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DELTA REPORT

10-K

HOOK - HOOKIPA PHARMA INC.

10-K - DECEMBER 31, 2023 COMPARED TO 10-K - DECEMBER 31, 2022

The following comparison report has been automatically generated

TOTAL DELTAS	5496
CHANGES	331
DELETIONS	2290
ADDITIONS	2875

REFINITIV

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

FORM 10-K

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

For the fiscal year ended December 31, 20222023

OR

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

Commission file number: 001-38869

HOOKIPA PHARMA INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Based on the closing price as reported on the Nasdaq Global Select Market, the aggregate market value of the Registrant's Common Stock held by non-affiliates on June 30, 2022 June 30, 2023 (the last business day of the Registrant's most recently completed second fiscal quarter) was approximately $82.6 $71.7 million. Shares of Common Stock held by each executive officer and director and by each shareholder affiliated with a director or an executive officer have been excluded from this calculation because such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes. The number of outstanding shares of the Registrant's Common Stock as of March 7, 2023 March 15, 2024 was 52,322,822 96,550,590 shares and 2,399,517 shares of Class A common stock outstanding, each $0.0001 par value per share.

Documents Incorporated by Reference

If the Registrant's Definitive Proxy Statement relating to the 2023 2024 Annual General Meeting of Shareholders (the "Proxy Statement") is filed with the Commission within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, then portions of the Proxy Statement will be incorporated by reference into Part III of this Annual Report on Form 10-K. If the Proxy Statement is not filed within such 120-day period, then the Registrant will file an amendment to this Annual Report within such 120-day period that will contain the information required to be included or incorporated by reference into Part III of this Annual Report.

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

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, including "Business" in Part I Item I and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II Item 7, contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act) "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 Commission 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 collaborations collaboration with Gilead Sciences,Inc., F.Hoffmann-La RocheLtd. and Hoffmann-LaRoche Inc. and establish or maintain future collaborations or strategic relationships or obtain additional funding;
- the rate and degree of market acceptance and clinical utility of our current and future product candidates;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering our non-replicating and replicating technologies and the product candidates based on these technologies, the validity of intellectual property rights held by third parties, and our ability not to infringe, misappropriate or otherwise violate any third-party intellectual property rights;
- future agreements with third parties in connection with the commercialization of our product candidates and any other approved product;
- regulatory developments in the United States and foreign countries;
- the effects of the recent coronavirus pandemic or other emerging global health threats on business and operations;
- competitive companies, technologies and our industry and the success of competing therapies that are or may become available;
- our ability to attract and retain key scientific or management personnel;
- our ability to obtain funding for our operations, including funding necessary to complete further development and commercialization of our product candidates;

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- the accuracy of our estimates of our annual total addressable market, future revenue, expenses, capital requirements and needs for additional financing;
- our expectations about market trends; and
- our ability to comply with Nasdaq listing rules and our expectations regarding the period during which we qualify as an emerging growth company under the Jumpstart Our Business Startups Act of 2012, as amended.

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

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

Note Regarding Trademarks

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

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

Summary Risk Factors

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

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

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- We will require substantial additional financing and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations.
- If we are unable to advance our current or future product candidates into and through clinical trials, obtain marketing approval and ultimately commercialize any product candidates we develop, or experience significant delays in doing so, our business will be materially harmed.
- The regulatory approval processes of the FDA, U.S. Food and Drug Administration ("FDA"), the EMA European Medicines Agency ("EMA"), the European Commission, and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.
- Failure or perceived failure to comply with existing or future laws, regulations, contracts, self-regulatory schemes, standards, and other obligations related to data privacy and security (including security incidents) could harm our business. Compliance or the actual or perceived failure to comply with such obligations could increase the costs of our products and services, limit their use or adoption, and otherwise negatively affect our operating results and business.
- Our product candidates are based on a novel approach to the treatment of cancer and infectious diseases, which makes it difficult to predict the time and cost of product candidate development.
- Our product candidates may cause serious adverse events, undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, require expansion of the trial size, limit their commercial potential or result in significant negative consequence.
- We are fully dependent on our collaboration with Gilead Sciences, Inc. ("Gilead") for the development of our hepatitis B virus program, and rely on funding from Gilead Sciences, Inc. for development of our human immunodeficiency virus program, and F. Hoffmann-La Roche Ltd. and Hoffmann-La Roche Inc. for development of our immunotherapeutic for KRAS-mutated cancers. We may depend on our current collaborators Gilead or additional third parties for the development and commercialization of our other programs and future product candidates. Our current and future collaborators may control aspects of our clinical trials, which could result in delays or other obstacles in the commercialization of the product candidates we develop. If our collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.
- The COVID-19 pandemic has adversely impacted, and may continue to adversely impact our business, including our clinical trials.

- Our rights to develop and commercialize our product candidates are subject, in part, to the terms and conditions of licenses granted to us by others, and, if we fail to comply with our obligations under these arrangements or resolve related disputes, we could lose such intellectual property rights or owe damages to the licensor of such intellectual property.
- If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market.
- We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in licenses. in-licenses.
- Our failure to meet the continued listing requirements of The Nasdaq Global Select Capital Market could result in a delisting of our common stock.

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PART I

Item 1. Business

Overview

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

We are building a proprietary immuno-oncology pipeline by targeting utilizing our replicating technology. Our oncology portfolio targets oncoviral cancer antigens self-antigens and next-generation antigens. Our oncology portfolio antigens and includes three disclosed two primary programs in development: HB-200 HB-300 and HB-700, all of which use our replicating technology. HB-700. HB-200 is in clinical development for the treatment of Human Papillomavirus 16-positive (HPV16+ (“HPV16+”) head and neck cancers in a Phase 1/2 clinical trial. HB-300, in development for the treatment of prostate cancer, is in an ongoing Phase 1 clinical trial, which opened for enrollment of patients in the first quarter of 2023. HB-700 which has been partnered with F. Hoffmann-La Roche Ltd. and Hoffmann-La Roche Inc. (collectively referred to as Roche), is in preclinical development for the treatment of KRAS mutated cancers, including lung, colorectal and pancreatic cancers. We also have a third oncology program, HB-300, targeting self-antigens for the treatment of prostate cancer, which the Company paused further development in January 2024, to conserve capital and ensure pipeline success and operational efficiency.

Our strategic priority is the development of our oncology portfolio, but most importantly the advancement of our HB-200 program, and we plan expect to continue initiate a randomized Phase 2/3 trial in 2024. Additionally, we are developing infectious disease therapies in partnership with other companies. Our Hepatitis B (HBV) (“HBV”) program, HB-400, and our HIV Human Immunodeficiency Virus (“HIV”) program, HB-500, are being developed in a partnership with Gilead Sciences Inc. (Gilead) Gilead.

2023 Highlights

In 2023, we executed on several key areas across our pipeline. The highlights include:

Oncology:

- HB-200 in combination with pembrolizumab: We presented positive preliminary Phase 2 data in patients with recurrent/metastatic HPV16+ head and neck cancers in the first line setting in May 2023 and additional patient data in October 2023 at the European Society for Medical Oncology (“ESMO”) Congress 2023.
    - Data showed 42% objective response rate for 19 evaluable checkpoint inhibitor (“CPI”)-naïve patients. These data represent a doubling of the historical response rate (19 percent) reported for pembrolizumab alone.

- We are preparing to start a randomized Phase 2/3 trial of HB-200 in combination with pembrolizumab in the 1st-line setting for patients with R/M HPV16+ head and neck cancers.

- HB-700: We continued Investigational New Drug ("IND") application-enabling activities and we are on track to submit an IND in the second quarter of 2024.

- HB-300: We enrolled the first two dose escalation cohorts in the Phase 1/2 study. The Study Safety Committee deemed that HB-300 was generally safe and well-tolerated in both dose escalation cohorts. However, we paused further development of this program in January 2024 to refocus our capital resources on the advancement of our HB-200 program and Gilead-partnered infectious disease programs.

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Infectious Disease: Gilead-Partnered Programs

- HB-400: In August 2023, the Journal of Infectious Disease published peer-reviewed preclinical data on HB-400. The data showed that HB-400 induced robust, HBV-specific T cell and antibody responses in non-human primates and cleared detectable serum HBV antigens in a mouse model for chronic HBV infection, with near elimination of detectable HBV antigen positive hepatocytes in the liver.

- HB-500: In November 2023, we announced FDA clearance of our IND application for HB-500 for the treatment of HIV. Additionally, Nature Partner Journals published peer-reviewed preclinical data for the program in November 2023. The data showed that HB-500 was well tolerated and generated robust, high-quality and durable immune responses (antigen-specific T cells and antibodies) in non-human primates, and that arenaviral therapeutic vaccination significantly reduced SIV viral load and clinical illness in those animals compared to placebo.

Financial Highlights:

- In January 2023, we received a $5.0 million milestone payment under our HB-400 collaboration agreement with Gilead. The success-based milestone payment reflected our completion and delivery of a regulatory support package for Gilead's Phase 1 clinical trial.

- In February 2023, we received a $10.0 million milestone payment under our HB-700 collaboration agreement with F. Hoffmann-La Roche Ltd. and Hoffmann-La Roche Inc. (collectively referred to as "Roche"). The success-based milestone payment reflected the start of the HB-700 manufacturing process to support a Phase 1 clinical trial.

- In June 2023, we completed a $50.0 million public offering of common stock and non-voting convertible preferred stock. The financing was completed in parallel with the initial Phase 2 data release for HB-200.

- In December 2023, we issued 15 million shares of common stock for approximately $21.25 million, at a price of $1.4167 per share, to Gilead under a stock purchase agreement with Gilead (as amended to date, the "Stock Purchase Agreement"). We have the right, subject to certain terms and conditions, to sell an additional approximately $8.75 million of common stock to Gilead as pro-rata participation in potential future equity raises.

Significant Recent Events

On January 29, 2024, we provided an update on our business priorities and oncology partnership programs. We announced that we will focus our resources in two strategic areas: (1) the clinical development of a randomized trial for our HB-200 program in HPV16+ head and neck squamous cell carcinoma ("HNSCC") and (2) our two Gilead-partnered infectious disease cure programs for HBV and HIV. As part of our strategic refocus, which we announced in January 2024, we have paused development activities related to HB-300 and most of our preclinical research activities.

We also announced in January 2024 that we received notification from Roche of their decision to terminate the collaboration and licensing agreement for our HB-700 program in KRAS mutated cancers. We have decided not met all go-forward criteria under the agreement and remain eligible for a final milestone payment associated with an IND submission. Effective April 25, 2024, we will regain full control of the associated intellectual property portfolio and have full collaboration and licensing rights for this program.

Additionally, we announced a reduction in our workforce by approximately 30% and rebalance in our cost structure in alignment with the reprioritization of our programs, and both are expected to invest further into any other be implemented and substantially completed by the end of the first quarter of 2024. As of December 31, 2023, we had $117.5 million in cash,

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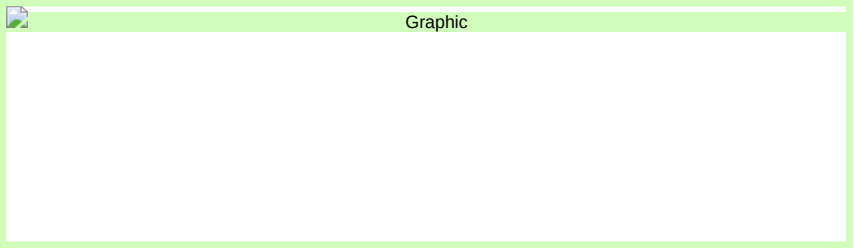
cash equivalents and restricted cash, and we believe that the planned reductions will help conserve resources and better align our organization in direct support of late-stage clinical development efforts.

Leadership

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. The fundamental discoveries underlying our arenavirus platform originated with our co-founders, Nobel laureate Rolf Zinkernagel, M.D., and Daniel Pinschewer, M.D., an internationally recognized arenavirus expert who serves as Scientific Advisor to our Chief Executive Officer.

Our Pipeline

We are leveraging our modular arenavirus platform to develop the following product candidates for multiple cancers and infectious disease program at this time. diseases:



Platform

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

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

We believe we are the first to reengineer arenaviruses for therapeutic purposes. Our systemic and reproduceable approach features two technologies capable of delivering disease-specific antigens for the prevention and treatment of disease. Our non-replicating technology is designed to induce a strong immune response for prophylactic and therapeutic use against infectious disease. Our replicating technology is engineered to produce an even more powerful immune

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response, which we are currently exploring in oncology indications. In preclinical studies, our replicating technology was able to reprogram the immune system such that more than half of the body's CD8+ T cells focused on a specific

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cancer self-antigen target without observed serious adverse events. We observed the ability of HB-200 monotherapy to induce robust, high-quality and durable antigen-specific CD8+ T cell responses in our HB-200 clinical trial in human patients. We have designed our platform to be modular in nature in order to allow substitution of antigens to target a broad range of infectious diseases and cancers. We have a robust intellectual property portfolio for our suite of arenaviruses with exclusive rights in issued patents and patent applications related to our non-replicating technology and exclusive and joint rights in issued patents and patent applications for our replicating technology. We believe the breadth and depth of our intellectual property portfolio is a strategic asset that has the potential to provide us with a significant competitive advantage.

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

Oncology Pipeline Highlights Background

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

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

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

Our Technology Platform

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

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

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

The arenavirus family is comprised of over 30 currently known species, many of which we believe have potential prophylactic and therapeutic applications. We believe we are the first to reengineer arenaviruses for the prevention and treatment of disease. We have created two types of viral technologies capable of delivering disease specific antigens: a replication defective vector, and a replication competent but attenuated vector.

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

Non-Replicating Technology Overview

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

Advantages of Non-Replicating Technology

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

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

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

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

Replicating Technology Overview

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Our proprietary replicating technology was designed to provide the beneficial properties of our non-replicating technology but to induce an even more robust immune response. Unlike naturally occurring arenaviruses which have two genomic segments, our replicating constructs were engineered to have three segments to allow for the introduction of genomic space in which to insert additional target antigens of choice. As a result of the larger genome, the virus' ability to replicate is reduced (attenuated).

Advantages of our Replicating Technology

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

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

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

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

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

Advantages of sequential administration of replicating PICV and replicating LCMV

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

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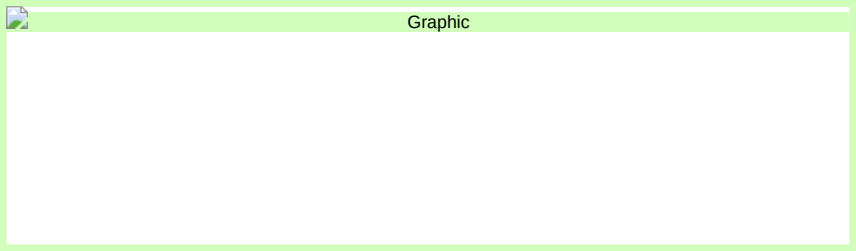

Figure: Bonilla, W. et al. Heterologous arenavirus vector prime-boost overrules self-tolerance for efficient tumor-specific CD8 T cell attack. journal.ppat. 100209. Cell Reports Medicine

Our Product Candidates

HB-200 Program for the Treatment of HPV16+ Cancers

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

All of our current product candidates are alternating, dual-vector arenaviral immunotherapies. HB-200 is a targeted dual vector arenaviral-based immunotherapy that uses alternating sequential injections of a LCMV vector and a PICV vector, both expressing the E7E6 fusion protein specific to HPV16+ cells. The two components of our HB-200 program are referred to as HB-201 (LCMV) and HB-202 (PICV).

HPV-Positive Cancers

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

HPV infection is linked to several cancer types, including HNSCC which is now the 8th most common cancer affecting men in the United States (Siegel et al. 2023). The high incidence rate of HNSCC is largely due to a rising epidemic of oropharyngeal squamous cell carcinoma ("OPSCC") associated with HPV (Price & Cohen 2012). The median overall survival ("OS") for R/M HNSCC remains less than 15 months despite modern chemotherapy, targeted agents, and recent studies have shown that approximately 70% immunotherapy. The high-risk genotype HPV 16 accounts for 88% of cancers HPV+ OPSCC cases in the United States (Chaturvedi et al. 2011) and for more than 50% of the tonsil HPV+ cases found in other head and tongue base and the majority neck anatomical locations (Abogunrin et al. 2014; Vokes et al. 2015). In 2023, an estimated 54,540 new cases of cervical and anal cancers may be linked to HPV. It is estimated that the yearly incidence of metastatic head and neck cancers were diagnosed in Spain, France, Germany, Italy, Japan, the United Kingdom and the United States will be 44,000 by 2030. Tumors caused by HPV alone, with anticipated deaths estimated at 11,580 (Siegel et al. 2023).

While there is no T cell therapy approved for HNSCC, retrospective analyses have shown that patients' outcomes are referred to as HPV-positive tumors (HPV+) and can be characterized by their expression improved for those with high levels of proteins from the HPV genome, particularly the viral E6 and E7 proteins. These two proteins are expressed CD8+ T cells in tumors but are absent in normal cells, which makes them ideal target candidates for immunotherapy; however, as compared to date, there are no therapeutically approved agents directed against these targets.

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

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

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

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

In preclinical studies, HB-201, as a monotherapy, was observed to suppress tumor growth and eliminated up to 40% of HPV+ tumors. HB-201 generated a strong and durable T cell response with successfully treated animals demonstrating resistance to a tumor rechallenge. Based on these preliminary results, we believe that treating patients with HB-201 has the potential to both control metastatic disease and prevent relapse. lower levels of CD8+ T cells.

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In December 2019, we opened Our Solution: HB-200 Program

HB-200 alternates the HB-200 Phase 1/2 trial (NCT04180215), investigating administration of both Phase 1 dose optimization HB-201 (LCMV) and Phase 2 dose expansion HB-202 (PICV) attenuated viral vectors, which on their own are replicating-based therapeutics expressing a non-oncogenic, but highly antigenic, E7E6 fusion protein from HPV16. We have observed strong immunogenicity and robust antitumor activity in a single trial. During the initial 10 months of the trial, the HB-201 single-vector therapy was studied through escalating doses. Starting in October 2020, enrollment into the HB-202/HB-201 alternating sequential dual-vector therapy began, representing a parallel dose escalation.

In November 2021, interim Phase 1 data on HB-201 single-vector therapy and HB-202/HB-201 dual-vector therapy mouse models for advanced/metastatic HPV16+ cancers showed promising anti-tumor activity and favorable tolerability. The interim data were derived from 62 patients who received either HB-201 single-vector therapy or HB-202/HB-201 dual-vector therapy for advanced/metastatic HPV16+ cancers. In June 2022, additional data on HB-201 single-vector therapy and HB-202/HB-201 dual-vector therapy and conclusions from the Phase 1 part of the Phase 1/2 trial were released. The data was derived from 68 patients with advanced HPV16+ cancers, including 54 patients with head and neck squamous cell carcinoma (HNSCC). This data demonstrated responses LCMV alone as well as stable disease for the sequential administration of LCMV and PICV.

Relevance of E6 and E7 as Tumor Antigens

Integration of HPV viral sequences into the genome of a cell can result in some head the introduction of E6 and neck cancer 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 who failed prior standard of care therapy, platinum therapy: PD(L)1 inhibitor, or both. We believe with HPV16+ tumors has identified E6 and E7 specific T cells, indicating that these early-stage data establish proof of concept for our replicating immunotherapy in oncology.

The interim Phase 1 data released in November 2021 enabled decisions on Phase 2 clinical plans for target tumor type as well as recommended schedule the E6 and route of administration for HB-200:

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

In addition to the interim data reported in November 2021, the June 2022 data enabled further decisions on the Phase 2 part of the trial:

- While promising anti-tumor activity was shown in both groups, alternating dual-vector HB-202/HB-201 demonstrated superior tumor response with 56% of treated patients showing target lesion shrinkage compared to 38% of HB-201 recipients. In addition, decreases in visceral lesions were predominantly seen in patients who received alternating dual-vector therapy: 59% of patients on HB-202/HB-201 compared to 18% on HB-201;
- The HB-202/HB-201 alternating dual-vector therapy demonstrated an 80% disease control rate, which compares favorably to historical disease control rates achieved by pembrolizumab in recurrent/metastatic HNSCC patients, specifically 35% overall and 40% in the HPV+ subset, based on peer-reviewed published data;
- While both HB-201 and alternating dual-vector HB-202/HB-201 were highly immunogenic, HB-202/HB-201 induced superior immune response with 32% of recipients achieving tumor-specific T cell levels greater than 5% of the circulating T cell pool.

Based on the safety profile, anti-tumor activity and E7 proteins are immunogenic, meaning that they trigger antigen specific CD8+ T cell response data observed responses. Because both E6 and E7 are highly expressed in the Phase 1 dose escalation part, the Phase 2 expansion portion tumor cells and are absent in normal cells, they are ideal candidates for use as targets of the tumor directed active immunization.

HB-200 Clinical Trial

HB-200 is being evaluated in an ongoing Phase 1/2 clinical trial for the treatment of HPV16+ cancers.

This trial is currently enrolling participants in Phase 2, evaluating HB-202/HB-201 HB-200 therapy in combination with pembrolizumab in 1st the first line patients with advanced setting of HPV16+ PD-L1+ oropharynx cancer.

Previously, the trial has, in multiple arms, explored several dose levels and administration regimens across multiple HPV16+ cancer indications. The Company has published interim data readouts at key scientific conferences dating back to 2021. Interim data readouts from 2021 to 2022 have shaped further the study design and protocol.

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

- Phase 1 evaluation of HB-200 as a monotherapy in second or later-line R/M setting of HPV16+ cancers and
- Phase 2 evaluation of HB-200 in combination with pembrolizumab in the first line R/M setting of HPV16+ OPSCC.

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

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

As of March 31, 2023, in the Phase 2 Dose (RP2D) using a two-step combination dose escalation. First, a small cohort of patients was dosed with HB-201 single-vector therapy in combination with pembrolizumab as a safety lead-in. Second, the alternating dual-vector HB-202/HB-201 therapy at a lower dose than RP2D was evaluated in combination with pembrolizumab, before beginning the current alternating dual-vector therapy at RP2D in combination with pembrolizumab. The Phase 2 1 portion of the trial is also open for enrollment of study, 93 patients with second line any HPV16+ cancer (72 HNSCC and greater advanced/metastatic 21 non-HNSCC) were enrolled to receive HB-200 therapy (LCMV 1-vector therapy or PICV/LCMV alternating 2-vector therapy). Patients were heavily pretreated with a median of three prior anticancer systemic therapies (range 1-11). The recommended phase 2 dose (“RP2D”) and regimen for HB-200 monotherapy was previously determined to be alternating 2-vector therapy IV at dose level 3 (PICV 1×107 RCV FFU, LCMV 5×107 RCV FFU). The reported efficacy and clinical biomarker data focused on the 41 patients with HPV16+ HNSCC for treatment treated with a HB-200 alternating 2-vector therapy, especially 29 patients with HPV16+ HNSCC treated with HB-200 alternating 2-vector therapy at the RP2D (DL3) or one dose lower than the RP2D (RP2D-1, DL2).

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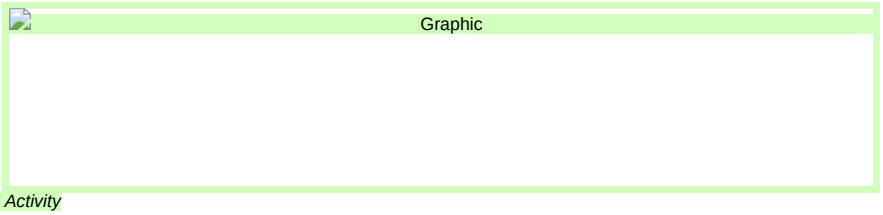
combination Safety and Tolerability

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



Clinical Activity

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

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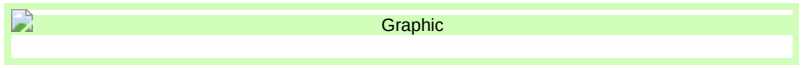

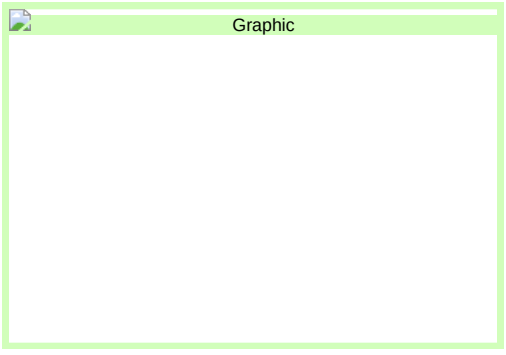

Biomarker and Translational Results

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

- Up to 48% of all CD8+ T cells in blood were specific for the tumor antigen (i.e., HPV16 E6 & E7), with a median specificity of 2.0% (Figure 2A).
- Figure 2C illustrates one representative patient with HNSCC (Patient #1) from DL3 cohort with tumor-specific CD8+ T cell responses measured by ICS, E6-E7–specific IFN-γ+ CD8+ T cells increasing from 0% at baseline to 10% after 2 doses of HB-200.

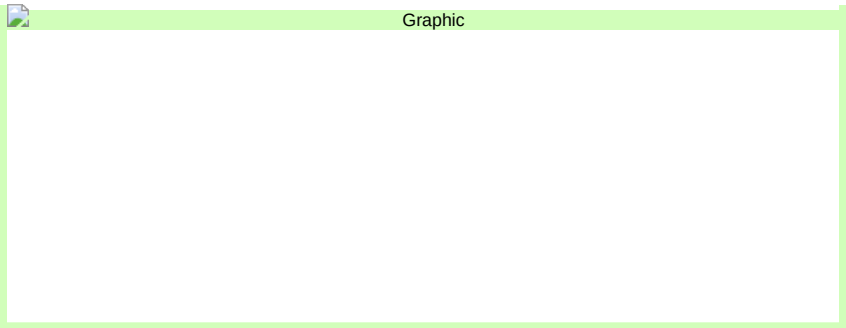

Figure 2. HPV16 E6-E7–specific T cell responses in HNSCC patients treated with HB-200 alternating 2-vector therapy.

A. Baseline and peak IFN-γ+ HPV16 E6-E7 T cell response measured by ICS. Peak responses were typically observed post 2 doses of HB-200 (N = 35/41 HNSCC patients receiving HB-200 alternating 2-vector therapy across DL1-4).

B. Box plots are representing IFN-γ+ HPV16 E6-E7 T cell response measured by ICS per DL (N = 35/41). Box and whiskers represent minimum, maximum and median. DL1 = PICV 1×106, LCMV 5×106 RCV FFU; DL2 (RP2D-1) = PICV 1×107, LCMV

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5×106 RCV FFU; DL3 (RP2D) = PICV 1×107, LCMV 5×107 RCV FFU; DL4 = PICV 1×108, LCMV 5×106 RCV FFU. Patients from DL2 & DL3 with available PBMC samples are highlighted (N = 26/29)

C. Representative pseudo-color plots (Patient #1) with the frequencies of double-positive IFN-γ+ TNF-α+ cells gated on CD8+ T cells at baseline and post 2 doses of HB-200.

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

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

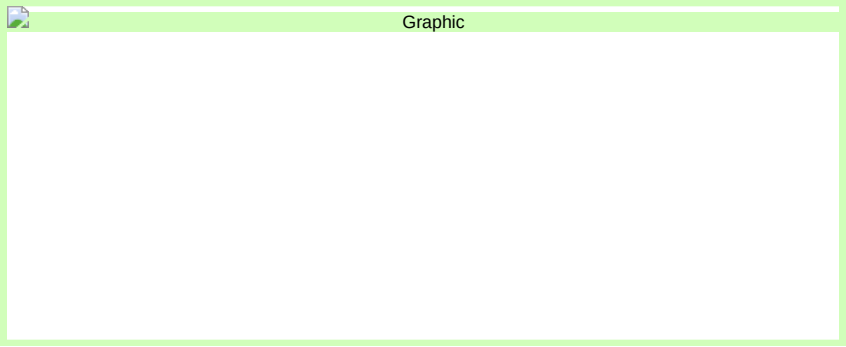

Figure 3.

A. Median of circulating E6-E7–specific T cells over time measured by ELISpot (solid line shows median SFU/1 x 106 PBMCs and dashed lines indicate Patient #1 and #2 in the case report in Figure 4). Pie charts below graph show percentage of tumor-specific T cells expressing the indicated number of cytokines/markers (IFN-γ, TNF-a, CD107a, IL-2) measured by ICS in available PBMCs from HNSCC patients undergoing HB-202/HB-201 alternating 2-vector therapy at DL2 & DL3 at the corresponding timepoints (N = 26/29).

B. Percent change in tumor-infiltrating CD8+ T cells pre and pembrolizumab. Enrollment of those post HB-200 treatment in patients is also proceeding with disease control (blue) and progressive disease (red) measured by IF IHC. Mean ± SD. Data shown are all patients with available paired biopsies, which includes patients from all groups explored in the unrandomized study (N = 13 out of 93 total patients enrolled in Phase 1).

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

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

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Figure 4. Tumor response, HPV16 ctDNA, and TILs in 2 patients with stable disease who received HB-200 alternating 2-vector therapy.

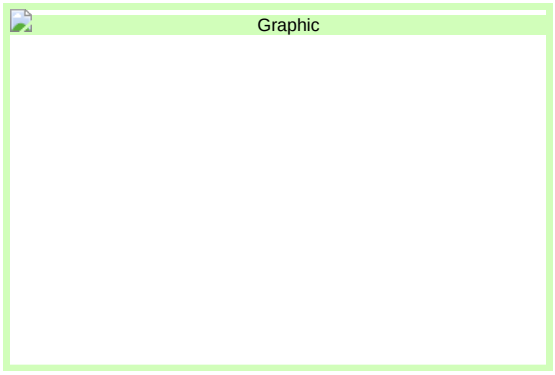
A. Percent change in sum of target lesion diameters from baseline over time in Patient #1 and #2.

B. Percent change in circulating HPV16 DNA from baseline in Patient #1 and #2.

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

Clinical Results: HB-200 in Combination with Pembrolizumab in the First Line Setting

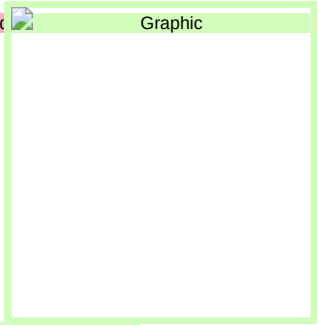
In October 2023, we presented updated Phase 2 dose expansion part data for HB-200 in combination with pembrolizumab in the first line setting at the ESMO annual congress (Abstract 2212) for the first 20 patients treated with HB-200 and pembrolizumab in the first-line setting (data cut-off August 7, 2023). The efficacy evaluable data set (≥1 tumor scan post-treatment) consisted of 19 patients, as one patient discontinued prior to tumor scans due to COVID-related death. Baseline characteristics are highlighted in the table below.



Safety and Tolerability

The data showed that HB-200 and pembrolizumab was generally well tolerated among the 20 patients treated. The majority of reported AEs were mild to moderate with the most common AEs being flu-like symptoms. Two patients (10%) reported serious adverse events related to the treatment with HB-200 or pembrolizumab. Only one patient (5%) discontinued due to a treatment-related adverse event of checkpoint inhibitor pneumonitis (related to pembrolizumab). The updated safety data adds to the previously reported safety and tolerability data from patients across all arms of the ongoing Phase 1/2 trial. trial who received HB-200 monotherapy or HB-200 in combination with pembrolizumab. This generally favorable tolerability profile highlights the potential of HB-200 – and arenaviral immunotherapies in general – to be successfully combined with other immunotherapies where tumor antigen-specific T cell induction is of potential benefit.

In July 2022, we announced



Presented at ESMO 2023

Clinical Activity

The preliminary data showed a 42% confirmed objective response rate (“ORR”) and disease control rate (“DCR”) of 74% across 19 evaluable patients, doubling the historical 19% ORR for pembrolizumab alone. Best overall response for the evaluable population included one patient with a confirmed complete response, seven patients with confirmed partial responses, and six patients with stable disease. The preliminary data showed sustained disease control in the majority of patients. All efficacy-evaluable patients were alive at the data cutoff (August 7, 2023), and the median follow-up time at DCO was 8.3 months. Median overall survival and progression-free survival data are still maturing.

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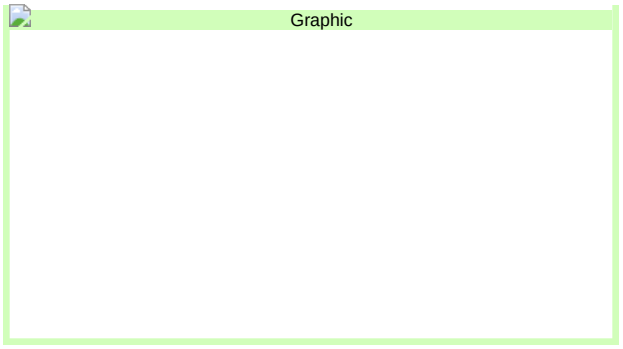

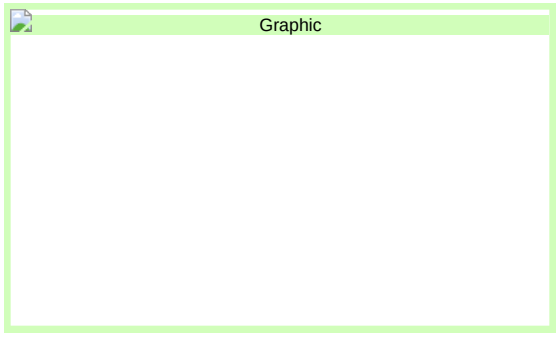

Biomarker and Translational Results

Importantly, the data showed significant activation of antigen-specific CD8+ T cells, the body's primary driver of tumor killing activity. Out of 17 patients with available peripheral blood mononuclear cells ("PMBC") samples, all patients showed an increase of tumor antigen-specific circulating HPV16+ CD8+ T cells. Peak percentage of antigen-specific circulating HPV16+ CD8+ T cells reached up to 31 percent with a median of 3.36%. Max response on treatment vs. before treatment of systemic HPV-16 E7 and E6 specific T cells measured by ELISPOT showed that the U.S. Food median fold-increase for these patients' total tumor specific T cells was a 451-fold increase over baseline, with the maximal increase of 4,000-fold.

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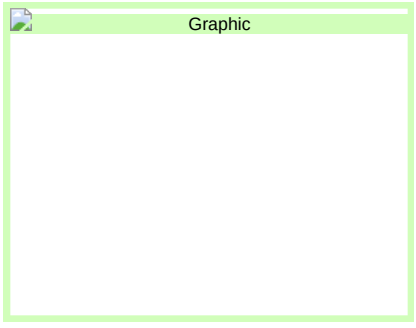

Based on the data generated in our clinical trials, we believe that HB-200, in combination with standard of care pembrolizumab, has the potential to improve treatment outcomes in persons diagnosed with HPV16+ PD-L1+ R/M OPSCC, and Drug Administration (FDA) accepted has the potential to be used in the first line setting. We believe that success in developing HB-200 into an effective therapy for HPV16+ OPSCC would suggest the potential of HB-200 to be an effective therapy in all HPV16+ cancers, regardless of the cancer's tissue of origin.

The totality of the data from our Investigational New Drug Application (IND) clinical trials of HB-200, both as a monotherapy and in combination with pembrolizumab, give us conviction to proceed with a randomized Phase 2/3 trial to evaluate HB-200 in combination with pembrolizumab in the first line setting for HB-300 patients with HPV16+ OPSCC. We plan to begin the randomized Phase 2/3 trial in 2024.

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

Targeting Shared Neoantigens

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

An early proof of concept for targeting KRAS mutations via CD8+ T cells was reported by Tran et al in 2016. Tran targeted a KRAS mutation on position 12 (G12D) in a patient with metastatic castration-resistant prostate cancer. A Drug Master File was also accepted, facilitating reduced cycle time between completion CRC by tumor infiltrating lymphocyte ("TILs"); Tran demonstrated objective regression of preclinical studies all seven lung metastatic lesions from underlying CRC after the infusion of KRAS G12D-directed tumor infiltrating lymphocytes. More recently, small molecule inhibitors targeting mutated KRAS were developed and have showed promising results in clinical entry trials. However, those targeted therapies are limited to a single, specific KRAS mutation (KRAS G12C), which is frequently found in LUAD (approximately 50% of our pipeline projects. In February 2023, the late-stage cancers). However, KRAS G12C is underrepresented in PAAD and CRC when compared to other KRAS mutations such as G12D, G12V, G12R and G13D, which are much more frequently found (greater than 60% and greater than 90% in advanced CRC or PAAD, respectively). Hence, we opened believe that there is an urgent medical need to develop effective therapies for those patients.

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Pancreatic cancer is considered one of the most lethal malignancies. Overall, approximately 500,000 new cases of pancreatic cancer per year are recorded globally. Incidence, prevalence and mortality for pancreatic cancer has increased by more than 50% during the last 25 years. Pancreatic cancer accounts for 1.8% of all cancers but causes 4.6% of all cancer deaths and pancreatic cancer deaths are expected to double by the year 2060. The high mortality rate can be explained in part as pancreatic cancer typically remains silent, not causing signs or symptoms for a Phase 1/2 trial (NCT05553639) long time. When patients become symptomatic, the cancer has usually reached an advanced and incurable stage. According to the American Cancer Society, the overall 5-year survival rate for enrollment pancreatic cancer is approximately 9%. 97% of patients with metastatic castration-resistant prostate cancer. cancer (i.e., stage IV) are expected to die within 5 years after diagnosis. Additional effective therapies are therefore urgently needed.

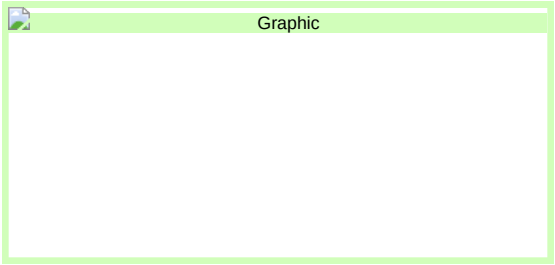
Colorectal cancer is the third most diagnosed malignancy worldwide and the second leading cause of cancer death. The incidence of colorectal cancer was estimated at 1.9 million cases in 2020, causing 0.9 million deaths worldwide. The incidence is higher in highly developed countries and it is increasing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

prospects of a cure. Although the prospect for colorectal cancer therapy is generally good, the increasing number of cases and rising incidence among younger generations still poses a heavy financial burden and a public health challenge.

Lung cancer is the most common cause of cancer death worldwide, with an estimated 1.6 million deaths annually. Approximately 85% of lung cancer patients suffer from a subgroup called non-small cell lung cancer ("NSCLC"), of which LUAD and lung squamous cell carcinoma are the most common subtypes. LUAD represents approximately 40% of NSCLC and is the most common primary lung cancer diagnosed in the United States. Despite new treatments, the 5-year survival rate is only 12% to 15%.

Our Solution: HB-700 for KRAS Mutated Cancers

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



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

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

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

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

The Collaboration Agreement was entered into to (i) grant Roche an exclusive license to research, develop, manufacture and commercialize our the Company's pre-clinical HB-700 cancer program, an arenaviral immunotherapeutic for KRAS-mutated cancers, and (ii) grant Roche an exclusive option right to exclusively license for research, development manufacturing and commercialization, a second, novel arenaviral immunotherapeutic program targeting undisclosed cancer antigens.

Pursuant to the Roche terms of the Collaboration Agreement and the Notice, the Collaboration Agreement will be terminated on April 25, 2024. The Company remains eligible for a final milestone payment associated with an IND submission. The Company plans to submit an IND to the FDA in April 2024. Effective April 25, 2024, the Company will regain full control of the associated intellectual property portfolio and will have full collaboration and licensing rights for the HB-700 program, and we received are evaluating a non-refundable upfront payment potential new partnership to advance HB-700. After the termination of $25.0 million the Collaboration Agreement, and except as disclosed above, there is no other material relationship between the Company and Roche.

HB-300 Program for Prostate Cancer

Targeting Self Antigens

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

Our HB-200 program targets viral antigens associated with tumors induced by HPV16. In these programs, the viral, or non self nature of the antigens, makes them a natural target for an immunotherapy approach. In addition, we are pursuing the development of product candidates based on our arenavirus platform to approximately $930 million target self antigens, nonviral antigenic proteins that are highly overexpressed in solid tumors or only minimally expressed in normal cells. Because self antigens are found in certain normal cells as well as tumor cells, the immune system does not typically recognize them as foreign proteins and does not respond to them. This protection of self antigens from immune system attack is known as immune tolerance. The results obtained by earlier generation marketed products such as sipuleucel T, developed as PROVENGE by Dendreon Pharmaceuticals, Inc., have proven that it is possible to overcome immune tolerance and activate the immune system to produce an antitumor response.

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Our Solution: HB 300 for Prostate Cancer

We are developing our most advanced self antigen candidate in this area, HB 300, based on our replicating technology in metastatic, hormone resistant prostate cancer. Prostate cancer provides a unique treatment opportunity for immunotherapy because prostate cancer cells express a number of tumor specific antigens that serve as potential future success-based milestone payments targets. HB-300 is an alternating, dual-vector replicating arenaviral immunotherapy which uses LCV and PCV as arenaviral backbones, with each expressing two well-defined antigens of prostate cancer, prostatic acid phosphatase (“PAP”) and prostate specific antigen. Subsequent clinical development may include addition of arenaviral therapeutics expressing a third antigen, prostate specific membrane antigen.

Direct evidence for both programs, plus tiered royalties. 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 and led to its approval in 2010. Other companies are developing dendritic cell therapies similar to PROVENGE by using other tumor antigens. These dendritic cell therapies generally require complex, patient-specific therapeutic manufacturing processes involving isolating cells from patients, loading them ex vivo with tumor antigens and then readministering the cells to patients.

Since HB-300 is a replicating-based product candidate, we can deliver it by simple infusion whereby it targets APCs, such as dendritic cells, without the need for cellular isolation or ex vivo processing. We have shown in preclinical experiments and in the HB-200 clinical program that replicating vectors can lead to robust CD8+ T cell responses to the encoded antigens.

In April 2022, we presented preclinical data at the American Association for Cancer Research Annual Meeting (abstract #3298 and abstract #4198) that showed antitumor activity with a single administration of replicating arenaviral immunotherapy targeting tumor self-antigens. Specifically, the arenaviral immunotherapy was able to overcome immune tolerance, induce potent T cell responses against two different tumor self-antigens and reduce tumor growth in these cancers. Notably, targeting tumor self-antigens can be a challenge because the immune system does not recognize these molecules as foreign. These preclinical data provided further support for the clinical evaluation of our HB-300 candidate for treatment of prostate cancer. The AACR data demonstrated the ability of our arenaviral immunotherapeutic

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technology to induce potent T cell responses against tissue-specific self-antigens, which is the same type of tumor self-antigens targeted by HB-300.

In July 2022, we announced that the FDA accepted our IND for HB-300 for the treatment of metastatic castration-resistant prostate cancer ("mCRPC"). A Drug Master File was also accepted, which we believe will facilitate reduced cycle time between completion of preclinical studies and clinical entry of our pipeline projects.

In February 2023, we opened a first-in-human Phase 1/2, multinational, multicenter, open-label study of HB-302/HB-301 alternating dual-vector therapy in participants with mCRPC. This study (NCT05553639) has 2 phases: a Phase 1 dose escalation with an RP2D confirmation and a Phase 2 dose expansion. The Phase 1 dose escalation will evaluate HB-302/HB-301 alternating dual-vector therapy for safety and tolerability, preliminary efficacy and immunogenicity, and determination of a RP2D. The Phase 2 dose expansion will assess HB-302/HB-301 alternating dual-vector therapy at the RP2D defined in the Phase 1 portion of the study. Based on lessons learned from the HB-200 program, HB-302/HB-301 Alternating dual-vector therapy will be administered intravenously every three weeks (Q3W) for the first five doses and every 6 weeks (Q6W) from the fifth dose and onward. HB-302 is to be administered first followed three or six weeks later by HB-301.

As of December 31, 2022 December 31, 2023, we have received from Roche the non-refundable upfront payment of $25.0 million. In the first quarter of 2023, we reported the achievement had completed enrollment of the first milestone event under Phase 1 dose escalation cohorts. The Study Safety Committee deemed that HB-300 was generally safe and well-tolerated in both dose escalation cohorts. Initial analysis of target antigen-specific T cell responses – using direct ELISPOT without pre-expansion of T cells – in ten patients between dose level 1 (N=5) and dose level 2 (N=5) indicated a 15- to 26-fold increase of target antigen specific T cells in 30% of patients (3/10).

In line with our previously announced strategy to prioritize the Roche agreement, triggering development of HB 200, we have terminated the Phase 1/2 study of HB-300 and will utilize the associated capital and resources for the advancement of our HB-200 program.

We will not proceed to the Phase 2 dose expansion component of this study, but we will keep the IND open to allow the potential for further development of this program in the future.

Next Generation Product Candidates

A critical advantage of our technology is that it is designed to deliver full length proteins directly to APCs, such as dendritic cells, for endogenous expression and direct presentation to CD8+ T cells. Having APCs, such as dendritic cells, express full-length proteins and present all fragments (epitopes) overcomes the major difficulty of attempting to predict which part of the protein, or epitope, will be presented by the patient's individual major histocompatibility complex ("MHC") class I alleles. This presentation is important in immunotherapy because T cells will only recognize and respond to the antigen when it is bound to the individual's MHC class I molecules, of which several hundred different versions exist in the population. While this approach overcomes the major issue faced by neoepitope-based personalized antigen approaches, it also has limitations in that the repertoire of known tumor-associated proteins that could be used for targets is limited. The best example of full-length proteins that are, to a milestone payment degree, cancer-specific and immunogenic include the cancer testis antigens, examples of $10.0 million. which include NYESO1, MAGE and CAGE. These cancer testis antigens have been known for decades, and many of them are currently being pursued by other companies. For many tumor types the cancer testis type of antigens remains unknown. Furthermore, most of the known tumor associated antigens are not commonly expressed or are not sufficiently specific to tumor tissue, making them suboptimal targets for clinical development.

