legal disputes arising from the grant shall be the competent court in Vienna. FFG reserves the right to take legal action against the Funding Recipient at its general place of jurisdiction.

Sec. 14 Contract components

14.1 The following documents constitute integral components of the Funding Contract:

- the grant application (“Development of innovative cancer immunotherapies based on Hookipa’s Vaxwave® technology”) received via eCall in the version from 10/01/2014
- General Funding Conditions for Funding Contracts as amended (version 1 from 2013)
- Guide for Individual Projects of Experimental Development, version 2.0
- Cost Guideline to treating project costs in grant applications and reports for projects with grant agreements according to the FTE Guidelines and the FFG Guidelines, version 1.4

14.2 The legal bases of this Funding Contract are, in particular:

- The Austrian Research Promotion Agency Establishment Act (Forschungsförderungs-Strukturreformgesetz, Research Funding Structural Reform Law) as amended
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  The validity of the guidelines was extended until 12/31/2014 by the Federal Minister of Transport, Innovation and Technology on 03/12/2014 (No. BMVIT-609.986/0004-111/12/2014) i.e. by the Federal Minister of Science, Research and the Economy on 06/04/2014 (No. BMWFJ-98.310/0101-C1/10/2013) in accordance with the State aid regulations applicable as of 07/01/2014.

The Funding Recipient confirms knowledge of all contract components and fully accepts them.

It should be noted that the present grant offer is deemed to be withdrawn unless the Funding Recipient returns it to FFG signed within 3 months.

For the Funding Agency:
The Austrian Research Promotion Agency (FFG)

Vienna, 12/09/2014

/s/ Dr. Henrietta Egerth-Stadlhuber
Dr. Henrietta Egerth-Stadlhuber,
Managing Director

/s/ Dr. Klaus Pseiner
Dr. Klaus Pseiner
Managing Director

Funding Recipient

Vienna, Dec. 16. 2014

/s/ DR. KATHERINE COHEN
DR. KATHERINE COHEN, CEO

Appendix:

Guidelines for the Austrian Research Promotion Agency FFG to promote research, technology, development, and innovation (FFG Guidelines) via link http://www.ffg.at/Allgemeine-Richtlinien

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Österreichische
Forschungsförderungsgesellschaft mbH
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Tel +43 (0)5 7755 — 0
Fax +43 (0)5 7755 — 97900
www.ffg.at, office@ffg.at
FN 252263.a Commercial Court Vienna

UniCredit Bank Austria AG
Account no. 10216727200, Routing no. 12000
IBAN AT66 1200 0102 1672 7200
SWIFT BKAUATVVW

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The Austrian Research Promotion Agency (FFG)

Vienna, 12/09/2014

/s/ Dr. Henrietta Egerth-Stadlhuber
Dr. Henrietta Egerth-Stadlhuber,
Managing Director

/s/ Dr. Klaus Pseiner
Dr. Klaus Pseiner
Managing Director

Funding Recipient

Vienna, Dec. 16. 2014

/s/ DR. KATHERINE COHEN
DR. KATHERINE COHEN, CEO

Appendix:

Guidelines for the Austrian Research Promotion Agency to promote research, technology, development, and innovation (FFG Guidelines) via link http://www.ffg.at/Allgemeine-Richtlinien

General Funding Conditions for Funding Contracts as amended (version 1 from 2013) Guide for Individual Projects of Experimental Development, version 2.0

Cost Guideline to treating project costs in grant applications and reports for projects with grant agreements according to the FTE Guidelines and the FFG Guidelines, version 1.4

Funding Contract

concluded between

The Austrian Research Promotion Agency (FFG)

as Funding Agency

and

HOOKIPA Biotech AG
Helmut-Qualtinger-Gasse 2
1030 Vienna

Commercial register no. FN 365895g

as Funding Recipient.