Infectious Disease Pipeline Highlights Our Technology Platform

While our strategic priority Our proprietary platform is the development 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 our oncology portfolio, 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 that our platform is also uniquely positioned to provide value from represent the prophylactic and therapeutic use against infectious diseases. We plan to continue developing infectious disease therapies in partnership with other companies.

Our collaboration with Gilead to develop functional cures optimal characteristics for chronic HBV and HIV infections has become our main driver of our infectious disease pipeline progress. We entered into our collaboration and licensing agreement (the Gilead Collaboration Agreement) with Gilead in June 2018. To date, we have received $46.2 million in upfront and milestone payments and $40.9 million of cost reimbursements from Gilead. Both programs have completed preclinical research and are being progressed towards entry into Phase 1 clinical trials.

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

In February 2022, we signed an amended and restated collaboration agreement (the Restated Gilead Collaboration Agreement) which revised the terms only for the HIV program, whereby we will take on development responsibilities for the HIV program candidate through a Phase 1b clinical trial and Gilead will provide funding through a combination of an initiation payment of $15.0 million, a milestone payment of $5.0 million and equity contributions of up to $35.0 million. Gilead retains an exclusive right ("the Option") to take back the rights for the HIV program, including further research, development and commercialization. If Gilead elects to exercise the Option, we will be entitled to a $10.0 million program completion fee.

Our first product candidate, HB-101, through which we established proof of concept for our non-replicating arenaviral technology, is a potential vaccine for the prevention of CMV disease. CMV infection poses a considerable risk to infants in utero, as well as immune-compromised individuals, such as solid organ transplant recipients.

In our Phase 1 clinical trial, reviewed in the April 2020 issue of The Journal of Infectious Diseases, HB-101 was well-tolerated and elicited strong CMV-specific immune responses in all 42 of the treatment arm volunteers. antigen specific immunotherapy. Specifically, they:

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

Importantly, The arenavirus family is comprised of over 30 currently known species, many of which we observed robust CD8+ believe have potential prophylactic and CD4+ T cell responses, therapeutic applications. We believe we are the first to reengineer arenaviruses for the prevention and treatment of disease. We have created two types of viral technologies capable of delivering disease specific antigens: a replication defective vector, and a replication competent but attenuated vector.

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

Non-Replicating Technology Overview

Our proprietary non-replicating technology disables arenavirus replication by substituting one of its four structural genes with the gene for a desired antigen. The modified, non-replicating arenavirus is able to directly infect individual APCs, such as CMV-neutralizing antibody responses, without meaningful vector-neutralizing antibody responses. In our Phase 2 trial, we proceeded dendritic cells and deliver proteins that serve as antigens to assess safety, immunogenicity, activate the immune system but is not able to replicate and efficacy of HB-101 in individuals receiving a kidney transplant from live donors to measure the decrease of post-transplant viremia. In March 2023, we reported final data from our Phase 2 trial, showing that HB-101 induced CMV neutralizing antibodies after at least two doses at levels that were similar to those observed infect additional cells in the Phase 1 study. All patients who received three doses body.

Advantages of HB-101, Non-Replicating Technology

Based on the preclinical and for whom viable T cell assays were available, exhibited a CMV-specific T cell immune response. In clinical data that we have generated to date, we believe our non-replicating technology supports the efficacy analysis, a lower incidence benefits of CMV viremia was observed for patients who received three doses of HB-101 compared to patients who received three doses of placebo. The incidence of CMV infection, CMV disease, and the need for antiviral treatment post-transplant were not reduced for patients receiving only two doses of HB-101 compared to placebo. Overall, the small numbers and lower-than-expected incidence of CMV disease limit conclusion regarding efficacy.

In line with our strategy to focus on oncology programs and to pursue infectious disease programs only in partnerships, we decided to not further invest into the HB-101 program.

Leadership

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. The fundamental discoveries underlying our arenavirus platform originated with our co-founders, Nobel laureate Rolf Zinkernagel, M.D., approach. Specifically, in preclinical studies and Daniel Pinschewer, M.D., an internationally recognized arenavirus expert who serves as Scientific Advisor to our Chief Executive Officer.

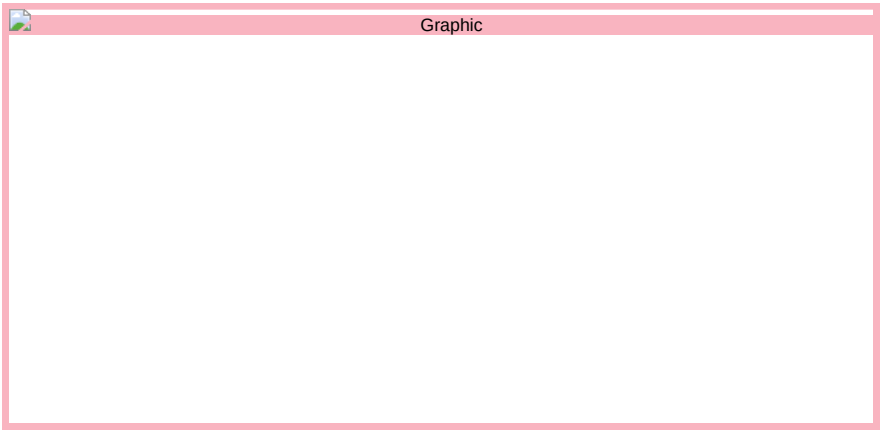
Our Pipeline

We are leveraging our modular arenavirus platform to develop clinical trials this technology has demonstrated that it is well tolerated and has the following product candidates additional benefits:

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

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

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



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Via Our proprietary replicating technology was designed to provide the beneficial properties of our non-replicating technology but to induce an even more robust immune response. Unlike naturally occurring arenaviruses which have two genomic segments, our replicating constructs were engineered to have three segments to allow for the introduction of genomic space in which to insert additional target antigens of choice. As a result of the larger genome, the virus' ability to replicate is reduced (attenuated).

Advantages of our Replicating Technology

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

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

Qualitatively: Immunological Memory and Protection Against Challenge. Our replicating technology has shown the ability to trigger a New York City-based bioinformatics company pioneering novel bioinformatic approaches, we are also pursuing the development of "off-the-shelf" long term CD8+ T cell response. Furthermore, in various animal models replicating immunization resulted in complete tumor remission after a single treatment and protection against a cancer therapies by identifying the next generation cancer testis antigens, which are tumor associated antigens that are generally not expressed in normal tissue.

Background

Immune System Function: Antigen Presentation by Dendritic and Other Antigen Presenting Cells re-challenge months after primary treatment.

The immune system is designed additional benefits noted above are attributable 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 our technology's ability to as epitopes.

The innate immune system is the body's first line of defense and enables a rapid, short-lived and nonspecific response. In contrast, the adaptive immune system utilizes highly specialized immune cells called lymphocytes that have been selected replicate. This allows it 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 infect not only APCs, such as dendritic cells.

Immunotherapy cells, but also lymphoid stromal cells, which are immune support cells found in lymph nodes and Current Limitations

The clinical application the spleen. Infection of immunotherapy lymphoid stromal cells results in the context release of managing infectious diseases a signaling protein which further drives the proliferation and cancers is distinctly different. The approach taken for infectious diseases is commonly that differentiation of "vaccination", whereby the aim is to prevent onset of disease by administering a derivative of the disease-causing agent to a healthy individual. In contrast, for cancer, the approach is typically one of therapeutic intervention in patients with active disease.

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

Lack of Robust CD8+ T cell Response. APCs, like Dendritic cells, are the most efficient antigen presenting cells of the body and the natural mechanism by which to induce a robust CD8+ T cell response to fight the disease. However, we do not believe there are any existing immunotherapies that have the ability to independently and directly deliver full length proteins to target and activate dendritic cells to present antigens directly to CD8+ T cells. This limitation prevents them from inducing a robust and durable mechanism has the potential to generate ten fold more antigen specific CD8+ T cell response. cells as compared to viral delivery systems that are unable to trigger this pathway. Furthermore, we believe our replicating technologies may also be synergistic with other approved immuno-oncology agents and currently are conducting a clinical trial of our replicating technology in combination with checkpoint inhibitors.

Presence In additional preclinical models, including a mouse melanoma model and a cancer testis self-antigen cancer model, we again demonstrated the ability of Virus Neutralizing Antibodies sequential administration of replicating PICV and Pre-Existing Immunity. Nearly all viral vectors used LCMV constructs to deliver antigens elicit neutralizing antibodies against both direct up to 50% of a body's T cells to focus on a single target of choice.

Advantages of sequential administration of replicating PICV and replicating LCMV

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

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population carries adenovirus 5 neutralizing antibodies

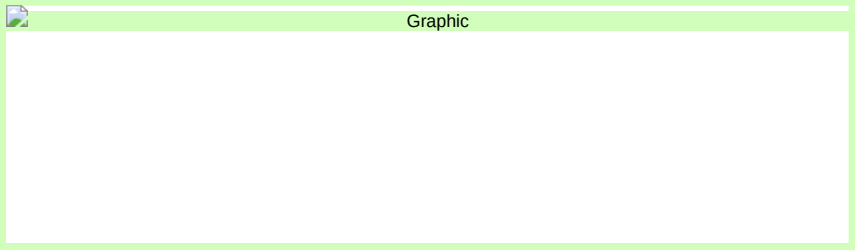

Figure: Bonilla, W. et al. Heterologous arenavirus vector prime-boost overrules self-tolerance for efficient tumor-specific CD8 T cell attack. journal.ppat. 100209. Cell Reports Medicine

Our Product Candidates

HB-200 Program for the Treatment of HPV16+ Cancers

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

All of our current product candidates are alternating, dual-vector arenaviral immunotherapies. HB-200 is a targeted dual vector arenaviral-based immunotherapy that uses alternating sequential injections of a LCMV vector and a PICV vector, both expressing the E7E6 fusion protein specific to HPV16+ cells. The two components of our HB-200 program are referred to as HB-201 (LCMV) and HB-202 (PICV).

HPV-Positive Cancers

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

HPV infection is linked to several cancer types, including HNSCC which can affect vector immunogenicity. Even is now the 8th most common cancer affecting men in the absence United States (Siegel et al. 2023). The high incidence rate of pre-existing immunity, if virus neutralizing antibodies HNSCC is largely due to a rising epidemic of oropharyngeal squamous cell carcinoma ("OPSCC") associated with HPV (Price & Cohen 2012). The median overall survival ("OS") for R/M HNSCC remains less than 15 months despite modern chemotherapy,

targeted agents, and recent immunotherapy. The high-risk genotype HPV 16 accounts for 88% of HPV+ OPSCC cases in the United States (Chaturvedi et al. 2011) and for more than 50% of HPV+ cases found in other head and neck anatomical locations (Abogunrin et al. 2014; Vokes et al. 2015). In 2023, an estimated 54,540 new cases of head and neck cancers were diagnosed in the United States alone, with anticipated deaths estimated at 11,580 (Siegel et al. 2023).

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

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Our Solution: HB-200 Program

HB-200 alternates the administration of both HB-201 (LCMV) and HB-202 (PICV) attenuated viral vectors, which on their own are replicating-based therapeutics expressing a non-oncogenic, but highly antigenic, E7E6 fusion protein from HPV16. We have observed strong immunogenicity and robust antitumor activity in mouse models for LCMV alone as well as for the sequential administration of LCMV and PICV.

Relevance of E6 and E7 as Tumor Antigens

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

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

HB-200 Clinical Trial

HB-200 is being evaluated in an ongoing Phase 1/2 clinical trial for the treatment of HPV16+ cancers.

This trial is currently enrolling participants in Phase 2, evaluating HB-200 therapy in combination with pembrolizumab in the first line setting of HPV16+ PD-L1+ oropharynx cancer.

Previously, the trial has, in multiple arms, explored several dose levels and administration regimens across multiple HPV16+ cancer indications. The Company has published interim data readouts at key scientific conferences dating back to 2021. Interim data readouts from 2021 to 2022 have shaped further the study design and protocol.

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

- Phase 1 evaluation of HB-200 as a monotherapy in second or later-line R/M setting of HPV16+ cancers and
- Phase 2 evaluation of HB-200 in combination with pembrolizumab in the first line R/M setting of HPV16+ OPSCC.

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

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

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

therapy, especially 29 patients with HPV16+ HNSCC treated with HB-200 alternating 2-vector therapy at the RP2D (DL3) or one dose lower than the RP2D (RP2D-1, DL2).

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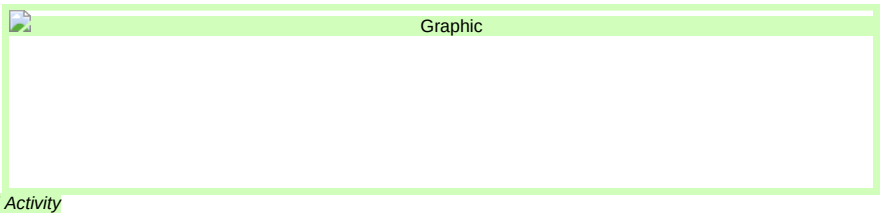
Safety and Tolerability

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



Clinical Activity

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

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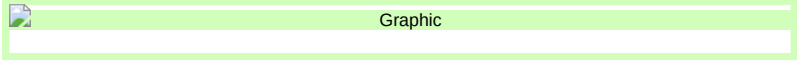

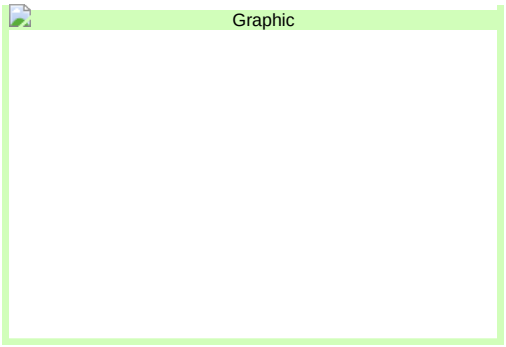

Biomarker and Translational Results

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

- Up to 48% of all CD8+ T cells in blood were specific for the tumor antigen (i.e., HPV16 E6 & E7), with a median specificity of 2.0% (Figure 2A).
- Figure 2C illustrates one representative patient with HNSCC (Patient #1) from DL3 cohort with tumor-specific CD8+ T cell responses measured by ICS, E6-E7–specific IFN-γ+ CD8+ T cells increasing from 0% at baseline to 10% after 2 doses of HB-200.

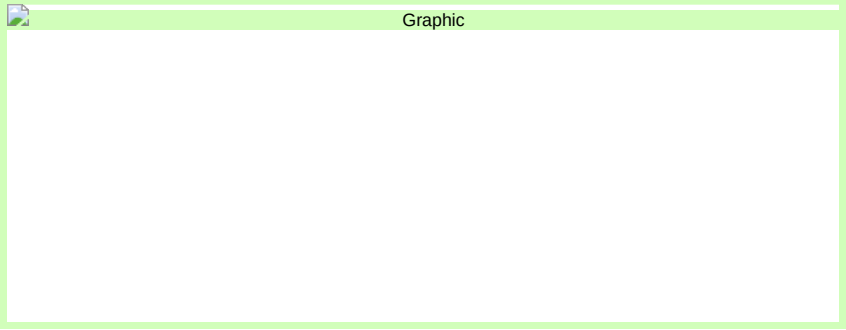

Figure 2. HPV16 E6-E7–specific T cell responses in HNSCC patients treated with HB-200 alternating 2-vector therapy.

A. Baseline and peak IFN-γ+ HPV16 E6-E7 T cell response measured by ICS. Peak responses were typically observed post 2 doses of HB-200 (N = 35/41 HNSCC patients receiving HB-200 alternating 2-vector therapy across DL1-4).

B. Box plots are representing IFN-γ+ HPV16 E6-E7 T cell response measured by ICS per DL (N = 35/41). Box and whiskers represent minimum, maximum and median. DL1 = PICV 1×106, LCMV 5×106 RCV FFU; DL2 (RP2D-1) = PICV 1×107, LCMV

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5×106 RCV FFU; DL3 (RP2D) = PICV 1×107, LCMV 5×107 RCV FFU; DL4 = PICV 1×108, LCMV 5×106 RCV FFU. Patients from DL2 & DL3 with available PBMC samples are highlighted (N = 26/29)

C. Representative pseudo-color plots (Patient #1) with the frequencies of double-positive IFN-γ+ TNF-α+ cells gated on CD8+ T cells at baseline and post 2 doses of HB-200.

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

- Results showed rapid induction of tumor-specific T cells, sustained for more than 8 months and increasing in polyfunctionality during treatment (Figure 3A).

- Patients with increased CD8+ T cell influx in tumors during HB-200 treatment tended to show clinical benefit (stable disease vs. progressive disease) (Figure 3B).

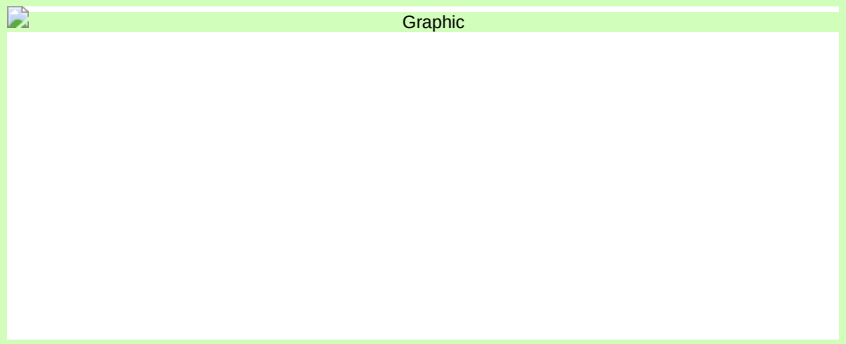

Figure 3.

A. Median of circulating E6-E7–specific T cells over time measured by ELISpot (solid line shows median SFU/1 x 106 PBMCs and dashed lines indicate Patient #1 and #2 in the case report in Figure 4). Pie charts below graph show percentage of tumor-specific T cells expressing the indicated number of cytokines/markers (IFN-γ, TNF-a, CD107a, IL-2) measured by ICS in available PBMCs from HNSCC patients undergoing HB-202/HB-201 alternating 2-vector therapy at DL2 & DL3 at the corresponding timepoints (N = 26/29).

B. Percent change in tumor-infiltrating CD8+ T cells pre and post HB-200 treatment in patients with disease control (blue) and progressive disease (red) measured by IF IHC. Mean ± SD. Data shown are all patients with available paired biopsies, which includes patients from all groups explored in the study (N = 13 out of 93 total patients enrolled in Phase 1).

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

- Tumor-specific T cell responses were induced rapidly and remained at high levels throughout therapy in these 2 patients (Figure 3A), both of whom also exhibited clinical benefit (stable disease / disease control) (Figure 4A).

- In these patients, HB-200 therapy induced high levels of tumor-specific CD8+ T cells in the circulation (Figure 2A and 3A), as well as elevated CD8+ T cell numbers in tumors (Figure 3B & 4C).

- The patients with disease control exhibited only small increases or modest reductions in ctDNA levels (Figure 4B), with respective best percent change in target lesions -29% (pt #1) and -11% (pt #2) (Figure 1).

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Figure 4. Tumor response, HPV16 ctDNA, and TILs in 2 patients with stable disease who received HB-200 alternating 2-vector therapy.

A. Percent change in sum of target lesion diameters from baseline over time in Patient #1 and #2.

B. Percent change in circulating HPV16 DNA from baseline in Patient #1 and #2.

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

Clinical Results: HB-200 in Combination with Pembrolizumab in the First Line Setting

In October 2023, we presented updated Phase 2 data for HB-200 in combination with pembrolizumab in the first line setting at the ESMO annual congress (Abstract 2212) for the first 20 patients treated with HB-200 and pembrolizumab in the first-line setting (data cut-off August 7, 2023). The efficacy evaluable data set (≥1 tumor scan post-treatment) consisted of 19 patients, as one patient discontinued prior to tumor scans due to COVID-related death. Baseline characteristics are highlighted in the table below.

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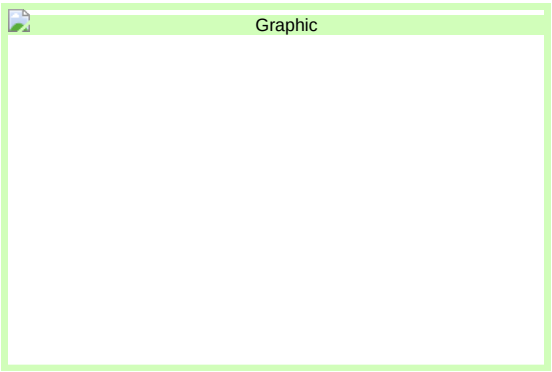
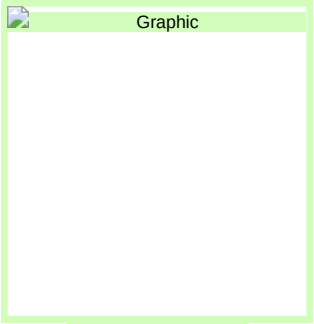


Safety and Tolerability

The data showed that HB-200 and pembrolizumab was generally well tolerated among the 20 patients treated. The majority of reported AEs were mild to moderate with the most common AEs being flu-like symptoms. Two patients (10%) reported serious adverse events related to

the treatment with HB-200 or pembrolizumab. Only one patient (5%) discontinued due to a treatment-related adverse event of checkpoint inhibitor pneumonitis (related to pembrolizumab). The updated safety data adds to the previously reported safety and tolerability data from patients across all arms of the trial who received HB-200 monotherapy or HB-200 in combination with pembrolizumab. This generally favorable tolerability profile highlights the potential of HB-200 – and arenaviral immunotherapies in general – to be successfully combined with other immunotherapies where tumor antigen-specific T cell induction is of potential benefit.



Presented at ESMO 2023

Clinical Activity

The preliminary data showed a 42% confirmed objective response rate ("ORR") and disease control rate ("DCR") of 74% across 19 evaluable patients, doubling the historical 19% ORR for pembrolizumab alone. Best overall response for the evaluable population included one patient with a confirmed complete response, seven patients with confirmed partial responses, and six patients with stable disease. The preliminary data showed sustained disease control in the majority of patients. All efficacy-evaluable patients were alive at the data cutoff (August 7, 2023), and the median follow-up time at DCO was 8.3 months. Median overall survival and progression-free survival data are still maturing.

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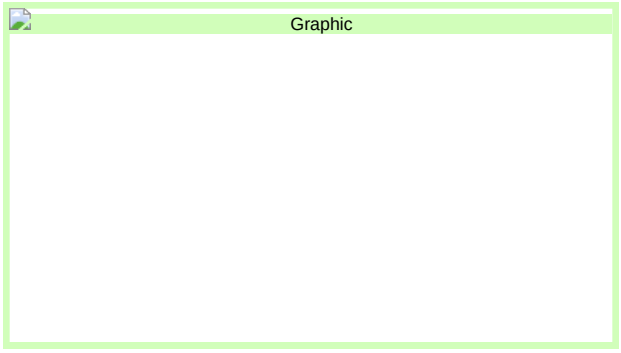

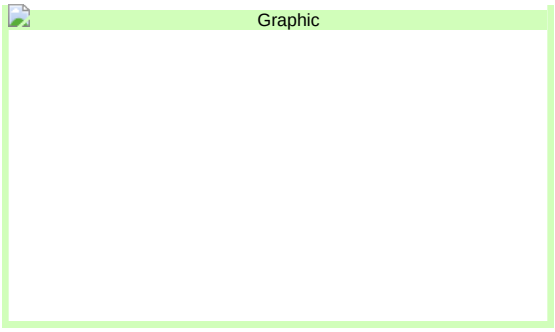

Biomarker and Translational Results

Importantly, the data showed significant activation of antigen-specific CD8+ T cells, the body's primary driver of tumor killing activity. Out of 17 patients with available peripheral blood mononuclear cells ("PMBC") samples, all patients showed an increase of tumor antigen-specific circulating HPV16+ CD8+ T cells. Peak percentage of antigen-specific circulating HPV16+ CD8+ T cells reached up to 31 percent with a median of 3.36%. Max response on treatment vs. before treatment of systemic HPV-16 E7 and E6 specific T cells measured by ELISPOT showed that the median fold-increase for these patients' total tumor specific T cells was a 451-fold increase over baseline, with the maximal increase of 4,000-fold.

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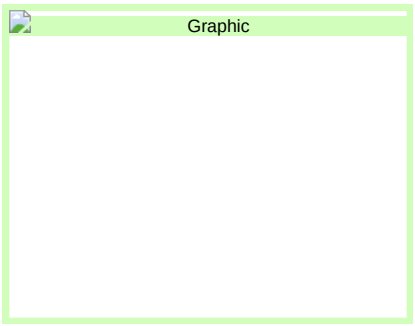

Based on the data generated in our clinical trials, we believe that HB-200, in combination with standard of care pembrolizumab, has the potential to improve treatment outcomes in persons diagnosed with HPV16+ PD-L1+ R/M OPSCC, and has the potential to be used in the first line setting. We believe that success in developing HB-200 into an effective therapy for HPV16+ OPSCC would suggest the potential of HB-200 to be an effective therapy in all HPV16+ cancers, regardless of the cancer's tissue of origin.

The totality of the data from our clinical trials of HB-200, both as a monotherapy and in combination with pembrolizumab, give us conviction to proceed with a randomized Phase 2/3 trial to evaluate HB-200 in combination with pembrolizumab in the first line setting for patients with HPV16+ OPSCC. We plan to begin the randomized Phase 2/3 trial in 2024.

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

Targeting Shared Neoantigens

KRAS is a gene that acts as an on/off switch for cell growth as it is a key regulator of cell proliferation and survival. When there is a mutation, or error, in the gene, cells can grow out of control. KRAS is one of the most frequently mutated proto-oncogenes with respective mutations found in approximately 30% of all human cancers. KRAS mutations are most frequently found in pancreatic cancer (85% to 90%), colorectal cancer (approximately 40%) and lung cancer (approximately 32%). However, the spectrum of mutations mainly target amino acid position 12 (G12D, G12V, G12R, and G12C) and position 13 (G13D), rendering these mutations an attractive target for immunotherapy. We

plan to develop our KRAS targeted therapy for patients suffering from pancreatic adenocarcinoma (“PAAD”), colorectal cancer (“CRC”) and lung adenocarcinoma (“LUAD”) and carrying one or more of the five most prevalent G12D, G12V, G12R, and G12C and position 13 G13D mutations. Our arenavirus technology enables us to integrate all five mutations into one single-vector, which allows our product to potentially be a single therapeutic targeting multiple large cancer indications.

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

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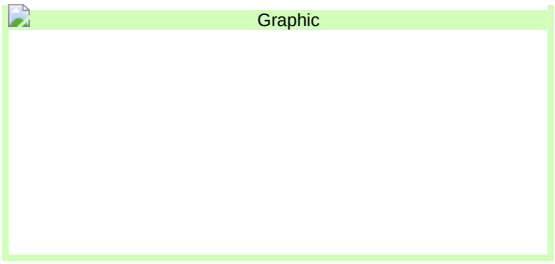
Pancreatic cancer is considered one of the most lethal malignancies. Overall, approximately 500,000 new cases of pancreatic cancer per year are recorded globally. Incidence, prevalence and mortality for pancreatic cancer has increased by more than 50% during the last 25 years. Pancreatic cancer accounts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

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

Lung cancer is the most common cause of cancer death worldwide, with an estimated 1.6 million deaths annually. Approximately 85% of lung cancer patients suffer from a subgroup called non-small cell lung cancer (“NSCLC”), of which LUAD and lung squamous cell carcinoma are the most common subtypes. LUAD represents approximately 40% of NSCLC and is the most common primary lung cancer diagnosed in the United States. Despite new treatments, the 5-year survival rate is only 12% to 15%.

Our Solution: HB-700 for KRAS Mutated Cancers

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



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

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

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

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

The Collaboration Agreement was entered into to (i) grant Roche an exclusive license to research, develop, manufacture and commercialize the Company's pre-clinical HB-700 cancer program, an arenaviral immunotherapeutic for KRAS-mutated cancers, and (ii) grant Roche an option right to exclusively license for research, development manufacturing and commercialization, a second, novel arenaviral immunotherapeutic program targeting undisclosed cancer antigens.

Pursuant to the terms of the Collaboration Agreement and the Notice, the Collaboration Agreement will be terminated on April 25, 2024. The Company remains eligible for a final milestone payment associated with an IND submission. The Company plans to submit an IND to the FDA in April 2024. Effective April 25, 2024, the Company will regain full control of the associated intellectual property portfolio and will have full collaboration and licensing rights for the HB-700 program, and we are evaluating a potential new partnership to advance HB-700. After the termination of the Collaboration Agreement, and except as disclosed above, there is no other material relationship between the Company and Roche.

HB-300 Program for Prostate Cancer

Targeting Self Antigens

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

Our HB-200 program targets viral antigens associated with tumors induced by HPV16. In these programs, the viral, or non self nature of the antigens, makes them a natural target for an immunotherapy approach. In addition, we are pursuing the development of product candidates based on our arenavirus platform to target self antigens, nonviral antigenic proteins that are highly overexpressed in solid tumors or

only minimally expressed in normal cells. Because self antigens are found in certain normal cells as well as tumor cells, the immune system does not typically recognize them as foreign proteins and does not respond to them. This protection of self antigens from immune system attack is known as immune tolerance. The results obtained by earlier generation marketed products such as sipuleucel T, developed as PROVENGE by Dendreon Pharmaceuticals, Inc., have proven that it is possible to overcome immune tolerance and activate the immune system to produce an antitumor response.

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Our Solution: HB 300 for Prostate Cancer

We are developing our most advanced self antigen candidate in this area, HB 300, based on our replicating technology in metastatic, hormone resistant prostate cancer. Prostate cancer provides a unique treatment opportunity for immunotherapy because prostate cancer cells express a number of tumor specific antigens that serve as potential targets. HB-300 is an alternating, dual-vector replicating arenaviral immunotherapy which uses LCV and PCV as arenaviral backbones, with each expressing two well-defined antigens of prostate cancer, prostatic acid phosphatase ("PAP") and prostate specific antigen. Subsequent clinical development may include addition of arenaviral therapeutics expressing a third antigen, prostate specific membrane antigen.

Direct evidence for the ability to induce a therapeutically relevant immune response to immunization, 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 and led to its approval in 2010. Other companies are developing dendritic cell therapies similar to PROVENGE by using other tumor antigens. These dendritic cell therapies generally require complex, patient-specific therapeutic manufacturing processes involving isolating cells from patients, loading them ex vivo with tumor antigens and then readministering the cells to patients.

Since HB-300 is a replicating-based product candidate, we can deliver it by simple infusion whereby it targets APCs, such as dendritic cells, without the need for cellular isolation or ex vivo processing. We have shown in preclinical experiments and in the HB-200 clinical program that replicating vectors can lead to robust CD8+ T cell responses to the encoded antigens.

In April 2022, we presented preclinical data at the American Association for Cancer Research Annual Meeting (abstract #3298 and abstract #4198) that showed antitumor activity with a single administration of replicating arenaviral immunotherapy targeting tumor self-antigens. Specifically, the arenaviral immunotherapy was able to overcome immune tolerance, induce potent T cell responses against two different tumor self-antigens and reduce tumor growth in these cancers. Notably, targeting tumor self-antigens can be a challenge because the

immune system does not recognize these molecules as foreign. These preclinical data provided further support for the clinical evaluation of our HB-300 candidate for treatment of prostate cancer. The AACR data demonstrated the ability of our arenaviral immunotherapeutic

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technology to induce potent T cell responses against tissue-specific self-antigens, which is the case same type of tumor self-antigens targeted by HB-300.

In July 2022, we announced that the FDA accepted our IND for HB-300 for the treatment of metastatic castration-resistant prostate cancer ("mCRPC"). A Drug Master File was also accepted, which we believe will facilitate reduced cycle time between completion of preclinical studies and clinical entry of our pipeline projects.

In February 2023, we opened a first-in-human Phase 1/2, multinational, multicenter, open-label study of HB-302/HB-301 alternating dual-vector therapy in participants with recombinant adenovirus mCRPC. This study (NCT05553639) has 2 phases: a Phase 1 dose escalation with an RP2D confirmation and a Phase 2 dose expansion. The Phase 1 dose escalation will evaluate HB-302/HB-301 alternating dual-vector therapy for safety and tolerability, preliminary efficacy and immunogenicity, and determination of a RP2D. The Phase 2 dose expansion will assess HB-302/HB-301 alternating dual-vector therapy at the RP2D defined in the Phase 1 portion of the study. Based on lessons learned from the HB-200 program, HB-302/HB-301 Alternating dual-vector therapy will be administered intravenously every three weeks (Q3W) for the first five doses and every 6 weeks (Q6W) from the fifth dose and onward. HB-302 is to be administered first followed three or poxvirus based vaccines, repeat doses administered six weeks later by HB-301.

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

In line with our previously announced strategy to prioritize the development of HB 200, we have terminated the Phase 1/2 study of HB-300 and will utilize the associated capital and resources for the advancement of our HB-200 program. We will not proceed to the patient may also be rendered ineffective or impractical. Phase 2 dose expansion component of this study, but we will keep the IND open to allow the potential for further development of this program in the future.

Safety and Toxicity Concerns. **Some immunotherapies, such as engineered T cells (CAR-T and TCR-T), use artificial constructs Next Generation Product Candidates**

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

Handling decades, 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 them are currently being pursued by other companies. For many tumor types the limitations that exist with current approaches. 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.

Our Technology Platform

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

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

The arenavirus family is comprised of over 30 currently known species, many of which we believe have potential prophylactic and therapeutic applications. We believe we are the first to reengineer arenaviruses for the prevention and treatment of disease. We have created two types of viral technologies capable of delivering disease specific antigens: a replication defective vector, and a replication competent but attenuated vector.

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Our non-replicating and replicating technologies utilize both LCMV a Lymphocytic Choriomeningitis Virus (“LCMV”) and PICV, a Pichinde Virus (“PICV”), two of over 30 species of arenaviruses, as a backbone of the product candidates we are developing. LCMV is principally carried and secreted by wild mice, with human infection being secondary to such exposure and uncommon. Approximately 2% to 5% of individuals in industrialized countries have circulating antibodies against LCMV, which indicates prior exposure in these individuals.

Individuals infected with LCMV typically remain asymptomatic or may present with a nonspecific and self-resolving flu-like illness. PICV is principally carried and secreted by Colombian rice rats (*oryzomys albigularis*) (oryzomys albigularis) and is a nonpathogenic virus that does not cause disease in humans.

Non-Replicating Technology Overview

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

Advantages of Non-Replicating Technology

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

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

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

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

Replicating Technology Overview

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Our proprietary replicating technology was designed to provide the beneficial properties of our non-replicating technology but to induce an even more robust immune response. Unlike naturally occurring arenaviruses which have two genomic segments, our replicating constructs were engineered to have three segments to allow for the introduction of genomic space in which to insert additional target antigens of choice. As a result of the larger genome, the virus' ability to replicate is reduced (attenuated).

Advantages of our Replicating Technology

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

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

Qualitatively: Immunological Memory and Protection Against Challenge. Our replicating technology has shown the ability to trigger a long term CD8+ T cell response. Furthermore, in various animal models

replicating immunization resulted in complete tumor remission after a single treatment and protection against a cancer re-challenge months after primary treatment.

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

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

Non-Replicating Preclinical Data

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

HIV Model

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

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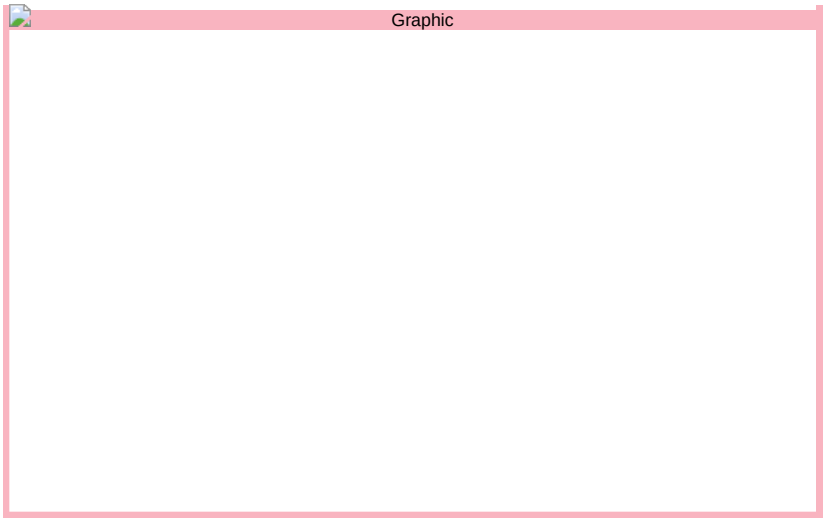

Figure: Flatz, L. et al. Gene-based vaccination with a mismatched envelope protects against simian immunodeficiency virus infection in nonhuman primates; https://pubmed.ncbi.nlm.nih.gov/22593152/

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* **A p-value of 0.05 or less represents statistical significance, meaning that there is a less than 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.**

Hepatitis B Virus Model

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

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

Replicating Vector Preclinical Data

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

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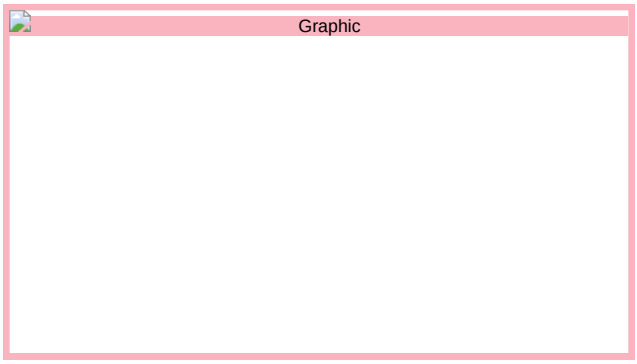
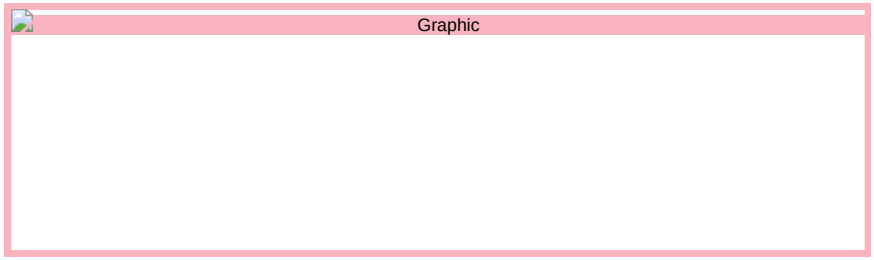
approximately half of the mice, by the same definition, while IT administration of replicating PICV significantly suppressed and delayed tumor growth (bottom left panel). These mice had complete remission without recurrence for at least six months, which represents over 25% of a mouse's lifetime (right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

activity. In these studies, we also observed resistance to a tumor re-challenge after six months (right panel).



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



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

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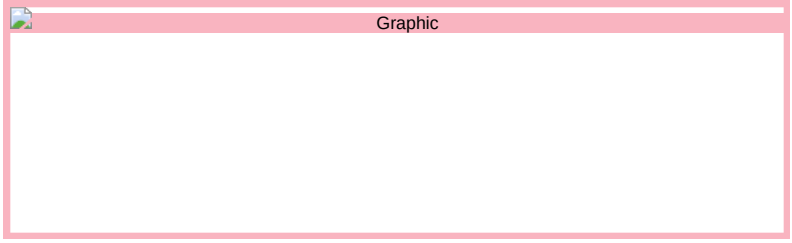
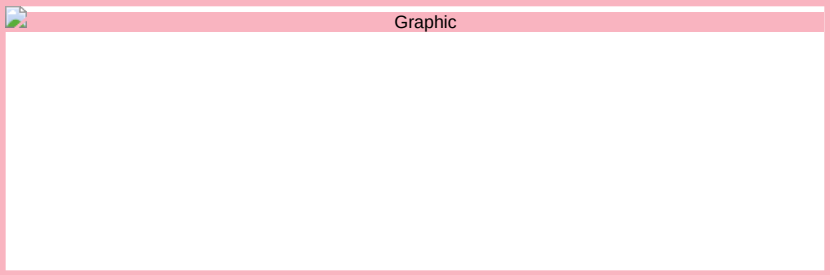
leading to a significant delay in disease progression. Similarly, in subcutaneously growing B16F10 tumors treated intravenously, histopathology showed clear evidence of strong CD8+ T cell infiltration.



When we combined the above two experiments, by initially introducing B16F10 malignant cells subcutaneously, and then intravenously, we achieved both a localized subcutaneous tumor and metastatic lung lesions. Subsequent administration of our intratumoral

replicating vector demonstrated both a localized response, through subcutaneous tumor shrinkage, and systemic response, through clearance of lung metastases. The long-term survivor mice were then rechallenged with B16F10 several months after remission with no observed subsequent tumor regrowth.



Advantages of sequential administration of replicating PICV and replicating LCMV

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

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

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Graphic

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

Our Product Candidates

HB-200 Program for the Treatment of HPV16+ Cancers

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

HB-201 All of our current product candidates are alternating, dual-vector arenaviral immunotherapies. HB-200 is a replicating LCMV-based product candidate targeted dual vector arenaviral-based immunotherapy that uses alternating sequential injections of a LCMV vector and a PICV vector, both expressing the E7E6 fusion protein specific to HPV16+ cells cells. The two components of our HB-200 program are referred to as HB-201 (LCMV) and being developed for the treatment of HPV16+ cancers, including head and neck squamous cell carcinoma (HNSCC), cervical and anal cancers. HB-201 is being evaluated as both monotherapy and in combination with a checkpoint inhibitor.

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

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

- **HB-201 single-vector therapy**: sequential injections of HB-201 (E7E6 fusion protein derived from HPV16 encoded in an LCMV vector);
- **HB-202/HB-201 dual-vector therapy**: alternating sequential injections of HB-201 and HB-202 (the same E7E6 fusion protein encoded in a PICV vector).

HPV-Positive Cancers

HPV is estimated to cause about 5% of cancers worldwide, including approximately 99% of cervical cancers, up to 60% of HNSCC, 70% of vaginal cancers and 88% of anal cancers, the majority of which are caused by the HPV serotype 16. cancers. While most infections with HPV are cleared from the body with no lasting consequences, in some cases, HPV DNA becomes integrated into chromosomal DNA. When host cells take up this DNA, they express the HPV E6 and E7 proteins. The expression of these proteins can lead to alterations in cell cycle control, which in turn predisposes these cells to become cancerous.

While HPV infection is linked to several cancer types, including HNSCC which is now the rates of HNSCC from causes such as smoking and alcohol are decreasing, the rates of HPV16+ HNSCC are increasing. HNSCC is the sixth 8th most common form of cancer. Each year, HNSCC is diagnosed in more than 600,000 people worldwide, with 65,000 new cases and more than 14,500 deaths occurring cancer affecting men in the United States alone.

Table (Siegel et al. 2023). The high incidence rate of Contents

HNSCC includes tumors of the oral cavity, oropharynx, larynx and hypopharynx. The current standard of care for HNSCC is the same regardless largely due to a rising epidemic of HPV status. Treatment typically involves immunotherapy, chemotherapy, radiation and surgery, the precise regimen varying based on the Stage of cancer and responses to prior therapies. These treatments are oropharyngeal squamous cell carcinoma ("OPSCC") associated with acute and long-term effects including mucositis, swallowing dysfunction, dry mouth, and dental problems. HPV (Price & Cohen 2012). The median overall survival time ("OS") for patients with advanced metastatic R/M HNSCC progressing on platinum and checkpoint-based therapies is remains less than six months. 15 months despite modern chemotherapy, targeted agents, and recent immunotherapy. The high-risk genotype HPV 16 accounts for 88% of HPV+ OPSCC cases in the United States (Chaturvedi et al. 2011) and for more than 50% of HPV+ cases found in other head and neck anatomical locations (Abogunrin et al. 2014; Vokes et al. 2015). In 2023, an estimated 54,540 new cases of head and neck cancers were diagnosed in the United States alone, with anticipated deaths estimated at 11,580 (Siegel et al. 2023).

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

We believe that 12

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Our Solution: HB-200 has potential to provide beneficial treatment to persons with HPV16+ HNSCC, in Program

HB-200 alternates the post-standard administration of care therapy or in combination with pembrolizumab in earlier line (e.g., 1st line or 2nd line) therapy. We believe that success in developing an effective therapy for HPV16+ 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 both HB-201 (LCMV) and HB-202 (PICV) attenuated viral vectors, which on their own are replicating based product candidates replicating-based therapeutics expressing a non-oncogenic, but highly antigenic, E7E6 fusion protein from HPV16. In animal models, HB-201 was observed to be highly immunogenic, resulting in a robust CD8+ T cell response. Based on the levels of antigen-specific CD8+ T cells induced by HB-201 in preclinical models, notably when compared to therapeutic levels induced by other published approaches including adoptive cell therapies, as observed in separately designed and conducted third-party clinical trials, we believe that HB-201 single-vector therapy has the potential to provide therapeutic benefit to patients across the broader HPV16+ cancer setting. We have observed strong immunogenicity and robust antitumor activity in mouse models for HB-201 LCMV alone as well as for the sequential administration of HB-201 LCMV and HB-202. PICV.

Relevance of E6 and E7 as Tumor Antigens

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

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

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 100mm3. In both cases, as depicted in the figures below, single doses of HB-201 led to suppression of tumor growth in a statistically significant manner ($p < 0.05$) in all treated mice, and intratumoral administrations resulted in an approximately 40% long-term survival rate. When these long-term survivor mice were rechallenged with the same tumor six months later, no new tumor growth was detected. We believe that these results demonstrate the potential for HB-201 to be active both in treating primary tumors and also controlling metastatic and recurring disease.