Sec. 1 Granting funds

1.1 On the basis of the grant application "Demonstration of the applicability of Hookipa's arenaviral vector technologies for cancer immunotherapy development," which was received via eCall on 05/31/2016, and on the basis of the expert decision of the advisory board in the 09/13/2016 meeting, funding will be granted for the following project:

Project number: 857224

eCall number: 8000616

Pre-project no: 849137

Project name (subject-matter of Contract):

Demonstration of the applicability of Hookipa's arenaviral vector technologies for cancer immunotherapy development

Program: General Program

Sec. 2 Project duration

2.1 The overall project duration starts on 10/01/2014 and ends on 12/31/2018.

2.2 FFG funding of the entire project depends on the results made apparent from the submitted reports, on further fulfilment of the evaluation and decision criteria, on the budget available to the Funding Agency, and on a renewed positive funding decision.

Sec. 3 Funding period

3.1 The funding period of this project begins on the approval date **03/01/2016** and ends on **02/28/2017.**

Sec. 4 Funding nature and amount

4.1 Funding will be provided in the following form for the funding period specified in Sec. 3:

Type of funding		Amount up to max.
FFG subsidy	**EUR**	**1,964,000**
FFG loan	**EUR**	**2,202,100**

Loan conditions

Interest rate	0.75% p.a. on a current-account basis
Repayment date:	on 03/31/2024
Repayment sum:	EUR 2,202,100
Interest and loan collection:	as direct debit payments
Interest payment request:	semi-annually in arrears or at loan due dates

4.2 The rate of finance of the project amounts to 70.0% of the verifiable and eligible project costs. Remaining funding of the project costs shall be carried out by the Funding Recipient. Based on the planning data, the cash value of the grant is EUR 2,311,959 or 38.8% of the eligible project costs in accordance with Section 5.1.

4.3 The maximum funding cash value under the current Union framework for State aid for research, development and innovation is 45%.

4.4 If the eligible project costs fall short, it will result in an aliquot reduction in funding.

4.5 The eligible project costs pursuant to Sec. 5 and the costs reported by way of interim or final accounts do not constitute an acknowledgement of costs on the part of FFG prior to their verification. The final amount of the total recognizable project costs and the funding will only be determined after project completion in the course of invoice verification.

Sec. 5 Eligible costs

5.1 The following eligible project costs form the basis of the funding:

Personnel expenses	EUR	1,846,636
Material costs	EUR	926,028
Third-party services	EUR	3,135,253
Travel expenses	EUR	43,750
Total eligible costs	**EUR**	**5,951,667**

5.2 All costs attributable to the project that are incurred directly, actually, and additionally (to conventional operating expenses) for the funding period according to Sec. 3 are eligible. Additional supplementary provisions regarding eligible costs may be found in the FFG Guidelines for SMEs, the Cost Guidelines and Guide for Individual Projects of Experimental Development (in each case in the version mentioned under 14.1).

5.3 Significant changes to the cost structure require the FFG’s prior written approval.

5.4 The value added tax on the costs of the eligible service is not eligible for funding. If, however, it can be shown that this value added tax is borne verifiably in actual fact and without recourse by the Funding Recipient, thereby not making the Funding Recipient entitled to deduct input tax, it will be taken into account as an eligible cost component.

The Funding Agency’s funding is a genuine grant that is not subject to value added tax because there is no exchange of services but a public interest in carrying out the research project.
The grant amount is a gross amount. Additional, separate compensation of fees and taxes by FFG—for whatever legal reason—is excluded.
The loan interest/the liability fees are subject to an exemption from value added tax under Sec. 6(1)(8) of the Value Added Tax Act.

5.5 If the amortization period of an item (Sec. 285 of the Austrian Civil Code, or ABGB) that was purchased for implementing the project exceeds the funding period, the depreciation costs are fundable in accordance with the method laid down in the Cost Guidelines and Guide for Individual Projects of Experimental Development (in each case in the version mentioned under 14.1).

5.6 Funds of the Funding Agency may not be used to form reserves or provisions according to the Income Tax Act 1988, Federal Law Gazette No. 400/1988. The funds are to be used only for the services and objectives described in the grant application.