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

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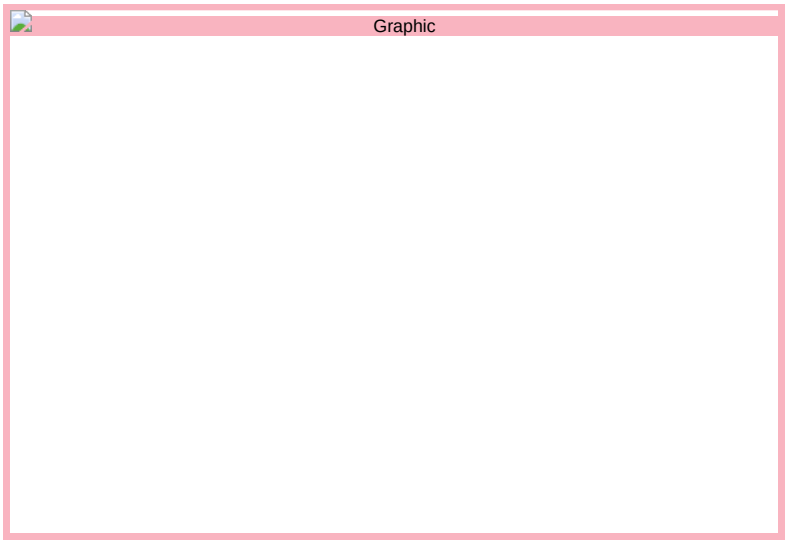
was already achieved at the lower of those three doses, or 10,000 RCV particles per dose. All doses of HB-201 were well tolerated in this model.



HB-202 Preclinical Studies

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

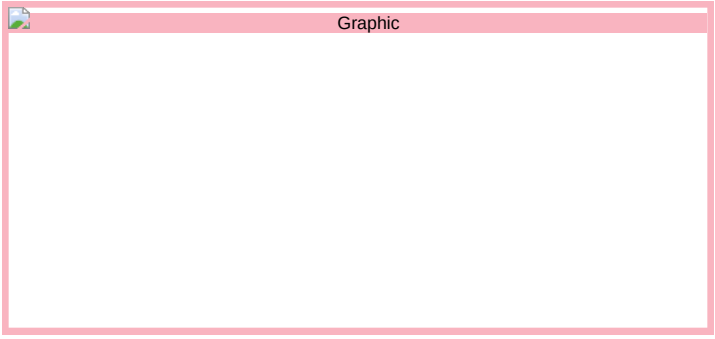


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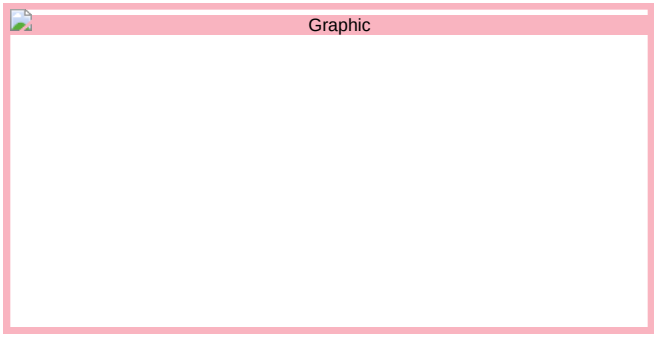
Figure: Bonilla, W. et al. Heterologous arenavirus vector prime-boost overrules self-tolerance for efficient tumor-specific CD8 T cell attack. journal.ppat. 100209. Cell Reports Medicine



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

Combination with Other Immunotherapy Modalities

In April 2022, we presented data at the American Association for Cancer Research (AACR) Annual Meeting expanding our preclinical combination data. Specifically, preclinical data accepted for poster presentation (abstract #4198) demonstrated that the combination of co-stimulatory 4-1BB agonists with arenaviral immunotherapy increased tumor control and resulted in a higher cure rate than arenaviral immunotherapy alone. Co-stimulatory agents, like 4-1BB agonists, are known as accelerators of cancer immunotherapy, because they help induce potent, tumor-specific T cells that can infiltrate and kill tumors. The combination of an arenaviral immunotherapy with a 4-1BB agonistic antibody resulted in complete tumor rejection in 30 % of mice following treatment. Importantly, improved tumor control and cure rates of up to 50 % were also observed with a 4-1BB ligand which was integrated into the arenaviral vector.

A separate preclinical analysis presented at AACR (abstract #3298) offered additional evidence of potential combination with other modalities. In this analysis, replicating arenaviral immunotherapy was sequentially combined with adoptively transferred TCR transgenic T cells, which resulted in tumor cures in all mice receiving combination therapy, with 100 % survival at the end of the experiment (60 days after administration). These data highlight the potential of arenaviral immunotherapies in combination with other treatment modalities beyond PD-1 inhibitors, as well as showcase the versatility of the platform as a potential backbone for various combination immunotherapies.

HB-200 Clinical Trial

Our oncology product candidates, HB-201 and HB-202, are HB-200 is being evaluated in an ongoing Phase 1/2 clinical trial for the treatment of HPV16+ cancers.

This trial is currently enrolling participants in Phase 2, evaluating HB-200 therapy in combination with pembrolizumab in the first line setting of HPV16+ PD-L1+ oropharynx cancer.

Previously, the trial has, in multiple arms, explored several dose levels and administration regimens across multiple HPV16+ cancer indications. The Company has published interim data readouts at key scientific conferences dating back to 2021. Interim data readouts from 2021 to 2022 have shaped further the study design and protocol.

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

- Phase 1 evaluation of HB-200 as a monotherapy in second or later-line R/M setting of HPV16+ cancers and
- Phase 2 evaluation of HB-200 in combination with pembrolizumab in the first line R/M setting of HPV16+ OPSCC.

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

In December 2019, November 2023, we opened the HB-200 Phase 1/2 trial, investigating both presented updated Phase 1 monotherapy data for HB-200 in the second or later-line R/M setting of HPV16+ cancer at the Society for Immunotherapy of Cancer annual congress (Abstract #679).

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

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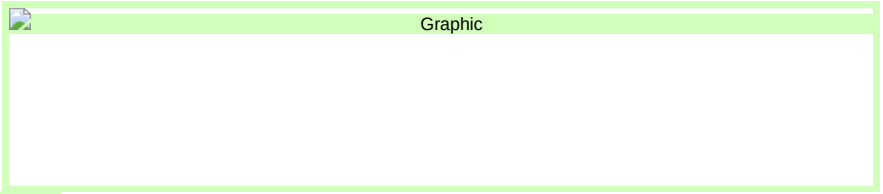
Safety and Tolerability

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



Clinical Activity

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

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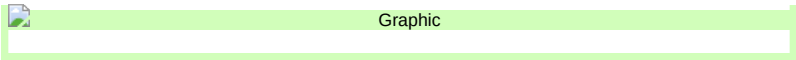

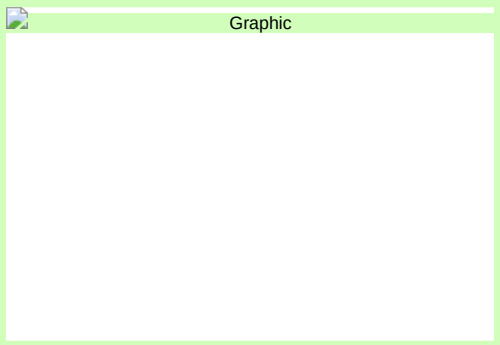

Biomarker and Translational Results

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

- Up to 48% of all CD8+ T cells in blood were specific for the tumor antigen (i.e., HPV16 E6 & E7), with a median specificity of 2.0% (Figure 2A).
- Figure 2C illustrates one representative patient with HNSCC (Patient #1) from DL3 cohort with tumor-specific CD8+ T cell responses measured by ICS, E6-E7–specific IFN-γ+ CD8+ T cells increasing from 0% at baseline to 10% after 2 doses of HB-200.

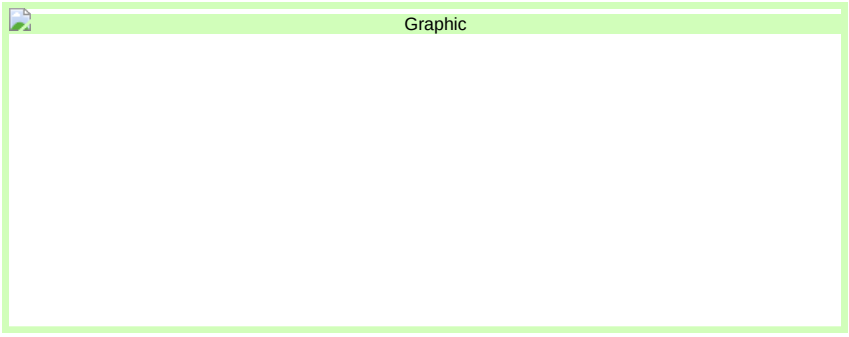

Figure 2. HPV16 E6-E7–specific T cell responses in HNSCC patients treated with HB-200 alternating 2-vector therapy.

A. Baseline and peak IFN-γ+ HPV16 E6-E7 T cell response measured by ICS. Peak responses were typically observed post 2 doses of HB-200 (N = 35/41 HNSCC patients receiving HB-200 alternating 2-vector therapy across DL1-4).

B. Box plots are representing IFN-γ+ HPV16 E6-E7 T cell response measured by ICS per DL (N = 35/41). Box and whiskers represent minimum, maximum and median. DL1 = PICV 1×106, LCMV 5×106 RCV FFU; DL2 (RP2D-1) = PICV 1×107, LCMV

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5×106 RCV FFU; DL3 (RP2D) = PICV 1×107, LCMV 5×107 RCV FFU; DL4 = PICV 1×108, LCMV 5×106 RCV FFU. Patients from DL2 & DL3 with available PBMC samples are highlighted (N = 26/29)

C. Representative pseudo-color plots (Patient #1) with the frequencies of double-positive IFN-γ+ TNF-α+ cells gated on CD8+ T cells at baseline and post 2 doses of HB-200.

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

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

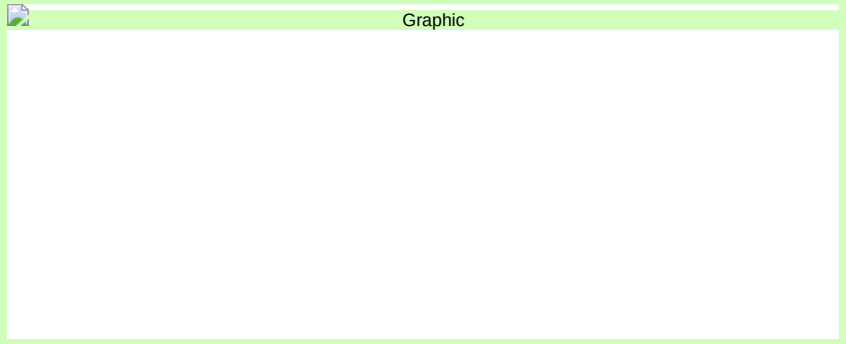

Figure 3.

A. Median of circulating E6-E7–specific T cells over time measured by ELISpot (solid line shows median SFU/1 x 106 PBMCs and dashed lines indicate Patient #1 and #2 in the case report in Figure 4). Pie charts below graph show percentage of tumor-specific T cells expressing the indicated number of cytokines/markers (IFN-γ, TNF-a, CD107a, IL-2) measured by ICS in available PBMCs from HNSCC patients undergoing HB-202/HB-201 alternating 2-vector therapy at DL2 & DL3 at the corresponding timepoints (N = 26/29).

B. Percent change in tumor-infiltrating CD8+ T cells pre and post HB-200 treatment in patients with disease control (blue) and progressive disease (red) measured by IF IHC. Mean ± SD. Data shown are all patients with available paired biopsies, which includes patients from all groups explored in the study (N = 13 out of 93 total patients enrolled in Phase 1).

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

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

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Figure 4. Tumor response, HPV16 ctDNA, and TILs in 2 patients with stable disease who received HB-200 alternating 2-vector therapy.

A. Percent change in sum of target lesion diameters from baseline over time in Patient #1 and #2.

B. Percent change in circulating HPV16 DNA from baseline in Patient #1 and #2.

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

Clinical Results: HB-200 in Combination with Pembrolizumab in the First Line Setting

In October 2023, we presented updated Phase 2 dose expansions data for HB-200 in combination with pembrolizumab in the first line setting at the ESMO annual congress (Abstract 2212) for the first 20 patients treated with HB-200 and pembrolizumab in the first-line setting (data cut-off August 7, 2023). The efficacy evaluable data set (≥1 tumor scan post-treatment) consisted of 19 patients, as one patient discontinued prior to tumor scans due to COVID-related death. Baseline characteristics are highlighted in the table below.

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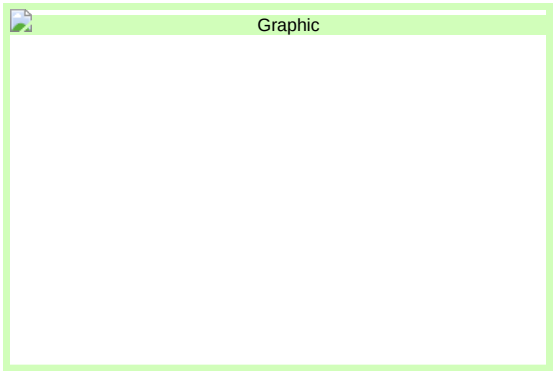
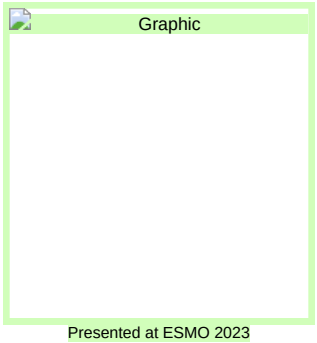


Safety and Tolerability

The data showed that HB-200 and pembrolizumab was generally well tolerated among the 20 patients treated. The majority of reported AEs were mild to moderate with the most common AEs being flu-like symptoms. Two patients (10%) reported serious adverse events related to

the treatment with HB-200 or pembrolizumab. Only one patient (5%) discontinued due to a single trial. During treatment-related adverse event of checkpoint inhibitor pneumonitis (related to pembrolizumab). The updated safety data adds to the initial 10 months previously reported safety and tolerability data from patients across all arms of the trial who received HB-200 monotherapy or HB-200 in combination with pembrolizumab. This generally favorable tolerability profile highlights the HB-201 potential of HB-200 – and arenaviral immunotherapies in general – to be successfully combined with other immunotherapies where tumor antigen-specific T cell induction is of potential benefit.



Presented at ESMO 2023

Clinical Activity

The preliminary data showed a 42% confirmed objective response rate ("ORR") and disease control rate ("DCR") of 74% across 19 evaluable patients, doubling the historical 19% ORR for pembrolizumab alone. Best overall response for the evaluable population included one patient with a confirmed complete response, seven patients with confirmed partial responses, and six patients with stable disease. The preliminary data showed sustained disease control in the majority of patients. All efficacy-evaluable patients were alive at the data cutoff (August 7, 2023), and the median follow-up time at DCO was 8.3 months. Median overall survival and progression-free survival data are still maturing.

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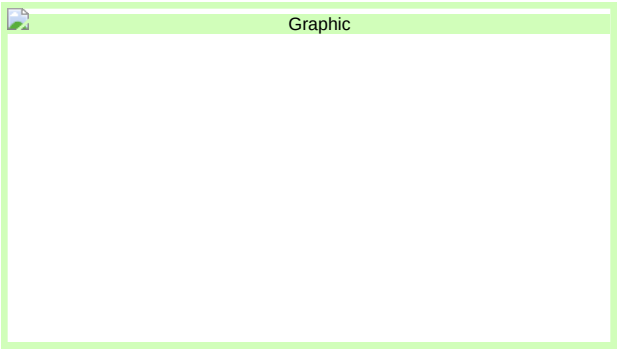

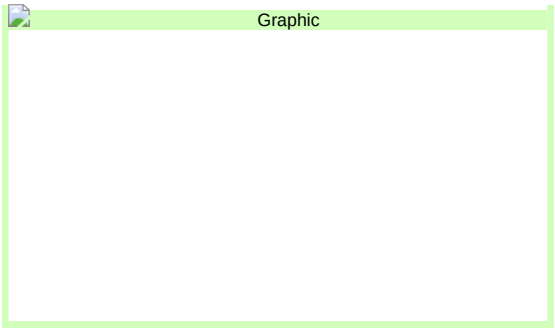

Biomarker and Translational Results

Importantly, the data showed significant activation of antigen-specific CD8+ T cells, the body's primary driver of tumor killing activity. Out of 17 patients with available peripheral blood mononuclear cells ("PMBC") samples, all patients showed an increase of tumor antigen-specific circulating HPV16+ CD8+ T cells. Peak percentage of antigen-specific circulating HPV16+ CD8+ T cells reached up to 31 percent with a median of 3.36%. Max response on treatment vs. before treatment of systemic HPV-16 E7 and E6 specific T cells measured by ELISPOT showed that the median fold-increase for these patients' total tumor specific T cells was a 451-fold increase over baseline, with the maximal increase of 4,000-fold.

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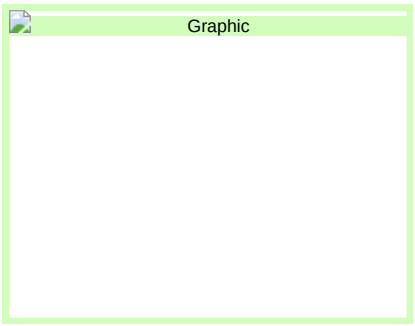

Based on the data generated in our clinical trials, we believe that HB-200, in combination with standard of care pembrolizumab, has the potential to improve treatment outcomes in persons diagnosed with HPV16+ PD-L1+ R/M OPSCC, and has the potential to be used in the first line setting. We believe that success in developing HB-200 into an effective therapy for HPV16+ OPSCC would suggest the potential of HB-200 to be an effective therapy in all HPV16+ cancers, regardless of the cancer's tissue of origin.

The totality of the data from our clinical trials of HB-200, both as a monotherapy and in combination with pembrolizumab, give us conviction to proceed with a randomized Phase 2/3 trial to evaluate HB-200 in combination with pembrolizumab in the first line setting for patients with HPV16+ OPSCC. We plan to begin the randomized Phase 2/3 trial in 2024.

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

Targeting Shared Neoantigens

KRAS is a gene that acts as an on/off switch for cell growth as it is a key regulator of cell proliferation and survival. When there is a mutation, or error, in the gene, cells can grow out of control. KRAS is one of the most frequently mutated proto-oncogenes with respective mutations found in approximately 30% of all human cancers. KRAS mutations are most frequently found in pancreatic cancer (85% to 90%), colorectal cancer (approximately 40%) and lung cancer (approximately 32%). However, the spectrum of mutations mainly target amino acid position 12 (G12D, G12V, G12R, and G12C) and position 13 (G13D), rendering these mutations an attractive target for immunotherapy. We

plan to develop our KRAS targeted therapy for patients suffering from pancreatic adenocarcinoma ("PAAD"), colorectal cancer ("CRC") and lung adenocarcinoma ("LUAD") and carrying one or more of the five most prevalent G12D, G12V, G12R, and G12C and position 13 G13D mutations. Our arenavirus technology enables us to integrate all five mutations into one single-vector, which allows our product to potentially be a single therapeutic targeting multiple large cancer indications.

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

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

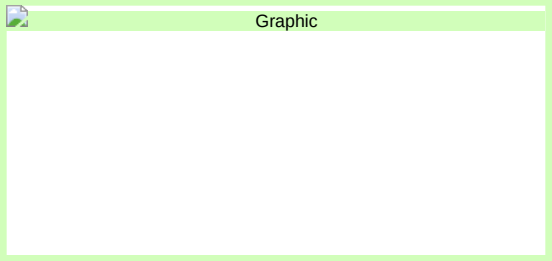
Colorectal cancer is the third most diagnosed malignancy worldwide and the second leading cause of cancer death. The incidence of colorectal cancer was estimated at 1.9 million cases in 2020, causing 0.9 million deaths worldwide. The incidence is higher in highly developed countries and it is increasing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

Lung cancer is the most common cause of cancer death worldwide, with an estimated 1.6 million deaths annually. Approximately 85% of lung cancer patients suffer from a subgroup called non-small cell lung cancer ("NSCLC"), of which LUAD and lung squamous cell carcinoma are the most common subtypes. LUAD represents approximately 40% of NSCLC and is the most common primary lung cancer diagnosed in the United States. Despite new treatments, the 5-year survival rate is only 12% to 15%.

Our Solution: HB-700 for KRAS Mutated Cancers

HB-700 is based on our replicating arenavirus platform and was studied through escalating doses. Starting in October 2020, enrollment into the HB-202/HB-201 alternating sequential designed for treatment of cancers encoding mutated KRAS, especially KRAS-mutated pancreatic, colorectal, and lung cancers. HB-700 is a replicating dual-vector therapy began, representing a parallel dose escalation. The primary endpoint that has been engineered to encode fragments encoding multiple KRAS mutations found in these three cancers, specifically KRAS mutations G12D, G12V, G12R, G12C and G13D. By simultaneously targeting these five most common mutations, we believe HB-700 has the potential to benefit more patients than single mutation inhibitors. Potential coverage of KRAS mutations of important cancer indications by our product candidate HB-700 is illustrated in the Phase 1 part of the Phase 1/2 trial was a recommended Phase 2 dose based on safety

and tolerability. Secondary endpoints included anti-tumor activity as defined by RECIST 1.1, immunogenicity, safety, and tolerability. following graph:



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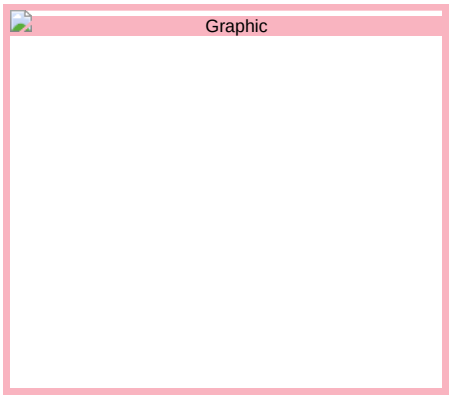
As a first-in-human trial, Similar to our other immuno-oncology candidate therapies, we can deliver HB-700 by simple infusion; HB-700 is designed to target APCs, such as dendritic cells, without the Phase 1 arm need for cellular isolation or *ex vivo* processing. Since induction of KRAS mutation-specific CD8+ T cells is the trial opened to investigate multiple questions for HB-200 program:

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



In November 2021, interim Phase 1 data on HB-201 single-vector mode of action of this investigational therapy, and HB-202/HB-201 dual-vector therapy for advanced/metastatic HPV16+ cancers showed promising anti-tumor activity administration of alternating LCMV- and favorable tolerability. The interim data was derived from 62 patients who received either HB-201 single-vector therapy or HB-202/HB-201 dual-vector therapy for advanced/metastatic HPV16+ cancers. Data demonstrated some responses and stable disease PICV-based vectors have been shown to induce unprecedented tumor antigen-specific CD8+ T cell levels in head and neck cancer patients who failed prior standard the context of care therapy: platinum therapy, PD(L)1 inhibitor, or both.

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

- IV administration was observed to be superior to IT administration; therefore, the IT route has been discontinued and IV only is being used in Phase 2;

- The initial Q3W dosing schedule was observed to be superior to Q2W; therefore, the Q2W regimen arm has been discontinued and the Q3W dosing is being used in Phase 2;

- The majority of data accrued to date has been from HNSCC patients; therefore, the Phase 2 target tumor type is HNSCC.

In June 2022, positive Phase 1 data were presented in a poster presentation (abstract #2517) at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting. The data included results from our HB-200 program, evaluating single-vector HB-201 and alternating dual-vector HB-202/HB-201 in advanced HPV16+ head and neck cancer patients. HB-200 was generally well tolerated, rapidly induced a high magnitude of tumor-specific T cells and showed early anti-tumor activity in these difficult-to-treat patients. We also announced the recommended Phase 2 dose

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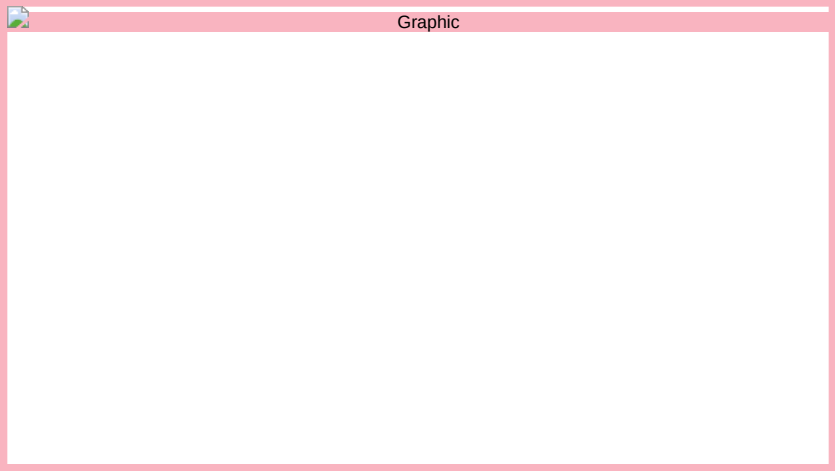
for alternating dual-vector HB-202/HB-201, which showed superior immune and tumor response compared we have designed HB-700 to single-vector HB-201.

Patient Details

In the June 2022 data release, a total of 68 patients with advanced HPV16+ cancers were treated in the Phase 1 trial as of March 31, 2022. Fifty-four patients had advanced HPV16+ head and neck cancers with a median of three prior therapies (range of 1-11), including a checkpoint inhibitor regimen in 50 of the 54.



Clinical Biomarker Data

The June 2022 data release included clinical biomarker data on patients who received HB-201 or alternating dual-vector HB-202/HB-201. These clinical biomarker data included measurements of tumor specific T cells, which are essential in eradicating cancer cells.

While both HB-201 and alternating dual-vector HB-202/HB-201 were highly immunogenic, HB-202/HB-201 induced superior immune response with 32 % of recipients achieving tumor-specific T cell levels greater than 5 % of the circulating T cell pool (7 % of HB-201 recipients achieved this threshold).

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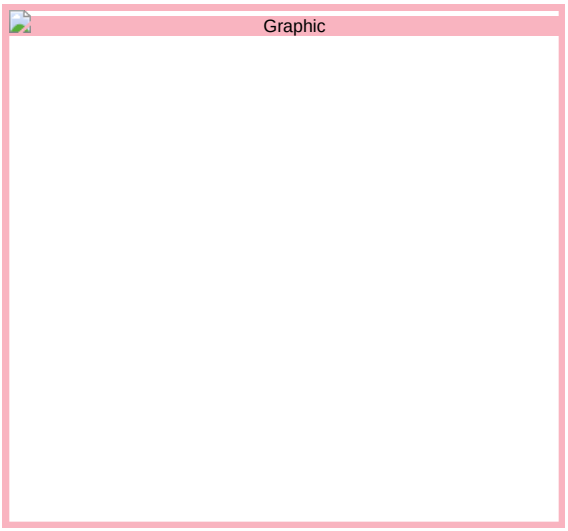
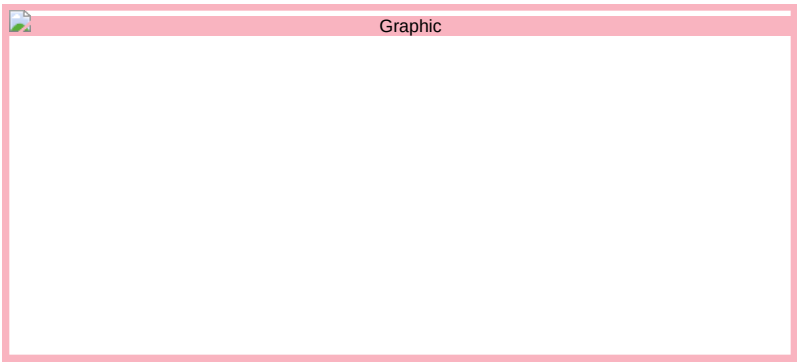


Additionally, three of six of biopsied patients showed TILs (i.e. potentially maximize HB-700-induced CD8+ T cells infiltrating tumors).



Clinical Safety Data

HB-200 Phase 1 results showed HB-200 was generally well tolerated, with comparable safety between the single-vector HB-201 and alternating dual-vector HB-202/HB-201. The most common treatment-related side effects were flu-like symptoms, with only 8.8 % of patients experiencing treatment-related side effects rated grade 3 or higher.

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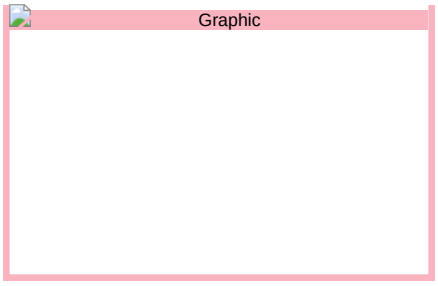
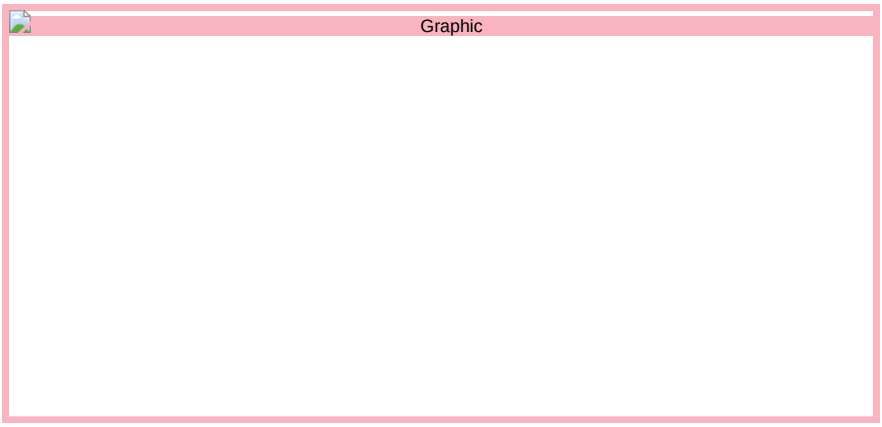
This favorable tolerability profile in heavily pre-treated patients highlights the potential for combination with checkpoint inhibitors and other agents.



Clinical Efficacy Data

The poster presented at ASCO provided updated anti-tumor activity on 43 Phase 1 patients with HPV16+ HNSCC who received therapy intravenously every three weeks (Q3W) for the first five doses and every six weeks (Q6W) thereafter, which is the route and frequency selected for further evaluation in Phase 2 cohorts. The 43 patients were comprised of 20 persons who received single-vector HB-201 and 23 who received alternating dual-vector HB-202/HB-201.



In addition to the interim data reported in November 2021, the June 2022 data enabled further decisions on the Phase 2 part of the trial by revealing the following:

- While promising anti-tumor activity was shown in both groups, alternating dual-vector HB-202/HB-201 showed superior tumor responses with 56 % of treated patients showing target lesion shrinkage compared to 38 % of HB-201 recipients.

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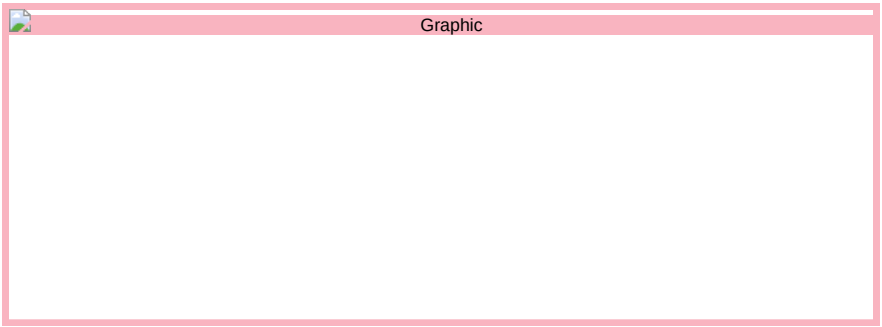
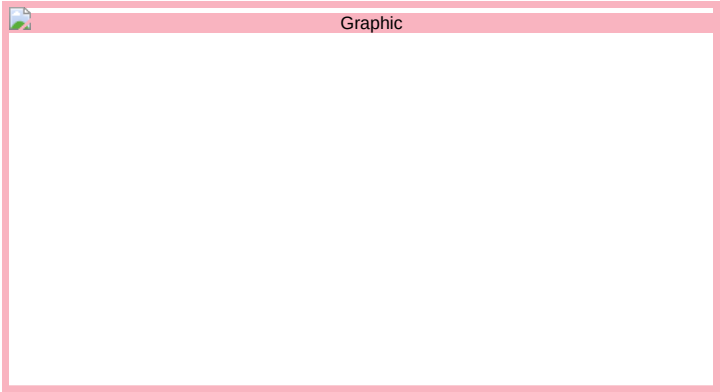


- In addition, decreases in visceral lesions were predominantly seen in patients who received dual-vector therapy: 59 % of patients on HB-202/HB-201 compared to 18 % on HB-201.

- The HB-202/HB-201 dual-vector therapy demonstrated an 80 % disease control rate (DCR), which compares favorably to historical DCRs achieved by pembrolizumab in recurrent/metastatic HNSCC patients, specifically 35 % overall and 40 % in the HPV16+ subset, based on peer-reviewed published data (Mehra R et al. Efficacy and safety of pembrolizumab in recurrent/metastatic head and neck squamous cell carcinoma: pooled analysis after long-term follow up in KEYNOTE-012. British J of Cancer. 2018; 119:153-159).



Based on the safety profile, anti-tumor activity and T cell response data observed in the Phase 1 dose escalation part and reported in the June 2022 ASCO poster, the HB-202/HB-201 alternating dual-vector intravenous therapy was selected as the preferred regimen as it induced more robust circulating T cell responses and anti-tumor activity than HB-201 single-vector therapy. Additionally, HB-202/HB-201 dose level three was selected as the RP2D by using replicating vectors based on the acceptable safety profile both LCMV and preliminary Phase 1 anti-tumor activity.

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Therefore, the Phase 2 expansion portion of the ongoing Phase 1/2 trial proceeded to evaluate HB-202/HB-201 at the RP2D PICV in combination with pembrolizumab in 1st line patients with advanced or metastatic HPV16+ HNSCC using a two-step combination dose escalation. First, a small cohort of patients was dosed with HB-201 single-vector therapy in combination with pembrolizumab as a safety lead-in. Second, the alternating dual-vector HB-202/HB-201 therapy at a lower dose than RP2D was evaluated in combination with pembrolizumab, before beginning the alternating dual-vector therapy at RP2D in combination with pembrolizumab.

As communicated in November 2022, more than 20 patients have been dosed in the Phase 2 pembrolizumab combination expansion cohort, including those in the safety run-in, though only a small number of patients had received the RP2D of HB-202/HB-201 with pembrolizumab. More time and additional imaging assessments are required to mature the dataset and inform the next phase of development. We will provide a comprehensive data update in the first half of 2023.

The Phase 2 portion of the trial is also open for enrollment of patients with second line and greater advanced/metastatic HPV16+ HNSCC for treatment with a combination of HB-202/HB-201 and pembrolizumab. Enrollment of those patients is also proceeding in the unrandomized Phase 2 dose expansion part of the ongoing Phase 1/2 trial.

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

In addition to the ongoing nonrandomized Phase 1/2 clinical trial, in September 2021 October 2022, we announced a strategic collaboration and license agreement with Roche to develop HB-700 for KRAS-mutated cancers. Through the collaboration, we have conducted research and early clinical development for HB-700.

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

On January 25, 2024, Inc, we received written notice from Roche of their decision to study HB-200 terminate the Research Collaboration and License Agreement dated October 18, 2022. Roche's decision to terminate the Collaboration Agreement was made according to Roche's right to terminate without cause, acknowledging that we had met all go-forward criteria under the Collaboration Agreement.

The Collaboration Agreement was entered into to (i) grant Roche an exclusive license to research, develop, manufacture and commercialize the Company's pre-clinical HB-700 cancer program, an arenaviral immunotherapeutic for KRAS-mutated cancers, and (ii) grant Roche an option right to exclusively license for research, development manufacturing and commercialization, a second, novel arenaviral immunotherapeutic program targeting undisclosed cancer antigens.

Pursuant to the terms of the Collaboration Agreement and the Notice, the Collaboration Agreement will be terminated on April 25, 2024. The Company remains eligible for a final milestone payment associated with an IND submission. The Company plans to submit an IND to the FDA in combination with pembrolizumab in April 2024. Effective April 25, 2024, the Company will regain full control of the associated intellectual property portfolio and will have full collaboration and licensing rights for the HB-700 program, and we are evaluating a randomized Phase 2 trial potential new partnership to advance HB-700. After the termination of patients with 1st line advanced/metastatic HPV16+ HNSCC. We anticipate making a decision on when to start this Phase 2 clinical trial in 2023. the Collaboration Agreement, and except as disclosed above, there is no other material relationship between the Company and Roche.

HB-300 Program for Prostate Cancer

Targeting Self Antigens

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

Our HB-200 program targets viral antigens associated with tumors induced by HPV16. In these programs, the viral, or non-self 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, self antigens, nonviral antigenic proteins that are highly overexpressed in solid tumors or only minimally expressed in normal cells. Because self-antigens 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 self antigens from immune system attack is known as immune tolerance. The results obtained by earlier-generation earlier generation marketed products such as sipuleucel-T, sipuleucel T, developed as PROVENGE by Dendreon Pharmaceuticals, Inc., have proven that it is possible to overcome immune tolerance and activate the immune system to produce an antitumor response.

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Our Solution: HB-300 HB 300 for Prostate Cancer

We are developing our most advanced self-antigen self antigen candidate in this area, HB-300, HB 300, based on our replicating technology in metastatic, hormone resistant prostate cancer. Prostate cancer provides a unique treatment opportunity for immunotherapy because prostate cancer cells express a number of tumor-specific tumor specific antigens that serve as potential targets. HB-300 is an alternating, dual-vector replicating arenaviral immunotherapy which uses the Lymphocytic Choriomeningitis Virus LCV and Pichinde Virus PCV as arenaviral backbones, with each expressing two well-defined antigens of prostate cancer, prostatic acid phosphatase (PAP) ("PAP") and prostate specific antigen (PSA). antigen. Subsequent clinical development may include addition of arenaviral therapeutics expressing a third antigen, prostate specific membrane antigen (PSMA). antigen.

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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 and led to its approval in 2010. Other companies are developing dendritic cell therapies similar to PROVENGE by using other tumor antigens. These dendritic cell therapies generally require complex, patient-specific therapeutic manufacturing processes involving isolating cells from patients, loading them *ex vivo* with tumor antigens and then readministering the cells to patients.

Since HB-300 is a replicating-based product candidate, we can deliver it by simple infusion whereby it targets APCs, such as dendritic cells, in the body, without the need for cellular isolation or ex vivo processing. We have shown in preclinical experiments and in the HB-200 clinical program that replicating vectors can lead to robust CD8+ T cell responses to the encoded antigens.

Graphic

In April 2022, we presented preclinical data at the American Association for Cancer Research Annual Meeting (abstract #3298 and abstract #4198) that showed antitumor activity with a single administration of replicating arenaviral immunotherapy targeting tumor self-antigens. Specifically, the arenaviral immunotherapy was able to overcome immune tolerance, induce potent T cell responses against two different tumor self-antigens and reduce tumor growth in these cancers. Notably, targeting tumor self-antigens can be a challenge because the immune system does not recognize these molecules as foreign. These preclinical data provided further support for the clinical evaluation of our HB-300 candidate for treatment of prostate cancer. The AACR data demonstrated the ability of our arenaviral immunotherapeutic

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technology to induce potent T cell responses against tissue-specific self-antigens, which is the same type of tumor self-antigens targeted by HB-300.

In July 2022, we announced that the FDA accepted our IND for HB-300 for the treatment of metastatic castration-resistant prostate cancer (mCRPC) ("mCRPC"). A Drug Master File was also accepted, which we believe will facilitate reduced cycle time between completion of preclinical studies and clinical entry of our pipeline projects.

In February 2023, we opened a first-in-human Phase 1/2, multinational, multicenter, open-label study of HB-302/HB-301 alternating dual-vector therapy in participants with mCRPC. This study (NCT05553639) has 2 phases: a Phase 1 Dose Escalation dose escalation with an RP2D confirmation and a Phase 2 dose expansion. The Phase 1 dose escalation will

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evaluate HB-302/HB-301 alternating dual-vector therapy for safety and tolerability, preliminary efficacy and immunogenicity, and determination of a RP2D. The Phase 2 dose expansion will assess HB-302/HB-301 alternating dual-vector therapy at the RP2D defined in the Phase 1 portion of the study. Based on lessons learned from the HB-200 program, HB-302/HB-301 Alternating dual-vector therapy will be administered intravenously every three weeks (Q3W) for the first five doses and every 6 weeks (Q6W) from the fifth dose and onward. HB-302 is to be administered first followed three or six weeks later by HB-301.

In the future, As of December 31, 2023, we intend to develop further product candidates against other self-antigens with the aim of eventually establishing a franchise of dendritic cell-targeting agents that take advantage had completed enrollment of the ability Phase 1 dose escalation cohorts. The Study Safety Committee deemed that HB-300 was generally safe and well-tolerated in both dose escalation cohorts. Initial analysis of arenaviruses to stimulate CD8+ target antigen-specific T cell responses.

HB-700 for Targeting Mutated KRAS responses – using direct ELISPOT without pre-expansion of T cells – in Pancreatic, Colorectal ten patients between dose level 1 (N=5) and Lung Cancers

Targeting Shared Neoantigens

KRAS is dose level 2 (N=5) indicated a gene that acts as an on/off switch for cell growth as it is a key regulator 15- to 26-fold increase of cell proliferation and survival. When there is a mutation, or error, target antigen specific T cells in the gene, cells can grow out of control. KRAS is one of the most frequently mutated proto-oncogenes with respective mutations found in approximately 30% of all human cancers. KRAS mutations are most frequently found in pancreatic cancer (85% patients (3/10).

In line with our previously announced strategy to 90%), colorectal cancer (approximately 40%) prioritize the development of HB 200, we have terminated the Phase 1/2 study of HB-300 and lung cancer (approximately 32%). However, will utilize the spectrum of mutations mainly target amino acid position 12 (G12D, G12V, G12R, associated capital and G12C) and position 13 (G13D), rendering these mutations an attractive target resources for immunotherapy. We plan to develop our KRAS targeted therapy for patients suffering from pancreatic adenocarcinoma (PAAD), colorectal cancer (CRC) and lung adenocarcinoma (LUAD) and carrying one or more of the five most prevalent G12D, G12V, G12R, and G12C and position 13 G13D mutations. By integrating all 5 mutations into one single-vector, our product will potentially be a single therapeutic targeting multiple large cancer indications.

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

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

Colorectal cancer is the third most diagnosed malignancy worldwide and the second leading cause of cancer death. The incidence of colorectal cancer was estimated at 1.9 million cases in 2020, causing 0.9 million deaths worldwide. The incidence is higher in highly developed countries and it is increasing in middle- and low-income countries due to westernization. The death rate from colorectal cancer in 2018 was approximately 55%. The 5-year survival rate of patients with localized stage colorectal cancer is 90%. About 38% of patients are diagnosed at this early stage. If the cancer has spread to surrounding tissues or organs and/or the regional lymph nodes, the 5-year survival rate is 72%. If the cancer has metastasized to distant parts of the body, the 5-year survival rate is less than 15%. The

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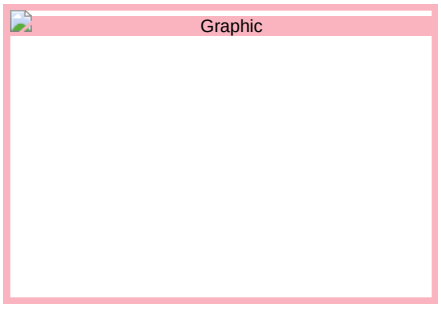
advancements made in understanding colorectal cancer pathophysiology have led to increased treatment options, including endoscopic and surgical excision, radiotherapy, immunotherapy, palliative chemotherapy, targeted therapy, and extensive surgery and local ablative therapies for metastases. These treatments have prolonged overall survival and screening through endoscopy also greatly enhanced the early detection, leading to good prospects of a cure. Although the prospect for colorectal cancer therapy is generally good, the increasing number of cases and rising incidence among younger generations still poses a heavy financial burden and a public health challenge.

Lung cancer is the most common cause of cancer death worldwide, with an estimated 1.6 million deaths annually. Approximately 85% of lung cancer patients suffer from a subgroup called non-small cell lung cancer (NSCLC), of which LUAD and lung squamous cell carcinoma are the most common subtypes. LUAD represents approximately 40% of NSCLC and is the most common primary lung cancer diagnosed in the United States. Despite new treatments, the 5-year survival rate is only 12% to 15%.

Our Solution: HB-700 for KRAS Mutated Cancers

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



Similar to our other immuno-oncology candidate therapies, we can deliver HB-700 by simple infusion; HB-700 is designed to target APCs, such as dendritic cells, in the body, without the need for cellular isolation or ex vivo processing. Since induction of KRAS mutation-specific CD8+ T cells is the mode of action of this investigational therapy, and administration of alternating LCMV (HB-201)- and PICV (HB-

202)-based vectors have been shown to induce unprecedented tumor antigen-specific CD8+ T cell levels in the context advancement of our HB-200 program, we also intend program. We will not proceed to maximize HB-700-induced CD8+ T cell responses the Phase 2 dose expansion component of by using replicating vectors based on both LCMV and PICV in a sequential dosing regimen.

In October 2022, we announced a strategic collaboration and license agreement with Roche to develop HB-700 for KRAS-mutated cancers. Through the collaboration, this study, but we will conduct research and early clinical keep the IND open to allow the potential for further development through Phase 1b for HB-700. Upon the completion of the Phase 1b trial, Roche has the exclusive right to assume development responsibility and to commercialize licensed products across multiple indications upon approval. Under the terms of the agreement, we received an upfront payment of $25.0 million. We are eligible for research, development and commercialization milestone-based payments for HB-700 and for an additional oncology candidate totaling up to approximately $930 million.

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In February 2023, we achieved a $10.0 million milestone payment under our HB-700 collaboration agreement with Roche. The success-based milestone payment reflected the start of the HB-700 manufacturing process to support a Phase 1 clinical trial. We plan to submit an IND for HB-700 to the FDA this program in the first half of 2024. future.

Next Generation Product Candidates

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

In November 2018, we entered into a research collaboration and license agreement with DarwinHealth, a New York City based bioinformatics company pioneering novel bioinformatic approaches, with Infectious Disease Pipeline Highlights

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

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

Summary

The HB-101 program was our first clinical program and allowed us to establish proof of concept for our non-replicating technology, validating several important advantages of our arenaviral therapies. However, based on the limited data available from our three-dose schedule from our Phase 2 study and the strength of the data emerging from our immune-oncology programs, we have decided not to move forward with further development of the current HB-101 product formulation.

Project Details

HB-101 is a prophylactic vaccine designed to prevent transmission and clinical sequelae from cytomegalovirus (CMV). CMV is a virus that is commonly transmitted in childhood and early adulthood. Infections result in lifelong latent persistence of the virus with few symptoms, if any. However, CMV infections present a serious risk for patients with suppressed immune systems, such as solid organ and stem cell transplant recipients. HB-101 is designed with our non-replicating technology that delivers two clinically validated antigens: pp65, to induce CMV-specific CD8+ T cells, and gB, to elicit CMV-neutralizing antibodies.

As announced in November 2021, based on the strength of our HB-200 data in HPV16+ cancers, we have prioritized our oncology portfolio, over we believe that our platform is also uniquely positioned to provide value from the prophylactic and therapeutic use against infectious disease programs. diseases. We plan to continue developing infectious disease therapies only in partnership with other companies companies.

Our collaboration with Gilead to develop functional cures for chronic HBV and decided to not further invest HIV infections has become our main driver of our infectious disease pipeline progress. We entered into the HB-101 program. our collaboration and licensing agreement (the "Gilead Collaboration Agreement") with Gilead in June 2018. To date, we have received $46.2 million in upfront and

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In milestone payments and $42.2 million of cost reimbursements from Gilead. Both programs have completed preclinical studies, we have observed that HB-101 has research and the ability to improve the survival rates in animal models HBV program is currently in a statistically significant manner. Phase 1 clinical trial. The HIV program is being progressed towards entry into a Phase 1 clinical trial.

In our January 2023, we announced the achievement of a $5.0 million milestone payment for the completion and delivery of a regulatory support package for Gilead's Phase 1 clinical trial HB-101 of the HBV therapeutic vaccine developed under the Gilead Collaboration Agreement. The first participant in the Phase 1 clinical trial being conducted by Gilead was dosed in 2023. The preclinical data on the HBV vaccine as a potential component for a curative regimen were presented at the American Association for the Study of Liver Diseases ("AASLD") in November 2022 and was selected by AASLD as a "Best of the Liver Meeting" highlight. These data were published in The Journal of Infectious Disease in August of 2023. Gilead is solely responsible for further development and commercialization of the HBV product candidate.

In February 2022, we signed an amended and restated collaboration agreement (the "Restated Gilead Collaboration Agreement") which revised the terms only for the HIV program, whereby we took on development responsibilities for the HIV program through a Phase 1b clinical trial and Gilead provides funding through a combination of an initiation payment of $15.0 million, a milestone payment of $5.0 million and equity contributions of up to $35.0 million. In November 2023, we announced FDA clearance of our IND application for the treatment of HIV. Additionally, Nature Partner Journals published peer-reviewed preclinical data for the program. Data show that HB-500 was well tolerated and elicited strong generated robust, high-quality and durable CMV-specific immune responses (antigen-specific T cells and antibodies) in all 42 volunteers non-human primates, and arenaviral therapeutic vaccination significantly reduced SIV viral load and clinical illness in those animals compared to placebo.

As of December 31, 2023, we received approximately $26.25 million from Gilead's purchases of our common stock under the treatment arm. Importantly, Stock Purchase Agreement with Gilead entered into in connection with the Restated Gilead Collaboration Agreement. We have the right, subject to certain terms and conditions, to sell an additional approximately $8.75 million of common stock to Gilead as pro-rata participation in potential future equity raises. Gilead retains an exclusive right (the "Option") to take back the rights for the HIV program, including further research, development and commercialization. If Gilead elects to exercise the Option, we observed robust CD8+ will be entitled to a $10.0 million program completion fee.

Infectious Disease: In Collaboration with Gilead

HB-400 for the Treatment of HBV

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

In collaboration with Gilead Sciences, Inc. a HBV-specific immunotherapy consisting of 2 non-replicating arenavirus vectors derived from PICV (HB-402) and CD4+ T cell responses as well as CMV-neutralizing antibody responses. As anticipated, 2 non-replicating arenavirus vectors derived from LCMV (HB-401) was developed. The immunotherapy is intended to utilize the LCMV vector did not elicit clinically meaningful vector-neutralizing antibodies, as only one volunteer developed patient`s own immune system to induce a transient neutralizing strong cellular and antibody response against HBV.

Arenavirus vectors were constructed to encode three different HBV antigens: HBV Core, Pol (an inactivated version of the vector after three administrations. Furthermore, upon repeat administration, the pp65 CD8+ T cell levels achieved by the non-replicating vector increased HBV polymerase) and HBV surface antigen ("HBsAg"). In a preclinical study, conducted in nonhuman primates ("NHPs"), animals were immunized with HB-402 and HB-401 in an alternating, sequential manner, which resulted in a statistically significant manner. The Phase 1 clinical findings were published in the April 2020 issue robust cellular immune response with HBV-specific CD8+ T-cell responses against all 3 encoded HBV antigens, and induction of The Journal high titers of Infectious Diseases.

In the fourth quarter of 2018, we commenced a randomized, double-blinded Phase 2 clinical trial for HB-101 in CMV-negative patients awaiting kidney transplantation from living CMV-positive donors. Based on HB-101's tolerability profile observed in the target patient population, and to gain further insights to inform a Phase 3 trial design, we added a new cohort of CMV-positive recipients awaiting kidney transplantation from CMV-positive or CMV-negative donors to the trial in early 2020 and amended the IND accordingly in January 2020. The goal of our Phase 2 trial was to assess safety, immunogenicity and efficacy of HB-101 in individuals receiving a kidney transplant from live donors to measure the decrease of post-transplant viremia.

In November 2020, we reported initial positive interim safety, immunogenicity and efficacy data in which we observed a pre-transplant three-dose vaccination schedule was able to reduce incidence of CMV viremia, reduce antiviral use and prevent CMV disease.

The Phase 2 HB-101 clinical trial concluded recruitment in June 2021 with 80 patients dosed. Given the challenges of enrollment of voluntary, live donor kidney transplantation during the COVID pandemic, the total number of patients enrolled in the trial was smaller than the originally planned 150 patients. Of the 80 patients dosed, 66 were CMV-negative and 14 were CMV-positive. Patients were followed up through a period of 12 months after transplantation.

In March 2023, we reported final data from our Phase 2 trial. Safety of the vaccine was assessed for 80 patients who received at least 1 dose of HB-101 or placebo. The most commonly reported localized adverse event was tenderness post injection. Fatigue, headache and generalized myalgia were the most commonly reported adverse events associated with reactogenicity. None of these events were severe or life-threatening. No systemic adverse events associated with systemic reactogenicity were reported in the placebo group. HLA sensitization was reported for five patients (6.3%) receiving HB-101 and none of the patients who received placebo. A higher incidence of post-transplant kidney biopsy was observed in patients receiving HB-101 as compared to placebo. A total of 16 patients (24.6%) out of 65 who received kidney transplantation required post-transplant kidney biopsy. Of these 16 patients, 14 (31.8%) received HB-101 and two (9.5%) received placebo. There were five cases of biopsy-confirmed rejection, four in the HB-101 group and one in the placebo group. None of the cases of biopsy-confirmed rejection were considered by the investigator to be related to HB-101 and none of these participants lost their graft.

Of the 66 CMV-negative patients who were enrolled in the trial, 52 received at least two doses of HB-101 or placebo prior to transplantation (n=34 HB-101, n=18 placebo) anti-HBsAg antibodies (Figure 1). 17 patients received three doses prior to kidney transplantation (n=9 HB-101, n=8 placebo). The incidence of CMV infection, CMV syndrome or CMV disease, or need for antiviral treatment post-transplant was not reduced in CMV-negative participants who received only two doses of HB-101 as compared to placebo. Among the CMV-negative patients who received three doses of HB-101 prior to transplantation, a lower incidence of CMV viremia and use of antivirals post-transplant was observed. Two of nine patients (22.2%) who received HB-101 developed CMV viremia and required post-transplant antivirals as compared to three of eight patients (37.5%) who received three doses of placebo. No CMV disease was reported in the group of patients receiving three doses of HB-101 or placebo. Of the 14 CMV-positive patients enrolled in the trial, nine patients received at least two doses of HB-101 prior to transplantation and three patients received three doses. The CMV-positive arm of the trial did not include a placebo group. From the nine CMV-positive patients who received at least two doses of HB-101, four patients (44.4%) developed CMV viremia, including one patient (11.1%) who required anti-viral treatment. None of the CMV-positive patients reported CMV disease. These data are comparable to previously reported rates of CMV viremia in CMV-positive transplant recipients.

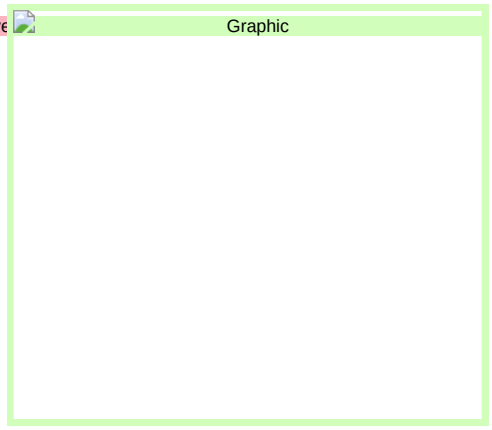
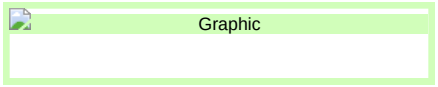
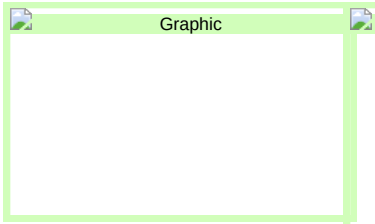
CMV neutralizing antibodies were observed in CMV-negative 

Figure 1: PICV-LCMV vaccination produces robust antibody and in CMV-positive patients after at least two doses of HB-101. Six of seven patients (85.7%) who received three doses of HB-101 and six of twenty patients (30.0%) who received two doses of HB-101 showed CMV neutralizing antibody responses. The magnitude of response observed was similar after two or three doses of HB-101 and comparable to that observed in Phase 1 with healthy subjects. Technically valid results from assays on CMV-specific T cell responses in non-human primates. (A) Anti-HBsAg responses induced by monthly dosing with alternating HB-402/GS-2829 and HB-401/GS-6779. Vector dosing timepoints are indicated by red (LCMV vector) or green (PICV vector) arrowheads. (B) Peak anti-HBsAg responses in individual animals. (C) Total HBV-specific ELISpot response kinetics. (D) Peak total HBV-specific T cell responses in individual animals.

In vivo efficacy of HB-402 and HB-401 was tested in mice transduced with varying amounts of AAV-HBV vector (high: $2x10^9$ viral genomes AAV-HBV; low: $5x10^8$ viral genomes AAV-HBV) to establish HBV persistence (chronic HBV animal model). It was found that, in mice with low serum HBV surface antigen (HBsAg) levels HB-402/HB-401 vaccination cleared detectable HBsAg in 6 of 8 mice and reduced antigens to just above the limit of detection in the remaining two animals (Figure 2, left panel). HBsAg loss was accompanied by near elimination of detectable HBV+ hepatocytes in liver of those mice (Figure 2, right panel) and significant increases in HBV-specific cellular immune responses in splenocytes.





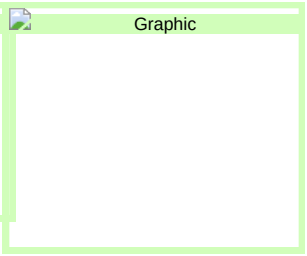


Figure 2: Vaccine efficacy in the AAV-HBV mouse model. C57BL/6 mice were transduced with $5x10^8$ or $2x10^9$ viral genomes (vg) of AAV-HBV on day -35. HB-402/GS-2829 and HB-401/GS-6779 or vehicle control immunization were administered every 2 weeks starting on Day 0 (arrows). (Left panel) Plasma HBsAg levels over time. (Right panel) HBV core+ cells in liver immunohistochemistry at day 84. **p < 0.01.

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(Figures from: Schmidt et al., Alternating arenavirus vector immunization generates robust polyfunctional genotype cross-reactive HBV-specific CD8 T cell responses and high anti-hbs titers. The Journal of Infectious Diseases, jiad340, https://doi.org/10.1093/infdis/jiad340).

HB-400 Clinical Development

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

A phase 1a/1b study (GS-US-642-5670 / NCT05770895) is underway and is designed to evaluate the safety and immunogenicity of HB-402 and HB-401 healthy volunteers and participants with CHB. Gilead Sciences initiated screening in the first quarter of 2023. Enrollment continues as the date of this report.

HB-500 for the Treatment of HIV

HB-500 Preclinical Data Package for HIV Cure Program

In collaboration with Gilead Sciences, Inc. a preclinical study in a NHP model of HIV infection was conducted. The model uses Simian Immunodeficiency Virus ("SIV") as a surrogate virus for HIV. The study shows that immunization of monkeys with replicating arenavirus vaccine vectors encoding SIV antigens (i.e., SIV Gag, Env, and Pol) is safe, immunogenic, and efficacious. The immunization induced a robust immune response, composed of SIV-specific T-cell responses and SIV Env-binding antibodies, which resulted in a reduction of SIV viral load and clinical illness in monkeys after subsequent SIV challenge.

In this study, 24 monkeys were immunized with an alternating, heterologous prime/boost of PICV and LCMV based vectors, encoding the respective SIV antigens. Eight monkeys were treated with a placebo and served as control group (Figure 1). Four weeks after the last vaccination, the monkeys were challenged with a high dose of SIV.

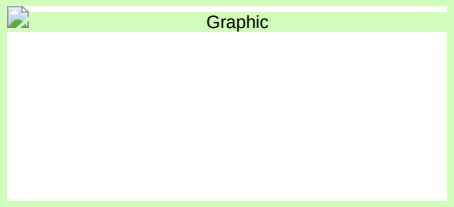

Figure 1: Schematic of the preclinical monkey study

The vaccine induced cellular response was determined by IFNγ ELISpot, an assay which allows to measure T-cells and other immune cells, which respond to a specific antigen (in this case SIV vaccine antigen) by releasing IFNγ. It was found that after vaccination, animals developed robust SIV Gag-, Env-, and Pol-specific cellular responses (median 44-fold increase after each vaccine boost) compared with pre-vaccination (Figure 2).

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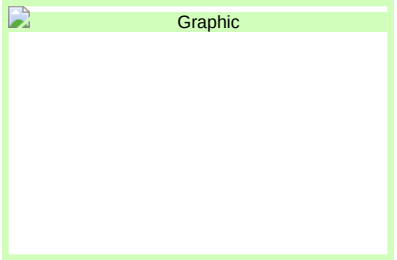

Figure 2: Total SIV-specific IFN-γ response measured in peripheral blood mononuclear cells (PBMCs) over weeks 0–32 of the study; circles on the x-axis indicate the day of transplantation vaccination with PICV (closed circles) and LCMV (open circles) with median responses represented by horizontal black lines. ***p < 0.0001

(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).

Four weeks after the last vaccination, animals (24 monkeys in the treatment group and 7 monkeys in the Placebo group) were available challenged with a high dose of SIV. Over the course of 40 weeks, SIV viral load in blood as well as signs for only seven patients (as a consequence of sample logistics and assay performance). Two clinical illness of the seven participants animals was monitored (Figure 3).

Animals which were vaccinated with arenavirus vectors had received significant reductions in median SIV viral load (1.45-log10 copies/mL) after SIV challenge compared with placebo and five had received HB-101. All three patients (100%) who had received three doses of HB-101 and one of the two patients (50%) who had received two doses of HB-101 showed CMV-specific (Figure 3, left panel). In addition, clinical illness after SIV infection (which is characterized by a decrease in CD4 T cell immune responses. The two patients counts and body weight, non-resolving diarrhea, anemia, mild edema, loss of appetite, jaundice, lymph node swelling along with valid assays an increase in viral load) was monitored for 40 weeks after infection. It was found that vaccination resulted in significant reduction in SIV-induced clinical illness versus the placebo group did not show at 40 weeks after challenge (Figure 3, right panel). Only 2 out of 24 monkeys in the vaccination group showed symptoms of clinical illness (app. 8%), whereas 3 out of 7 monkeys in the Placebo group exhibited signs of clinical illness (app. 42%).

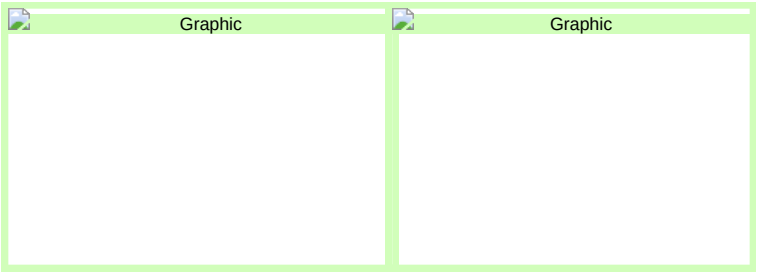

Figure 3: SIV viral load after challenge with SIV.

Left panel: Kinetics of SIV viral load over weeks 0–40 after challenge in placebo (closed triangles; n = 7 NHPs) and PICV/LCMV (closed circles; n = 24 NHPs) groups. Data are median ± IQR (interquartile range).

Right panel: Clinical disease progression after SIV challenge.

Correlation of (f) peak breadth of Gag-specific T-cell responses at 2 weeks after the third vaccine dose and

*p < 0.05.

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(Figures from: Boopathy et al., Immunogenic arenavirus vector SIV vaccine reduces setpoint viral load in SIV-challenged rhesus monkeys. npj Vaccines (2023) 8:175 ; https://doi.org/10.1038/s41541-023-00768-x).

HB-500 Clinical Development

We believe, the results of this preclinical monkey study support clinical investigation of arenavirus-based vectors as a CMV-specific T cell immune response.

As mentioned earlier, based on central component of therapeutic vaccination for HIV cure. We expect to initiate a Phase 1 clinical study of HB-500 in people with HIV in the limited data available from our three-dose schedule from our Phase 2 study and second quarter of 2024. Under the strength of collaboration agreement with Gilead, we are eligible for a milestone payment upon dosing the data emerging from our immune-oncology programs, we have decided not to move forward with further development of the current HB-101 product formulation. first patient in this study.

Intellectual Property

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

As of February 24, 2022 February 19, 2024, we are the owner, co-owner or exclusive licensee to 13 issued U.S. patents and 11 12 pending U.S. patent applications, four three pending international Patent Cooperation Treaty (PCT) ("PCT") applications, one two pending U.S. provisional patent application, applications, and 215 approximately 200 issued foreign patents and approximately 100 foreign patent applications. These patents and patent applications are related to our technologies concerned with the arenavirus-based immunization systems, non-replicating and replicating, our product candidates and various development programs, which are directed to the use of these immunization systems for the treatment and/or prevention of various infectious diseases or cancer, and certain clinical uses of our current or future product candidates in oncology. The issued patents and pending patent applications contain claims directed to various aspects of our work, including compositions of matter, methods of treatment and prevention, methods of producing certain compositions, and use of our product candidates in combination with certain other therapeutics.

Non-Replicating Technology Portfolio

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

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Replicating Technology Portfolio

We are the owner or exclusive licensee to proprietary patent positions related to our replicating technology. Our patent portfolio related to our replicating technology includes a patent family exclusively licensed from the University of Geneva. This patent family includes a patent granted in the United States and patents granted in Europe (validated in Albania, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany,

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

Split Vector Technology Portfolio

We have an are the owner or exclusive license from the University of Basel licensee to proprietary patent positions related to a novel molecular strategy to vectorize arenavirus genomes, which we refer to as the Split Vector Technology. Our patent portfolio related to the Split Vector Technology includes a patent family exclusively licensed from the University of Basel. This patent family includes pending applications in the United States, Europe, Hong Kong, Canada, Australia, Japan, India and China, exclusively licensed from China. The second patent family related to the University of Basel as well as an international PCT application Split Vector Technology 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 the United States and Europe. The pending applications and any applications claiming priority related to the respective PCT application Split Vector Technology are expected to expire in November 2040 and May 2042, respectively, not giving effect to any potential patent term extensions or patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. The Split Vector technology is currently not employed in any of our clinical stage product candidates or late-stage preclinical programs.

Oncology Technology Portfolio

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

HB-101 (Cytomegalovirus) ***HB-200 (HPV16+ Head and Neck Squamous Cell Carcinoma)***

Our HB-101 HB-201 and HB-202, the two components of our HB-200 product candidate, relies rely on our non-replicating technology. replicating technology and, depending on their clinical implementation, may relate to one or more applications in our oncology patent portfolio. In addition to the non- replicating and oncology patent portfolio, portfolios, we own one two patent family families that relate more specifically relates to our HB-101 HB-200 product candidate. This The first patent family includes two patents granted in the United States and patents granted in Europe (validated in Albania, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Macedonia, Malta, Monaco, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland/LI, The Netherlands, Turkey and the United Kingdom), Australia, Hong Kong, China, Macao, India and Japan as well as with claims directed to compositions of matter. This patent family also includes pending applications in the United States, Europe, Hong Kong, Australia, Canada, China, India, Japan and India. Hong Kong. The second patent family includes pending applications in the United States, Europe, Eurasia, Australia, Brazil, Canada, China, Costa Rica, Hong Kong, India, Israel, Japan, Korea, Mexico, New Zealand, Peru, Singapore, South Africa relating to HB-200 treatment regimens. Excluding the non- replicating and oncology patent portfolio, portfolios, the granted patents and pending applications specifically related to our HB-101 HB-200 product candidate are expected to expire in 2034, 2036 and 2041, respectively, not giving effect to any potential patent term extensions or patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

Hepatitis B Virus ***HB-700 (KRAS Mutated Tumors)***

Our HBV program, HB-700 product candidate relies on our replicating technology and, depending on its clinical implementation, may relate to one or more applications in our oncology patent portfolio. In addition to the replicating and oncology patent portfolios, we currently own one pending international PCT application, one pending application in Taiwan, and one pending application in Argentina that more specifically relate to our HB-700 product candidate. Any patent claiming priority to this pending PCT application specifically related to our HB-700 product candidate is expected to expire in 2042, not giving effect to any potential patent term extensions or patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

HB-300 (Prostate Cancer)

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

HB-400 (Hepatitis B Virus)

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

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HB-500 (HIV)

Our HIV program, HB-500 product candidate, codeveloped with Gilead, is in preclinical phase and is being built on either our non-replicating or replicating technologies. technology. In February 2022, we signed an amended and restated collaboration agreement, wherein we will assume assumed development responsibilities through the end of Phase 1b. In November 2023, our investigational new drug application was cleared by the FDA and we anticipate initiating the Phase 1b trial in the first half of 2024. We currently do not own any patents or patent applications that more specifically relate to an HIV program outside of the non-replicating and replicating patent portfolios.

HB-201 and HB-202 (HPV16+)

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

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HB-300

Our HB-300 product candidate relies on our replicating technology and, depending on its clinical implementation, may relate to one or more applications in our oncology patent portfolio. In addition to the replicating and oncology patent portfolios, we currently own one pending international Patent Cooperation Treaty (PCT) application that more specifically relates to our HB-300 product candidate. Any patent claiming priority to this pending PCT application specifically related to our HB-300 product candidate is expected to expire in 2042, not giving effect to any potential patent term extensions or patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

HB-700

Our HB-700 product candidate relies on our replicating technology and, depending on its clinical implementation, may relate to one or more applications in our oncology patent portfolio. In addition to the replicating and oncology patent portfolios, we currently own one pending international Patent Cooperation Treaty (PCT) application, one pending application in Taiwan, and one pending application in Argentina that more specifically relate to our HB-700 product candidate. Any patent claiming priority to this pending PCT application specifically related to our HB-700 product candidate is expected to expire in 2042, not giving effect to any potential patent term extensions or patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

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

Our ability to maintain and solidify our proprietary position for our product candidates and technologies will depend on our success in obtaining effective patent claims and enforcing those claims once granted. We do not know whether any of our patent applications will result in

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

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

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Gilead Collaboration Agreement and Stock Purchase Agreement

Overview

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

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

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

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

If the Option is not exercised by Gilead during the term of the Option, or if Gilead provides written notice to us of its intention to not exercise the Option, then the terms of the Restated Gilead Collaboration Agreement will be deemed terminated with respect to the HIV Development Plan and HIV Licensed Products (each as defined in the Restated Gilead Collaboration Agreement), and the Field and rights granted under the Restated Gilead Collaboration Agreement will be limited to the HBV indication. Furthermore, if the Option expires or is terminated, the non-competition and right of first negotiations terms contained in the Restated Gilead Collaboration Agreement and summarized below will not be applicable to the development for HIV indications. In the event the Option is not exercised, we and Gilead will work in good faith to enter into a license agreement pursuant to which Gilead will grant us a milestone and/or royalty-bearing license under certain Gilead owned intellectual property necessary or reasonably useful to allow us to research, develop, manufacture and commercialize HIV product candidates as of the date on which the Option is declined.

Financial support from Gilead to us includes a $15.0 million $15.0 million non-refundable initiation fee and $35.0 million $35.0 million equity commitment pursuant to a the Stock Purchase Agreement.

Governance

The development As of December 31, 2023, we received approximately $26.25 million from Gilead's purchases of our common stock under the terms of this equity commitment. In December 2023, the Stock Purchase Agreement was amended. Under the amended terms we have the right to sell an additional $8.75 million of common stock to Gilead as pro-rata participation with an equity financing (either public or private) at the offer price of the programs governed by the Gilead Collaboration Agreement is overseen by a six member joint steering committee (JSC), comprised of three representatives from each of us and Gilead. The JSC will oversee the activities carried out pursuant financing. Our option to the Gilead Collaboration Agreement, including settling disputes arising under the Restated Gilead Collaboration Agreement, and approving a Licensed Product as being ready for development.

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Similarly, the Gilead Collaboration Agreement establishes a four member joint development committee (JDC) to oversee HIV development activities.

Research on HBV and HIV products

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

Development and Commercialization of products

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

under the Restated Gilead Collaboration Agreement, and if the Option is exercised, it will responsible, at its expense, for the manufacture and commercialization of any HIV Licensed Product.

Non-Compete

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

Right of First Negotiation on December 20, 2025.

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

Financial Terms

Upon execution of the Gilead Collaboration Agreement, Gilead paid us a one-time upfront fee of $10.0 million and through to December 31, 2022 December 31, 2023, we received $16.2 $21.2 million in milestone payments for the achievement of pre-clinical research milestones.

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

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each HBV Licensed Product, and royalties of a mid-single-digit to 10% of worldwide net sales of each HIV Licensed Product, if the Option is exercised. The royalty payments are subject to reduction under specified conditions set forth in

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

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

expand the reimbursement for our resources allocated to the collaboration.

Termination

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

Supply Agreement

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

Stock Purchase Agreement

In connection with the Restated Gilead Collaboration Agreement, on February 15, 2022, the Effective Date, we entered into a Stock Purchase Agreement, the Stock Purchase Agreement with Gilead. Pursuant to, and subject to the terms and conditions of, the Stock Purchase Agreement, Gilead will be required, at our option, to purchase up to $35,000,000 of our common stock, the proceeds of which we intend to use to fund additional research and development activities of our HIV program. On the Effective Date, Gilead purchased an initial amount of 1,666,666 unregistered shares of our common stock in exchange for approximately $5.0 million at a purchase price per share equal to $3.00. On December 20, 2023, the parties amended the terms of the Stock Purchase Agreement and Gilead purchased 15,000,000 shares of our common stock in exchange for approximately $21.25 million in cash at a purchase price per share equal to $1.4167. Pursuant to the terms of the Stock Purchase Agreement, we may require Gilead to purchase the balance of the $30.0 $8.75 million of common stock as pro-rata participation in two subsequent purchases. The purchase price per share of the first subsequent purchase shall be equal to (a) the VWAP Purchase Price (as defined in the Stock Purchase Agreement), calculated at the date we exercise our right to require Gilead to purchase shares, plus (b) a premium of 30% on the VWAP Purchase Price, and the purchase price per share of the second subsequent purchase shall be equal to the VWAP Purchase Price, calculated at the date we exercise our right to require Gilead to purchase shares. potential future equity raises. Our ability to sell shares of our common stock to Gilead are subject to specified limitations, including compliance with Nasdaq Rule 5635(d) and continued compliance with the Nasdaq listing rules. The Stock Purchase Agreement also prohibits Gilead from purchasing shares of our common stock if such purchase would result in Gilead being a beneficial owner of more than 19.9% of the total number of our then-issued and outstanding shares of common stock.

The Stock Purchase Agreement may be terminated: (1) by Gilead (a) any time an Event of Default (as defined in the Stock Purchase Agreement) exists or (b) if we suspend, terminate or otherwise cease to perform our obligations under the HIV Development Plan; (2) automatically if Gilead exercises its Option pursuant to the Restated Gilead Collaboration Agreement; (3) by us for any reason; (4) automatically on the date that we sell and Gilead purchases the full $35.0 million of common stock; or (5) automatically on December 31, 2023 December 20, 2025.

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

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Roche Collaboration Agreement

Overview

On October 18, 2022, we entered into the Roche Collaboration Agreement, with Roche, to (i) grant Roche an exclusive license to research, develop, manufacture and commercialize our pre-clinical HB-700 cancer program, an arenaviral immunotherapeutic for KRAS-mutated cancers, and (ii) grant Roche an exclusive option right to exclusively license for research, development manufacturing and commercialization, a second, novel arenaviral immunotherapeutic program targeting undisclosed cancer antigens (collectively UCAs or UCA Program). Pursuant to the Roche Collaboration Agreement, we received a non-refundable upfront payment of $25.0 million and are eligible to receive up to approximately $930 have received $10.0 million in potential future success-based milestone payments for both programs, plus tiered royalties. the achievement of a GMP manufacturing milestone.

Governance

The development of On January 25, 2024, Roche terminated the programs governed by the Roche Collaboration Agreement is overseen by without cause, effective as of April 25, 2024. The Company remains eligible for a six-member joint research committee ("JRC"), comprised of three representatives from each of us and Roche. final milestone payment associated with an IND submission. The JRC will oversee the activities carried out pursuant Company plans to submit an IND to the Roche Collaboration Agreement.

Development and Commercialization of HB-700 Program

Under the Roche Collaboration Agreement, we are responsible for pre-clinical research, development, manufacturing and supply activities and early clinical development for the HB-700 Program pursuant to the "HB-700 Collaboration Plan" (as defined in the Roche Collaboration Agreement). In addition to the upfront payment, Roche shall pay success-based milestone payments related to achievement of manufacturing and IND-related events for the HB-700 Program. The clinical trial costs through Phase 1b will be shared equally between us and Roche.

Based on the data and a final report of the Phase 1b clinical trial to be delivered by us, Roche may elect to progress the development of the HB-700 Program and assume responsibility and cost for all further research, development, manufacturing, supply and commercialization activities of the HB-700 Programs.

Roche also has the option to elect to progress the development of the HB-700 Program FDA prior to the completion of termination effective date and achieve the Phase 1b trial.

Option Right to License UCA Program

Under the Roche Collaboration Agreement, we are responsible to perform research activities relating to the selection of a UCA Program. We will deliver to Roche a specified package of preclinical data and results with respect to the UCA Program. Roche may exercise an exclusive option to license the UCA Program and to extend the collaboration of the parties in relation to the UCA Program through the completion of a first in human trial (the "UCA Option"). Roche shall pay event-based milestone payments related to the achievement of manufacturing and IND-related events for the UCA Program. If the UCA Option is not exercised by Roche, the Roche Collaboration Agreement shall be deemed terminated with respect to the UCA Program. payment.

Financial Terms

Upon execution of the Roche Collaboration Agreement, Roche paid us a one-time upfront fee of $25.0 million.

Roche will pay us an additional $15.0 million payment if the UCA Option for the UCA Program is exercised. We are also eligible for event-based milestone payments of up to an aggregate of $335 million during the research and development phase of the HB-700 Program for up to four oncology indications and up to an aggregate of $250 million in payments related to the achievement of sales-based milestones. For the additional UCA Program, subject to UCA Option-exercise, we are eligible for up to an aggregate of $173 million in event-based milestone payments during research and development for up to four oncology indications as well as up to an aggregate of $160 million in sales-

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based milestones. Upon commercialization, we are eligible to receive tiered royalties of a high single-digit to mid-teens percentage on the worldwide net sales of HB-700 and, subject to UCA Option exercise, the UCA Program. The royalty payments are subject to reduction under specified conditions set forth in the Roche Collaboration Agreement. In aggregate, we are eligible to receive up to approximately $930 million in potential future success-based milestone payments in addition to the $25 million in upfront cash and tiered royalties.

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, Roche may terminate the Roche 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 Roche Collaboration Agreement is not otherwise terminated prior to the expiration of the last to expire royalty term, upon such expiration the license granted to Roche 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.

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University of Basel License Agreement

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

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

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

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

University of Basel Split License Agreement

In October 2020, we entered into an Exclusive License Agreement with the University of Basel, which was subsequently amended in July 2022 and September 2022, hereinafter referred to as the Basel Split Agreement. Pursuant to the Basel Split Agreement, the University of Basel granted us a worldwide, exclusive license to proprietary patent positions related to a novel molecular strategy to vectorize arenavirus genomes (Split Vector Technology as described in the Intellectual Property Section), the Basel Licensed Split Patent Rights, to make or to have made, to develop or have developed, to use, have used, sell, have sold, market, have marketed, offer for sale, distribute, have distributed, import or have imported products, the manufacture, use, sale, or importation of which would infringe a claim of the Basel Licensed Split Patent Rights, each a Basel Licensed Split Product. Pursuant to the Basel Split Agreement, the University of Basel further granted us a worldwide, exclusive license under the University of Basel's share in an international Patent Cooperation Treaty (PCT) PCT application related to certain improvements of the Split Vector Technology, including any patents and patent applications that claim priority thereto, such patents and patent applications are further included in the Basel Licensed Split Patent Rights.

Pursuant to the terms of the Basel Split Agreement, we are obligated to use commercially reasonable efforts to develop and manufacture Basel Licensed Split Products and make commercially available Basel Licensed Split Products in the United States and at least three major European countries. In addition, we have to reach certain pre-clinical and clinical development milestones within specified time periods. Based on technical difficulties and changing priorities / strategic considerations, we did not meet the first pre-clinical milestone as defined in the original Basel Split Agreement and had to pay a re-scheduling fee of CHF 100,000 to University of Basel. We subsequently agreed with the University of Basel to amend the original Basel Split Agreement and entered into an amendment under which we defined a new

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pre-clinical development plan and pre-clinical development milestones. Under the respective amendment we further agreed to make additional non-material milestone payments upon achievement of the newly defined pre-clinical development milestones.

Under the amended Basel Split Agreement, we have the right to request postponement of pre-defined pre-clinical or clinical development milestones against payment of rescheduling fees in the range of CHF 250,000 to CHF 1,000,000.

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

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

We paid the University of Basel nominal amounts upon entering into the agreement as well as upon execution of the second amendment in September 2022 and are required to pay a non-material annual maintenance fee, which is deductible from any milestone payments, royalties or sublicense payments payable by us to the University of Basel during the same year. We are required to pay the University of Basel, subject to the achievement of specified development and regulatory milestones, payments aggregating up to CHF 2,000,000 per Basel Licensed Split Product. While the Basel Split Agreement remains in effect, we are required to pay the University of Basel low single digit royalties on net sales of Basel Licensed Split Products. We must also pay the University of Basel a low double digit to low single digit percentage, decreasing as a Basel Licensed Split Product proceeds through development stages, of any consideration we receive from sublicensees, depending on the timing of such sublicense. We are also responsible for the prosecution and maintenance of the Basel Licensed Split Patent Rights, and the costs related thereto.

Unless earlier terminated, the Basel Split Agreement remains in effect until the expiration of the last to expire of the Basel Licensed Split Patent Rights. Following the expiry of the Basel Split Agreement due to the last to expire of the Basel Licensed Split Patent Rights, we will have a fully paid up, royalty free right to use, sell and commercialize Basel Licensed Split Products. We or the University of Basel may terminate the agreement for the other party's breach that remains uncured after 60 days' notice. We may terminate the Basel Agreement for convenience upon prior notice. The University of Basel may terminate the Basel Split Agreement if we file a petition for bankruptcy or insolvency or both, or reorganization relating to bankruptcy or insolvency, or in the event of an adjudication that we have become bankrupt or insolvent or both. The University of Basel may further terminate the Basel Split Agreement if we oppose or dispute the validity of any of the Basel Licensed Split Patent Rights or assist a third party to do the same. If we fail to perform any of our diligence obligations specified in the Basel Split Agreement, after having exercised all available postponement options, and if we fail to agree with the University of Basel on any amendments to our development and marketing plans based on the procedure specified in the Basel Split Agreement upon such demand for amendments from the University of Basel, the University of Basel may terminate the Basel Split Agreement.

University of Zurich License Agreement

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

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Licensed Patent Rights, each a Zurich Licensed Product and to practice the Zurich Licensed Patent Rights and methods that fall within the scope of the Zurich Licensed Patent Rights, each a Zurich Licensed Method.

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

In consideration for the license granted to us under the Zurich Agreement, we issued 26,744 shares with a nominal value of EUR 2,297 of our common stock to the University of Zurich and agreed to provide them certain antidilution rights, which rights have subsequently expired. We are required to pay the University of Zurich low single digit royalties on net sales of Zurich Licensed Products or Zurich Licensed Methods. We must also pay the University of Zurich percentages ranging from the mid-single digits to 20% of any sublicense fees and consideration we receive from sublicensees, depending on the amount of fees received from sublicensees and the cumulative monetary value of the consideration and fees received from all sublicensees. We are responsible for the prosecution and maintenance of the Zurich Licensed Patent Rights, and the costs related thereto.

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

National Institutes of Health License Agreement

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

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Agreement and do not remedy such default within a specified period upon notice thereof. We may terminate the NIH Agreement for convenience upon prior notice.

University of Minnesota License Agreement

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

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

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

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

Competition

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

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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 Our competitors in the development of product candidates in our therapeutic areas lead immunooncology indication of therapies for HPV+ cancers, include, among others: others, companies such as Cue Biopharma, ISA Pharmaceuticals B.V., Nyode, PDS Biotech, TCR Cure, Transgene and Ultimovacs.

- In CMV management, companies such as Helocyte, Inc., VBI Vaccines Inc., Moderna, Inc., Biotest, Allovir, Merck & Co, and GSK plc.;
- In immunooncology for HPV+ cancers, companies such as ISA Pharmaceuticals B.V., Transgene, Nyode, PDS Biotech, Cue Biopharma, Ultimovacs, and TCR Cure; and
- In metastatic Hormone Resistant Prostate Cancer, companies such as BRL Medicine, Inc, Regeneron, AvenCell, BioNTech, Ultimovacs and Madison Vaccines are investigating an immuno-oncology approach.

On the Companies developing technology level, direct competitor is that competes directly or indirectly with our technology include Abalos GmbH, which is developing mammarenavirus vectors for cancer. Indirect technology competitors with relevance in cancer, and infectious diseases include companies developing oncolytic viruses, bispecific antibodies, engineered cell therapies, tumor specific antigens, and other active immunization technologies. Specific indirect technology competitor companies include, technologies including, among others, Adaptimmune PLC, BioNTech, CureVac AG, Gritstone Bio, Inc., Replimune Group, Inc., Merck & Co., BioNTech, Moderna, Novartis, Replimune Group, Inc., Roche and Turnstone Biologics Inc., Adaptimmune PLC, CureVac AG, Roche, and Novartis.

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

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

Manufacturing

We have been establishing robust manufacturing processes, reliable assays and strong supply agreements for all of the components used in our product candidates to support ongoing and planned clinical trials. These include the components for our non-replicating based and replicating based product candidates. For GMP production and testing we rely on qualified CMOs to produce and test our clinical material. Currently we do not own or operate manufacturing facilities beyond laboratory scale non-GMP production. We require that our CMOs produce bulk drug substances and finished drug products in accordance with cGMP, and all other applicable laws and regulations. Although we plan to establish our own manufacturing facility in the future, 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.

Table Although we made the decision to discontinue our current GMP facility project as part of Contents

We the Reduction Plan announced in January 2024 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 in the whole manufacturing process will allow us to further increase the robustness and consistency of the process. We

expect that control over our own manufacturing facility will also help to shorten overall timelines for new product candidates in our development pipeline, as well as help us develop drug formulations or presentations to simplify distribution as well as administration of future immuno-therapeutics. We also believe that having a dedicated manufacturing facility will allow us to optimize commercial scale processes and to develop a suitable workforce capable of supporting market launch. future.

Government Regulation

Government authorities in the United States at the federal, state and local level and in other countries regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, recordkeeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of biological products, such as those developed from our non-replicating and replicating technologies and any other product candidates we develop. Generally, before a new drug or biologic can be marketed, considerable

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data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority.

U.S. Biological Product Development

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

Our product candidates and any future biological product candidates we develop must be approved by the FDA through a biologics license application (BLA) process before they may be legally marketed in the United States. The BLA is a request for approval to market the biologic for one or more specified indications and must contain proof of safety, purity and potency. The FDA review and approval process generally involves the following:

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

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

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

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

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

Preclinical Studies and IND

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

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

Clinical Trials

The clinical stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Further, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries.

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

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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.

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

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

Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biologic has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated check points based on access to certain data from the trial. Concurrent with clinical trials, companies usually complete additional animal studies and also must develop additional information about the chemistry and physical characteristics of the biologic as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product and, among other things, companies must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidates do not undergo unacceptable deterioration over their shelf life. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws.

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FDA Review Process

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

Under the Prescription Drug User Fee Act (PDUFA) as amended, each BLA must be accompanied by a user fee. The FDA adjusts the PDUFA user fees on an annual basis. According to the FDA's fee schedule, effective through September 30, 2023, the user fee for an application requiring clinical data, such as a BLA, is $3,242,026. The sponsor of an approved BLA is also subject to an annual prescription drug program fee, which for fiscal year 2023 is $393,933. 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

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six months from the filing date of an original BLA designated for priority review. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs, and the review process is often extended by FDA requests for additional information or clarification.

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

Letter may require additional clinical data, pivotal Phase 3 clinical trial(s) as well as other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in

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the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making the product available in the United States for this type of disease or condition will be recovered from sales of the product.

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

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

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Expedited Development and Review Programs

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

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

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

A product may also be eligible for accelerated approval, if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality (IMM) that is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA may require that a sponsor of a drug or biologic receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. Under the Food and Drug Omnibus Reform Act of 2022 (FDORA), the FDA is now permitted to require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. Sponsors are also required to send updates to the FDA every 180 days on the status of such studies, including

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progress toward enrollment targets, and the FDA must promptly post this information publicly. Under FDORA, the FDA has increased authority for expedited procedures to withdraw approval of a drug or indication approved under accelerated approval if, for example, the sponsor fails to conduct such studies in a timely manner and send the necessary updates to the FDA, or if a confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, the FDA generally requires, unless otherwise informed by the agency, pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

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

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

Pediatric Information

Under the Pediatric Research Equity Act (PREA), a BLA or supplement to a BLA must contain data to assess the safety and efficacy of the biologic for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. The Food and Drug Administration Safety and

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Innovation Act (FDASIA) amended the FDCA to require that a sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan (PSP) within 60 days of an end of Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 study. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials as well as other clinical development programs.

Post-Marketing Requirements

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

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

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approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

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

Other U.S. Healthcare Laws

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, including the Centers for Medicare & Medicaid Services (“CMS”), other divisions of the

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Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments.

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

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

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

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

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH) and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates, independent contractors or agents of covered entities, that perform services for them that involve the creation, maintenance, receipt, use, or disclosure of, individually identifiable health information relating to the

the federal civil and criminal false claims laws and civil monetary penalty laws, such as the FCA, which impose criminal and civil penalties and authorize civil whistleblower or qui tam actions, against individuals or entities for, among other things: knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; knowingly making, using or causing to be made or used, a false statement of record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if

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privacy, security and transmission of individually identifiable health information, as well as their covered subcontractors. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions. In addition, there may be additional federal, state and non-U.S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts;

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

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

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

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individually identifiable health information relating to the privacy, security and transmission 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 gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, there may be additional federal, state and non-U.S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts;

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

Additionally, we are subject to state and foreign equivalents of each of the healthcare laws and regulations described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many U.S. states have adopted laws similar to the federal Anti-Kickback Statute and FCA, and may apply to our business practices, including, but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental payors, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other

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marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state and require the registration of pharmaceutical sales representatives. State and foreign laws, including for example the EU General Data Protection Regulation (GDPR) (EU GDPR), also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement we could be subject to penalties. Finally, there are state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

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

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

U.S. Healthcare Reform

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in 2010, the ACA was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, subjects biological products to potential competition by lower cost biosimilars, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and creates a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition to coverage under Medicare Part D for the manufacturer's outpatient drugs.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which remain in effect through 2031.