5.7 The costs incurred by the Funding Recipient or its affiliates for preparing the Contract or bank transfer charges must be borne by it/them and are not eligible costs.

5.8 The Funding Agency reserves the right to postpone, reduce, or suspend the payment of a grant if and as long as circumstances exist that do not appear to guarantee the proper implementation of the funded project (e.g. proof of costs is not provided to the extent planned).

5.9 Grants awarded by FFG for the direct promotion of science and research as compensation for expenses or expenditures come from public funds and are tax-free pursuant to Sec. 3(1)(3)(c) of the Income Tax Act (EStG) in connection with Sec. 3(4)(3) EStG.

Sec. 6 Conditions and requirements

6.1 Project-specific special conditions and requirements

1. The planned costs for the CSO position in the amount of €109,371.25 can only be charged for activities of one CSO. These costs can neither be reclassified nor used as part of other personnel costs.

2. The costs of the evaluation license, storage and shipments are covered by the overhead flat rate.

3. Travel expenses for quality audits and reaudits are not eligible.

4. The funding of further application possibilities of the Vaxwave technology platform is only provided after at least one field of application (infectious diseases or oncology) has been successfully completed.

6.2 The originally signed Funding Contract must be returned to the Funding Agency no later than 4 weeks after receipt.

6.3 By signing this Funding Contract, the Funding Recipient undertakes to inform the Funding Agency—in the course of the planned reports at the latest—of all applied for and/or approved public grants that directly or indirectly concern the project.

Sec. 7 Fund payment

7.1 The 1st instalment in the amount of 50% of the pledged funds will be paid after the Funding Contract has been concluded and the conditions and requirements agreed in Sec. 6 have been fulfilled.

The second instalment in the amount of 30% is paid after approval of an interim report, in which 50% of the approved total costs must be proved, and after the conditions and requirements under Sec. 6 have been fulfilled.

The final instalment in the amount of 20% of the total pledged funds will only be paid after all conditions and requirements (final accounting, final reports, etc.) have been fulfilled and after the FFG has verified and approved the where-used list.

7.2 The funds will be transferred to the Funding Recipient’s account:

Account holder:	HOOKIPA Biotech AG
Bank name:	RAIFFEISENLANDESBANK NIEDERÖSTERREICH-WIEN AG
IBAN:	AT61 3200 0000 1511 6726
BIC/SWIFT:	RLNWATWW

Sec. 8 Reporting obligation

8.1 According to clause 3 of the General Funding Conditions, the Funding Recipient must report to the FFG on the implementation of the funded project by submitting technical reports (interim and final reports) and billing statements.

Reports and statements must be sent via eCall (https://ecall.ffg.at). Using the forms stored in eCall is mandatory. Further documents must be submitted to FFG upon request.

8.2 Where prototypes are funded, the Funding Recipient must report to FFG on the whereabouts or further use of the prototype.

Sec. 9 Amendments to the Contract

9.1 Amendments to this Contract may only be made expressly and in writing. This shall also apply to any departure from this provision.

9.2 Subsequent amendments to the agreed conditions and requirements may, if necessary, under special circumstances, be made by mutual agreement in the form of written additional agreements after a new advisory board decision has been taken.

Sec. 10 Liability

10.1 The Funding Recipient shall be unconditionally liable to the FFG for compliance with all contractual provisions. The Funding Recipient shall also be liable for the conduct of third parties for which it is responsible (e.g. owners, corporate officers, etc.). The Funding Recipient shall indemnify and hold FFG harmless against third-party claims.

Sec. 11 Severability clause

11.1 Should any provision of this Funding Contract be invalid, it shall not affect the validity of the remaining provisions of the Funding Contract. The contracting parties undertake to replace an ineffective provision with one that comes closest to the purpose of this Funding Contract.

Sec. 12 Applicable law

12.1 This Contract and all of its Appendices shall be governed by Austrian law to the exclusion of the reference standards of the Austrian Private International Law (IPRG).

Sec. 13 Place of jurisdiction

13.1 The place of jurisdiction for all legal disputes arising from the grant shall be the competent court in Vienna. FFG reserves the right to take legal action against the Funding Recipient at its general place of jurisdiction.

Sec. 14 Contract components

14.1 The following documents constitute integral components of the Funding Contract:

- The grant application (“Demonstration of the applicability of Hookipa’s arenaviral vector technologies for cancer immunotherapy development”) submitted via eCall in the version from 07/07/2016.
- General Funding Conditions for Funding Contracts as amended (version 2015)
- Guide for Individual Projects of Experimental Development, version 3.1
- Cost Guideline version 2.0

14.2 The legal bases of this Funding Contract are, in particular:

- The Austrian Research Promotion Agency Establishment Act (Forschungsförderungs-Strukturreformgesetz, Research Funding Structural Reform Law) as amended
- Union framework for State aid for research, development and innovation (Official Journal C 198 from 06/27/2014)

- Commission Regulation (EU) No 651/2014 of 17 June 2014 declaring certain categories of aid compatible with the internal market in application of Articles 107 and 108 of the Treaty on the functioning of the European Union (TFEU 2014).

- Guideline for the Austrian Research Promotion Agency FFG to promote the applied research, development, and innovation (FFG Guideline for SMEs no: BMVIT-609.986/0012-111/12/2014 and BMWFW-98.310/0102-C1/10/2014) —These Guidelines were filed for exemption with the European Commission on the basis of the TFEU 2014.

The Funding Recipient confirms knowledge of all contract components and fully accepts them and notes that non-compliance with the above contractual provisions may lead to the funds being reclaimed.

The Funding Recipient confirms that no open reclaim order by the European Commission exists and that rescission, if any, of an incompatible funding is completed.

The Funding Recipient agrees that the data listed in Art. 9(1) of the TFEU (EU Regulation No. 651/2014) Appendix III may be used to publish the information if the cash value of the grant (gross subsidy equivalent) exceeds €500,000.

For the Funding Agency:
The Austrian Research Promotion Agency (FFG)

Vienna, 09/15/2016

/s/ Dr. Henrietta Egerth-Stadlhuber
Dr. Henrietta Egerth-Stadlhuber
Managing Director

/s/ Dr. Klaus Pseiner
Dr. Klaus Pseiner
Managing Director

Funding Recipient

Vienna, 10/04/2016

/s/ JÖRN ALDAG
JÖRN ALDAG, CEO

Appendix:

Guideline for the Austrian Research Promotion Agency FFG to promote the applied research, development, and innovation (FFG Guideline for SMEs)
via link https://www.ffg.at/recht-finanzen/rechtsgrundlagen
General Funding Conditions for Funding Contracts as amended (version 2015)
Guide for Individual Projects of Experimental Development, version 3.1
Cost Guideline version 2.0

Funding Contract

concluded between

The Austrian Research Promotion Agency (FFG)

as Funding Agency

and

HOOKIPA Biotech AG
Helmut-Qualtinger-Gasse 2
1030 Vienna

Commercial register no. FN 365895g

as Funding Recipient.

1 Granting funds

1.1 On the basis of the grant application "Demonstration of the applicability of Hookipa's arenaviral vector technologies for cancer immunotherapy development," which was received via eCall on 09/29/2017, and on the basis of the expert decision of the advisory board in the 01/31/2018 meeting, funding will be granted for the following project:

Project number: **865401**

eCall number: **14249646**

Pre-project no: 857224

Project name (subject-matter of Contract):

Demonstration of the applicability of Hookipa's arenaviral vector technologies for cancer immunotherapy development

Program: General Program

Österreichische
Forschungsförderungsgesellschaft mbH
Sensengasse 1
1090 Vienna

Tel +43 (0)5 7755 — 0
Fax +43 (0)5 7755 — 97900
www.ffg.at, office@ffg.at
FH 252263a Commercial Court Vienna

UniCredit Bank Austria AG
Account no. 10216727200, Routing no. 12000
IBAN AT66 1200 0102 1672 7200
SWIFT BKAUATWW

Sec. 2 Project duration

2.1 The overall project duration starts on 10/01/2014 and ends on 12/31/2018.

2.2 FFG funding of the entire project depends on the results made apparent from the submitted reports, on further fulfilment of the evaluation and decision criteria, on the budget available to the Funding Agency, and on a renewed positive funding decision.