Subsequent legislation extended the 2% reduction which remains in effect through 2031. 2032, absent additional congressional action. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers will be further reduced starting in 2025 absent further legislation. The U.S. American Taxpayer Relief Act of 2012 further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, on May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

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,

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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. President Biden has issued multiple executive orders that have sought to reduce prescription drug costs. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

The Inflation Reduction Act of 2022 (IRA) includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket spending cap for Medicare Part D beneficiaries from $7,050 to $2,000 starting in 2025, thereby effectively eliminating the coverage gap; impose new manufacturer financial liability on certain drugs under Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay until January 1, 2032 the implementation of the HHS rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one rare disease designation and for which the only approved indication is for that disease or condition. If a product receives multiple rare disease designations or has multiple approved indications, it may not qualify for the orphan drug exemption. These provisions take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. The effects of the IRA on our business and the healthcare industry in general is not yet known. In response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

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

In the United States, there has also been a lot of legislative activity at the state level with respect to privacy regulation. For example, in California, the California Consumer Privacy Act (CCPA), of 2018, as amended by the California Privacy Rights Act (CPRA), which amendments went into effect on January 1, 2023 of 2020 ("CPRA") (collectively the "CCPA"), broadly defines personal information and creates individual privacy rights and protections for California consumers (as defined in the law), places increased privacy and security obligations on entities handling personal data of consumers or households, and provides for civil penalties for violations and a private right of action for data breaches. The CCPA requires covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices, and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. While there is an exception for protected health information that is subject to HIPAA and clinical trial regulations, the CCPA may impact our

business activities if we become a "Business" regulated by the scope of the CCPA. Additionally, as of January 1, 2023, the effective date for the CPRA's amendments to the CCPA, California has a new state agency that is vested with authority to implement and enforce the CCPA. In addition to the CCPA, new privacy numerous other U.S. states – including Virginia, Colorado, Connecticut, and data security laws Utah – have been proposed in more than half of the states in the U.S. For example, on January 1, 2023, the Virginia Consumer Data Protection Act (CDPA) became effective. Further, many additional U.S. state enacted comprehensive privacy laws will go into effect throughout 2023: the Colorado Privacy Act (CPA) (July 1, 2023); the Connecticut Data Privacy Act (CTDPA) (July 1, 2023); and the Utah Consumer Privacy Act (UCPA) (December 31, 2023). The CDPA, CPA, CTDPA, and UCPA that are substantially similar in scope and contain many of the same requirements and exceptions as the CCPA, including exemptions for clinical trial data and limited obligations for entities regulated by HIPAA, that differ to a certain extent between the various laws. HIPAA. In addition, Congress regularly contemplates passing comprehensive privacy legislation at the federal level, reflecting a trend toward more stringent privacy legislation in the U.S., which trend may accelerate in the future. The effects of the CCPA, and other similar state or federal laws, are potentially significant and may require us to modify our data processing practices and policies and to incur substantial costs and potential liability in an effort to comply with such legislation. The existence of comprehensive privacy laws in different states in the country could make

our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance.

U.S. Patent Term Restoration and Marketing Exclusivity

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

An abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA licensed reference biological product was created by the Biologics Price Competition and Innovation Act of 2009 as part of the ACA. This amendment to the PHSA, in part, attempts to minimize duplicative testing. 2009. Biosimilarity, which requires that the biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, animal studies and a clinical trial or trials. Interchangeability requires that a biological product be biosimilar to the reference product and that the product can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times to an individual, that the product and the reference product may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product without such alternation or switch. A reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the FDA will not

accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. “First licensure” typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in

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a change in safety, purity, or potency. Therefore, one must determine whether a new product includes a modification to the structure of a previously licensed product that results in a change in safety, purity, or potency to assess whether the licensure of the new product is a first licensure that triggers its own period of exclusivity. Whether a subsequent application, if approved, warrants exclusivity as the “first licensure” of a biological product is determined on a case-by-case basis with data submitted by the sponsor.

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

European Union Drug Development

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

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Similar to the United States, the various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls. In April 2014, the EU adopted the new Clinical Trials Regulation (EU) No 536/2014 (Regulation) (CTR), which replaced entered into application on January 31, 2022, repealing and replacing the Clinical Trials Directive 2001/20/EC (Directive) on January 31, 2022 (CTD). The transitory provisions of the new Regulation offer sponsors the possibility extent to choose between the requirements of the previous Directive and the new Regulation if the request for authorization of a which on-going clinical trial is submitted in the year after the new Regulation became applicable. If the sponsor chooses to submit under the previous Directive, the clinical trial continues to trials will be governed by the Directive CTR will depend on the duration of the individual clinical trial. For clinical trials in relation to which an application for approval was made on the basis of the CTD before January 31, 2023, the CTD will continue to apply on a transitional basis until three years after January 31, 2025. By that date, all ongoing trials will become subject to the new Regulation became applicable. If a provisions of the CTR. The CTR will apply to clinical trials from an earlier date if the related clinical trial continues for more than three years after application was made on the Regulation became applicable, basis of the new Regulation will at that time begin to apply CTR or if the clinical trial has already transitioned to the clinical trial. CTR framework before January 31, 2025.

The new Regulation CTR aims to simplify and streamline the approval of clinical trials in the EU. EU, simplify adverse-event reporting procedures, improve the supervision of clinical trials and increase transparency. The main characteristics of the regulation include: a streamlined application procedure via a single-entry point through the Clinical Trials Information System (CTIS) (“CTIS”); a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a

harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts (Part I contains scientific and medicinal product documentation and Part II contains the national and patient-level documentation). parts. Part I assessment is assessed by a coordinated review led by the competent authorities of a reference Member State selected by the trial sponsor and relates to clinical trial aspects that are considered to be scientifically harmonized across EU Member States. This assessment is then submitted to the competent authorities of all EU concerned Member States in which an application the trial is to be conducted for authorization of a clinical trial has been submitted (Member States concerned) of a draft report prepared by a Reference Member State. their review. Part II is assessed separately by the competent authorities and Ethics Committees in each Member State concerned. Individual EU Member States retain the power to authorize the conduct of clinical trials on their territory. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned EU Member State. However, overall related timelines will be defined by the Regulation.

European Union Drug Review and Approval

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

The centralized procedure provides for the grant of a single MA is issued by the European Commission, based on the opinion of the Committee for Medicinal Products for Human Use ("CHMP") of the EMA, that is valid throughout the entire territory of the European Economic Area ("EEA") (which comprises the 27 EU Member States, Iceland, Liechtenstein and Norway). The centralized procedure is mandatory for certain types of marketing authorizations. products, such as medicines produced by biotechnological processes, products designated as orphan medicinal products, advanced therapy medicines (i.e. gene therapy, somatic cell therapy or tissue engineered medicines) and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases. The centralized procedure is optional for products containing a new active substance indicated for the treatment of other diseases and products not yet authorized in the EU, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EEA.

- The centralized MA is issued by the European Commission (EC) through the centralized procedure, based on the opinion of the Committee for Medicinal Products for Human Use (CHMP) of the EMA and is valid throughout the entire territory of the EU, and in the additional Member States of the European Economic Area (Iceland, Liechtenstein and Norway). The centralized procedure is mandatory for certain types of products, such as medicines produced by biotechnological processes, products designated as orphan medicinal products, advanced therapy medicines (i.e. gene therapy, somatic cell therapy or tissue engineered medicines) and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the EU, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.

Under the centralized procedure, the CHMP is responsible for conducting the initial assessment of a product and for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing MA. Under the centralized procedure in the EU, the maximum timeframe for the evaluation of an MAA by the EMA is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP. Clock stops may extend the timeframe of evaluation of an MAA considerably beyond 210 days. Where the CHMP gives a positive opinion, it provides the opinion together with supporting documentation to the European Commission, who adopts the final decision in relation to a MAA, which is issued within 67 days of receipt of the EMA's opinion. Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of major public health interest, particularly from the point of view of therapeutic innovation. If the CHMP accepts such request, the time limit of 210 days will be reduced to 150

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

- National MAs, which are issued by the competent authorities of the Member States of the EU and only cover their respective territory, are available for products not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in a Member State of the EU, this national MA can be recognized in other Member States through the mutual recognition procedure. If the product has not received a national MA in any Member State at the time of application, it can be approved simultaneously in various member states through the decentralized procedure. Under the decentralized procedure an identical dossier is submitted to the competent authorities of each of the member state in which the MA is sought, one of which is selected by the applicant as the Reference Member State (RMS). The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics (SmPC), and a draft of the labeling and package leaflet, which are sent to the other member state, referred to as the Concerned Member States, for their approval. If the Concerned Member States raise no objections, based on a potential serious risk to public health, to the assessment, SmPC, labeling, or packaging proposed by the RMS, the product is subsequently granted a national MA in all the member states (i.e., in the RMS and the Concerned Member States).

days, excluding clock stops, but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that the application is no longer appropriate to conduct an accelerated assessment.

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

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

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

Now that An MA has, in principle, an initial validity of five years. The MA may be renewed after five years on the United Kingdom (which comprises Great Britain basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the EU Member State in which the original MA was granted. To support the application, the MA holder must provide the EMA or the competent authority with a consolidated version of the Common Technical Document providing up-to-date data concerning the quality, safety and Northern Ireland) has left efficacy of the European Union, Great Britain will no longer be covered by centralized MAs (under product, including all variations introduced since the Northern Ireland Protocol, centralized MAs will continue MA was granted, at least nine months before the MA ceases to be recognized in Northern Ireland). All medicinal products with a current centralized MA were automatically converted to Great Britain MAs on January, 1, 2021. For a period valid. The European Commission or the competent authorities of two years from January 1, 2021, the Medicines and Healthcare products Regulatory Agency (MHRA) the UK medicines regulator, may rely on a decision taken by the EC on the approval of a new MA in the centralized procedure, in order to more quickly grant a new Great Britain MA. A separate application will, however, still be required. The MHRA also has the power to have regard to MAs approved in EU Member States through decentralized may decide on justified grounds relating to pharmacovigilance, to proceed with one further five year renewal period for the MA. Once subsequently definitively renewed, the MA shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on

the EU market (for a centralized MA) or mutual recognition on the market of the authorizing EU Member State within three years after authorization ceases to be valid (the so-called sunset clause).

Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the Priority Medicines, or PRIME, scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicinal products that target unmet medical needs. Eligible products must target conditions for which there is an unmet medical need (there is no satisfactory method of diagnosis, prevention or treatment in the EU or, if there is, the new medicinal product will bring a major therapeutic advantage) and they must demonstrate the potential to address the unmet medical need by introducing new methods of therapy or improving existing ones. Benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted.

In the EU, a "conditional" MA may be granted in cases where all the required safety and efficacy data are not yet available. The European Commission may grant a conditional MA for a medicinal product if it is demonstrated that all of the following criteria are met: (i) the benefit-risk balance of the medicinal product is positive; (ii) it is likely that the applicant will be able to provide comprehensive data post-authorization; (iii) the medicinal product fulfils an unmet medical need; and (iv) the benefit of the immediate availability to patients of the medicinal product is greater than the

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risk inherent in the fact that additional data are still required. The conditional MA is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and must be renewed annually until all related conditions have been fulfilled. Once any pending studies are provided, the conditional MA can be converted into a traditional MA. However, if the conditions are not fulfilled within the timeframe set by the EMA and approved by the European Commission, the MA will cease to be renewed.

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

Advanced Therapy Medicinal Products in the United Kingdom European Union

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

Cell-based products must also comply with Directive (EC) No. 2004/23 of the European Parliament and of the Council of March 31, 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, or the Tissues and Cells Directive, as well as its technical implementing directives. This Directive describes the

conditions and quality requirements which must be applied when sourcing the cells intended for manufacturing of the cell-based medicinal product. The EU Member States have transposed the Tissues and Cells Directive into their national laws. However, various interpretations of the Tissue and Cells Directive have occurred and are reflected in individual EU Member States national implementing legislation which have led to diverging approaches.

European Union Pediatric Development

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

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in effect at the time of authorization or, in the case of orphan medicinal products, a two-year extension of orphan market exclusivity.

European Union Data and Market Exclusivities

In the EU, innovative medicinal products approved on the basis of a complete independent data package qualify for eight years of data exclusivity upon grant of an MA and an additional two years of market exclusivity. The data exclusivity, if granted, prevents generic or biosimilar applicants from referencing the innovator's preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar MA in the EU, during a period of eight years from the date on which the reference product was first authorized in the EU. During the additional two-year period of market exclusivity, a generic or biosimilar MAA can be submitted, and the innovator's data may be referenced, but no generic or biosimilar product can be placed on the EU market until the expiration of the market exclusivity. The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of

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those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are determined to bring a significant clinical benefit in comparison with currently approved therapies. There is no guarantee that a product will be considered by the EMA EU's regulatory authorities to be an innovative medicinal product, and products may not qualify for data exclusivity. Even if

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

company could nevertheless also market another version of the product if such company obtained an MA based on an MAA with a complete independent data package of pharmaceutical tests, preclinical tests and clinical trials. biological product.

European Union Orphan Designation and Exclusivity

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

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

In the EU, orphan designation entitles a party to financial incentives such as reduction of fees or fee waivers, protocol assistance, and ten years access to the centralized marketing authorization procedure. Upon grant of a marketing authorization, orphan medicinal products are entitled to a ten-year period of market exclusivity is granted following grant of an MA. During this market exclusivity period, neither for the approved therapeutic indication, which means that the EMA nor the EC nor any of the competent authorities in the EU Members States can cannot accept another marketing authorization application or accept an application or grant an MA to extend for a "similar medicinal product approval." product" and the European Commission cannot grant a marketing authorization for the same indication for a period of ten years. A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. This The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed PIP. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan medicinal product designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The market exclusivity period may be reduced to six years if the orphan designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. Market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, an MA may also be revoked in very select cases, such as granted to a similar medicinal product with the same orphan indication during the 10 year period if (i) it is established that a similar medicinal product is safer, more

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effective or otherwise clinically superior to the authorized original orphan medicinal product; (ii) the marketing authorization holder of the authorized orphan product consents to such revocation; a second original orphan medicinal product application; or (iii) the marketing authorization holder of the authorized orphan product cannot supply enough orphan medicinal product. Orphan designation must be requested before submitting an application for MA. A company may also voluntarily remove a product from the register of orphan products. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Regulatory Requirements After Manufacturing Regulation in the EU

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

administrative sanctions, including suspension of manufacturing authorization, in case of non-compliance with the EU or EU Member States' requirements applicable to the manufacturing of medicinal products.

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

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

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

- In the EU, the advertising and promotion of medicinal products are subject to both EU and EU Member States' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. General requirements for which a separate manufacturer's license is mandatory, must also be conducted advertising and promotion of medicinal products, such as direct-to-consumer advertising of prescription medicinal products are established in strict compliance EU law. However, the details are governed by regulations in individual EU Member States and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the applicable EU laws, regulations product's Summary of Product Characteristics, or SmPC, which may require approval by the competent national authorities in connection with an MA. The SmPC is the document that provides information to physicians concerning the safe and guidance, including Directive 2001/83/EC, Directive 2003/94/EC, Regulation (EC) No 726/2004 and the EC Guidelines for Good Manufacturing Practice. These requirements include compliance with EU cGMP standards when manufacturing medicinal products and active pharmaceutical ingredients, including the manufacture of active pharmaceutical ingredients outside effective use of the EU product. Promotional activity that does not comply with the intention to import the active pharmaceutical ingredients into SmPC is considered off-label and is prohibited in the EU.

- Much like the Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. The provision of benefits or advantages to physicians is sometimes governed by the national anti-bribery laws of the EU Member States, and the Bribery Act 2010 in the UK. Infringement of these laws could result in substantial fines and

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imprisonment. EU Directive 2001/83/EC, which is the EU Directive governing medicinal products for human use, further provides that, where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. This provision has been transposed into the Human Medicines Regulations 2012 and so remains applicable in the UK despite its departure from the EU.

- Payments In addition, payments made to physicians in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization as well as the regulatory authorities of the individual EU Member States. These requirements Outside the United States, interactions between pharmaceutical companies and health care

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professionals including the provision of benefits or advantages to physicians , are provided also governed by strict laws, such as national anti-bribery laws of European countries such as the Bribery Act 2010 in the UK, national laws, sunshine rules, regulations, industry codes or professional self-regulation codes of conduct applicable in the EU Member States. and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

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

European Data Collection

The collection and use of personal health data in the EEA is governed by the EU GDPR. The EU GDPR applies to any company established in the EEA and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. The EU GDPR enhances data protection obligations for data controllers of personal data, including stringent requirements relating to the consent of data subjects, expanded disclosures about how personal data is used, requirements to conduct privacy impact assessments for "high risk" processing, limitations on retention of personal data, mandatory data breach notification and "privacy by design" requirements, and creates direct obligations on service providers acting as data processors. The GDPR also imposes strict rules on the transfer of personal data outside of the EEA to countries that do not ensure an adequate level of protection, like the United States.

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

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Addendum to the new standard contractual clauses (IDTA), which enable transfers from the UK. For new transfers, the IDTA already needs to be in place, Privacy Framework and must be in place for all existing transfers from the UK from March 21, 2024 Extension thereto (which allows for transfers for relevant U.S.-based organizations who self-certify compliance and participate in the Framework). Following a ruling from the

Court of Justice of the EU, in Data Protection Commissioner v Facebook Ireland Limited However, these mechanisms are subject to legal challenges, and Maximillian Schrems, Case C-311/18 (Schrems II), companies relying there is no assurance that we can satisfy or rely on standard contractual clauses these measures to govern transfers of lawfully transfer personal data to third countries (in particular the United States) will need to assess whether the data importer can ensure sufficient guarantees for safeguarding the personal data under GDPR. This assessment includes assessing whether third party vendors can also ensure these guarantees. The same assessment is required for transfers governed by the IDTA. We will be required to implement these new safeguards when conducting restricted data transfers under the GDPR and doing so will require significant effort and cost. States.

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

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Brexit and the Regulatory Framework in the United Kingdom

On June 23, 2016The United Kingdom's, or UK, withdrawal from the EU on January 31, 2020, the electorate in the United Kingdom voted in favor of leaving the European Union (commonly commonly referred to as Brexit), Brexit, has changed the regulatory relationship between the UK and the UK formally left EU. The Medicines and Healthcare products Regulatory Agency, or MHRA, is now the EU on January 31, 2020. There was a transition period during which EU pharmaceutical laws continued to apply to the UK, which expired on December 31, 2020. However, the EU and the UK have concluded a trade and cooperation agreement (TCA) which was provisionally applicable since January 1, 2021, and has been formally applicable since May 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP, inspections of manufacturing facilities UK's standalone regulator for medicinal products and GMP documents issued, but does not foresee wholesale mutual recognition of UK and EU pharmaceutical regulations. At present, medical devices. Great Britain has (England, Scotland and Wales) is now a third country to the EU. Northern Ireland will, with regard to EU regulations, continue to follow the EU regulatory rules for now.

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

Marketing authorizations in the UK are governed by the Human Medicines Regulations 2012 (as amended) (under the Northern Ireland Protocol, (SI 2012/1916), as amended. Since January 1, 2021, an applicant for the EU regulatory framework will continue centralized procedure marketing authorization can no longer be established in the UK. As a result, since this date, companies established in the UK cannot use the EU centralized procedure and instead must follow one of the UK national authorization procedures or one of the remaining post-Brexit international cooperation procedures to apply obtain a marketing authorization to market products in Northern Ireland). The regulatory regime the UK. All existing EU marketing authorizations for centrally authorized products were automatically converted or grandfathered into UK marketing authorization, effective in Great Britain therefore largely aligns with current only, free of charge on January 1, 2021, unless the marketing authorization holder opted-out of this possibility. Northern Ireland currently remains within the scope of EU regulations, however it authorizations in relation to centrally authorized medicinal products. Accordingly, until the Windsor Framework is possible implemented in

Northern Ireland on January 1, 2025, products falling within the scope of the EU centralized procedure can only be authorized through UK national authorization procedures in Great Britain.

The MHRA has also introduced changes to national marketing authorization procedures. This includes introduction of procedures to prioritize access to new medicines that these regimes will diverge in future now that Great Britain's regulatory system benefit patients, including a 150-day assessment route, a rolling review procedure and the International Recognition Procedure. Since January 1, 2024, the MHRA may rely on the International Recognition Procedure, or IRP, when reviewing certain types of marketing authorization applications. This procedure is independent available for applicants for marketing authorization who have already received an authorization for the same product from a reference regulator. These include the FDA, the EMA, and national competent authorities of individual EEA countries. A positive opinion from the EU EMA and CHMP, or a positive end of procedure outcome from the TCA does not provide for mutual recognition or decentralized procedures are considered to be authorizations for the purposes of UK and the IRP.

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

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

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the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. In addition, many jurisdictions outside of Europe are also considering and/or enacting comprehensive data protection legislation. These laws impose stringent requirements applicable to our collection, use and processing of personal data including identifiable health information.

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

Coverage and Reimbursement

Sales of our products, when and if approved, will depend, in part, on the extent to which our products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. In the United States, the principal decisions about reimbursement for new medicines are typically made

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by CMS, an agency within the HHS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. However, no uniform policy of coverage and reimbursement for drug or

biological products exists in the United States. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of our products will be made on a payor-by-payor basis. As a result, coverage determination is often a time consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. Factors payors consider in determining reimbursement are based on whether the product is:

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

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

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

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

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

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

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

In addition, in most foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the EU provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Other EU Member States allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. In addition, some EU Member States may require the completion of additional studies that compare the cost-effectiveness of a particular medicinal product candidate to currently available therapies. This Health Technology Assessment, or HTA, process is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in

the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. In December 2021, Regulation No 2021/2282 on Health Technology Assessment, or HTA Regulation, was adopted. The HTA Regulation is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. When it enters into application in 2025, the HTA Regulation will be intended to harmonize the clinical benefit assessment of HTA across the European Union. In light of the fact that the United Kingdom has left the EU, Regulation No 2021/2282 on HTA will not apply in the United Kingdom. However, the UK Medicines and

Healthcare products Regulation Agency (“MHRA”) is working with UK HTA bodies and other national organizations, such as the Scottish Medicines Consortium (“SMC”), the National Institute for Health and Care Excellence (“NICE”), and the All-Wales Medicines Strategy Group, to introduce new pathways supporting innovative approaches to the safe, timely and efficient development of medicinal products.

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

Human Capital Resources

As of February 28, 2023 February 29, 2024, we had 156 151 full-time employees and 22 28 part-time employees. Of our 178 179 full and part-time employees, 43, 42, or 24,2% 23.5%, have Ph.D. or M.D. degrees and 139, 140, or 78,1% 78.2%, are engaged in research and development activities. Pursuant to Austrian law, all of our Austrian employees are covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

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

Corporate History

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

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Facilities

Our principal executive offices are located in New York, New York, pursuant to a lease that expires in February 2024. August 2026. Our European research and preclinical development operations are located in Vienna, Austria, where we lease and occupy approximately 30,656 30,681 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 15,239 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 2,367 square feet of storage space. In 2019, we entered into a lease for a second facility located in Vienna, Austria that is set to expire in February 2029, where we occupy approximately 15,440 square feet of office and laboratory space. In May 2021 we signed an agreement to purchase a parcel of land in the north of Vienna and have received building permission to build a GMP manufacturing plant. We have completed the detailed engineering phase, and will take but decided to discontinue the construction project of a decision GMP manufacturing facility, which was written-off in the year ended December 31, 2023. Furthermore, we decided to kick off construction work if and when required by pipeline progress. divest all assets associated with this project, including, but not limited to the parcel of land. 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.

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Legal Proceedings

We are currently were recently a party to a patent proceeding opposing European Patent No. 3218504 (the "EP '504 Patent"), which was granted to the University of Geneva in July 2020 and is exclusively licensed to us. The patent is directed to our replicating arenavirus platform technology and is part In a decision that has become final, the Opposition Division of our strategy to protect current product candidates based on this platform technology, including our lead oncology product candidates HB-201 and HB-202. We filed our formal response to the opposition with the European Patent Office (EPO) on September 3, 2021, in which we requested that ("EPO") dismissed the opposition be rejected in an oral proceeding on May 9, 2023, and maintained the European Patent No. 3218504 be maintained patent as granted. With the communication of June 27, 2022, the EPO's Opposition Division has summoned the parties to oral proceedings scheduled for May 9, 2023, and issued a preliminary opinion, in which it followed our arguments and preliminarily rejected most of the attacks raised by the opponent, including the attacks against the claims that we consider most relevant for the protection of our technology. While the outcome of the matters can still not be predicted with certainty, and some lawsuits, claims or proceedings may be disposed or decided unfavorably, we do not expect that the pending patent opposition, and any asserted or unasserted legal claims or proceedings, individually or in the aggregate, will have a material adverse effect on us. However, if, as a result of the current patent proceeding, we would lose all, or at least part, of the protection under the opposed patent, such loss could erode our competitive position and harm our business and ability to achieve profitability. Besides the European opposition proceeding, we 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, proxy statements, and other information, including amendments and exhibits to such reports, filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, are available free of charge on our website located at www.hookipapharma.com, as soon as reasonably practicable after they are filed with or furnished to the SEC. These reports are also available at the SEC's Internet website at www.sec.gov.

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

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Annual Report on Form 10-K, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market

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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 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, 2021 December 31, 2022 and 2022, 2023, we reported a net loss of $75.7 $64.9 million and $64.9 $81.6 million, respectively. As of December 31, 2022 December 31, 2023, we had an accumulated deficit of $287.7 $369.3 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;

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- 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.

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If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Accordingly, our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our

research and development efforts, expand our business or continue our operations. A decline in the value of our company also could cause you to lose all or part of your investment.

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

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

As of December 31, 2022 December 31, 2023, we had approximately $113.4 $117.5 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, 2022 December 31, 2023, together with the funds payment we received under expect to receive prior to the Restated Gilead Collaboration Agreement in January 2023 and the funds we received under termination of the Roche Collaboration Agreement in March 2023, April 2024, will

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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;
- our ability to achieve efficiencies and expected cost reductions in connection with our recent strategic refocus;
- the stability, scale and yields of our future manufacturing process as we scale-up scaleup production and formulation of our product candidates for later stages of development and commercialization;
- the timing of, and the costs involved in, obtaining regulatory and marketing approvals and developing our ability to establish sales and marketing capabilities, if any, for our current and future product candidates we develop if clinical trials are successful;
- the success of our collaborations with Gilead and Roche; Gilead;
- our ability to establish and maintain collaborations, strategic licensing or other arrangements and the financial terms of such agreements; agreements. For example, in January 2024 Roche notified us of their decision to terminate their collaboration agreement with us;

- the cost of commercialization activities for our current and future product candidates that we may develop, whether alone or with a collaborator;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the timing, receipt and amount of sales of, or royalties on, our future products, if any; and
- the emergence of competing oncology and infectious disease therapies and other adverse market developments.

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

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

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

If we raise additional capital through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your

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

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

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

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

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

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- 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.

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

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

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

Risks Related to Our Business and Industry

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

All of our product candidates are in early stages of development, including our lead product candidates, HB-201 and HB-202, candidate, HB-200, which are is currently in a Phase 1/2 clinical trial, and as such will require extensive preclinical and clinical testing. We cannot predict with any certainty if or when we might submit an IND, or BLA, or comparable foreign applications, for regulatory approval for any of our product candidates or whether any such IND or BLA, or comparable foreign applications, will be accepted for review by the FDA or comparable foreign regulatory authority, or subsequently whether any such IND will go into effect or BLA will be approved upon review. review, or whether comparable foreign applications will fulfill the related milestones.

We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. For example, we recently announced a strategic refocus to prioritize clinical development of HB-200 for the treatment of HPV16+ head and neck cancers and Gilead-partnered programs in infectious disease and to pause development activities related to HB-300 and most other preclinical research activities. In connection with this strategic refocus, we implemented an approximately 30% reduction in our workforce and discontinued our GMP manufacturing facility project. In addition, in January 2024 Roche notified us of their decision to terminate the collaboration and licensing agreement for HB-700 in KRAS mutated cancers, despite acknowledging we had met all go-forward criteria under the agreement.

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

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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;

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- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- acceptance of INDs and comparable foreign applications for our planned clinical trials or future clinical trials;
- successful enrollment and completion of clinical trials;
- successful data from our clinical program that support an acceptable risk-benefit profile of our product candidates in the intended populations;
- receipt and maintenance of regulatory and marketing approvals from applicable regulatory authorities;

- scale-up of our manufacturing processes and formulation of our product candidates for later stages of development and commercialization;
- establishing our own manufacturing capabilities or agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if our product candidates are approved;
- entry into collaborations to further the development of our product candidates;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates;
- successfully launching commercial sales of our product candidates, if and when approved;
- acceptance of the product candidate's benefits and uses, if and when approved, by patients, the medical community and third-party payors;
- the prevalence and severity of adverse events experienced with our product candidates;
- maintaining a continued acceptable safety profile of the product candidates following approval;
- effectively competing with other therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors; and
- qualifying for, maintaining, enforcing and defending intellectual property rights and claims.

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

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

The time required to obtain approval from the FDA, the EMA European Commission and other comparable foreign regulatory authorities is unpredictable, but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval

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policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate, and it is possible that none of our current or future product candidates will ever obtain regulatory approval.

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

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

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

We have conducted, and intend to conduct, clinical trials of certain of our product candidates outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA, including compliance with all applicable U.S. laws and regulations. For example, the clinical trial must be well designed and conducted and performed by qualified investigators

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in accordance with GCP, including review and approval by an independent ethics committee and informed consent from subjects. The study population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. In general, the patient population for any clinical trials conducted outside of the United States must be representative of the population for whom we intend to label the product in the United States. There can be no assurance the FDA will accept data from trials

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conducted outside of the United States. Comparable risks apply abroad in relation to the data that was generated in the United States which we intend to leverage for purposes of obtaining regulatory authorizations abroad. There can be no assurance that foreign regulatory authorities

will accept data from trials conducted outside of their territory.

The FDA, the EMA and the European Commission and other comparable foreign regulatory authorities have 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 European Commission or any other comparable foreign regulatory authorities.

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

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

Before obtaining regulatory approvals for the commercial sale of our product candidates, including HB-101, HB-201, HB-202, HB-300, HB-200, HB-400, HB-500, HB-700 and any other future product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process, and, because our product candidates are in an early stage of development, there is a high risk of failure and we may never succeed in developing marketable products.

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

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

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

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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.

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

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

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

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

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

Further, others, including regulatory agencies, may not accept or agree with our interim, topline or preliminary analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

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

Success in preclinical studies and early clinical trials does not ensure that later clinical trials will be successful. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Even if we are able to commence clinical trials, issues may arise that could suspend or terminate such clinical trials. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in clinical trials, even after positive results in earlier preclinical studies or clinical trials. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. Notwithstanding any potential promising results in earlier studies and trials, we cannot be certain that we will not face similar setbacks. In addition, the results of our preclinical animal studies, including our

oncology mouse studies and animal studies, may not be predictive of the results of outcomes in human clinical trials. For example, our oncology product candidates that are in preclinical development may demonstrate different chemical and

biological properties in patients than they do in laboratory animal studies or may interact with human biological systems in unforeseen or harmful ways.

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

Our replicating technology is an attenuated viral vector technology which is in a Phase 1/2 clinical trial. If our ongoing Phase 1/2 clinical trial for HB-201 and HB-202/HB-201 HB-200 causes unexpected side effects that are not tolerable in the treatment of the relevant patient group, the further development of the product candidate and any other potential products based on the replicating technology may be significantly limited or become impossible. Although clinical trials of onco-viral therapies have supported their role as a potential treatment for cancer, there is the risk of uncontrolled replication in vivo and possible transmission to patients' contacts, such as other patients and health care workers. In recent years, clinical trials to address these concerns have been conducted. Any such transmission by our product candidates or a competitor would have an adverse impact on our future research and development efforts.

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

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

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

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

A trial design that is considered appropriate for regulatory approval includes a sufficiently large sample size with appropriate statistical power, as well as proper control of bias, to allow a meaningful interpretation of the results. In the Phase 2 portion of our Phase 1/2 trial for HB-200 in combination with pembrolizumab, we expect to enroll two groups of 10 to 20 patients each and future each. Future trials for HB-200 or other product candidates may similarly enroll a small number of patients although some trials will require the enrollment of more patients.

The preliminary results of trials with smaller sample sizes can be disproportionately influenced by the impact the treatment had on a few individuals, which limits the ability to generalize the results across a broader community, making the trial results less reliable than trials with a larger number of patients. As a result, there may be less certainty that such product candidates would achieve a statistically significant effect in any future clinical trials. If we conduct any future clinical trials, we may not achieve a statistically significant result or the same level of statistical significance, if any, that would have been possible to achieve in a larger trial.

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

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

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

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

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

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;

- the novel nature of the technology underlying our product candidates which may not be known to or be negatively perceived by clinical trial investigators or patients;

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- our ability to obtain and maintain patient consents;
- the risk that patients enrolled in clinical trials will drop out of the trials before the manufacturing and infusion of our product candidates or trial completion; and

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- current or potential pandemics that may limit patients, principal investigators or staff or clinical site availability (e.g. the recent COVID-19 pandemic).

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

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

We have limited experience as a company conducting clinical trials or managing a manufacturing facility for our product candidates. trials.

We have limited experience as a company in conducting clinical trials. In part because of this lack of experience, we cannot be certain that our ongoing clinical trial trials will be completed on time or if the our 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 (CROs), or consultants. Relying on third-party clinical investigators or CROs may force us to encounter delays that are outside of our control.

We do not have our own manufacturing facility for the production of clinical trial material or future commercial products and therefore depend on third-party contract manufacturing organizations (CMOs) and their knowhow for production of our product candidates. Because of our limited control of our third-party manufacturers and in part because of our inexperience, our third-party manufacturers may fail to produce our product in a reliable and consistent manner and in sufficient quality and quantity. We have encountered problems with our third-party manufacturers in the past, including delays and low yields, and there can be no assurance that we will not encounter similar or other difficulties in the future.

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

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

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

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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.

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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; FDA or comparable foreign regulatory authorities;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;

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- 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.

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

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

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and

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

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

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

In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price (ASP), and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs.

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

In addition, the requirements governing drug pricing vary widely from country to country. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. For example, the European Union provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. 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 An EU Member State may approve a specific price for the medicinal product, it may refuse to reimburse a product at the price set by the manufacturer or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Many EU Member States also periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status.

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profitability Moreover, in order to obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. This Health Technology Assessment ("HTA") of medicinal products is becoming an increasingly common part of the company placing pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product on in the market. national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product

candidates. Historically, products launched in the European Union do not follow price structures of the U.S. and generally prices tend to be significantly lower.

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

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

Our HB-200 program is being developed to be used in combination with or without an approved checkpoint inhibitor, a currently approved cancer therapy. In the future, we may develop other product candidates to be used with one or more currently approved cancer therapies. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or similar regulatory authorities outside of the United States could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. Combination therapies are commonly used for the treatment of cancer, and we would be subject to similar risks if we develop any of our product candidates for use in combination with other drugs or for indications other than cancer. This could result in our own products being removed from the market or being less successful commercially. In addition, if the results from our combination trials are not significantly better than results from the existing therapy that we are combining with, then regulatory authorities, clinical investigators, physicians and patients may perceive our product candidates negatively, which could adversely affect enrollment in our clinical trials, approval by regulatory authorities or commercial adoption of our product candidates, if approved.

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

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

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

The commercial success of product candidates based on our replicating technology will depend in part on public acceptance of the use of cancer immunotherapies. Adverse events in the HB-200 program or our other product candidates based on our replicating technology or in clinical trials of others developing similar products and the resulting publicity, as well as any other negative developments in the field of immuno-oncology that may occur in the future, including in connection with competitor therapies, could result in a decrease in demand for any product candidates based on our replicating technology that we may develop. These events could also result in the suspension, discontinuation, or clinical hold of or modification to our clinical trials. If public perception is influenced by claims that the use of cancer immunotherapies is unsafe, whether related to our therapies or those of our competitors, our product candidates may not

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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

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

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

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

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

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

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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

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commercial potential or target market for a particular product candidate, identify and successfully commercialize additional suitable product candidates, this would adversely impact our business strategy and our financial position.

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

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

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

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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.

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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 Many of our employees and a significant portion of our operations are located outside the United States, including in Vienna, Austria. In addition, we plan to seek regulatory approval of our product candidates outside of the

United States and, accordingly, we expect that we, and any potential collaborators in those jurisdictions, will be subject to additional risks related to operating in foreign countries, including:

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls, and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;

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

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

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

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

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

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

The extent to which the ongoing coronavirus pandemic may impact our business, results of operations world, and future growth prospects will depend on a variety of factors and future developments, which are highly uncertain and cannot be predicted with confidence, including the duration, scope and severity of the pandemic, particularly as virus variants continue to spread. For example, we experienced, and may experience again, some caused temporary delays or and disruptions due to the coronavirus pandemic, including pauses in and delays to patient dosing, limited or reduced patient access to ICU beds, hospitals and healthcare resources generally, delayed initiation of new our clinical trial sites and limited on-site personnel support at various trial sites. In addition, certain of our third-party manufacturers and suppliers paused their operations in the early stages of the pandemic, and some have paused their operations again as additional waves of the coronavirus pandemic have impacted local communities and/or as a result of national and local regulations.

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We are actively monitoring and managing our response and evaluating the actual and potential impacts to our business operations, including on our ongoing and planned clinical trials. We will continue to work closely with our third-party vendors, collaborators, and other parties in order to seek to advance our programs and pipeline of product candidates, while keeping the health and safety of our employees and their families, partners, third-party vendors, healthcare providers, patients and communities a top priority. development operations.

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

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

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

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

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

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

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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

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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 Roche for the development of our HB-700 program and our collaborations with Gilead for the development of our HBV programs, rely on funding from both Gilead and Roche for development of our human immunodeficiency virus and HB-700 program, respectively, and may depend on Gilead Roche or additional third parties for the development and commercialization of our other programs and future product candidates. Our current and future collaborators may control aspects of our clinical trials, which could result in delays or other obstacles in the commercialization of the product candidates we develop. If our collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates

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

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

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

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invalidate our intellectual property or proprietary information or expose us to potential litigation, or other intellectual property proceedings;

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- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- disputes may arise between a collaborator and us that cause the delay or termination of the research, development or commercialization of the product candidate, or that result in costly litigation or arbitration that diverts management attention and resources;
- if a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated;

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

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

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

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

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

We face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for other collaborations will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the progress of our clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of

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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

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product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view them as having the requisite potential to demonstrate safety and efficacy.

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

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

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

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

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

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

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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

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successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

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

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

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

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

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

Although we do intend to develop our own manufacturing facility, we currently rely on third parties as part of our manufacturing process and may, in any event, never be successful in developing our own manufacturing facility. Our reliance on a limited number of third-party manufacturers exposes us to the following risks:

- the production process for our product candidates is complex and requires specific know-how that only a limited number of CMOs can provide, as a result, we compete with other companies in the field for the scarce capacities of these organizations and may not be able to secure sufficient manufacturing capacity when needed;
- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA and comparable foreign regulatory authorities must inspect any manufacturers for cGMP compliance as part of our marketing application;
- a new manufacturer would have to be educated in, or develop substantially equivalent processes for, the production of our product candidates;

- a change in manufacturers or certain changes in manufacturing processes/procedures will require that we conduct a manufacturing comparability study to verify that any new manufacturer or manufacturing process/procedure will produce our product candidate according to the specifications previously submitted to the FDA or other regulatory authority, to which we may be unsuccessful;

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

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

Despite our efforts to audit and verify regulatory compliance, one or more of our third-party manufacturing vendors may be found on regulatory inspection by the FDA, competent authorities of EU Member States or other comparable foreign regulatory authorities to be noncompliant with cGMP regulations. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us,

including shutdown of the third-party vendor or invalidation of drug product lots or processes, fines, injunctions, civil penalties, delays, suspension, variation or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products, if approved, and significantly harm our business, financial condition, results of operations and prospects.

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

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

materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

Risks Related to Government Regulation

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

Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a (REMS) in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Comparable foreign regulatory authorities may impose similar requirements.

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

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

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning or untitled letters or holds on clinical trials;

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

The FDA's, the EMA's and the European Commission and other comparable foreign regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. As an example, the regulatory landscape related to clinical trials in the EU has evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. The CTR permits trial sponsors to make a single submission to both the competent authority and an ethics committee in each EU Member State, leading to a single decision for each EU Member State. The assessment procedure for the authorization of clinical trials has been harmonized as well, including a joint assessment of some elements of the application by all EU Member States in which the trial is to be conducted, and a separate assessment by each EU Member State with respect to specific requirements related to its own territory, including ethics rules. Each EU Member State's decision is communicated to the sponsor through a centralized EU portal, the Clinical Trial Information System, or CTIS. The CTR provides a three-year transition period. The extent to which ongoing clinical trials will be governed by the CTR varies. For clinical trials in relation to which an application for approval was made on the basis of the Clinical Trials Directive before January 31, 2023, the CTD will continue to apply on a transitional basis until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR. The CTR will apply to clinical trials from an earlier date if the related clinical trial application was made on the basis of the CTR or if the clinical trial has already transitioned to the CTR framework before January 31, 2025. In light of the entry into application of the CTR on January 31, 2022, we may be required to transition clinical trials for which we have obtained regulatory approvals in accordance with the CTD to the regulatory framework of the CTR by October 31, 2024. A transitioning application will need to be submitted to the competent authorities of E.U. Member States through the Clinical Trials Information Systems and related regulatory approval obtained to continue the clinical trial past January 30, 2025. This will require financial, technical and human resources. If we are unable to transition our clinical trials in time, the conduct of those clinical trials may be negatively impacted. We cannot predict the likelihood, nature or extent of government regulation that may arise from future

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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

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additional downward pressure on the price that we, or our collaborators, may receive for any approved products. See “Business – Other U.S. Healthcare Laws.” We cannot predict the initiatives that may be adopted in the future.

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

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

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

In addition, on April 26, 2023, the European Commission adopted a proposal for a new Directive and Regulation to revise the existing pharmaceutical legislation. If adopted in the form proposed, the recent European Commission proposals to revise the existing EU laws governing authorization of medicinal products may result in a decrease in data and market exclusivity opportunities for our product candidates in the EU and make them open to generic or biosimilar competition earlier than is currently the case with a related reduction in reimbursement status.

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

The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products. Legislative and regulatory proposals may also

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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. See "Business – U.S. Healthcare Reform."

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

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

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

Companion diagnostics, which provide information that is essential for the safe and effective use of a corresponding therapeutic product, are subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and require separate regulatory approval from therapeutic approval prior to commercialization. The FDA previously has required in vitro companion diagnostics intended to

select the patients who will respond to a product candidate to obtain pre-market approval (PMA), simultaneously with approval of the therapeutic candidate. The PMA process, including the gathering of preclinical and clinical data and the submission and review by the FDA, can take several years or longer. It involves a rigorous premarket review during which the applicant must prepare and provide FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing, and labeling. After a device is placed on the market, it remains subject to significant regulatory requirements, including requirements governing development, testing, manufacturing, distribution, marketing, promotion, labeling, import, export, record-keeping, and adverse event reporting. We will be subject to additional obligations and regimes with respect to such companion diagnostic tests with regulators outside the United States.

In the EEA, companion diagnostics are deemed to be in vitro diagnostic medical devices, or IVDs, and are governed by Regulation 2017/746, or IVDR, which entered into application on May 26, 2022, repealing and replacing Directive 98/79/EC. The IVDR defines a companion diagnostic as a device which is essential for the safe and effective use of a corresponding medicinal product to: (a) identify, before and/or during treatment, patients who are most likely to benefit from the corresponding medicinal product; or (b) identify, before and/or during treatment, patients likely to be at increased risk of serious adverse reactions as a result of treatment with the corresponding medicinal product. The IVDR and its associated guidance documents and harmonized standards govern, among other things, device design and development, preclinical and clinical or performance testing, premarket conformity assessment, registration and listing, manufacturing, labeling, storage, claims, sales and distribution, export and import and post-market surveillance, vigilance, and market surveillance. IVDs, including companion diagnostics, must conform with the general safety and performance requirements, or GSPR, of the IVDR. Compliance with these requirements is a prerequisite to be able to affix the CE mark to devices, without which they cannot be marketed or sold in the EEA. To demonstrate compliance with the GSPR laid down in Annex I to the IVDR, and obtain the right to affix the CE mark, IVD manufacturers must

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conduct a conformity assessment procedure, which varies according to the type of IVD and its classification. Companion diagnostics must undergo a conformity assessment by a Notified Body. Depending on the relevant conformity assessment procedure, the Notified Body audits and examines the technical documentation and the quality system for the manufacture, design and final inspection of the medical devices. The Notified Body issues a CE Certificate of Conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the GSPRs. If the related medicinal product has, or is in the process of, been authorized through the centralized procedure for the authorization of medicinal products, the notified body will, before it can issue a CE Certificate of Conformity, be required to seek a scientific opinion from the EMA on the suitability of the companion diagnostic for use in relation to the medicinal product concerned. For medicinal products that have or are in the process of authorization through any other route provided in EU legislation, the Notified Body must seek the opinion of the national competent authority of an EU Member State. The CE Certificate of Conformity and the related conformity assessment process entitles the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related EC Declaration of Conformity.

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

commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our product candidates.

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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

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FDA may later decide that such product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

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

We may seek Fast Track Designation for the product candidates we develop. If a product is intended for the treatment of a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, the product sponsor may apply for Fast Track Designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track Designation, as we have for single-vector HB-201 and alternating 2-vector HB-202/HB-201, both HB-200 in combination with pembrolizumab, for the treatment of first-line advanced/metastatic HPV16+ HNSCC, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may rescind the Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program.

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

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

Similarly, in Europe, the EC grants European Commission may grant orphan designation after receiving the opinion of the EMA Committee for Orphan Medicinal Products on an orphan designation application. Orphan designation is intended to promote the development of drugs that are intended (i) for the diagnosis, prevention or treatment of life-threatening or chronically

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debilitating conditions, affecting (ii) either the conditions affect no more than 5 in 10,000 persons in the EU and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or without the product would be a significant benefit to those affected). Additionally, designation is granted for products intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, benefits derived from orphan status, it is unlikely that sales of the product in the EU would be sufficient to justify the necessary investment in developing the product. product, and (iii) there exists no satisfactory authorized method of diagnosis, prevention, or treatment of the condition that has been authorized in the EU, or even if such method exists, the product will be of significant benefit to those affected by that condition. In the EU, orphan designation entitles a party to a number of incentives, such as protocol assistance, and scientific advice specifically for designated orphan medicines, access to the centralized marketing authorization procedure, and potential fee reductions or waivers depending on the status of the sponsor.

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

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Even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product candidate from competition because different therapies can be approved for the same condition and the same therapies can be approved for different conditions but used off-label. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the

FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan Drug Designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. Similar considerations apply abroad. While we may seek Orphan Drug Designation for applicable indications for our current and any future product candidates, we may never receive such designations. Even if we do receive such designations, there is no guarantee that we will enjoy the benefits of those designations.

Our business operations and current and future relationships with investigators, health care professionals, consultants, third-party payors and customers will be subject, directly or indirectly, to federal, state and state foreign healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Although we do not currently have any products on the market, if we obtain FDA approval for our product candidates, and begin commercializing those products in the United States, our operations may be directly, or indirectly through our prescribers, customers and third-party payors, subject to various U.S. federal and state healthcare laws and regulations, including, without limitation, the U.S. federal Anti-Kickback Statute, the U.S. federal civil and criminal false claims laws, federal health data privacy laws, and the Physician Payments Sunshine Act and regulations. Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. These laws may impact, among other things, our current business operations, including our clinical research activities, and proposed sales, marketing and education programs and constrain the business of financial arrangements and relationships with healthcare providers, physicians and other parties through which we market, sell and distribute our products for which we obtain marketing approval. In addition, we may be subject to patient data privacy and security regulation by both the U.S. federal government and the states in which we conduct our business. Finally, we may be subject to additional healthcare, statutory and regulatory requirements and enforcement by comparable foreign regulatory authorities in jurisdictions in which we conduct our business that may affect our ability to operate. See “Business – Other U.S. Healthcare Laws.”

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the

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

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental and regulatory authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the delay, reduction,

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termination or curtailment or restructuring of our operations. Further, defending against any such actions can be costly and time-consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business is found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, our ability to operate our business and our results of operations could be adversely affected.

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

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

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

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

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

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

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

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

The EU GDPR also imposes strict rules on the transfer of personal data out of the EEA, including to the United States. Although the UK is regarded as a third country under the EU GDPR, the EC has now issued a decision recognizing the UK as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the EU to the UK remain unrestricted. Like the EU GDPR, the UK GDPR restricts personal data transfers outside the UK to countries not regarded by the UK as providing adequate protection. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing. To enable the transfer of personal data outside of the EEA or the UK, adequate safeguards must be implemented in compliance with EU and UK data protection laws. On June 4, 2021, There are currently various mechanisms that may be used to transfer personal data from the EC issued new forms of standard contractual clauses for data transfers from controllers or processors in the EU/EEA (or otherwise subject and UK to the GDPR) to controllers or processors established outside United States in compliance with law, such as the EU/EEA (and not subject to EU's Standard Contractual Clauses, the GDPR). The new standard contractual clauses replace the standard contractual clauses that were adopted previously under the EU Data Protection Directive. The UK is not subject to the EC's new standard contractual clauses but has published the UK UK's International Data Transfer Agreement / Addendum, and International the EU-U.S. Data Transfer Addendum to the new standard contractual clauses (IDTA), which enable transfers from the UK. For new transfers, the IDTA already needs to be in place, Privacy Framework and must be in place for all existing transfers from the UK from March 21, 2024 Extension thereto (which allows for transfers for relevant U.S.-based organizations who self-certify compliance and participate in the Framework). Following a ruling from the Court of Justice of the EU, in Data Protection Commissioner v Facebook Ireland Limited However, these mechanisms are subject to legal challenges, and Maximillian Schrems, Case C-311/18 (Schrems II), companies relying there is no assurance that we can satisfy or rely on standard contractual clauses these measures to govern transfers of lawfully transfer personal data to third countries (in particular the United States) will need to assess whether the data importer can ensure sufficient guarantees for safeguarding the personal data under GDPR. This assessment includes assessing whether third party vendors can also ensure these guarantees. The same assessment is required for transfers governed by the IDTA. We will be required to implement these new safeguards when conducting restricted data transfers under the GDPR and doing so will require significant effort and cost. States.

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

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practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities.

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

Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the U.K. Bribery Act. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. The anti-bribery provisions of the FCPA are enforced primarily by the Department of Justice (DOJ) and the Securities and Exchange Commission, (SEC) is involved with enforcement of the books and records provisions of the FCPA and may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions. Recently the SEC and DOJ have increased their FCPA enforcement activities with respect to pharmaceutical companies. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA.

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

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

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

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

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

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Risks Related to Our Intellectual Property

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

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

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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

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could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

Our success depends in large part on our ability to obtain and maintain patent protection with respect to our non-replicating technology, including our HB-101 product candidate, obtain patent protection with respect to our replicating technology, including our HB-201, HB-202 HB-200 and HB-300 HB-700 product candidates, the vaccine product candidates we are developing with Gilead for HBV (HB-400) and HIV (HB-500), and other proprietary product candidates. Although we own or license from others certain patents and patent applications that cover some of the foregoing technologies and product candidates, we do not currently own or license from others issued patents covering all of the foregoing. foregoing technologies and product candidates. Our reliance on patent applications carries certain risks associated with pending patent applications prior to the issuance of patents, as described below. If we do not adequately obtain and protect our intellectual property rights, competitors may be able to erode, negate or preempt any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we file patent applications in the United States and abroad related to our product candidates that are important to our business. The patent application and approval process is expensive and time-consuming and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We cannot predict:

- if and when patents will issue from our patent applications;

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

We cannot be certain that the claims in our pending patent applications covering composition of matter of our product candidates will be considered patentable by the USPTO or by patent offices in foreign countries, or that the claims in any of our issued patents will be

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

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights may be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries. Even if patents do successfully issue from such applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. If our patents are rendered invalid or unenforceable, or narrowed in scope, the patent coverage afforded our products could be impaired. Such impairment could significantly impede our ability to market our products, negatively affect our competitive position and harm our business and operating results. In addition, changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent or in the same manner as the laws of the United States. For example, patent laws in various jurisdictions, including significant commercial markets such as Europe, restrict the patentability of methods of treatment of the human body more than United States law does. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our patent protection. No assurances can be given that third parties will not create new products or methods that achieve similar

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results without infringing upon patents we own. If these developments were to occur, it could have an adverse effect on our sales or market position. If the breadth or strength of protection provided by the patents and patent applications we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates.

If we enter into additional collaboration agreements and strategic partnerships or license our product candidates, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the

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Hatch-Waxman Amendments, and similar legislation in the European Union. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent may be extended, and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced and could have a material adverse effect on our business.

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

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

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

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

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Third parties may assert that we are employing their proprietary technology without authorization. Generally, conducting clinical trials and certain other development activities in the United States is not considered an act of infringement. If and when any of our another product

candidates are approved by the FDA, a third party may then seek to

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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 patents and/or patent applications that we own or will own, related to HB-101, HB-201 and HB-202 HB-200, HB-700, HB-400, HB-500 and certain other product candidates. Because additional product candidates may require the use of proprietary rights held by third parties, such as the rights to use certain antigens that are, specific to future disease targets, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights. In addition, while we have patent rights directed to certain non-replicating and replicating technologies we may not be able to obtain intellectual property to all uses of non-replicating and replicating technologies. Our product candidates may also require specific formulations to work effectively and efficiently and these rights to such formulations may be held by others. Similarly, efficient production or delivery of our product candidates may also require specific compositions or methods, and the rights to these compositions or methods may be owned by third parties. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify. Even if we are able to obtain a license to use such intellectual property, it may be non-exclusive, which would not restrict the licensor party from giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or

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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.

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

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

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

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

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

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

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

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on any issued patents and/or patent are applications will be due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of our patents and/or patent applications and any patent rights we may obtain in the patent. future. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which

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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.

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

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

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology or pharmaceutical industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the United States continues to adapt to wide-ranging patent reform legislation that became effective starting in 2012. Moreover, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once

obtained. Furthermore, the specific content of patents and patent applications that are necessary to support and interpret patent scope is highly uncertain due to the complex nature of the relevant legal, scientific, and factual issues. Changes in either patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Changes in the laws and regulations governing patents in other jurisdictions could similarly have an adverse effect on our ability to obtain and effectively enforce our patent rights.

For example, the Biden administration recently indicated its support for a proposal at the World Trade Organization to waive patent rights with respect to COVID-19 vaccines. Any waiver of our patent or other intellectual property protection by the U.S. and other foreign governments could have a material adverse effect on our competitive position, business, financial condition and results of operations. For example, recent decisions raise questions regarding the award of patent term adjustment (PTA) for patents in families where related patents have been issued without PTA. Thus, it cannot be said with certainty how PTA will or will not be viewed in the future and whether patent expiration dates may be impacted. In addition, the European patent system is relatively stringent in the type of amendments that are allowed during prosecution, but, the complexity and uncertainty of European patent laws has also increased in recent years. For example, in Europe, a new unitary patent system took effect June 1, 2023, which will significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court (UPC). As the UPC is a new court system, there is no precedent for the court,

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increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes. Complying with these laws and regulations could limit our ability to obtain new patents in the future that may be important for our business.

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

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

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- 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.

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

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

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

potential disagreement or dispute that may arise with the University of Basel relating to the ownership of Dr. Pinschewer's inventions, conflicts of interest or otherwise may result in a delay or termination of the research, development or commercialization of our product candidates or may have other negative consequences for our company.

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

We are highly dependent on members of our executive team. The loss of the services of any of them may adversely impact the achievement of team, including our objectives. Chief Executive Officer, Joern Aldag. 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

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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 our executive officers or more of our current other key employees might impede may adversely impact the achievement of our research, development and commercialization objectives. objectives and seriously harm our ability to successfully implement our business strategy.

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

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employees, consultants or advisors, may impede the progress of our research, development and commercialization objectives and have a material adverse effect on our business, financial condition, results of operations and prospects.

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

In January 2024, we announced a reduction in workforce by approximately 30% in connection with the strategic refocus of our business to prioritize and focus on our lead assets. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our operating structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring, our results of operation and financial condition would be adversely affected. We expect to incur additional costs as we recognize one-time employee termination-related charges. We also cannot guarantee that we will not have to undertake additional workforce reductions or restructuring activities in the future. Furthermore, our strategic Restructuring Plan may be disruptive to our operations. For example, our workforce reductions could yield unanticipated consequences, such as attrition beyond planned staff reductions, increased difficulties in our day-to-day operations and reduced employee morale. If employees who were not affected by the reduction in force seek alternate employment, this could result in us seeking contract support which may result in unplanned additional expense or harm our productivity. Our workforce reductions could also harm our ability to attract and retain qualified management, scientific, and clinical personnel who are critical to our business. Any failure to attract or retain qualified personnel could prevent us from successfully developing our product candidates in the future.

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

In addition to the risks associated with a reduction in force, as our finances, development and commercialization plans and strategies evolve, we may choose to expand or contract our employee base for managerial, operational, manufacturing, financial and other resources. Future growth or additional contraction would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. Also, our management may need to divert a disproportionate amount of their attention away from our day-to-day activities and devote a substantial amount of time to managing either growth or contraction activities. We may not be able to effectively manage our operations which may result in weaknesses in our infrastructure, give rise to operational errors, loss of business opportunities, loss of employees and reduced productivity among remaining employees.

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

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

As Although we recently implemented an approximately 30% reduction in our workforce and discontinued our GMP manufacturing facility project as part of our recent strategic refocus, as our research, 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;

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- 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.

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

Risks Related to Ownership of Our Common Stock

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

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

Our failure to meet the continued listing requirements of The Nasdaq Global Select Capital Market could result in a delisting of our common stock.

If we fail to satisfy the continued listing requirements of The Nasdaq Global Select Capital Market, such as the minimum closing bid price requirement, The Nasdaq Stock Market, LLC (Nasdaq) may take steps to delist our common stock. Under Nasdaq rules, the closing bid price for our common stock must remain at or above $1.00 per share to comply with Nasdaq's minimum bid requirement for continued listing.

On January 17, 2023 August 3, 2023, we received a letter from the Listing Qualifications Department of Nasdaq notifying us that, for the last 30 consecutive business days, the closing bid price for our common stock has been below the minimum $1.00 per share required for continued listing on The Nasdaq Global Select Market pursuant to Nasdaq Listing Rule 5450(a)(1) (the Minimum Bid Price Requirement). Under Nasdaq Listing Rule 5810(c)(3)(A), we have been granted a 180 calendar day grace period, or until July 17, 2023 January 30, 2024, to regain compliance with the Minimum Bid Price

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Requirement. The Minimum Bid Price Requirement will be met if our common stock has a minimum closing bid price of at least $1.00 per share for a minimum of ten consecutive business days during the 180 calendar day grace period. If However, we fail failed to regain compliance with prior to January 30, 2024. Accordingly, on January 18, 2024, we applied for and on January 31, 2024 were granted by the Minimum Bid Price Requirement before July 17, 2023, then we may be eligible Listing Qualifications Department of Nasdaq the right to list our common stock on the Capital Market and to have an additional 180 calendar days, or until January 15, 2024 June 29, 2024, to regain compliance with the Minimum Bid Price Requirement.

We are monitoring the closing bid price of our common stock; however, there can be no assurance that we will be able to regain compliance or that Nasdaq will grant us a further extension of time to regain compliance, if necessary. with the Minimum Bid Price Requirement.

The delisting of our common stock from Nasdaq may make it more difficult for us to raise capital on favorable terms in the future. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. Further, if we were to be delisted from Nasdaq, our common stock would cease to be recognized as covered securities and we would be subject to regulation in each state in which we offer our securities. Moreover, there is no assurance that any actions that we take to restore our compliance with the Minimum Bid Price Requirement would stabilize the market price or improve the liquidity of our common stock, prevent our common stock from falling below the minimum bid price required for continued listing again or prevent future non-compliance with Nasdaq's listing requirements.

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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;

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- 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; growth or concentration;
- the size and growth of our initial cancer target markets;
- our ability to successfully treat additional types of cancers or at different stages;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;

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- 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.

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 58% 40% of our outstanding voting stock. These stockholders may be able to determine many matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock.

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

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

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

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

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

- the timing and cost of, and level of investment in, research and development activities relating to our current and any future product candidates, which will change from time to time;
- the timing and outcomes of clinical trials for our current and any other future product candidates;
- the cost of manufacturing our current and any future product candidates, which may vary depending on FDA guidelines and requirements, the quantity of production and the terms of our agreements with manufacturers;
- our ability to adequately support our future growth;

- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic environment.

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

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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. Our status as an “emerging growth company” will end on December 31, 2024, at the latest. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The

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Nasdaq Global Select Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We expect that we will continue to need to hire additional accounting, finance, and other personnel in connection with our efforts to comply with the requirements of being, a public company and our management and other personnel will need to devote a substantial amount of time towards maintaining compliance with these requirements. These requirements will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. We are continuously evaluating these rules and regulations which are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of the Sarbanes-Oxley Act (SOX Section 404) we are required to furnish a report by our management on our internal control over financial reporting with our Annual Report on Form 10-K with the SEC. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. After no longer qualifying as an emerging growth company, we may, under certain conditions, still qualify as a “smaller reporting company” and benefit from similar exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. To achieve compliance with SOX Section 404 within the prescribed period, we 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;

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- 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;

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- 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 as the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

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

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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

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how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

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

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

Pursuant to Section 404 of Sarbanes-Oxley, our management is required to report upon the effectiveness of our internal control over financial reporting. When we lose our status as an "emerging growth company," company" and if we do not qualify as a "smaller reporting company" at such time, 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 Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

General Risks

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

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, such as the failure of Silicon Valley Bank and various regional banks in 2023, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank (SVB) was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (FDIC) as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. Although a statement by the Department of the Treasury, the Federal Reserve and the FDIC indicated that all depositors of SVB would have access to all of their money after only one business day of closure, including funds held in uninsured deposit accounts, borrowers under credit agreements, letters of credit and certain other financial instruments with SVB, Signature Bank or any other financial institution that is placed into

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receivership by the FDIC may be unable to access undrawn amounts thereunder. Although we are not a borrower or party to any such instruments with SVB, Signature or any other financial institution currently in receivership, if If any of our lenders or counterparties to any such instruments were to be placed into receivership, we may be unable to access such funds. In addition, if any of our customers, suppliers or other parties with whom we conduct business are unable to access funds pursuant to such instruments or lending arrangements with such a

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financial institution, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected. In this regard, counterparties to SVB credit agreements and arrangements, and third parties such as beneficiaries of letters of credit (among others), may experience direct impacts from the closure of SVB and uncertainty remains over liquidity concerns in the broader financial services industry. Similar impacts have occurred in the past, such as during the 2008-2010 financial crisis. We hold no deposits or securities with SVB, Signature Bank or Silvergate Capital.

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

Although inflation has not had a material impact on our business or operating results historically, inflation, has had, and may continue to have, led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. Although the U.S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to $25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses an impact on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediate liquidity may exceed the capacity of such program. Additionally, there is no guarantee that the U.S. Department of Treasury, FDIC labor costs we incur to attract and Federal Reserve Board will provide access retain qualified personnel, costs to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.

Although we assess our banking and customer relationships as we believe necessary or appropriate, our access to funding sources conduct clinical trials and other credit arrangements in amounts adequate to finance or capitalize operational costs. Inflationary costs could adversely affect our current and projected future business, operations could be significantly impaired by factors that affect the Company, the financial institutions with which the Company has credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which the Company has financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, the following:

- Delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- Delayed or lost access to, or reductions in borrowings available under revolving existing credit facilities or other working capital sources and/or delays, inability or reductions in the company's ability to refund, roll over or extend the maturity of, or enter into new credit facilities or other working capital resources;
- Potential or actual breach of contractual obligations that require the Company to maintain letters of credit or other credit support arrangements;
- Potential or actual breach of financial covenants in our credit agreements or credit arrangements;
- Potential or actual cross-defaults in other credit agreements, credit arrangements or operating or financing agreements; or

- Termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

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In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher Increased interest rates or costs may adversely affect our borrowing rate and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by our customers or suppliers, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition. For example, a customer may fail to make payments when due, default under their agreements with us, become insolvent or declare bankruptcy, or a supplier may determine that it will no longer deal with us as a customer. In addition, a customer or supplier could be adversely affected by any of the liquidity or other risks that are described above as factors that could result in material adverse impacts on the Company, including but not limited to delayed access or loss of access to uninsured deposits or loss of the ability to draw on existing credit facilities involving a troubled or failed financial institution. Any customer or supplier bankruptcy or insolvency, obtain, or the failure of terms under which we can obtain, any customer to make payments when due, or any breach or default by a customer or supplier, or the loss of any significant supplier relationships, could result in material losses to the Company and may have a material adverse impact on our business.potential additional funding.

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

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

We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee and other third-party misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to

resolve allegations of noncompliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business, financial condition and results of operations.

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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

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injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of changes to applicable laws and regulations and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

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

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

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

relating to data privacy and security.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), imposes specific requirements relating to the privacy, security, and transmission of individually identifiable protected health information. For more information regarding risks associated with HIPAA, please refer to the section above that discusses risks associated with U.S. healthcare laws.

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

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

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

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

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA) and the United Kingdom (UK) have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally

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

In addition to data privacy and security laws, we are bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. We also publish privacy policies, marketing materials, and other statements regarding data privacy and security and if these policies, materials, or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

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

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We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties on whom we rely may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal data (including clinical trial data); and orders to destroy or not use personal data. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations

Cybersecurity risks and the failure to maintain the security, confidentiality, integrity, and availability of our information technology systems or data, and those used by maintained on our third-party CROs or other contractors or consultants, may fail or suffer security breaches, which behalf, could result in adverse consequences that materially affect our business, including without limitation regulatory investigations or actions, a material disruption of the development programs of our product candidates.

We candidates, damage to our reputation and/or subject us to costs, loss of customers or sales, fines 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 penalties 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. lawsuits.

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

We and the third parties upon which we rely are subject to a variety of evolving threats, including but not limited to computer hacking, phishing attacks and social engineering (including through deep fakes, which may be increasingly more difficult to identify as fake), supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by AI, ransomware, dissemination of malware, computer viruses, worms and other destructive or disruptive software, denial of service attacks and other malicious activity, credential stuffing, credential harvesting, personnel misconduct or error as well as power outages, telecommunications failures, natural disasters (including extreme weather), terrorist attacks or other similar events. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Such events could have an adverse impact on us and our business, including loss of data and damage to equipment and data. In addition, system redundancy may be ineffective or inadequate, and our disaster recovery planning may not be sufficient to cover all eventualities. If such events were to occur and cause interruptions in

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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.

Table Remote work has become more common and has increased risks to our information technology systems and data, as more of Contentsour employees utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit and in public locations. Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or

integrated entities' systems and technologies. We may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

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

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

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, cyber-attack, security breach, industrial espionage attacks or insider threat attacks which could result in financial, legal, business or reputational harm.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We are an emerging growth company, also take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties upon which we cannot rely). We may not, however, detect and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors. exploited and result in a security incident.

We may expend significant resources or modify our business activities to try to protect against security incidents. Additionally, certain data privacy and security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive data. Applicable data privacy and security obligations may require us to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents. Such disclosures are an emerging growth company, as defined in costly, and the Jumpstart Our Business Startups Act of 2012, as amended (JOBS Act), enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required disclosure or the failure to comply with the auditor attestation such requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended (Sarbanes-Oxley Act), 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 lead to five years following the year in which we complete our initial public offering, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of our initial public offering in April 2019, (b) in which we have total annual gross adverse consequences.

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revenue If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of at least $1.07 billion management attention; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may prevent or (c) cause customers to stop using our services, deter new customers from using our services, and negatively impact our ability to grow and operate our business.

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

In addition to experiencing a large accelerated filer, which requires the security incident, third parties may gather, collect, or infer sensitive data about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market value of our common stock that is held by non-affiliates to exceed $700 million as position. Additionally, sensitive data 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 Company or 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 customers could be leaked, disclosed, or revealed as a result there may be a less active trading market for of or in connection with our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new employees’, personnel’s, or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves vendors’ use of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

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

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Cybersecurity Risk Management and Strategy

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

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

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

Our process for identifying and assessing material risks from cybersecurity threats operates alongside our broader overall enterprise risk assessment process. We have a cybersecurity-specific risk assessment process designed to

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assess identified material risks from cybersecurity threats. This process is designed to help us manage our material risks from cybersecurity threats and protect against, detect, and respond to cybersecurity incidents.

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

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

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

Cybersecurity Governance

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

Our executive management team, with regulatory and governance oversight from our Audit Committee, are responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into the Company's overall risk management strategy, and communicating key priorities to relevant personnel. Our Digital and IT Steering Committee is responsible for approving budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

Our cybersecurity function, led by our Head of DevSecOps and supported by our Head of IT and third-party service providers, is responsible for our cybersecurity risk management and strategy processes. Our Head of IT, who is a Certified Information Security Manager (CISM ISACA) and a Certified Information Systems Auditor (CISA ISACA), and our Head of DevSecOps, collectively have significant prior work experience in various roles involving managing information security, developing cybersecurity strategy and implementing effective information and cybersecurity programs.

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

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Item 2. Properties

Our principal executive offices are located in New York, New York, pursuant to a lease that expires in February 2024. August 2026. Our European research and preclinical development operations are located in Vienna, Austria, where we lease and occupy approximately 30,656 30,681 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 15,239 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 2,367 square feet of storage space. In 2019, we entered into a lease for a second facility located in Vienna, Austria that is set to expire in February 2029, where we occupy approximately 15,440 square feet of office and laboratory space. In May 2021 we purchased a parcel of land in the north of Vienna and have received building permission to build a GMP manufacturing plant of approximately 48,440 square feet. In December 2018, we entered into January 2024 our Board decided to implement a collaboration and manufacturing agreement Restructuring Plan, which included embedded leases the discontinuation of the GMP manufacturing facilities which are located project and the divestment of all associated assets, including the parcel of land. Strategic considerations preceding the adoption of the Restructuring Plan resulted in Solna, Sweden, and expired the impairment of the full carrying value of the GMP manufacturing facility project in April 2022. the year ended December 31, 2023. 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.

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PART II—OTHER INFORMATION

Item 3. Legal Proceedings.

In April 2021, a third party opposed European Patent No. 3218504 (the EP "EP '504 Patent) Patent") which was granted to the University of Geneva in July 2020 and is exclusively licensed to us. The patent is directed to our replicating arenavirus platform technology and is part of our strategy to protect current product candidates based on this platform technology, including our lead oncology product candidates HB-201 and HB-202. We filed our formal response to candidate HB-200. In a decision that has become final, the opposition with Opposition Division of the European Patent Office ("EPO") dismissed the opposition in an oral proceeding on September 3, 2021. While it is not feasible May 9, 2023, and maintained the patent as granted.

From time to predict time, we may become involved in other litigation or legal proceedings relating to claims arising from the outcome ordinary course of these matters with certainty, and some lawsuits, claims or proceedings may be disposed or decided unfavorably, we do not expect that the pending patent opposition, and any asserted or unasserted legal claims or proceedings, individually or in the aggregate, will have a material adverse effect on us. However, if, as a result of the current patent proceeding, we would lose all, or at least part, of the protection under the opposed patent, such loss could erode our competitive position and harm our business and ability to achieve profitability. 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 Capital Market and has been publicly traded since April 18, 2019. Prior to this time, there was no public market for our common stock.

Holders of Our Common Stock

As of March 8, 2023 March 22, 2024, there were approximately four holders of record of shares of our common stock, which does not include stockholders for whom shares are held in "nominee" or "street" name, and two holders of record of shares of our Class A common stock.

Dividends

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

Securities Authorized for Issuance Under Equity Compensation Plans

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

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

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Item 6. Selected Financial Data

Reserved. [Reserved]

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

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

Overview

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

We are building a proprietary immuno-oncology pipeline by targeting utilizing our replicating technology. Our oncology portfolio targets oncoviral cancer antigens self-antigens and next-generation antigens. Our oncology portfolio antigens and includes three disclosed two primary programs in development: HB-200 HB-300 and HB-700, all of which use our replicating technology. HB-700. HB-200 is in clinical development for the treatment of Human Papillomavirus 16-positive ("HPV16+") head and neck cancers (HPV16+) in an ongoing a Phase 1/2 clinical trial. HB-300 HB-700, which has been partnered with F. Hoffmann-La Roche Ltd. and Hoffmann-La Roche Inc. (collectively referred to as "Roche"), is in development for the treatment of prostate cancer and expected to move into the clinic in the first quarter of 2023. HB-700 is our newest asset in preclinical development for the treatment of KRAS mutated cancers, including, lung, colorectal and pancreatic cancers.

Our HB-200 third oncology program, is comprised HB-300, targeting self-antigens for the treatment of potential therapeutic agents prostate cancer, was paused for people with cancers caused by the Human Papillomavirus (HPV), specifically HPV16+ and includes HB-201 single-vector therapy and HB-202/HB-201 dual-vector therapy. Both therapies are being evaluated further development in an ongoing HB-200 Phase 1/2 clinical trial. In the second quarter of 2022, data presented at scientific conferences showed that HB-202/HB-201 alternating dual-vector candidate induced immune and clinical responses, as well as stable disease in some HPV16+ advanced metastatic/recurrent head

and neck cancer patients who failed prior standard of care therapy. We believe that these early-stage data establish proof of concept for our replicating viral vector immunotherapy candidate in oncology. January 2024.

Based on the safety profile, anti-tumor activity and T cell response data observed to date, we are evaluating HB-202/HB-201 in combination with pembrolizumab in 1st line and 2nd line patients with advanced/metastatic head and neck cancer.

While our Our strategic priority is the development of our oncology portfolio, most importantly the advancement of our HB-200 program, and we believe that our platform is also uniquely positioned expect to provide value from the prophylactic and therapeutic use against infectious diseases. We plan to continue initiate a randomized Phase 2/3 trial in 2024. Additionally, we are developing infectious disease therapies in partnership with other companies. Our Hepatitis B ("HBV") program, HB-400, and our Human Immunodeficiency Virus ("HIV") program, HB-500, are developed in a partnership with Gilead Sciences Inc. ("Gilead").

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2023 Highlights

In 2023, we executed on several key areas across our pipeline. The highlights include:

Oncology:

- HB-200 in combination with pembrolizumab: We presented positive preliminary Phase 2 data in patients with recurrent/metastatic ("R/M") HPV16+ head and neck cancers in the first line setting in May 2023 and additional patient data was provided in October at the European Society for Medical Oncology (ESMO) Congress 2023.
    - Data showed 42% objective response rate for 19 evaluable checkpoint inhibitor ("CPI")-naïve patients. These data represent a doubling of the historical response rate (19%) reported for pembrolizumab alone.
    - We are preparing to start a randomized Phase 2/3 trial of HB-200 in combination with pembrolizumab in the 1st-line setting for patients with R/M HPV16+ head and neck cancers.
- HB-700: We continued Investigational New Drug ("IND") application-enabling activities. We are on track to submit an IND in the second quarter of 2024.
- HB-300: We have enrolled the first two dose escalation cohorts in the Phase 1/2 study. The Study Safety Committee deemed that HB-300 was generally safe and well-tolerated in both dose escalation cohorts. However, we paused further development of this program in January 2024 to refocus our capital resources on the advancement of our HB-200 program and Gilead-partnered infectious disease programs.

Infectious Disease: Gilead-Partnered Programs

- HB-400: In August, the Journal of Infectious Disease published peer-reviewed preclinical data on HB-400. The data showed that HB-400 induced robust, HBV-specific T cell and antibody responses in non-human primates and cleared detectable serum HBV antigens in a mouse model for chronic HBV infection, with near elimination of detectable HBV antigen positive hepatocytes in the liver.
- HB-500: In November 2023, we announced FDA clearance of our IND application for HB-500 for the treatment of HIV. Additionally, Nature Partner Journals published peer-reviewed preclinical data for the program in November 2023. The data showed that HB-500 was well tolerated and generated robust, high-quality and durable immune responses (antigen-specific T cells and antibodies) in non-human primates, and arenaviral therapeutic vaccination significantly reduced SIV viral load and clinical illness in those animals compared to placebo.

We have funded our operations to date primarily from public offerings of common stock and convertible preferred stock, including our initial public offering, as well as private placements of our redeemable convertible preferred stock, grant funding and loans from an Austrian government agency, and upfront, milestone and initiation payments from Gilead in connection with a research collaboration and license agreement, and upfront payments from Roche in connection with a research our respective collaboration and license agreement.

On April 23, 2019, we completed an initial public offering of our common stock (the IPO) in which we issued 6.0 million shares of our common stock, at $14.00 per share, for gross proceeds of $84.0 million, or net proceeds of $74.6 million. On December 11, 2020, we completed a follow-on public offering in which we issued 3.9 million shares of our common stock, at $11.75 per share, and 2,978 shares of our Series A convertible preferred stock, at $11,750.00

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per share, for net proceeds of $75.0 million after deducting underwriting discounts and commissions and offering expenses. In addition, in February 2022, Gilead Sciences, Inc. (Gilead) purchased 1.7 million shares of our common stock for $5.0 million. On March 4, 2022, we completed a follow-on public offering in which we issued 21.7 million shares of our common stock, at $2.00 per share, and 15,800 shares of our Series A-1 convertible preferred stock, at $2,000.00 per share, for net proceeds of $70.2 million after deducting underwriting discounts and commissions and offering expenses. As of December 31, 2022, the principal amount outstanding under loans from government agencies was $2.9 million and we had cash, cash equivalents and restricted cash of $113.4 million agreements.

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.

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All of our product candidates, including our most advanced oncology product candidate, HB-200, will require substantial additional development time and resources before we would be able to apply for and receive regulatory approvals and begin generating revenue from product sales. Before launching our first products, if approved, we plan to establish our own manufacturing facility to reduce or eliminate our reliance on contract manufacturing organizations (CMOs) ("CMOs") which will require substantial capital expenditures and cause additional operating expenses. We currently have no marketing and sales organization and have no experience in marketing products; accordingly, we will incur significant expenses to develop a marketing organization and sales force in advance of generating any commercial product sales. As a result, we will need substantial additional capital to support our operating activities. In addition, we expect to continue to incur legal, accounting and other expenses in operating our business, including the costs associated with operating as a public company.

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

On January 29, 2024, we announced our decision to prioritize the clinical development of our HB-200 program for the treatment of HPV16+ head and neck cancers and our two Gilead-partnered infectious disease programs and to pause development activities related to HB-300 and most of our preclinical research activities. In connection with this strategic refocus, our Board of Directors approved a plan to reduce our workforce by 55 fulltime employees, or approximately 30% of the then-current employee base, and to rebalance our cost structure in alignment with the new prioritization of research and development programs. The prioritization of our HB-200 program and our two Gilead-partnered programs also includes the discontinuation of our GMP manufacturing facility project. We expect the restructuring to be implemented

and substantially completed by the end of the first quarter of 2024. In connection with the Restructuring Plan, we estimate that we will incur cash charges of approximately $1.6 million for severance and other personnel and restructuring related costs.

We also announced in January 2024 that we received notification from Roche of their decision to terminate the collaboration and licensing agreement for our HB-700 program in KRAS mutated cancers. We have met all go-forward criteria under the agreement and remain eligible for a final milestone payment associated with an IND submission. Effective April 25, 2024, we will regain full control of the associated intellectual property portfolio and have full collaboration and licensing rights for this program.

We have incurred net losses each year since our inception in 2011, including net losses of $81.6 million for the year ended December 31, 2023 and $64.9 million for the year ended December 31, 2022 and $75.7 million for the year ended December 31, 2021. As of December 31, 2022 December 31, 2023, we had an accumulated deficit of $287.7 $369.3 million and we do not expect positive cash flows from operations in the foreseeable future, if ever. We expect to continue to incur net operating losses for at least the next several years as we advance our product candidates through clinical development, seek regulatory approval, prepare for and, if approved, proceed to commercialization, continue our research and development efforts and invest to establish further commercial manufacturing capacity.

We believe that our cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements at least through the next 12 months from the issuance date of the consolidated financial statement. See "—Liquidity and Capital Resources."

Impacts of Coronavirus and Market Conditions on Our Business

We have been actively monitoring the coronavirus pandemic situation and its impact globally. We believe our financial results for the years ended December 31, 2022 December 31, 2023, 2021 2022 and 2020 2021 were not significantly impacted by the outbreak any lingering effects of the coronavirus. We believe our hybrid and remote working arrangements have had limited impact on our ability to maintain internal operations during the years ended December 31, 2022, 2021 and 2020. recent coronavirus pandemic. Further, disruption of global financial markets and a recession or market correction, including as a result of any resurgence of the coronavirus pandemic, the ongoing military conflict between Russia and Ukraine and the related sanctions imposed against Russia, any escalation of the conflict in Israel and the

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Gaza Strip, and other global macroeconomic factors, could reduce our ability to access capital, which could, in the future, negatively affect our business and the value of our common stock.

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Effects of Inflation

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

Components of Our Results of Operations

Revenue from collaboration and licensing

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

Gilead Collaboration Agreement

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

Under the Gilead Collaboration Agreement, we granted Gilead an exclusive, royalty-bearing license to our technology platform for researching, developing, manufacturing and commercializing products for HIV or HBV. We received a non-refundable $10.0 million upfront payment upon entering the Gilead Collaboration Agreement. In February 2022, we signed an amended and restated collaboration agreement (the Restated "Restated Gilead Collaboration Agreement) Agreement") which revised the terms only for the HIV program, whereby we will take on development responsibilities for the HIV program candidate through a Phase 1b clinical trial. Pursuant to the Restated Gilead Collaboration Agreement, Gilead will retain an exclusive right, the Option, to take back the development responsibilities, thus keeping the rights for the HIV program, including further development and commercialization in return for an option exercise payment of $10.0 million. Pursuant to the Restated Gilead Collaboration Agreement, we are eligible for up to $140.0 million in developmental milestone payments for the HBV program and $50.0 million in commercialization milestone payments. If Gilead exercises the Option, we are eligible for up to $172.5 million in developmental milestone payments for the HIV program, inclusive of the $10.0 million Option exercise payment, and $65.0 million in commercialization milestone payments for the HIV program. Upon the commercialization of a product, we are eligible to receive tiered royalties of a high single-digit to mid-teens percentage on the worldwide net sales of each HBV product, and royalties of a mid-single-digit to 10% of worldwide net sales of each HIV product. Gilead is obligated to reimburse us for our costs, including all benefits, travel, overhead, and any other expenses, relating to performing research and development activities under the Restated Gilead Collaboration Agreement with respect to the HBV program, and if the Option is exercised, any manufacturing costs related to the HIV program. Through December 31, 2022 December 31, 2023, we have received from Gilead the a non-refundable upfront payment of $10.0 million, a program initiation fee of $15.0 million and $16.2 $21.2 million in milestone payments for the achievement of pre-clinical research milestones. milestones from Gilead. In addition, we have recognized $40.8 $42.2 million of cost reimbursements for research and development services performed under the Gilead Collaboration Agreement. In the first quarter of 2023, we received an additional milestone payment of $5.0 million under the Restated Gilead Collaboration Agreement.

We determined that our performance obligations under the terms of the original Gilead Collaboration Agreement included one combined performance obligation for each of the HBV and HIV research programs, comprised of the transfer of intellectual property rights and providing research and development services. Accordingly, we recognized these amounts as revenue over the performance period of the respective services on a percent of completion basis using total estimated research and development labor hours for each of the performance obligations. The terms of

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the Restated Gilead Collaboration Agreement added an additional performance obligation to us to perform research and development work for the HIV program. We recognize the amounts of revenue allocated to the performance obligation

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resulting from the Restated Gilead Collaboration Agreement on a percent of completion basis over the performance period, using total estimated research and development costs as the measure of progress.

Roche Collaboration Agreement

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

Under the terms of the terminated Roche Collaboration Agreement, we granted Roche an exclusive, royalty-bearing license to our technology platforms. Upon signing platforms for KRAS-mutated cancers, and an option right to exclusively license a second, novel arenaviral immunotherapeutic program targeting undisclosed cancer antigens. Pursuant to the terms of the Roche Collaboration Agreement, in October 2022, we received a non-refundable upfront payment of $25.0 million and Roche will be obliged to pay an additional $15.0 million payment if following the option for the UCA program is exercised. We are also eligible for event-based milestone payments of up to an aggregate of $335.0 million during the research and development phase of the HB-700 program for up to four oncology indications and up to an aggregate of $250.0 million in payments related to the achievement of sales-based milestones. For the additional UCA Program, subject to UCA Option-exercise, we are eligible for up to an aggregate of $173.0 million in event-based milestone payments during research and development for up to four oncology indications as well as up to an aggregate of $160.0 million in sales-based milestones. Upon commercialization, we are eligible to receive tiered royalties on the worldwide net sales of HB-700 and, subject to UCA Option exercise, the UCA Program. The royalty payments are subject to reduction under specified conditions set forth in termination notice, the Roche Collaboration Agreement. Agreement will be terminated on April 25, 2024. We remain eligible for a final milestone payment associated with an IND submission. Effective April 25, 2024, we will regain full control of the associated intellectual property portfolio and will have full collaboration and licensing rights for the KRAS program.

Through December 31, 2022 December 31, 2023, we have received from Roche the non-refundable upfront payment of $25.0 million and in the first quarter of 2023 we received an additional milestone payment of $10.0 million in milestone payments for the achievement of a GMP manufacturing milestone. milestone under the HB-700 program. In addition, we have recognized $0.5 million of cost reimbursements for research and development activities related to a first human trial.

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

At December 31, 2023, $26.8 million of non-refundable upfront and milestone payments received from Roche were still recorded as deferred revenue and will be early recognized as revenue as a result of the termination in the first half of 2024.

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 Phase 1 and Phase 2 clinical trials, for HB-101 as well as including the ongoing HB-200 Phase 1/2 study, trial, and an progressing investigational new drug (IND) application ("IND") applications, including for HB-300. HB-500 and HB-700. Research and development activities

account for a significant portion of our operating expenses. Research and development costs are expensed as incurred. These costs include:

- salaries, benefits and other related costs, including stock-based compensation, for personnel engaged in research and development functions;

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

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

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

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

- successful completion of preclinical studies and clinical trials;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- 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 scaleup of our manufacturing processes and formulation of our product candidates for later stages of development and commercialization;

- establishing our own manufacturing capabilities or agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if our product candidate is approved;
- entry into collaborations to further the development of our product candidates;

- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates;
- successfully launching commercial sales of our product candidates, if and when approved;
- acceptance of the product candidates benefits and uses, if and when approved, by patients, the medical community and third-party payors;
- the prevalence and severity of adverse events experienced with our product candidates;
- maintaining a continued acceptable safety profile of the product candidates following approval;
- effectively competing with other therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors; and
- qualifying for, maintaining, enforcing and defending intellectual property rights and claims.

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

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

	Year ended December 31,	
	2022	2021
HB-200 program	$ 28,409	$ 35,876
HB-300 program	9,938	7,491

Gilead partnered programs(1)	13,529	17,208
Other and earlier-stage programs	14,815	18,504
Other unallocated research and development expenses	1,954	3,774
Total research and development expenses	$ 68,645	$ 82,853

	Year ended December 31,	
	2023	2022
HB-200 program	$ 41,301	$ 28,409
HB-300 program	11,654	9,938
Gilead partnered programs	13,020	13,529
Roche partnered programs	14,187	—
Other and earlier-stage programs	4,946	14,815
Other unallocated research and development expenses	1,316	1,954
Total research and development expenses	$ 86,424	$ 68,645

(1) Expenses incurred in connection with Gilead partnered programs were fully reimbursed by Gilead in 2021 and partially reimbursed in 2022, and such reimbursements were accounted for as revenue.

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

General and Administrative Expenses

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

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and maintain compliance with requirements of the Nasdaq Global Select Capital Market and the Securities and Exchange Commission.

Impairment Expenses

Impairment expenses consist of non-cash impairment charges relating to long-lived assets. Impairments are determined using management's judgment about the anticipated performance of our business in relation to expectations, significant negative technological, scientific or economic trends and significant changes or planned changes in the use of the assets and their effects based on information available as of the date of these consolidated financial statements. Management disposes of fixed assets during the regular course of business due to damage, obsolescence, strategic shifts, and loss.

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset group may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset group to future undiscounted net cash flows expected to be generated by the assets. If the carrying amount of an asset group exceeds its estimated undiscounted net future cash flows, an impairment charge is recognized for the amount by which the carrying amount of the asset group exceeds its fair value.

Grant Income

Since inception, we have received grants from the Austrian Research Promotions Agency, either under funding agreements or under research incentive programs. In addition, we have received loans under funding agreements that bear interest at below market interest rate.

We account for the grants received as other income and for the imputed benefits arising from the difference between a market rate of interest and the rate of interest as additional grant income, and record interest expense for the loans at a market rate of interest.

We participate in a research incentive program provided by the Austrian government under which we are entitled to reimbursement of a percentage of qualifying research and development expenses and capital expenditures incurred in Austria. Submissions for reimbursement under the program are submitted annually. Incentive amounts are

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generally paid out during the calendar year that follows the year of the expenses but remain subject to subsequent examinations by the responsible authority.

Furthermore, we participated in the life sciences research and development program provided by the New York State government under which we were entitled to reimbursement of a percentage of qualifying research and development expenses in New York State up to $0.5 million per year for the years 2019 to 2021. Submissions for reimbursement under the program were submitted in the fourth quarter of 2023 and certificates of tax credits were received. Incentive amounts are generally paid out six to nine months after amended tax returns including a certificate of tax credit issued by Empire State Development are filed. We account for the grants received as other income.

We also participate in the New York City biotechnology tax credit program, according to which certain expenses for business in the biotechnology field in New York City limited to $0.25 million per year for three consecutive years from January 1, 2023 to December 31, 2025 are incentivized. We account for the grants received as other income.

Interest Income

Interest income results of interest earned on our cash, cash equivalents, and restricted cash.

Interest Expense

Interest expense results primarily from loans under funding agreements with the Austrian Research Promotion Agency, recorded at a market rate of interest. The difference between interest payments payable pursuant to the loans, which rates are at below market interest rates, and the market interest rate, is accounted for as grant income.

Income Taxes

Income tax expense results from U.S. federal and state income tax as well as foreign minimum income tax and profit on a legal entity basis. The losses that we have incurred since inception result primary from the losses of our Austrian subsidiary. As of December 31, 2022 December 31, 2023, we had a deferred tax asset of $70.2 $94.4 million primarily resulting from foreign net operating loss carryforwards of $275.3 $378.1 million with no expiry date. We have considered that, at this point in time, it is uncertain whether we will ever be able to realize the benefits of the deferred tax asset, and accordingly, have established a full valuation allowance as of December 31, 2022 December 31, 2023.

Results of Operations

Comparison of Years Ended December 31, 2022 December 31, 2023 and 2021 2022

The following table summarizes our results of operations for the years ended December 31, 2022 December 31, 2023 and 2021 2022 (in thousands). Discussions of 2020 2021 items and year-to-year comparisons between 2021 2022 and 2020 2021 that are not included in this Annual Report on Form 10-K can be found in “Management’s Discussion and Analysis of Financial Condition and

Results of Operations" Part II, Item 7 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 December 31, 2022 filed with the SEC on March 24, 2022 March 15, 2023.