Sec. 3 Funding period

3.1 The funding period of this project begins on the approval date **07/01/2017** and ends on **06/30/2018.**

Sec. 4 Funding nature and amount

4.1 Funding will be provided in the following form for the funding period specified in Sec. 3:

Type of funding		Amount up to max.
FFG subsidy	**EUR**	**2,152,900**

4.2 The rate of finance of the project amounts to 28.0% of the verifiable and eligible project costs. Remaining funding of the project costs shall be carried out by the Funding Recipient. Based on the planning data, the cash value of the grant is EUR 2,152,900 or 28.0% of the eligible project costs in accordance with Section 5.1.

4.3 The maximum funding cash value under the current Union framework for State aid for research, development and innovation is 45%.

4.4 If the eligible project costs fall short, it will result in an aliquot reduction in funding.

4.5 The eligible project costs pursuant to Sec. 5 and the costs reported by way of interim or final accounts do not constitute an acknowledgement of costs on the part of FFG prior to their verification. The final amount of the total recognizable project costs and the funding will only be determined after project completion in the course of invoice verification.

Sec. 5 Eligible costs

5.1 The following eligible project costs form the basis of the funding:

Personnel expenses	EUR	2,326,743
R&D Infrastructure use	EUR	75,232
Material costs	EUR	1,367,588
Third-party services	EUR	3,844,564
Travel expenses	EUR	75,000
Total eligible costs	**EUR**	**7,689,127**

5.2 All costs attributable to the project that are incurred directly, actually, and additionally (to conventional operating expenses) for the funding period according to Sec. 3 are eligible. Additional supplementary provisions regarding eligible costs may be found in the FFG Guidelines for SMEs, the Cost Guidelines and Guide for Individual Projects of Experimental Development (in each case in the version mentioned under 14.1).

5.3 Significant changes to the cost structure require the FFG’s prior written approval.

5.4 The value added tax on the costs of the eligible service is not eligible for funding. If, however, it can be shown that this value added tax is borne verifiably in actual fact and without recourse by the Funding Recipient, thereby not making the Funding Recipient entitled to deduct input tax, it will be taken into account as an eligible cost component.

The Funding Agency’s funding is a genuine grant that is not subject to value added tax because there is no exchange of services but a public interest in carrying out the research project.
The grant amount is a gross amount. Additional, separate compensation of fees and taxes by FFG—for whatever legal reason—is excluded.

5.5 If the amortization period of an item (Sec. 285 of the Austrian Civil Code, or ABGB) that was purchased for implementing the project exceeds the funding period, the depreciation costs are fundable in accordance with the method laid down in the Cost Guidelines and Guide for Individual Projects of Experimental Development (in each case in the version mentioned under 14.1).

5.6 Funds of the Funding Agency may not be used to form reserves or provisions according to the Income Tax Act 1988, Federal Law Gazette No. 400/1988. The funds are to be used only for the services and objectives described in the grant application.

5.7 The costs incurred by the Funding Recipient or its affiliates for preparing the Contract or bank transfer charges must be borne by it/them and are not eligible costs.

5.8 The Funding Agency reserves the right to postpone, reduce, or suspend the payment of a grant if and as long as circumstances exist that do not appear to guarantee the proper implementation of the funded project (e.g. proof of costs is not provided to the extent planned).

5.9 Grants awarded by FFG for the direct promotion of science and research as compensation for expenses or expenditures come from public funds and are tax-free pursuant to Sec. 3(1)(3)(c) of the Income Tax Act (EStG) in connection with Sec. 3(4)(3) EStG.