	Year ended December 31,		Year ended December 31,		
	2022	2021	2023	2022	Change
Revenue from collaboration and licensing	$ 14,249	$ 18,448	$ 20,129	$ 14,249	$ 5,880
Operating expenses:					
Research and development	(68,645)	(82,853)	(86,424)	(68,645)	(17,779)
General and administrative	(18,759)	(17,269)	(18,633)	(18,759)	126
Impairment expense			(12,766)	—	(12,766)
Total operating expenses	(87,404)	(100,122)	(117,823)	(87,404)	(30,419)
Loss from operations	(73,155)	(81,674)	(97,694)	(73,155)	(24,539)
Other income (expense):					
Grant income	7,916	9,724	11,193	7,916	3,277
Interest income	1,633	27	5,293	1,633	3,660
Interest expense	(687)	(898)	(317)	(687)	370
Other income and expenses, net	(392)	(2,843)	313	(392)	705
Total other income (expense), net	8,470	6,010	16,482	8,470	8,012
Net loss before tax	(64,685)	(75,664)	(81,212)	(64,685)	(16,527)
Income tax expense	(230)	(1)	(368)	(230)	(138)
Net loss	$ (64,915)	$ (75,665)	$ (81,580)	$(64,915)	$(16,665)

Revenue from Collaboration and Licensing

Revenue was $20.1 million for the year ended December 31, 2023, compared to $14.2 million for the year ended December 31, 2022, compared to $18.4 .

The increase of $5.9 million for the year ended December 31, 2021. December 31, 2023 compared to the year ended December 31, 2022 was primarily due to higher partial recognition of the upfront and milestone payments under the Gilead and Roche collaborations, partially offset by lower aggregate cost reimbursements received under these collaborations.

The decrease For the years ended December 31, 2023 and 2022, revenue included $1.9 million and $5.2 million, respectively, from reimbursement of $4.2 million research and development expenses, and $18.2 million and $4.0 million, respectively, from partial recognition of milestone and initiation payments that were initially recorded as deferred revenue. In addition, revenue for the year ended December 31, 2022 compared to the year ended December 31, 2021 was primarily due to lower cost reimbursements received under the Gilead collaboration, partially offset by revenue included $5.0 million that was were recognized upon the achievement of a research milestone under related to the Restated Gilead collaboration achieved in December 2022, and higher partial recognition of the upfront payments under the Gilead and Roche collaborations. Substantial parts of the payments received from collaborations in Collaboration Agreement.

For the year ended December 31, 2022 December 31, 2023, were not immediately recognized as revenue. In particular, the biggest parts of a $4.0 revenue included $8.5 million milestone payment and the $15.0 million initiation fee received under related to the Restated Gilead Collaboration Agreement, of which $1.4 million resulted from reimbursement of research and a $25.0 development expenses, and $7.1 million upfront payment received under from partial recognition of milestone and initiation payments that were initially recorded as deferred revenue. In addition, revenue included $11.6 million related to the Roche Collaboration Agreement, of which $11.1 million resulted from partial recognition of milestone and initiation payments that were initially recorded as deferred revenue, to be recognized as revenue in future accounting periods. and $0.5 million from reimbursement of expenses.

For the year ended December 31, 2022, revenue included $13.9 million related to the Restated Gilead Collaboration Agreement, of which $5.2 million resulted from reimbursement of research and development expenses, $3.7 million from partial recognition of milestone and initiation payments that were initially recorded as deferred revenue as well as and $5.0 million of from revenue that was immediately recognized upon the achievement of a research milestone in December 2022, all of which are related to the Restated Gilead Collaboration Agreement. milestone. In the year ended December 31, 2022 we completed the recognition of the deferred revenue related to the $4.0 million milestone payment that we received in 2020 related to the Restated Gilead Collaboration Agreement. In addition,

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revenue included $0.3 million from partial recognition of the $25.0 million upfront payment under related to the Roche Collaboration Agreement, that was initially recorded as deferred revenue.

For the year ended December 31, 2021, revenue included $16.3 million from reimbursement of research and development expenses, and $2.1 million which resulted from partial recognition of milestone and initiation payments that were initially recorded as deferred revenue related to the Gilead Collaboration Agreement. In the year ended December 31, 2021 we

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completed the recognition of the deferred revenue related to the upfront payment of $10.0 million that we received in June 2018 related to the Gilead Collaboration Agreement. revenue.

Research and Development Expenses

For the year ended December 31, 2022 December 31, 2023, our research and development expenses were $68.6 $86.4 million, compared to $82.9 $68.6 million, for the year ended December 31, 2021 December 31, 2022.

The decrease increase of $14.3 $17.8 million for the year ended December 31, 2022 December 31, 2023 compared to the year ended December 31, 2021 December 31, 2022 was attributable to a decrease an increase in direct research and development expenses of $12.4 million, and a decrease an increase in indirect research and development expenses of $1.9 $5.4 million. The decrease increase in direct research and development expenses was primarily driven by lower manufacturing higher clinical trial expenses for our HB-200 HB-300 and Gilead partnered programs and lower clinical study expenses due program, which continued to enroll patients, primarily in the completion of patient enrollment of the Phase 2 trial first line combination arm with pembrolizumab, as well as increased spending for our HB-101 Roche partnered HB-700 program. These increases were partially offset by lower manufacturing expenses, including for our HB-300 program. Indirect research and development expenses decreased increased mainly because of a decrease in personnel related expenses including stock based stock-based compensation, of $2.0 million, a decrease in other operating income and expense of $1.1 million, and a decrease in laboratory consumables of $0.1 million, partially offset by an increase in lower expenses for consulting and professional and consulting fees of $0.7 million and an increase in training and recruitment expenses of $0.6 million. Stock based compensation decreased primarily due to the lower stock price of our common stock resulting in lower fair values of the granted stock options. services.

General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2022 December 31, 2023 were $18.8 $18.6 million, compared to $17.3 $18.8 million for the year ended December 31, 2021 December 31, 2022.

The increase of $1.5 million decrease was primarily due to a decrease in other expenses of $1.1 million, partially offset by an increase in personnel-related expenses of $0.8 million, and an increase in professional and consulting fees of $2.6 million and an increase in training and recruitment expenses of $0.5 million, partially offset by a decrease in personnel-related expenses of $1.3 million and a $0.2 million. The decrease in other expenses of $0.3 million. was primarily due to lower insurance expenses. The increase in professional and consulting fees was primarily attributable to the purchase of third-party services and to $1.9 million of intellectual property costs incurred in connection with filing and prosecuting patent applications. The decrease in personnel-related expenses resulted from decreased stock compensation expenses, the conversion of a portion of the base salaries of our executive team for the six months ended June 30, 2022 in common stock,

partially offset by a growth in headcount along with increased salaries in our general and administrative functions. Stock based functions as well as expenses for contractors, partially offset by decreased stock compensation decreased primarily due expenses.

Impairment Expenses

Impairment expenses for the year ended December 31, 2023 was comprised of $12.8 million of asset write-downs related to our GMP manufacturing facility project. As a result of the strategic considerations preceding the decision to implement a Restructuring Plan, we assessed the recoverability of the long-lived assets related to the lower stock price of our common stock resulting GMP manufacturing project at December 31, 2023, and concluded it was more likely than not, that the GMP manufacturing facility project will be discontinued leading to a trigger for the impairment test that ultimately resulted in lower fair values of the granted stock options. write-offs.

Grant Income

In the year ended December 31, 2022 December 31, 2023 we recorded grant income of $7.9 $11.2 million, compared to $9.7 $7.9 million in the year ended December 31, 2021 December 31, 2022 from grants, research incentives and imputed benefits from below market interest rates on loans from governmental agencies. The decrease increase of $1.8 $3.3 million was primarily due to lower higher income of $2.1 million from Austrian research and development incentives as a result of lower higher eligible research and development expenses. expenses, $1.4 million related to the New York State life sciences research and development program for the years 2019 to 2021, and $0.1 million related to the New York City biotechnology tax credit program, partially offset by lower imputed benefits from below market interest rates on loans from governmental agencies of $0.3 million.

Interest Income and Expense

Interest income was $5.3 million for the year ended December 31, 2023, compared to $1.6 million for the year ended December 31, 2022, compared to less than $0.1 million for the year ended December 31, 2021. The increase in interest income of $1.6 $3.7 million for the year ended December 31, 2022 December 31, 2023 was a result of the rising U.S. dollar and euro interest rates. Interest income represents interest from cash and cash equivalents held in U.S. dollars and euros resulting from the proceeds from the issuance of common and preferred stock as well as payments received under our Gilead and Roche collaborations. During the year ended December 31, 2022 December 31, 2023 our cash, cash equivalents and restricted cash were mainly held in dollars at U.S. investment grade financial institutions or in money

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market funds. In addition, smaller the necessary amounts to cover short-term working capital requirements were held in euros and dollars at our Austrian subsidiary.

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Interest expenses for loans from government agencies were $0.3 million for the year ended December 31, 2023, compared to $0.7 million for the year ended December 31, 2022, compared to $0.9 million for the year ended December 31, 2021. Interest expense was recorded at the market rate of interest, which exceeded the contractual interest.

Other Income and Expenses

Other income was $0.3 million for the year ended December 31, 2023, compared to other expenses were of $0.4 million for the year ended December 31, 2022, compared to $2.8 million for. The change in the year ended December 31, 2021. The decrease December 31, 2023 resulted primarily from the prior year effect of exchange rate differences and foreign currency remeasurements.

Liquidity and Capital Resources

Since our inception in 2011, we have funded our operations primarily from public offerings and private placements of common stock and convertible preferred stock, including our initial public offering, as well as private placements of our redeemable convertible preferred stock, grant funding and loans from an Austrian government agency, and upfront, milestone and initiation payments from Gilead and Roche in connection with research collaboration agreements.

Prior to our IPO, we raised gross proceeds of approximately $142.5 million from the issuance of our redeemable convertible preferred stock. In April 2019, we completed our IPO in which we issued and sold 6,000,000 shares of our common stock, at $14.00 per share, for gross proceeds of $84.0 million, or net proceeds of $74.6 million. On December 11, 2020, In December 2020, we completed a follow-on public offering in which we issued 3,910,000 shares of our common stock, at $11.75 per share, and 2,978 shares of our Series A convertible preferred stock, at $11,750.00 per share, for net proceeds of $75.0 million after deducting underwriting discounts and commissions and offering expenses. In addition, in February March 2022, Gilead purchased 1,666,666 shares of our common stock for $5.0 million. On March 4, 2022, we completed a follow-on public offering in which we issued 21,700,000 shares of our common stock, at $2.00 per share, and 15,800 shares of our Series A-1 convertible preferred stock, at $2,000.00 per share, for net proceeds of $70.2 million after deducting underwriting discounts and commissions and offering expenses. In June 2023, we completed a follow-on public offering in which we issued 22,900,768 shares of our common stock, at $1.31 per share, and 15,268 shares of our Series A-2 convertible preferred stock, at $1,310.00 per share, for net proceeds of $46.2 million after deducting underwriting discounts and commissions and offering expenses. In addition, in February 2022, Gilead purchased 1,666,666 shares of our common stock for $5.0 million, at a purchase price of $3.00 per share, and in December 2023, Gilead purchased 15,000,000 shares of our common stock, at $1.4167 per share, for net proceeds of $21.1 million after deducting offering expenses. Gilead also committed to purchase an additional $8.7 million of common stock as pro-rata participation in potential future equity raises (see "Note 11. Common stock, Class A common stock and convertible preferred stock" to our consolidated financial statements appearing elsewhere in this Annual Report). We also received $41.2 $46.2 million from non-refundable upfront, milestone and initiation payments pursuant to the Restated Gilead Collaboration Agreement and $25.0 $35.0 million from a non-refundable upfront payment and milestone payments related to the Roche Collaboration Agreement. In the first quarter 2023 we received a $5.0 million milestone payment related to the Restated Gilead Collaboration Agreement and a $10.0 million milestone payment related to the Roche collaboration. As of December 31, 2022 December 31, 2023, we had cash, cash equivalents and restricted cash of $113.4 $117.5 million.

On July 12, 2022, we filed a registration statement on Form S-3 (the Registration Statement) with the SEC, which was declared effective on July 21, 2022. The Registration Statement registers the offering, issuance and sale of an unspecified amount of common stock, preferred stock, debt securities, warrants and/or units of any combination thereof. We simultaneously entered into a Sales Agreement with SVB Securities LLC, as sales agent, to provide for the issuance and sale by us of up to $50.0 million of common stock from time to time in "at-the-market" offerings under the Registration Statement and related prospectus filed with the Registration Statement (the or the ATM Program). Program. As of December 31, 2022 December 31, 2023, no sales had been made pursuant to the ATM Program.

We entered into various funding agreements with the Austrian Research Promotion Agency (Österreichische Forschungsförderungsgesellschaft, or FFG) "FFG"). The loans by FFG (the FFG Loans) "FFG Loans"), were made on a project-by-project basis and bear interest at a rate of 0.75% per annum. In the event that the underlying program research results in a

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scientific or technical failure, the principal then outstanding under any loan may be forgiven by FFG and converted to non-repayable grant funding on a project-by-project basis. The FFG Loans contain no financial covenants and are not secured by any of our assets. The remaining debt obligation is $2.9 million, principal repayments are due as follows: $1.7 million are due in 2023, and under the remaining FFG loan is $1.2 million, are which is due for repayment upon final maturity in 2024.

Because the FFG Loans bear interest at below market rates we account for the imputed benefit arising from the difference between an estimated market rate of interest and the contractual interest rate as grant funding from FFG, which is included in grant income. On the date that FFG Loan proceeds are received, we recognize the portion of the

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loan proceeds allocated to grant funding as a discount to the carrying value of the loan and as unearned income. As of December 31, 2022 December 31, 2023, the unamortized debt discount related to FFG Loans was $0.4 $0.1 million.

We entered into arrangements with contract manufacturing organizations. As of December 31, 2022 December 31, 2023, we had total non-cancellable obligations under such contracts of $9.3 $7.4 million.

We do not expect positive cash flows from operations in the foreseeable future, if at all. Historically, we have incurred operating losses as a result of ongoing efforts to develop our arenavirus technology platform and our product candidates, including conducting ongoing research and development, preclinical studies, clinical trials, providing general and administrative support for these operations and developing our intellectual property portfolio. We expect to continue to incur net operating losses for at least the next several years as we progress clinical development, seek regulatory approval, prepare for and, if approved, proceed to commercialization of our most advanced oncology product candidate HB-200, continue our research and development efforts relating to our other and future product candidates, and invest in our manufacturing capabilities and our own manufacturing facility.

Future Funding Requirements

We have no products approved for commercial sale. To date, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, undertaking preclinical studies and clinical trials of our product candidates. As a result, we are not profitable and have incurred losses in each period since our inception in 2011. As of December 31, 2022 December 31, 2023, we had an accumulated deficit of $287.7 $369.3 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

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- incur additional legal, accounting and other expenses in operating our business, including ongoing costs associated with operating as a public company.

Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses

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and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

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

Since our inception, we have invested a significant portion of our efforts and financial resources in research and development activities for our non-replicating and replicating technologies and our product candidates derived from these technologies. Preclinical studies and clinical trials and additional research and development activities will require substantial funds to complete. We believe that we will continue to expend substantial resources for the foreseeable future in connection with the development of our current product candidates and programs as well as any future product candidates we may choose to pursue, as well as the gradual gaining of control over our required manufacturing capabilities and other corporate uses. These expenditures will include costs associated with conducting preclinical studies and clinical trials, obtaining regulatory approvals, and manufacturing and supply, as well as marketing and selling any products approved for sale. In addition, other unanticipated costs may arise. Because the outcome of any preclinical study or clinical trial is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our current or future product candidates.

Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing our current and future product candidates and programs, and of conducting preclinical studies and clinical trials;
- the number and development requirements of other product candidates that we may pursue, and other indications for our current product candidates that we may pursue;
- the stability, scale and yields of our future manufacturing process as we scale-up production and formulation of our product candidates for later stages of development and commercialization;
- the timing of, and the costs involved in, obtaining regulatory and marketing approvals and developing our ability to establish sales and marketing capabilities, if any, for our current and future product candidates we develop if clinical trials are successful;
- the success of our collaborations collaboration with Gilead and Roche; 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

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- 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.

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We do not have any committed external source of funds or other support for our development efforts. Until we can generate sufficient product and royalty revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements as well as grant funding. Based on our research and development plans, we expect that our existing cash and cash equivalents, including the funds received under the Restated Gilead Collaboration Agreement, and the funds received under the Roche Collaboration Agreement, 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,		Year ended December 31,	
	2022	2021	2023	2022
Net cash used in operating activities	$ (19,997)	$ (66,016)	$ (57,524)	$ (19,997)
Net cash used in investing activities	(5,017)	(12,581)	(4,159)	(5,017)
Net cash provided by (used in) financing activities	72,271	(235)		
Net increase (decrease) in cash and cash equivalents	47,257	(78,832)		
Net cash provided by financing activities			65,670	72,271
Net increase in cash and cash equivalents			3,987	47,257

Cash Used in Operating Activities

During the year ended December 31, 2023, cash used in operating activities was $57.5 million, which consisted of a net loss of $81.6 million, adjusted by non-cash charges of $18.8 million and cash provided due to changes in our operating assets and liabilities of $5.3 million. The non-cash charges consisted primarily of restructuring expenses of $12.8 million, resulting from a write-off of our GMP manufacturing facility project, depreciation and amortization expense of $3.6 million, stock-based compensation of $2.3 million and other non-cash items of $0.1 million. The change in our operating assets and liabilities was primarily due to an increase in accounts payable of $6.5 million, a decrease in accounts receivable of $6.2 million, primarily resulting from the collection of a $5.0 million milestone payment and cost reimbursements from Gilead, an increase in other non-current liabilities of $2.7 million, a decrease in prepaid expenses and other current assets of $1.7 million, an increase in accrued expenses and other current liabilities of $0.5 million, and a decrease in other non-current assets of $0.3 million, partially offset by a decrease in deferred revenues of $8.3 million, an increase in receivable research incentives of $2.7 million, and a decrease in operating lease liabilities of $1.6 million.

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During the year ended December 31, 2022, cash used in operating activities was $20.0 million, which consisted of a net loss of $64.9 million, adjusted by non-cash charges of $8.8 million and cash provided due to changes in our operating assets and liabilities of $36.1 million. The non-cash charges consisted primarily of stock-based compensation of $5.0 million, depreciation and amortization expense of $3.6 million, and other non-cash items of $0.2 million. The change in our operating assets and liabilities was primarily due to an increase of deferred revenues current and non-current of $35.5 million, an increase in accrued expenses and other current liabilities of $2.5 million, a decrease in prepaid expenses and other current and non-current assets of $2.5 million, and an increase in other non-current liabilities of $1.5 million, partially offset by a decrease in accounts payable of $2.0 million, an increase in receivable research incentives of $2.0 million, a decrease in operating lease liabilities of $1.6 million, and an increase in accounts receivable of $0.3 million. Changes in deferred revenues were due to upfront and initiation payments related to our collaboration agreements. Changes in research incentives were due to increased receivables under the research incentive program provided by the Austrian government. Changes in prepaid expenses and other current assets, accounts payable and other non-current assets in the year ended December 31, 2022 were generally due to lower research and development expenses and the timing of invoicing and payments. Changes in other current and non-current liabilities were generally related to the advancement of our research programs. Changes in operating lease liabilities in the year ended December 31, 2022 were mainly due to regular lease payments.

During the year ended December 31, 2021, cash used in operating activities was $66.0 million, which consisted of a net loss of $75.7 million, adjusted by non-cash charges of $13.6 million and cash used due to changes in our

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operating assets and liabilities of $3.9 million. The non-cash charges consisted primarily of stock-based compensation of $7.6 million, depreciation and amortization expense of $4.7 million, and other non-cash items of $1.3 million. The change in our operating assets and liabilities was primarily due to an increase in prepaid expenses and other current assets of $7.1 million, an increase in accounts receivable of $1.9 million, a decrease in operating lease liabilities of $1.6 million, a decrease in other non-current liabilities of $0.4 million, and an increase in receivable research incentives of $0.3 million, partially offset by an increase in accrued expenses and other current liabilities of $4.8 million, an increase of deferred revenues of $1.4 million, an increase in accounts payable of $0.9 million, and a decrease in other non-current assets of $0.4 million. Changes in prepaid expenses and other current assets, accounts receivable, accounts payable, and other non-current assets in

the year ended December 31, 2021 were generally due to growth in our business, the advancement of our research programs and the timing of invoicing and payments. Changes in operating lease liabilities in the year ended December 31, 2021 were mainly due to regular lease payments.

Cash Used in Investing Activities

During the years ended December 31, 2022 December 31, 2023 and 2021, 2022, cash used in investing activities was $5.0 $4.2 million and $12.6 $5.0 million, respectively. The decrease of $7.6 $0.8 million compared to the year ended December 31, 2021 December 31, 2022 resulted from lower capital expenditures in connection with our GMP manufacturing facility project the prior year effect of an acquisition of land in the year ended December 31, 2021 and lower expenditures for purchase of equipment. Cash used in investing activities in the year ended December 31, 2021 December 31, 2023 resulted from the acquisition of land and capital expenditures in connection with our own GMP manufacturing facility project and capital expenditures in connection with our laboratory space and for purchase of property and equipment.

During the year ended December 31, 2022, cash used in investing activities resulted primarily from capital expenditures in connection with our GMP manufacturing facility project as well as expenditures for laboratory and office space extension and purchase of equipment.

Cash (Used in) Provided by Financing Activities

During the year ended December 31, 2023, cash provided by financing activities was $65.7 million, which consisted mainly of net proceeds of $46.3 million from our follow-on public offering in June 2023 and of net proceeds of $21.2 million from Gilead's purchase of 15,000,000 shares of our common stock in December 2023, partially offset by principal repayments of loans of $1.8 million.

During the year ended December 31, 2022, cash provided by financing activities was $72.3 million, which consisted mainly of net proceeds of $70.2 million from our follow-on public offering in March 2022 and of net proceeds of $5.0 million from Gilead's purchase of 1,666,666 shares of our common stock in February 2022, partially offset by a repayment of a loan of $2.8 million.

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

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

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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.

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In September 2013, we entered into a Biological Materials License Agreement with NIH for a worldwide, nonexclusive license to make, have made, import and use certain cells and cell clones developed at the Vaccine Research Center of the NIH, i.e., the NIH Licensed Products, to manufacture viral vectors based on our proprietary arenavirus-based vectors. Pursuant to the terms of the NIH Agreement, we are obligated to pay the NIH low to mid six figure annual royalty payments, increasing as our most developed product candidate manufactured from NIH Licensed Products proceeds through development stages. We must also pay the NIH 10% of any consideration we receive from sublicensees.

In October 2020, we entered into a license agreement with the University of Basel for an exclusive, worldwide, royalty-bearing license for a tri-segmented arenavirus Split vector technology. We are required to use reasonable efforts to make commercially available licensed products. Pursuant to the license agreement, we are obligated to pay the University of Basel an annual fee which is fully deductible from any milestone, royalty or sublicense payments. We are also obligated to pay nominal milestone payments for each licensed product upon the achievement of certain development and regulatory milestones and to pay royalties of low single digits of net sales of licensed products. We are also obligated to pay a low double digit to low single digit percentage of the sublicense fees that we may receive from sublicensing.

In October 2022, we entered into a non-exclusive license agreement with the Regents of the University of Minnesota for a worldwide, non-exclusive license to patent rights related to our replicating technology patent which is exclusively licensed to us by the University of Geneva. We paid the University of Minnesota a low six figure amount upon entering into the agreement and are required to pay a non-material annual maintenance fee, and, upon commercialization of the first Minnesota Licensed Product, an annual minimum royalty which is creditable against royalties payable in the same year. While the Minnesota Agreement remains in effect, we are required to pay the University of Minnesota royalties on aggregate net sales of Minnesota Licensed Products, of a generally below single digit percentage. We must also pay the University of Minnesota low single digit percentages of certain considerations we receive from sublicensees, subject to pre-defined minimum and maximum payments. We further have to pay the University of Minnesota a nominal amount if we assign the Minnesota Agreement as part of a change of control.

In the year ended December 31, 2023, we recorded $1.6 million in licensing fees from intellectual property licenses as research and development expenses. At December 31, 2023, no payable from sublicensing fees was included in accrued expenses and other current liabilities. In the year ended December 31, 2022, we recorded $1.0 million in licensing fees from intellectual property licenses as research and development expenses. At December 31, 2022, $1.2 million payable from sublicensing fees were included in accrued expenses and other current liabilities. In the year ended December 31, 2021, we recorded $1.3 million in licensing fees from intellectual property licenses as research and development expenses. At December 31, 2021, $0.3 million payable payables from sublicensing fees were included in accounts payable.

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

Critical Accounting Policies and Estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which we have prepared in accordance with the rules and regulations of the SEC, and generally accepted accounting principles in the United States (GAAP) (“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

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the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

Our critical accounting policies and the methodologies and assumptions we apply under them have not materially changed as compared to those disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations - Critical Accounting Policies" in our Annual Report on Form 10-K for the year ended December 31, 2021 December 31, 2022, filed with the SEC Securities and Exchange Commission ("SEC") on March 24, 2022 March 15, 2023.

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Recognition of revenue from contracts with customers

We have entered into the Restated Gilead Collaboration Agreement for the development and commercialization of certain of our product candidates. Our performance obligations under the terms of this agreement include one combined performance obligation for each research program comprised of the transfer of intellectual property rights (licenses) and providing research and development services. Payments by Gilead to us under this agreement included a non-refundable up-front payment, payments for research and development activities, and may include payments based upon the achievement of defined pre-clinical development and commercial milestones and royalties on product sales if certain future conditions are met.

We have entered into the Roche Collaboration Agreement for the development and commercialization of certain of our product candidates. Our performance obligations under the terms of this agreement include one combined performance obligation for the transfer of intellectual property rights (licenses) and providing research and development services for the HB-700 program, and a second, separate performance obligation to perform research and development services and to deliver a specified package of preclinical data and results with respect to targeting undisclosed cancer antigens ("UCA program"). Payments by Roche under the Roche Collaboration Agreement included a non-refundable up-front payment, payments based upon the achievement of defined milestones, an additional payment if the option for the UCA program is exercised and royalties on product sales if certain future conditions are met. In January 2024, Roche provided us with written notice of the termination of the collaboration and licensing agreement.

We evaluate our collaboration and licensing arrangements pursuant to Accounting Standards Codification 606 (ASC 606). To determine the recognition of revenue from arrangements that fall within the scope of ASC 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when, or as, we satisfy a performance obligation. We present revenues from collaboration and licensing arrangements separately from other sources of revenue.

Amounts received by us as non-refundable upfront payment under the Restated Gilead Collaboration Agreement and the Roche Collaboration Agreement as well as success-based milestone payments under the Roche Collaboration Agreement prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in our consolidated balance sheets. Contingent milestone payments related to specified preclinical and clinical development milestones are not initially recognized within the transaction price as they are fully constrained under the guidance in ASC 606. Such amounts are recognized as revenue over the performance period of the respective services on a percent of completion basis for each of the obligations. We measure the progress toward complete satisfaction of the performance obligations based on the total cost of each collaboration program. This method of measuring progress results in recognizing revenue in proportion to the cost incurred during the quarter in relation to total expected cost for the respective program, according to the respective collaboration budget. Reimbursement of costs for our services under the Restated Gilead Collaboration Agreement and the Roche Collaboration Agreement are presented as revenue and not deducted from expenses. The Restated Gilead Collaboration Agreement and the Roche Collaboration Agreement also include 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.

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Leasing

The determination of whether an arrangement is qualified as a lease is made at contract inception. Operating lease assets and liabilities are recognized at the commencement date of the lease based upon the present value of lease payments over the lease term. When determining the lease term, we include options to extend or terminate the lease when it is reasonably certain that the option will be exercised. We use the implicit rate when readily determinable and our incremental borrowing rate when the implicit rate is not readily determinable based upon the information available at the commencement date in determining the present value of the lease payments. The incremental borrowing rate is determined using a secured borrowing rate for the same currency and term as the associated lease. The lease payments used to determine operating lease assets may include lease incentives, stated rent increases and escalation clauses linked to rates of inflation when determinable and are recognized as operating lease assets on the consolidated balance sheets. Certain of our arrangements contain lease and non-lease components. We applied an accounting policy choice to separate or not to separate lease payments for the identified assets from any non-lease payments included in the contract

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by asset class. Operating leases are reflected in operating lease assets, in accrued expenses and other current liabilities and in non-current operating lease liabilities in our consolidated balance sheets. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including salaries and bonuses, stock-based compensation, employee benefits, facilities costs, laboratory supplies, depreciation, manufacturing expenses and external costs of vendors engaged to conduct preclinical development activities and clinical trials as well as the cost of licensing technology. Advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed.

Upfront payments, milestone payments and annual payments made for the licensing of technology are generally expensed as research and development in the period in which they are incurred. Incremental sublicense fees triggered by contracts with customers are capitalized and expensed as research and development expenses over the period in which the relating revenue is recognized.

Stock-Based Compensation

We measure all stock options and other stock-based awards granted to employees and directors based on the fair value on the date of the grant and recognize compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award. We classify stock-based compensation expense in our consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified. Generally, we issue stock options, with service-only vesting conditions and record expense using the graded-vesting method.

We estimate the fair value of each stock option award using the Black-Scholes option-pricing model, which uses as inputs the fair value of our common stock and assumptions we make for make. As we have only been a public company since 2019, we estimate the

expected stock volatility based on the volatility of our common own stock as well as the historical volatility of a publicly traded set of peer companies until such time that we have adequate historical data regarding the volatility of our own traded stock price. For options with service-based vesting conditions, the expected term of our stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for a period that approximates time periods approximately equal to the expected term of our stock options the award. Expected dividend yield is based on the fact that we have never paid cash dividends and our expected dividend yield. do not expect to pay any cash dividends in the foreseeable future. We do not estimate and apply a forfeiture rate as we have elected to account for forfeitures as they occur.

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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. agencies as well as from New York State and New York City government agencies in the United States. Income from grants and incentives is recognized in the period during which the related qualifying expenses are incurred, provided that the conditions under which the grants or incentives were provided have been met. For grants under funding agreements and for proceeds under research incentive programs, we recognize grant and incentive income in an amount equal to the qualifying expenses incurred in each period multiplied by the applicable reimbursement percentage.

Grant income that we have received in advance of incurring qualifying expenses is recorded in the consolidated balance sheets as deferred income. Grant and incentive income recognized upon incurring qualifying expenses in advance of receipt of grant funding or proceeds from research and development incentives is recorded in the consolidated balance sheets as prepaid expenses and other current assets.

We have received loans under funding agreements that bear interest below market rates. We account for the imputed benefit arising from the difference between an estimated market interest rate and the actual interest rate charged on such loans as additional grant income, and record interest expense for the loans at a market interest. On the date that loan proceeds are received, we recognize the portion of the loan proceeds allocated to grant funding as a discount to the

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carrying value of the loan and as unearned income, which is subsequently recognized as additional grant income over the term of the funding agreement.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our consolidated financial statements appearing in this Annual Report on Form 10-K.

Emerging Growth Company Status and Smaller Reporting Company

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

therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We are also a “smaller reporting company” meaning that the market value of our stock held by non-affiliates is less than $700 million and our annual revenue was less than $100 million during our most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. For so long as we remain a smaller reporting company, we are permitted and intend to rely on exemptions from certain disclosure and other requirements that are applicable to other public companies that are not smaller reporting companies.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk from changes in interest rates, foreign exchange rates and inflation. All of these market risks arise in the ordinary course of business, as we do not engage in speculative trading activities. The following analysis provides additional information regarding these risks.

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Foreign Currency and Exchange Risk

We are subject to the risk of fluctuations in foreign currency exchange rates, specifically with respect to the euro. Our functional currency is the U.S. dollar and the functional currency of our wholly owned foreign subsidiary, Hookipa Biotech GmbH, is the euro. Our cash, cash equivalents and restricted cash as of December 31, 2022 December 31, 2023 included small amounts of cash balances held by Hookipa Biotech GmbH in euro. Assets and liabilities of Hookipa Biotech GmbH are translated into U.S. dollars at the exchange rate in effect on the balance sheet date. Income items and expenses are translated at the average exchange rate in effect during the period. Unrealized translation gains and losses are recorded as a cumulative translation adjustment, which is included in the condensed consolidated Statements of Convertible Preferred Stock and Stockholders’ Equity as a component of accumulated other comprehensive loss. Adjustments that arise from exchange rate changes on transactions denominated in a currency other than the local currency are included in other income and expenses, net in the condensed consolidated Statements of Operations and Comprehensive Loss as incurred. A significant portion of our operating costs are in Austria, which are denominated in the euro. This foreign currency exposure gives rise to market risk associated with exchange rate movements of the U.S. dollar against the euro. Furthermore, we anticipate that a significant portion of our expenses will continue to be denominated in the euro. A hypothetical 10% weakening of the U.S. dollar compared to the euro would have increased our net loss for the year ended December 31, 2023, by approximately $2.8 million and decreased our currency translation adjustment by approximately $0.3 million. A hypothetical 10% strengthening of the U.S. dollar compared to the euro would have an equal and opposite effect on our financial statements.

Interest Rate Risk

We are exposed to market risk related to changes in interest rates. We had cash, cash equivalents and restricted cash of $113.4 $117.5 million as of December 31, 2022 December 31, 2023, 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.

Table Impacts of Contents Inflation

While it is difficult to accurately measure the impact of inflation due to the imprecise nature of the estimates required, we do not believe inflation has had a material effect on our historical results of operations and financial condition. However, inflation, has had, and may continue to have, an impact on the labor costs we incur to attract and retain qualified personnel, costs to conduct clinical trials and other operational costs. If our costs were to become subject to significant inflationary pressures, we may not be able to fully offset higher costs through raising funds or other corrective measures, and our inability or failure to do so could adversely affect our business, financial condition, and results of operations. In addition, increased inflation has had, and may continue to have, an effect on interest rates. Increased interest rates may adversely affect our borrowing rate and our ability to obtain, or the terms under which we can obtain, any potential additional funding.

Item 8. Financial Statements and Supplementary Data

The financial statements required to be filed pursuant to this Item 8 are appended to this report. An index of those financial statements is found in Item 15 of Part IV of this Annual Report on Form 10-K.

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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) 13a-15(e) and 15d 15(e) 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

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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, 2022 December 31, 2023, management, with the participation of our Principal Executive Officer and Principal Financial and Accounting Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act of 1934). Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and the Chief Financial and Accounting Officer, to allow timely decisions regarding required disclosures.

Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on that evaluation, our Principal Executive Officer and Principal Financial and Accounting Officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of December 31, 2022 December 31, 2023.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act). Under the supervision of and with the participation of our Principal Executive Officer and Principal Financial and Accounting Officer, our management assessed the effectiveness of our internal control over financial report as of December 31, 2022 December 31, 2023 based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in "Internal Control-Integrated Framework" (2013). Based on this assessment, management concluded that our internal control over financial reporting was effective as of December 31, 2022 December 31, 2023.

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

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Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a 15(f) and 15d 15(f) under the Exchange Act) identified that occurred during the year quarter ended December 31, 2022 December 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None. During the quarter ended December 31, 2023, none of the Company's directors or officers (as defined in Rule 16a-1(f) of the Securities Exchange Act of 1934) adopted, terminated or modified a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (as such terms are defined in Item 408 of Regulation S-K).

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

Not applicable.

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PART III

We intend to file a definitive Proxy Statement for our 2024 Annual Meeting of Stockholders ("2024 Proxy Statement") with the SEC, pursuant to Regulation 14A, not later than 120 days after the end of our fiscal year. Accordingly, certain information required by Part III has been omitted under General Instruction G(3) to Form 10-K. Only those sections of the 2024 Proxy Statement that specifically address the items set forth herein are incorporated by reference.

Item 10. Directors, Executive Officers, and Corporate Governance

Incorporated by reference from the information in our Proxy Statement for our 2023 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates. If the Proxy Statement is not filed within such 120-day period, the The information required by this item will be contained in an amendment Item 10 is incorporated by reference to this Annual Report on Form 10-K to be filed with the Securities sections of the 2024 Proxy Statement under the captions "Director Biographies," "Executive Officers," "The Board of Directors and Exchange Commission, or the Form 10-K/A. its Committees," "Corporate Governance" and "Delinquent Section 16(a) Reports".

Item 11. Executive Compensation

Incorporated by reference from the information in our Proxy Statement for our 2023 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates. If the Proxy Statement is not filed within such 120-day period, the The information required by this item will be contained in an amendment Item 11 is incorporated by reference to this Annual Report on Form 10-K to be filed with the Securities sections of the 2024 Proxy Statement under the captions "Executive Compensation" and Exchange Commission, or the Form 10-K/A. "Director Compensation."

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 2023 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates. If the Proxy Statement is not filed within such 120-day period, the The information required by this item will be contained in an amendment Item 12 is incorporated by reference to this Annual Report on Form 10-K to be filed with the Securities sections of the 2024 Proxy Statement under the captions "Security Ownership of Certain Beneficial Owners and Exchange Commission, or the Form 10-K/A. Management and Related Stockholder Matters" and "Equity Compensation Plan Information."

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

Incorporated by reference from the information in our Proxy Statement for our 2023 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates. If the Proxy Statement is not filed within such 120-day period, the The information required by this item will be contained in an amendment Item 13 is incorporated by reference to this Annual Report on Form 10-K to be filed with the Securities sections of the 2024 Proxy Statement under the captions "Certain Relationships and Exchange Commission, or the Form 10-K/A. Related Person Transactions" and "The Board of Directors and Its Committees – Board Independence."

Item 14. Principal Accountant's Fees and Services

Incorporated by reference from the information in our Proxy Statement for our 2023 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates. If the Proxy Statement is not filed within such 120-day period, the The information required by this item will be contained in an amendment Item 14 is incorporated by reference to this Annual Report on Form 10-K to be filed with the Securities and Exchange Commission, or sections of the Form 10-K/A. 2024 Proxy Statement under the caption "Ratification of the Selection of Independent Registered Public Accounting Firm."

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Part IV

Item 15. Exhibits.

(1) Financial Statements and Financial Statement Schedules

The following documents are included on pages F-1 through F-6 F-7 attached hereto and are filed as part of this Annual Report on Form 10-K.

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(2) Financial Statement Schedules:

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

(3) Exhibits.

The following is a list of exhibits filed as part of this Annual Report on Form 10-K.

Exhibit Number	Description

3.1	Amended and Restated Certificate of Incorporation of the Company (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed on July 1, 2022 (File No. 001- 38869) and incorporated herein by reference)
3.2	Amended and Restated Bylaws of the Company (filed as Exhibit 3.2 to the Company's Current Report on Form 8-K filed on April 23, 2019 (File No. 001-38869) and incorporated herein by reference)
4.1	Specimen Common Stock Certificate (filed as Exhibit 4.1 to the Company's Registration Statement on Form S-1 filed on April 8, 2019 (File No. 333-230451) and incorporated herein by reference)
4.2	Shareholders Agreement among HOOKIPA Pharma Inc. and certain of its shareholders, dated February 15, 2019 (filed as Exhibit 4.1. to the Company's Current Report on Form 8-K filed on April 23, 2019 (File No. 001-38869) and incorporated herein by reference)
4.3 4.3*	Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 (filed as Exhibit 4.3 to the Company's Annual Report on Form 10-K filed on March 24, 2021 (File No. 001- 38869) and incorporated herein by reference)
4.4	Registration Rights Agreement, dated June 17, 2022, by and between the Company and Gilead Sciences, Inc. (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 22, 2022 (File No. 001- 38869) 001-38869) and incorporated herein by reference)
10.1#	HOOKIPA Pharma Inc. 2018 Stock Option and Grant Plan and forms of awards thereunder (filed as Exhibit 10.1 to the Company's Registration Statement on Form S-1 filed on March 22, 2019 (File No. 333-230451) and incorporated herein by reference)
10.2#	Amended and Restated 2019 Stock Option and Incentive Plan (filed as Exhibit 10.2 10.1 to the Company's Registration Statement Quarterly Report on Form S-1 10-Q filed on April 8, 2019 May 11, 2023 (File No. 333-230451) No.001-38869) and incorporated herein by reference)
10.3#	Incentive Stock Option Agreement under the Company's 2019 Stock Option and Incentive Plan (filed as Exhibit 10.3 to the Company's Registration Statement on Form S-1 filed on April 8, 2019 (File No. 333-230451) and incorporated herein by reference)
10.4#	Non-Qualified Stock Option Agreement for Company Employees under the Registrant's 2019 Stock Option and Incentive Plan (filed as Exhibit 10.4 to the Company's Registration Statement on Form S-1 filed on April 8, 2019 (File No. 333-230451) and incorporated herein by reference)
10.5#	Non-Qualified Stock Option Agreement for Non-Employee Directors under the Registrant's 2019 Stock Option and Incentive Plan (filed as Exhibit 10.5 to the Company's Registration Statement on Form S-1 filed on April 8, 2019 (File No. 333-230451) and incorporated herein by reference)

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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)

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10.7#	Restricted Stock Award Agreement for Company Employees under the Registrant's 2019 Stock Option and Incentive Plan (filed as Exhibit 10.7 to the Company's Registration Statement on Form S-1 filed on April 8, 2019 (File No. 333-230451) and incorporated herein by reference)
10.8#	Restricted Stock Award Agreement for Non-Employee Directors under the Registrant's 2019 Stock Option and Incentive Plan (filed as Exhibit 10.8 to the Company's Registration Statement on Form S-1 filed on April 8, 2019 (File No. 333-230451) and incorporated herein by reference)
10.9#	2019 Employee Stock Purchase Plan (filed as Exhibit 10.9 to the Company's Registration Statement on Form S-1 filed on April 8, 2019 (File No. 333-230451) and incorporated herein by reference)
10.10#	HOOKIPA Pharma Inc. 2023 Inducement Plan and form of award agreements thereunder (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 13, 2023 (File No. 001-38869) and incorporated herein by reference)
10.11#	Form of Director Indemnification Agreement (filed as Exhibit 10.10 to the Company's Registration Statement on Form S-1 filed on March 22, 2019 (File No. 333-230451) and incorporated herein by reference)
10.11# 10.12#	Form of Officer Indemnification Agreement (filed as Exhibit 10.11 to the Company's Registration Statement on Form S-1 filed on March 22, 2019 (File No. 333-230451) and incorporated herein by reference)
10.12# 10.13#	Employment Agreement between Joern Aldag and the Registrant HOOKIPA Biotech GmbH (filed as Exhibit 10.12 to the Company's Registration Statement on Form S-1 filed on April 8, 2019 (File No. 333-230451) and incorporated herein by reference)
10.13#	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 Reinhard Kandera and the Registrant HOOKIPA Biotech GmbH (filed as Exhibit 10.14 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)
10.15#	Employment Agreement between Klaus Orlinger and the Registrant, HOOKIPA Biotech GmbH, dated January 1, 2022 (filed as Exhibit 10.15 to the Company's Annual Report on Form 10-K filed on March 24, 2021 (File No. 001- 38869) 001-38869) and incorporated herein by reference)
10.16 10.16#	Employment Agreement between Christine Baker and the Registrant, dated August 1, 2019 (filed as Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on May 11, 2023 (File No. 001-38869) and incorporated herein by reference)
10.17#	Consultancy Service Agreement between Hookipa Biotech GmbH and Malte Peters, effective September 15, 2023 (filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on November 9, 2023 (File No. 001-38869) and incorporated herein by reference)
10.18	Lease by and between the Registrant HOOKIPA Biotech GmbH and Marxbox Bauprojekt GmbH & Co OG, dated February 3, 2012, as supplemented by the Lease Agreement, dated April 2, 2014 (filed as Exhibit 10.16 to the Company's Registration Statement on Form S-1 filed on March 22, 2019 (File No. 333-230451) and incorporated herein by reference)

10.17 10.19		Lease by and between the Registrant HOOKIPA Biotech GmbH and Wüstenrot Marxbox GmbH & Co KG, dated May 15, 2018 (filed as Exhibit 10.17 to the Company's Registration Statement on Form S-1 filed on March 22, 2019 (File No. 333-230451) and incorporated herein by reference)
10.18† 10.20†		Amended and Restated Collaboration and License Agreement, by and between Hookipa Biotech GmbH and Gilead Sciences, Inc., dated as of February 15, 20, 2022 22 (filed as Exhibit 10.1. to the Company's Current Report on Form 8-K/A filed on March 1, 2022 (File No. 001-38869) and incorporated herein by reference)

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10.19† 10.21†		Patent License Agreement, by and between Hookipa Biotech GmbH and the University of Zurich, dated as of October 6, 2011 (filed as Exhibit 10.19 to the Company's Registration Statement on Form S-1 filed on March 22, 2019 (File No. 333-230451) and incorporated herein by reference)

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10.20† 10.22†		Patent License Agreement, by and between Hookipa Biotech AG and the University of Basel, dated as of January 16, 2017 (filed as Exhibit 10.20 to the Company's Registration Statement on Form S-1 filed on March 22, 2019 (File No. 333-230451) and incorporated herein by reference)
10.21† 10.23†		Patent License Agreement, by and between Hookipa Biotech AG and the University of Geneva, dated as of February 8, 2017 (filed as Exhibit 10.21 to the Company's Registration Statement on Form S-1 filed on March 22, 2019 (File No. 333-230451) and incorporated herein by reference)
10.22† 10.24†		The National Institutes of Health Biological Materials License Agreement, by and between the National Institutes of Health within the Department of Health and Human Services through the Office of Technology Transfer and Hookipa Biotech AG, dated as of September 25, 2013, as amended by the First Amendment, dated April 12, 2017, and the Second Amendment, dated July 11, 2018 (filed as Exhibit 10.22 to the Company's Registration Statement on Form S-1 filed on March 22, 2019 (File No. 333-230451) and incorporated herein by reference)
10.23 10.25		Funding Contract, by and between Hookipa Biotech AG and The Austrian Research Promotion Agency, dated August 8, 2012, as extended by the Funding Contract, dated December 17, 2013, and the Funding Contract, dated May 22, 2015 (filed as Exhibit 10.23 to the Company's Registration Statement on Form S-1 filed on March 22, 2019 (File No. 333-230451) and incorporated herein by reference)
10.24 10.26		Funding Contract, by and between Hookipa Biotech AG and The Austrian Research Promotion Agency, dated December 16, 2014, as extended by the Funding Contract, dated October 4, 2016, the Funding Contract, dated February 27, 2018, and the Funded Contract dated October 25, 2019 (filed as Exhibit 10.23 to the Company's Annual Report on Form 10-K filed on March 18, 2021 (File No. 001- 38869) and incorporated herein by reference)

10.25 10.27	Lease by and between the Registrant and Wüstenrot Marxbox GmbH & Co. KG, dated February 26, 2019 (filed as Exhibit 10.25 to the Company's Registration Statement on Form S-1 filed on March 22, 2019 (File No. 333-230451) and incorporated herein by reference)
10.26 10.28	Amended and Restated Stock Purchase Agreement, by and between the Registrant and Gilead Sciences, Inc., dated as of February 15, 2022 December 20, 2023 (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on February 15, 2022 December 21, 2023 (File No. 001-38869) and incorporated herein by reference)
10.27† 10.29††	Research Collaboration and License Agreement, dated October 19, 2022, by and among Hookipa Biotech GmbH, F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 20, 2022 (File No. 001-38869) and incorporated herein by reference)
10.28* 10.30	Amendment No. 1 to License Agreement, by and between University of Basel and Hookipa Biotech GmbH, dated July 11, 2022 (filed as Exhibit 10.28 to the Company's Annual Report on Form 10-K filed on March 15, 2023 (File No. 001-38869) and incorporated herein by reference).
10.29* 10.31	Amendment No. 2 to License Agreement, by and between University of Basel and Hookipa Biotech GmbH, dated September 15, 2022 (filed as Exhibit 10.29 to the Company's Annual Report on Form 10-K filed on March 15, 2023 (File No. 001-38869) and incorporated herein by reference).
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

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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

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31.2*	Certificate of Principal Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1+	Certificate of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes Oxley Act of 2002

97.1*	Clawback Policy
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

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

†† Portions of this document (indicated by "[***]" have been omitted because they are not material and are the type that the Company treats as private and confidential.