Sec. 6 Conditions and requirements

6.1 Project-specific special conditions and requirements
none

6.2 The originally signed Funding Contract must be returned to the Funding Agency no later than 4 weeks after receipt.

6.3 By signing this Funding Contract, the Funding Recipient undertakes to inform the Funding Agency—in the course of the planned reports at the latest—of all applied for and/or approved public grants that directly or indirectly concern the project.

Sec. 7 Fund payment

7.1 The 1st instalment in the amount of 50% of the pledged funds will be paid after the Funding Contract has been concluded and the conditions and requirements agreed in Sec. 6 have been fulfilled.

The second instalment in the amount of 30% is paid after approval of an interim report, in which 50% of the approved total costs must be proved, and after the conditions and requirements under Sec. 6 have been fulfilled.

The final instalment in the amount of 20% of the total pledged funds will only be paid after all conditions and requirements (final accounting, final reports, etc.) have been fulfilled and after the FFG has verified and approved the where-used list.

7.2 The funds will be transferred to the Funding Recipient's account:

Account holder:	HOOKIPA Biotech AG
Bank name:	RAIFFEISENLANDESBANK NIEDERÖSTERREICH-WIEN AG
IBAN:	AT61 3200 0000 1511 6726
BIC/SWIFT:	RLNWATWW

Sec. 8 Reporting obligation

8.1 According to clause 3 of the General Funding Conditions, the Funding Recipient must report to the FFG on the implementation of the funded project by submitting technical reports (interim and final reports) and billing statements.
Reports and statements must be sent via eCall (https://ecall.ffg.at). Using the forms stored in eCall is mandatory. Further documents must be submitted to FFG upon request.

8.2 Where prototypes are funded, the Funding Recipient must report to FFG on the whereabouts or further use of the prototype.

Sec. 9 Amendments to the Contract

9.1 Amendments to this Contract may only be made expressly and in writing. This shall also apply to any departure from this provision.

9.2 Subsequent amendments to the agreed conditions and requirements may, if necessary, under special circumstances, be made by mutual agreement in the form of written additional agreements after a new advisory board decision has been taken.

Sec. 10 Liability

10.1 The Funding Recipient shall be unconditionally liable to the FFG for compliance with all contractual provisions. The Funding Recipient shall also be liable for the conduct of third parties for which it is responsible (e.g. owners, corporate officers, etc.). The Funding Recipient shall indemnify and hold FFG harmless against third-party claims.

Sec. 11 Severability clause

11.1 Should any provision of this Funding Contract be invalid, it shall not affect the validity of the remaining provisions of the Funding Contract. The contracting parties undertake to replace an ineffective provision with one that comes closest to the purpose of this Funding Contract.

Sec. 12 Applicable law

12.1 This Contract and all of its Appendices shall be governed by Austrian law to the exclusion of the reference standards of the Austrian Private International Law (IPRG).

Sec. 13 Place of jurisdiction

13.1 The place of jurisdiction for all legal disputes arising from the grant shall be the competent court in Vienna. FFG reserves the right to take legal action against the Funding Recipient at its general place of jurisdiction.

Sec. 14 Contract components

14.1 The following documents constitute integral components of the Funding Contract:

- The grant application ("Demonstration of the applicability of Hookipa's arenaviral vector technologies for cancer immunotherapy development") submitted via eCall in the version from 12/21/2017
- General Funding Conditions for Funding Contracts as amended (version 2015)
- Guide for Individual Projects of Experimental Development, version 3.3
- Cost Guideline 2.1

14.2 The legal bases of this Funding Contract are, in particular:

- The Austrian Research Promotion Agency Establishment Act (Forschungsförderungs-Strukturreformgesetz, Research Funding Structural Reform Law) as amended
- Union framework for State aid for research, development and innovation (Official Journal C 198 from 06/27/2014)
- Commission Regulation (EU) No 651/2014 of 17 June 2014 declaring certain categories of aid compatible with the internal market in application of Articles 107 and 108 of the Treaty on the functioning of the European Union (TFEU 2014).
- Guideline for the Austrian Research Promotion Agency FFG to promote the applied research, development, and innovation (FFG Guideline for SMEs no: BMVIT-609.986/0012-111/12/2014 and BMWFW-98.310/0102-C1/10/2014) —These Guidelines were filed for exemption with the European Commission on the basis of the TFEU 2014.

The Funding Recipient confirms knowledge of all contract components and fully accepts them and notes that non-compliance with the above contractual provisions may lead to the funds being reclaimed.

The Funding Recipient confirms that no open reclaim order by the European Commission exists and that rescission, if any, of an incompatible funding is completed.

The Funding Recipient agrees that the data listed in Art. 9(1) of the TFEU (EU Regulation No. 651/2014) Appendix III may be used to publish the information if the cash value of the grant (gross subsidy equivalent) exceeds €500,000.

For the Funding Agency:
The Austrian Research Promotion Agency (FFG)

Vienna, 02/12/2018

/s/ Dr. Henrietta Egerth-Stadlhuber
Dr. Henrietta Egerth-Stadlhuber
Managing Director

/s/ Dr. Klaus Pseiner
Dr. Klaus Pseiner
Managing Director

Funding Recipient

Vienna, 02/27/2018

/s/ REINHARD KANDERA
REINHARD KANDERA, CFO

Appendix:

Guideline for the Austrian Research Promotion Agency FFG to promote the applied research, development, and innovation (FFG Guideline for SMEs)
via link https://www.ffg.at/recht-finanzen/rechtsgrundlagen
General Funding Conditions for Funding Contracts as amended (version 2015)
Guide for Individual Projects of Experimental Development, version 3.3
Cost Guideline 2.1

HOOIKIPA Biotech Gmbh
attn Dr Vera Baumgartl-Strasser Helmut-Qualtinger-Gasse 2
1030 Vienna

AIP
DW – 1206

Vienna, 25 October 2019

Project 865401, 857224, 850420, 849137, 844309, 836998
Your application to waive reclamation

Dear Dr Baumgartl-Strasser,

During the meeting of 23 October 2019, the Advisory Board of the FFG Basic Programmes discussed your application of 26 September to waive the reclamation of the subsidies paid out for the above-mentioned projects and approved your application under the following conditions:

A) Postponement of the repayment dates as proposed in your application:
- Project 836998: early repayment by 31.12.2019 in the amount of € 752,168.00
- Project 844309: early repayment by 31.03.2020 in the amount of € 1,140,021.00
- Project 857224: early repayment of 50% of the loan by 30.06.2023 in the amount of € 1,059,900.00 and repayment by 31.03.2024 in the amount of € 1,059,941.00.

B) Letter of intent (as proposed) from Hookipa lnc. regarding the liabilities of Hookipa Biotech GmbH to FFG
C) Guarantee of employment of at least the present number (76 employees) until at least 31.03.2024
D) Guarantee of location including operational activities until at least 31.03.2024

Please submit signed company documents for conditions B, C and D by 30.11.2019 at the latest. Furthermore, the discussion concluded that further funding is only possible after a successful Phase II study as well as a further substantial repayment of outstanding loans.

Yours sincerely,

(one signature in handwriting)

Dr Alexander Reiterer
Division Management Deputy
Basic Programmes

(one signature in handwriting)

Mag. Harald Polak
Programme director
Basic programmes

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-230995) of HOOKIPA Pharma Inc. of our report dated March 19, 2020 relating to the financial statements, which appears in this Form 10-K.

Vienna, Austria
March 19, 2020

PwC Wirtschaftsprüfung GmbH
/s/ Alexandra Rester
Austrian Certified Public Accountant

Exhibit 31.1

CERTIFICATIONS PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, 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)) 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) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

   (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 19, 2020

/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)) 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) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

   (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 19, 2020

/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, 2019, 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 19, 2020

/s/ Joern Aldag
Joern Aldag
Chief Executive Officer
(Principal Executive Officer)

Date: March 19, 2020

/s/ Reinhard Kandera
Reinhard Kandera
Chief Financial Officer
(Principal Financial Officer)