# Indicates a management contract or any compensatory plan, contract or arrangement required to be filed as an exhibit pursuant to Item 15(a)(3) of Form 10-K.

* Filed herewith.

+ Furnished herewith.

Item 16. Form 10-K Summary

Not applicable

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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 15, 2023 March 22, 2024

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 15, 2023 22, 2024
/s/ Reinhard Kandera Reinhard Kandera	Chief Financial Officer and Director (Principal Financial and Accounting Officer)	March 15, 2023 22, 2024
/s/ Jan van de Winkel Jan van de Winkel, Ph.D.	Chairman of the Board	March 15, 2023 22, 2024
/s/ Michael A. Kelly Terry Coelho Michael A. Kelly Terry Coelho	Director	March 15, 2023 22, 2024
/s/ David Kaufman David Kaufman	Director	March 15, 2023 22, 2024
/s/ Malte Peters Malte Peters, M.D,	Director	March 15, 2023 22, 2024
/s/ Timothy Reilly Timothy Reilly, Ph.D.	Director	March 15, 2023 22, 2024
/s/ Julie O'Neill Julie O'Neill	Director	March 15, 2023 22, 2024

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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, 2022 December 31, 2023 and 2021, 2022, and the related consolidated statements of operations and comprehensive loss, of convertible preferred stock and stockholders' equity (deficit) and of cash flows for each of the three years in the period ended December 31, 2022 December 31, 2023, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 December 31, 2023 and 2021, 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022 December 31, 2023 in conformity with accounting principles generally accepted in the United States of America America.

Basis for Opinion

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

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

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

Emphasis of Matter

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

Vienna, Austria
March 15, 2023 22, 2024

PwC Wirtschaftsprüfung GmbH
/s/ Stefano Mulas Gabor Kruepl
German 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.

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PART I—FINANCIAL INFORMATION

HOOKIPA PHARMA INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except share amounts)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 112,488	$ 65,921
Restricted cash	537	566
Accounts receivable	6,533	6,895
Receivable research incentives	15,479	14,271
Prepaid expenses and other current assets	12,159	14,482
Total current assets	147,196	102,135
Non-current assets:		
Restricted cash	419	425
Property, plant and equipment, net	17,970	16,352
Operating lease right of use assets	4,006	5,673
Finance lease right of use assets	—	90
Other non-current assets	863	1,370
Total non-current assets	23,258	23,910
Total assets	$ 170,454	$ 126,045
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 5,488	$ 8,762
Deferred revenues	15,684	5,538
Operating lease liabilities, current	1,688	1,682
Accrued expenses and other current liabilities	11,178	8,880
Loans payable, current	1,594	2,792
Total current liabilities	35,632	27,654
Non-current liabilities		
Loans payable, non-current	911	2,219
Operating lease liabilities, non-current	2,310	3,911
Deferred revenues, non-current	25,664	21
Other non-current liabilities	3,420	2,648
Total non-current liabilities	32,305	8,799
Total liabilities	67,937	36,453
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at December 31, 2022 and December 31, 2021, respectively; Series A convertible preferred stock, 2,978 shares designated, 1,697 shares outstanding at December 31, 2022 and December 31, 2021, respectively; Series A-1 convertible preferred stock, 15,800 shares and no shares designated, 15,800 shares and no shares outstanding at December 31, 2022 and December 31, 2021, respectively	0	0
Common stock, $0.0001 par value; 200,000,000 shares and 100,000,000 shares authorized at December 31, 2022 and December 31, 2021, respectively; 52,317,138 shares and 27,383,483 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	5	3
Class A common stock, $0.0001 par value; 3,900,000 shares authorized at December 31, 2022 and December 31, 2021, respectively; 2,399,517 shares and 3,819,732 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	0	0

Additional paid-in capital	397,349	317,135
Accumulated other comprehensive loss	(7,156)	(4,780)
Accumulated deficit	(287,681)	(222,766)
Total stockholders' equity	102,517	89,592
Total liabilities and stockholders' equity	$ 170,454	$ 126,045

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 117,096	$ 112,488
Restricted cash	—	537
Accounts receivable	511	6,533
Receivable research incentives	18,760	15,479
Prepaid expenses and other current assets	10,749	12,159
Total current assets	147,116	147,196
Non-current assets:		
Restricted cash	425	419
Property, plant and equipment, net	7,742	17,970
Operating lease right of use assets	5,473	4,006
Other non-current assets	581	863
Total non-current assets	14,221	23,258
Total assets	$ 161,337	$ 170,454
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 12,498	$ 5,488
Deferred revenues	14,631	15,684
Operating lease liabilities, current	1,638	1,688
Accrued expenses and other current liabilities	12,101	11,178
Loans payable, current	1,120	1,594
Total current liabilities	41,988	35,632
Non-current liabilities		
Loans payable, non-current	—	911
Operating lease liabilities, non-current	3,801	2,310
Deferred revenues, non-current	19,674	25,664
Other non-current liabilities	6,017	3,420
Total non-current liabilities	29,492	32,305
Total liabilities	71,480	67,937
Commitments and contingencies (Note 14)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at December 31, 2023 and December 31, 2022, respectively; Series A convertible preferred stock, 2,978 shares designated, 370 and 1,697 shares outstanding at December 31, 2023 and December 31, 2022, respectively; Series A-1 convertible preferred stock, 15,800 shares designated, 10,800 and 15,800 shares outstanding at December 31, 2023 and December 31, 2022, respectively; Series A-2 convertible preferred stock, 15,268 shares and no shares designated, and 15,268 and no shares outstanding at December 31, 2023 and December 31, 2022, respectively	0	0
Common stock, $0.0001 par value; 200,000,000 shares authorized at December 31, 2023 and December 31, 2022, respectively; 96,550,590 shares and 52,317,138 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	10	5
Class A common stock, $0.0001 par value; 3,900,000 shares authorized at December 31, 2023 and December 31, 2022, respectively; 2,399,517 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	0	0

Additional paid-in capital	467,041	397,349
Accumulated other comprehensive loss	(7,933)	(7,156)
Accumulated deficit	(369,261)	(287,681)
Total stockholders' equity	89,857	102,517
Total liabilities and stockholders' equity	$ 161,337	$ 170,454

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

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HOOKIPA PHARMA INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share amounts)

	Year ended December 31,		
	2022	2021	2020
Revenue from collaboration and licensing	$ 14,249	$ 18,448	$ 19,584
Operating expenses:			
Research and development	(68,645)	(82,853)	(54,787)
General and administrative	(18,759)	(17,269)	(18,082)
Total operating expenses	(87,404)	(100,122)	(72,869)
Loss from operations	(73,155)	(81,674)	(53,285)
Other income (expense):			
Grant income	$ 7,916	$ 9,724	$ 6,517
Interest income	1,633	27	400
Interest expense	(687)	(898)	(786)
Other income and (expenses), net	(392)	(2,843)	3,072
Total other income, net	8,470	6,010	9,203
Net loss before tax	(64,685)	(75,664)	(44,082)
Income tax expense	(230)	(1)	(0)
Net loss	(64,915)	(75,665)	(44,082)
Other comprehensive (loss) income:			
Foreign currency translation gain (loss), net of tax	(2,376)	1,287	(1,414)
Comprehensive loss	$ (67,291)	$ (74,378)	$ (45,496)
Net loss per share — basic and diluted	$ (0.99)	$ (2.30)	$ (1.69)

	Year ended December 31,		
	2023	2022	2021
Revenue from collaboration and licensing	$ 20,129	$ 14,249	$ 18,448

Operating expenses:			
Research and development	(86,424)	(68,645)	(82,853)
General and administrative	(18,633)	(18,759)	(17,269)
Impairment expense	(12,766)	—	—
Total operating expenses	(117,823)	(87,404)	(100,122)
Loss from operations	(97,694)	(73,155)	(81,674)
Other income (expense):			
Grant income	$ 11,193	$ 7,916	$ 9,724
Interest income	5,293	1,633	27
Interest expense	(317)	(687)	(898)
Other income and (expenses), net	313	(392)	(2,843)
Total other income, net	16,482	8,470	6,010
Net loss before tax	(81,212)	(64,685)	(75,664)
Income tax expense	(368)	(230)	(1)
Net loss	(81,580)	(64,915)	(75,665)
Other comprehensive (loss) income:			
Foreign currency translation (loss) gain, net of tax	(777)	(2,376)	1,287
Comprehensive loss	$ (82,357)	$ (67,291)	$ (74,378)
Net loss per share — basic and diluted	$ (0.86)	$ (0.99)	$ (2.30)

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

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HOOKIPA PHARMA INC.

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

(In thousands, except share amounts)

	Convertible Preferred Stock		Common Stock				Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
			Common Stock		Class A Common Stock					
	Shares	Amount	Shares	Amount	Shares	Amount				
Balances as of December 31, 2022	**17,497**	**$ 0**	**52,317,138**	**$ 5**	**2,399,517**	**$ 0**	**$ 397,349**	**$ (7,156)**	**$ (287,681)**	**$ 102,517**
Issuance of Series A-2 convertible preferred stock upon public offering at $1,310 per share for cash, net of issuance costs of $1,471	15,268	0	—	—	—	—	18,530	—	—	18,530

Issuance of common stock upon public offering at $1.31 per share for cash, net of issuance costs of $2,207	—	—	22,900,768	2	—	—	27,791	—	—	27,793
Issuance of common stock upon stock purchase agreement with Gilead at $1.4167 per share for cash, net of issuance costs of $136	—	—	15,000,000	2	—	—	21,112	—	—	21,114
Conversion of Series A convertible preferred stock to common stock	(1,327)	(0)	1,327,000	0	—	—	(0)	—	—	—
Conversion of Series A-1 convertible preferred stock to common stock	(5,000)	(0)	5,000,000	1	—	—	(1)	—	—	—
Issuance of common stock upon exercise of stock options	—	—	5,684	0	—	—	1	—	—	1
ATM costs	—	—	—	—	—	—	(86)	—	—	(86)
Foreign currency translation adjustment, net of tax	—	—	—	—	—	—	—	(777)	—	(777)
Stock-based compensation expense	—	—	—	—	—	—	2,345	—	—	2,345
Net loss	—	—	—	—	—	—	—	—	(81,580)	(81,580)
Balances as of December 31, 2023	**26,438**	**$ 0**	**96,550,590**	**$ 10**	**2,399,517**	**$ 0**	**$ 467,041**	**$ (7,933)**	**$ (369,261)**	**$ 89,857**

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	Convertible Preferred Stock		Common Stock		Class A Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity	Preferred Stock		Common Stock		Class A Common Stock		Addition Paid-In Capital
	Shares	Amount	Shares	Amount	Shares	Amount					Shares	Amount	Shares	Amount	Shares	Amount	
Balances as of January 1, 2020	**—**	**$ —**	**21,746,392**	**$ 3**	**3,819,732**	**$ 0**	**$ 225,568**	**$ (4,653)**	**$ (103,019)**	**$ 117,899**							
Issuance of Series A convertible preferred stock upon public offering at $11,750 per share for cash, net of issuance costs of $2,565	2,978	0	—	—	—	—	32,426	—	—	32,426							

Issuance of common stock upon public offering at $11.75 per share for cash, net of issuance costs of $3,368	—	—	3,910,000	0	—	—	42,574	—	—	42,574								
Issuance of common stock upon exercise of stock options	—	—	255,011	0	—	—	63	—	—	63								
Vesting of restricted stock	—	—	1,060	0	—	—	(0)	—	—	—								
Vesting of equity grants	—	—	36,249	0	—	—	(0)	—	—	—								
Foreign currency translation adjustment, net of tax	—	—	—	—	—	—	—	(1,414)	—	(1,414)								
Stock-based compensation expense	—	—	—	—	—	—	8,657	—	—	8,657								
Net loss	—	—	—	—	—	—	—	—	(44,082)	(44,082)								
Balances as of December 31, 2020	**2,978**	**$**	**0**	**25,948,712**	**$**	**3**	**3,819,732**	**$**	**0**	**$ 309,288**	**$**	**(6,067)**	**$**	**(147,101)**	**$**	**156,123**		
Balances as of January 1, 2021																	**2,978**	**$**
Conversion of Series A convertible preferred stock to common stock	(1,281)	(0)	1,281,000	0	—	—	(0)	—	—	—	(1,281)	(0)	1,281,000	0	—	—		
Issuance of common stock upon exercise of stock options	—	—	110,071	0	—	—	203	—	—	203	—	—	110,071	0	—	—		
Vesting of restricted stock	—	—	43,700	0	—	—	(0)	—	—	—	—	—	43,700	0	—	—		
Foreign currency translation adjustment, net of tax	—	—	—	—	—	—	—	1,287	—	1,287	—	—	—	—	—	—		

Stock-based compensation expense	—	—	—	—	—	—	7,644	—	—	7,644	—	—	—	—	—	—	7,64
Net loss	—	—	—	—	—	—	—	—	(75,665)	(75,665)	—	—	—	—	—	—	-
Balances as of December 31, 2021	**1,697**	**$ 0**	**27,383,483**	**$ 3**	**3,819,732**	**$ 0**	**$ 317,135**	**$ (4,780)**	**$ (222,766)**	**$ 89,592**	**1,697**	**$ (0)**	**27,383,483**	**$ 3**	**3,819,732**	**$ 0**	**$ 317,13**
Issuance of Series A-1 convertible preferred stock upon public offering at $2,000 per share for cash, net of issuance costs of $1,975	15,800	0	—	—	—	—	29,625	—	—	29,625	15,800	0	—	—	—	—	29,62
Issuance of common stock upon public offering at $2.00 per share for cash, net of issuance costs of $2,713	—	—	21,700,000	2	—	—	40,685	—	—	40,687	—	—	21,700,000	2	—	—	40,68
Issuance of common stock upon stock purchase agreement with Gilead at $3.00 per share for cash, no issuance costs	—	—	1,666,666	0	—	—	5,000	—	—	5,000	—	—	1,666,666	0	—	—	5,00
Conversion of Class A common stock to common stock	—	—	1,420,215	0	(1,420,215)	(0)	—	—	—	—	—	—	1,420,215	0	(1,420,215)	(0)	-
Issuance of common stock upon exercise of stock options	—	—	34,223	0	—	—	3	—	—	3	—	—	34,223	0	—	—	
Vesting of equity grants	—	—	112,551	0	—	—	(0)	—	—	—	—	—	112,551	0	—	—	(
ATM costs	—	—	—	—	—	—	(142)	—	—	(142)	—	—	—	—	—	—	(14

Foreign currency translation adjustment, net of tax	—	—	—	—	—	—	—	(2,376)	—	(2,376)	—	—	—	—	—	—	-
Stock-based compensation expense	—	—	—	—	—	—	5,043	—	—	5,043	—	—	—	—	—	—	5,04
Net loss	—	—	—	—	—	—	—	—	(64,915)	(64,915)	—	—	—	—	—	—	-
Balances as of December 31, 2022	**17,497**	**$ 0**	**52,317,138**	**$ 5**	**2,399,517**	**$ 0**	**$ 397,349**	**$ (7,156)**	**$ (287,681)**	**$ 102,517**	**17,497**	**$ 0**	**52,317,138**	**$ 5**	**2,399,517**	**$ 0**	**$ 397,34**

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

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HOOKIPA PHARMA INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year ended December 31,		
	2022	**2021**	**2020**
Operating activities:			
Net loss	$ (64,915)	$ (75,665)	$ (44,082)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	5,043	7,644	8,657
Depreciation and amortization expense	3,602	4,640	4,150
Other non-cash items	160	1,226	53
Changes in operating assets and liabilities:			
Accounts receivable	(341)	(1,943)	(3,576)
Receivable research incentives	(1,958)	(295)	(5,825)
Prepaid expenses and other current assets	2,007	(7,091)	(2,286)
Other non-current assets	424	416	(1,080)
Accounts payable	(1,999)	858	6,298
Deferred revenues	35,508	1,422	511
Operating lease liabilities	(1,584)	(1,588)	(1,833)
Accrued expenses and other liabilities	2,510	4,776	(184)
Other non-current liabilities	1,546	(416)	(142)
Net cash used in operating activities	(19,997)	(66,016)	(39,339)
Investing activities:			
Purchases of property and equipment	(5,017)	(12,581)	(2,371)
Net cash used in investing activities	(5,017)	(12,581)	(2,371)
Financing activities:			
Payments related to finance leases	(25)	(438)	(108)

Proceeds from issuance of convertible preferred stock, net of issuance costs	29,625	—	32,426
Proceeds from issuance of common stock, net of issuance costs	45,691	203	42,637
Payments for deferred offering costs	(195)	—	(224)
Repayments of borrowings	(2,825)	—	(1,311)
Net cash provided by (used in) financing activities	72,271	(235)	73,420
Net increase (decrease) in cash, cash equivalents and restricted cash	47,257	(78,832)	31,710
Cash, cash equivalents and restricted cash at beginning of period	66,912	143,177	113,575
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(725)	2,567	(2,108)
Cash, cash equivalents and restricted cash at end of period	$ 113,444	$ 66,912	$ 143,177
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ (32)	$ (48)	$ (97)
Cash paid for income taxes	$ (1)	$ (1)	$ (0)
Supplemental disclosure of non-cash financing activities:			
Property and equipment additions in accounts payable and accrued expenses	$ (56)	$ (742)	$ 16
Lease assets obtained in exchange for new operating lease liabilities	$ 225	$ 2,727	$ 12
Lease assets derecognized upon lease cancellation	$ —	$ 1,061	$ 30

	Year ended December 31,		
	2023	2022	2021
Operating activities:			
Net loss	$ (81,580)	$ (64,915)	$ (75,665)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	2,345	5,043	7,644
Depreciation and amortization expense	3,552	3,602	4,640
Impairment expense	12,766	—	—
Other non-cash items	64	160	1,226
Changes in operating assets and liabilities:			
Accounts receivable	6,180	(341)	(1,943)
Receivable research incentives	(2,726)	(1,958)	(295)
Prepaid expenses and other current assets	1,735	2,007	(7,091)
Other non-current assets	304	424	416
Accounts payable	6,499	(1,999)	858
Deferred revenues	(8,258)	35,508	1,422
Operating lease liabilities	(1,622)	(1,584)	(1,588)
Accrued expenses and other liabilities	490	2,510	4,776
Other non-current liabilities	2,727	1,546	(416)
Net cash used in operating activities	(57,524)	(19,997)	(66,016)
Investing activities:			
Purchases of property and equipment	(4,159)	(5,017)	(12,581)
Net cash used in investing activities	(4,159)	(5,017)	(12,581)
Financing activities:			
Payments related to finance leases	—	(25)	(438)
Proceeds from issuance of convertible preferred stock, net of issuance costs	18,530	29,625	—
Proceeds from issuance of common stock, net of issuance costs	49,043	45,691	203
Payments for deferred offering costs	(149)	(195)	—
Repayments of borrowings	(1,754)	(2,825)	—

Net cash provided by (used in) financing activities	65,670	72,271	(235)
Net increase (decrease) in cash, cash equivalents and restricted cash	3,987	47,257	(78,832)
Cash, cash equivalents and restricted cash at beginning of period	113,444	66,912	143,177
Effect of exchange rate changes on cash, cash equivalents and restricted cash	90	(725)	2,567
Cash, cash equivalents and restricted cash at end of period	$ 117,521	$ 113,444	$ 66,912
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ (14)	$ (32)	$ (48)
Cash paid for income taxes	$ (403)	$ (1)	$ (1)
Supplemental disclosure of non-cash financing activities:			
Property and equipment additions in accounts payable and accrued expenses	$ (34)	$ (56)	$ (742)
Lease assets obtained in exchange for new operating lease liabilities	$ 2,874	$ 225	$ 2,727
Lease assets derecognized upon lease cancellation	$ —	$ —	$ 1,061

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

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HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of the business and organization

HOOKIPA Pharma Inc. (“HOOKIPA” or the “Company”) is a clinical stage biopharmaceutical company developing a new class of immunotherapeutics based on its proprietary arenavirus platform that is designed to reprogram the body’s immune system.

The Company was incorporated under the name of Hookipa Biotech, Inc. under the laws of the State of Delaware in February 2017 as a fully-owned subsidiary of Hookipa Biotech AG. In June 2018, the Company changed its name from Hookipa Biotech, Inc. to HOOKIPA Pharma Inc. and in order to effectuate the change of the jurisdiction of incorporation, the Company acquired all of the shares of Hookipa Biotech AG, now Hookipa Biotech GmbH. HOOKIPA is headquartered in New York, with European research and preclinical development operations headquartered in Vienna, Austria. In April 2019, the Company closed its initial public offering (“IPO”) and its common stock started trading on the Nasdaq Global Select Market under the ticker symbol “HOOK”.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, the ability to establish clinical- and commercial-scale manufacturing processes and the ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities and may not ultimately lead to a marketing approval and commercialization of a product. Even if the Company’s drug development efforts are successful, it is uncertain if and when the Company will realize significant revenue from product sales.

2. Summary of significant accounting policies

Basis of presentation

The Company's consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiary. All intercompany accounts and transactions have been eliminated in consolidation.

Going concern

Since inception, the Company's activities have consisted primarily of performing research and development to advance its technologies. The Company is still in the development phase and has not been marketing its technologies to date. Through December 31, 2022 December 31, 2023, the Company has funded its operations with proceeds from sales of common stock, sales of convertible preferred stock, sales of redeemable convertible preferred stock, collaboration and licensing agreements, grants and borrowings under various agreements with foreign public funding agencies. Since inception, the Company has incurred recurring losses, including net losses of $81.6 million, $64.9 million $75.7 million and $44.1 $75.7 million for the years ended December 31, 2022 December 31, 2023, 2021 2022 and 2020, 2021, respectively. As of December 31, 2022 December 31, 2023, the Company had an accumulated deficit of $287.7 $369.3 million. The Company expects to continue to generate operating losses in the foreseeable future. As of March 15, 2023 March 22, 2024, the filing date of this Annual Report on Form 10-K, the Company expects that its cash and cash equivalents together with the funds received under the Restated Gilead Collaboration Agreement and the funds received under the Roche Collaboration Agreement, both described below, would will 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.

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The Company will seek additional funding in order to reach its development and commercialization objectives. The Company may seek funds through further equity financings, debt financings, collaborations, strategic alliances and

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marketing, distribution or licensing arrangements. The Company may not be able to obtain financing on acceptable terms, or at all, and the Company may not be able to enter into collaborations or other arrangements. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders. If the Company is unable to obtain funding, the Company could be forced to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The consolidated financial statements do not reflect any adjustments relating to the recoverability and classification of assets or the amounts and classification of liabilities that might be necessary if the Company is unable to continue as a going concern.

Use of estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue, income and expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the recognition of revenue and income, the accrual of research and development expenses and general and administrative expenses, the present value of lease right of use assets and corresponding liabilities, the valuation of stock-based awards, and the valuation of current and non-current loans payable. payable and the impairment of long-lived assets. 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.

The COVID-19 pandemic continues to affect economies and business around the world. The extent and duration of such effects remain uncertain and difficult to predict, particularly as virus variants continue to spread. The Company is actively monitoring and managing its response and assessing actual and potential impacts to its operating results and financial condition, as well as developments in its business, which could further impact the developments, trends and expectations described below. As of the date of issuance of these consolidated financial statements, the Company is not aware of any specific event or circumstance that would require the Company to update estimates, judgments or revise the carrying value of any assets or liabilities. Actual results may differ from those estimates or assumptions.

Foreign currency and currency translation

The functional currency for the Company is the United States dollar and the functional currency for the Company's wholly owned foreign subsidiary, Hookipa Biotech GmbH, is the euro.

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

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Concentrations of credit risk and of significant suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents and short-term bank deposits held with banks in excess of publicly insured limits. For the years ended December 31, 2022 December 31, 2023 and December 31, 2021 December 31, 2022 the net proceeds from the Company's offerings have been deposited in interest-bearing bank accounts with two of the largest investment grade U.S. financial institutions and have been partially invested in money market funds. The money market funds, held in U.S. dollars, are primarily invested in U.S. and foreign short-term debt obligations. As of December 31, 2022 December 31, 2023 and December 31, 2021 December 31, 2022, the Company's cash and

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cash equivalents included smaller amounts of cash balances held in accounts with regional European banks at the Company's Austrian subsidiary, partially in euros. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

The Company relies, and expects to continue to rely, on a small number of vendors to manufacture supplies and raw materials for its development programs. These programs could be adversely affected by a significant interruption in these manufacturing services or the availability of raw materials.

As of December 31, 2022 December 31, 2023 and December 31, 2021 December 31, 2022, respectively, Gilead Sciences, Inc. ("Gilead") and F. Hoffmann-La Roche Ltd. and Hoffmann-La Roche Inc. (together "Roche") accounted for the majority of the accounts receivable balance. For the years ended December 31, 2022 December 31, 2023, December 31, 2022 and December 31, 2021 Gilead and December 31, 2020 Gilead Roche accounted for the majority of the Company's revenues. No other Other customers accounted for more less than 10.0% of accounts receivable or net sales. In the year ended December 31, 2022, the Company recorded significant deferred revenues under an agreement with F. Hoffmann-La Roche Ltd. and Hoffmann-La Roche Inc. (together "Roche") representing more than 10.0% of the Company's revenues from customers, when recognized. The Company monitors the financial performance of its customers so that it can appropriately respond to changes in their credit worthiness. To date, the Company has not experienced any significant losses with respect to collection of its accounts receivable.

Cash equivalents

The Company considers all highly liquid investments with maturities of three months or less at the date of purchase to be cash equivalents. As of December 31, 2022 December 31, 2023 and December 31, 2021 December 31, 2022 cash equivalents consisted of money market funds and short-term deposits.

Deferred offering costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of an equity financing, these costs are recorded in stockholders' equity as a reduction of the additional paid-in capital on a pro-rata basis generated as a result of the offering. Should the in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the consolidated statements of operations and comprehensive loss.

Fair value measurements

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three

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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.

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The Company's cash equivalents are carried at fair value, determined according to the fair value hierarchy described above (see Note 4) 5).

Property and equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation and amortization expense is recognized using the straight-line method over the estimated useful life of each asset as follows:

	Estimated useful life
Leasehold improvements	shorter of useful life or term of lease
Laboratory equipment	2 - 10 years
Furniture and fixtures	2 - 10 years
Computer equipment and software	2 - 4 years

Costs for capital assets not yet placed into service are capitalized as construction-in-progress and depreciated once placed into service. Expenditures for repairs and maintenance are charged to expense as incurred. When property and equipment is sold or otherwise disposed of, the cost and related accumulated depreciation are eliminated from the accounts and any resulting gain or loss is reflected in the consolidated statements of operations.

Leases

The determination whether an arrangement qualifies as a lease is made at contract inception. A lease qualifies as a finance lease if any of the following criteria are met at the inception of the lease: (i) there is a transfer of ownership of the leased asset to the Company by the end of the lease term, (ii) the Company holds an option to purchase the leased asset that it is reasonably certain to exercise, (iii) the lease term is for a major part of the remaining economic life of the leased asset, (iv) the present value of the sum of lease payments equals or exceeds substantially all of the fair value of the leased asset, or (v) the nature of the leased asset is specialized to the point that it is expected to provide the lessor no alternative use at the end of the lease term. All other leases are recorded as operating leases and are included in right of use ("ROU") assets and lease liabilities in the consolidated balance sheets. For leases with an initial term of 12 months or less, the Company does not recognize a right of use asset or lease liability. These short-term leases are expensed on a straight-line basis over the lease term.

ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent its obligation to make lease payments arising from the lease. ROU assets and lease liabilities are recognized at the commencement date of the lease based upon the present value of lease payments over the lease term. When

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determining the lease term, the Company includes options to extend or terminate the lease when it is reasonably certain that the option will be exercised. The Company uses the implicit rate when readily determinable and uses its incremental borrowing rate when the implicit rate is not readily determinable based upon the information available at the commencement date in determining the present value of the lease payments. The incremental borrowing rate is determined using a secured borrowing rate for the same currency and term as the associated lease. The lease payments used to determine ROU assets may include lease incentives, stated rent increases and escalation clauses linked to rates of inflation when determinable and are recognized as ROU asset on the consolidated balance sheet. In addition, certain of the Company's arrangements contain lease and non-lease components. The Company generally separates lease payments from non-lease payments. Operating leases are reflected in operating lease assets, in current operating lease liabilities and non-current operating lease liabilities in the consolidated balance sheets. Finance leases are reflected in finance lease assets, in accrued expenses and other current liabilities and in other non-current operating lease liabilities in the consolidated balance sheets. The ROU asset is tested for impairment in accordance with Accounting Standards Codification ("ASC") 360.

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Capitalized Software Development Cost

The Company capitalizes certain implementation costs for internal-use software incurred in a cloud computing agreement that is a service contract. Eligible costs associated with cloud computing arrangements, such as software business applications used in the normal course of business, are capitalized in accordance with ASC 350. These costs are recognized on a straight-line basis in the same line item in the statement of operations and comprehensive loss as the expense for fees for the associated cloud computing arrangement, over the term of the arrangement, plus reasonably certain renewals. Amortization expense of $0.1 million associated with the Company's cloud computing arrangements has been recognized during each of the fiscal year years ended December 31, 2023 and December 31, 2022. Amortization expense of less than $0.1 million associated with the Company's cloud computing arrangements has been recognized during the fiscal year ended December 31, 2021 (see Note 5) 6). The Company tests for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable.

Impairment of long-lived assets

Long-lived assets, including operating and finance lease right of use assets, consist of property and equipment. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative technological, scientific or economic trends and significant changes or planned changes in the use of the assets.

If an impairment review is performed to evaluate a long-lived asset group for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset group to its carrying value. An impairment loss would be recognized in loss from operations when estimated undiscounted future cash flows expected to result from the use of an asset group are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset group over its fair value determined based on discounted cash flows. The Company did not record any impairment losses on long-lived assets during the years ended December 31, 2022, 2021 (see Note 4. and 2020. Note 6.).

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

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HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

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 recognized revenue from collaboration and license agreements with Gilead and Roche.

Under the collaboration and license agreement with Gilead (as amended and restated, the "Gilead Collaboration Agreement"), the parties agreed to collaborate with respect to two preclinical research programs to evaluate potential vaccine products for the treatment, cure, diagnosis or prevention of the hepatitis B virus ("HBV") and the human immunodeficiency virus ("HIV"). In February 2022, the parties signed an amended and restated collaboration agreement (the "Restated Gilead Collaboration Agreement"), which revised the terms only for the HIV program, whereby the Company will take took on development responsibilities for the HIV program candidate through a Phase 1b clinical trial. The Company's performance obligations under the terms of the original agreement include one combined performance obligation for each research program (HBV and HIV) comprised of the transfer of intellectual property rights (licenses) and providing research and development services. The terms of the Restated Gilead Collaboration Agreement added an additional performance obligation to perform research and development work for the HIV program. The licenses do not

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HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

represent distinct performance obligations, because they cannot be used without the research and development services. Payments to the Company under the Restated Gilead Collaboration Agreement include a non-refundable up-front payment, payments for research and development activities, payments based upon the achievement of defined milestones, and if certain future conditions are met, payments for manufacturing services, commercial milestones and royalties on product sales.

Under the research collaboration and license agreement with Roche (the "Roche Collaboration Agreement"), the Company will has agreed to conduct research and early clinical development through Phase 1b for HB-700, a novel investigational arenaviral immunotherapy for the treatment of KRAS-mutated cancers. The Roche Collaboration Agreement also includes an obligation of the Company to deliver a specified package of preclinical data and results with respect to a second program, targeting undisclosed cancer antigens (collectively "UCAs") and an option for Roche to license the UCA program. The Company's performance obligations under the terms of the Roche Collaboration Agreement include one combined performance obligation for the transfer of intellectual property rights (licenses) and providing research and development services for the HB-700 program, and a second, separate performance obligation to perform research and development services with respect to the UCA program. The UCA option Option provides a right to license the program at the standalone selling price and therefore does not constitute a separate performance obligation. Payments to the Company under the Roche Collaboration Agreement include a non-refundable up-front payment, payments based upon the achievement of defined milestones, an additional payment if the option for the UCA program is exercised and royalties on product sales. In January 2024, Roche provided written notice of the termination of the collaboration and licensing agreement to the Company.

The Company evaluates its collaboration and licensing arrangements pursuant to ASC 606 Revenue from Contracts with Customers. To determine the recognition of revenue from arrangements that fall within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation.

Under ASC 606, the Company applies significant judgement to evaluate whether the promises under the collaboration and licensing arrangements, represent separate or one or more combined performance obligations, the allocation of the transaction price to identified performance obligations, the timing of revenue recognition, whether the UCA Option constitutes a material right, and the determination of when milestone payments are probable of being received.

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Upfront payment and program initiation fee

The non-refundable upfront-payment received by the Company upon signing of the Gilead Collaboration Agreement, and milestone payments that were linked to future performance obligations, were initially recorded as deferred revenue and allocated between the two research program performance obligations. Such amounts are recognized as revenue over the performance period of the respective services on a percent of completion basis using total estimated research and development labor hours (input method) for each of the obligations. The percent of completion basis using labor hours was considered the best measure of progress in which control of the combined performance obligations transfers to the customer, due to the short time intervals in which research results are shared with the collaboration partner and the nature of the work being performed.

The non-refundable program initiation payment received from Gilead upon signing of the Restated Collaboration Agreement was also initially recorded as deferred revenue and is recognized on a percent of completion basis using total estimated research and development costs (input method) for the performance of the obligations. The percent of completion basis using research and development costs was considered the best measure of progress in which control of the performance obligations transfers to the customer, due to the immediate benefit that it adds to the value of

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the customer's rights on the program, the short time intervals in which development results are shared and the nature of the work being performed.

The non-refundable upfront-payment received by the Company upon signing of the Roche Collaboration Agreement, was initially recorded as deferred revenue and allocated between the HB-700 program and the UCA program. Such amounts are recognized as revenue over the performance period of the respective services on a percent of completion basis using total estimated research and development costs (input method) for each of the obligations during the initial term of the contract. The percent of completion basis using research and development costs was considered the best measure of progress in which control of the performance obligations transfers to the customer.

Reimbursement for services

Under the Gilead Collaboration Agreement and the Roche Collaboration Agreement, the Company incurs employee expenses as well as external costs for research, manufacturing and clinical trial activities presented as operating expenses or prepaid expenses. Based on the nature of the Company's responsibilities under the collaboration arrangements, reimbursement of those costs are presented as revenue and not deducted from expenses, as the Company controls the research activities. Amounts of consideration allocated to the performance of research or manufacturing services are recognized over the period in which services are performed. Reimbursements for external costs are recognized as revenues as progress is achieved. Unpaid reimbursement amounts are presented as Accounts receivable. Receivable.

Research and development milestones

The Gilead Collaboration Agreement and the Roche Collaboration Agreement include contingent milestone payments related to specified preclinical and clinical development milestones. These milestone payments represent variable consideration that are not initially recognized within the transaction price as they are fully constrained under the guidance in ASC 606, due to the scientific uncertainties and the required commitment from Gilead and Roche. The Company will continue to assess the probability of significant reversals for any amounts that become likely to be realized prior to including the variable consideration associated with these payments within the transaction price.

Sales-based milestones and royalty payments

The Gilead Collaboration Agreement and the Roche Collaboration Agreement also include certain sales-based milestone and royalty payments upon successful commercialization of a licensed product. In accordance with ASC 606-10-55-65 Sales Based or Usage Based Royalties, the Company recognizes revenues from sales-based milestone and

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HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

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.

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HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

Research and development costs

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including salaries and bonuses, stock-based compensation, employee benefits, facilities costs, laboratory supplies, depreciation, manufacturing expenses and external costs of vendors engaged to conduct preclinical development activities and clinical trials as well as the cost of licensing technology. Advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed.

Upfront payments, milestone payments and annual payments made for the licensing of technology are generally expensed as research and development in the period in which they are incurred. Incremental sublicense fees triggered by contracts with customers are capitalized and expensed as research and development expenses over the period in which the related revenue is recognized.

Research and manufacturing contract costs and accruals

The Company has entered into various research and development and manufacturing contracts. Related payments are recorded as the corresponding expenses are incurred. The Company records accruals for estimated ongoing costs and prepaid expenses for advance payments. When evaluating the adequacy of the accrued liabilities and prepaid expenses, the Company analyzes progress of the research studies or clinical trials and manufacturing activities, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Government grant agreements and research incentives

The Company recognizes funding from grants and research incentives received from Austrian government agencies as well as from New York State and New York City government agencies in the United States as other income. Income from grants and incentives is recognized in the period during which the related qualifying expenses are incurred, provided that the conditions under which the grants or incentives were provided have been met. For grants under funding agreements and for proceeds under research incentive programs, the Company recognizes grant and incentive income in an amount equal to the estimated qualifying expenses incurred in each period multiplied by the applicable reimbursement percentage.

Grant funding that has been received by the Company in advance of incurring qualifying expenses is recorded as deferred income. Grant and incentive income recognized upon incurring qualifying expenses in advance of receipt of

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HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

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.

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Stock-based compensation

The Company measures stock-based awards granted to employees and directors based on the fair value on the date of grant using the Black-Scholes option-pricing model for options or the difference between the purchase price per share of the award, if any, and the fair value of the Company's common stock for restricted common stock awards. Compensation expense for those awards is recognized over the requisite service period, which is generally the vesting period of the respective award. The Company uses the graded-vesting method to record the expense of awards with service-based vesting conditions.

The Company classifies stock-based compensation expense in its Consolidated Statements of Operations and Comprehensive Loss in the same manner in which the recipient's payroll costs are classified or in which the recipient's service payments are classified.

Comprehensive loss

Comprehensive loss includes net loss and foreign currency translation adjustments. For the year years ended December 31, 2023 and December 31, 2022 comprehensive loss included $0.8 million and $2.4 million, respectively, of foreign currency translation loss adjustments. For the year ended December 31, 2021, comprehensive loss included $1.3 million of foreign currency translation gain adjustments. For the year ended December 31, 2020, comprehensive loss included $1.4 million of foreign currency translation loss adjustments.

Net loss per share

Basic net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock outstanding for the period. Diluted net loss per share is computed by dividing net loss by the weighted average number of shares outstanding for the period, including potential dilutive shares assuming the dilutive effect of outstanding stock options and of convertible preferred stock. For periods in which the Company has reported net losses, diluted net loss per common share is the same as basic net loss per share, since dilutive common shares are not assumed to have been issued if their affect is anti-dilutive.

The Company reported a net loss attributable to common stockholders for the years ended December 31, 2022 December 31, 2023, 2021 2022 and 2020. 2021.

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

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on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date. Changes in deferred tax assets and liabilities are recorded in income tax expense. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the

tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

The 2017 Tax Cuts and Jobs Act subjects a US shareholder to tax on global intangible low-taxed income (“GILTI”) earned by certain foreign subsidiaries. The FASB Staff Q&A, Topic 740, No. 5, Accounting for Global Intangible Low-Taxed Income, states that an entity can make an accounting policy election to either recognize deferred taxes for temporary basis differences expected to reverse as GILTI in the future years or provide for tax expense related to GILTI in the year the tax is incurred. The Company has elected to recognize tax expense related to GILTI in the year the tax is incurred.

Recent accounting pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (“FASB”) or other standard setting bodies that the Company adopts as of the specified effective date.

Adopted as of current period

In November 2021, July 2023, the FASB issued ASU 2021-10, Government Assistance 2023-03, Presentation of Financial Statements (Topic 832): Disclosures by Business Entities about Government Assistance, which requires business entities 205), Income Statement - Reporting Comprehensive Income (Topic 220), Distinguishing Liabilities from Equity (Topic 480), Equity (Topic 505), and Compensation - Stock Compensation (Topic 718) to amend various SEC paragraphs in the Accounting Standards Codification to primarily reflect the issuance of SEC Staff Accounting Bulletin No. 120. Staff Accounting Bulletin No. 120 provides guidance to companies issuing share-based awards shortly before announcing material, nonpublic information to consider such material nonpublic information to adjust observable market prices if the release of material nonpublic information is expected to affect the share price. The ASU does not provide certain disclosures when they have received government assistance any new guidance so there is no transition or effective date associated with it and when they use a grant or contribution accounting model by analogy therefore, the Company adopted the ASU with no impact to other accounting guidance (e.g., a grant model under IAS 20, Accounting for Government Grants and Disclosure of Government Assistance, or ASC 958-605, Not-For-Profit Entities – Revenue Recognition). Topic 832 requires the annual disclosures about transactions with a government that are accounted for by applying a

grant or contribution accounting model by analogy of information about the nature of the transactions and the related accounting policy used to account for the transactions, the line items on the balance sheet and income statement that are affected by the transactions, and the amounts applicable to each financial statement line item, significant terms and conditions of the transactions, including commitments and contingencies. The guidance in ASU 2021-10 is effective for all entities for fiscal years beginning after December 15, 2021. The Company has already provided all relevant disclosures regarding Government Assistance on its consolidated financial statements prior adoption of ASU 2021-10. Therefore, the early adoption of this standard as of January 1, 2022 on a prospective basis did not have a material impact on the Company's consolidated financial statements.

Recently Issued Accounting Pronouncements

In August 2020, the FASB issued ASU 2020-06, Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40). The ASU provides guidance that

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simplified the accounting for certain financial instruments with characteristics of liabilities and equity. The new guidance reduced the number of accounting models for convertible debt and convertible preferred stock instruments and made certain disclosure amendments intended to improve the information provided to users. The guidance also amended the derivative guidance for the "own stock" scope exception, which exempts qualifying instruments from being accounted for as derivatives if certain criteria are met. Finally, the standard changed the way certain convertible instruments are treated when calculating earnings per share. This guidance is effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years with early adoption permitted. The Company adopted this standard with no impact to its consolidated financial statements.

Recently Issued Accounting Pronouncements

In December 2023, the FASB issued final guidance in ASU No. 2023-09, Income Taxes (ASC 740): Improvements to Income Tax Disclosures requiring entities to provide additional information in the rate reconciliation and disclosures about income taxes paid. For public business entities, the guidance is currently assessing effective for annual periods beginning after December 15, 2024. The Company is not early adopting, and therefore, this ASU is not adopted in the current period. The Company does not expect this ASU to have a material impact that on the consolidated financial statements.

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In November 2023, the FASB issued ASU No. 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures which requires public entities to disclose significant segment expenses regularly provided to the chief operating decision-maker. Public entities with a single reporting segment have to provide all disclosures required by ASC 280, including the significant segment expense disclosures. For public business entities, the guidance is effective for annual periods beginning after December 15, 2024. The Company is not early adopting, and therefore this guidance will ASU is not adopted in the current period. The Company does not expect this ASU to have a material impact on its the consolidated financial statements.

3. Collaboration and Licensing Agreements

Gilead Collaboration and License Agreement

In June 2018, the Company entered into the Gilead Collaboration Agreement whereby the Company and Gilead agreed to collaborate with respect to two preclinical research programs to evaluate potential vaccine products for the treatment, cure, diagnosis or prevention of HBV and HIV. In February 2022, the Company signed an the Amended and Restated Collaboration Agreement, which altered key aspects of the collaboration pertaining to the HIV therapeutic. Most importantly, the Amended and Restated Collaboration Agreement allocated additional research and development responsibility to the Company with respect to the Company's HIV candidate and provided for additional funding by Gilead of such research and development activities as well as increased later stage development and commercial milestone payments.

Under the Gilead Collaboration Agreement, the Company granted Gilead an exclusive, royalty-bearing license to the Company's technology platforms. Upon entering into the agreement in June 2018, the Company received a non-refundable $10.0 million upfront payment from Gilead and upon signing of the Restated Gilead Collaboration Agreement in February 2022, the Company received a program initiation fee of $15.0 million. Gilead is also obligated to make additional payments to the Company upon the achievement of pre-clinical, development and commercial milestones. The development milestones amount to $140.0 million for the HBV program, and up to $172.5 million for the HIV program, inclusive of a $10.0 million program completion fee, payable upon Gilead's exercise of the option to pursue further development activities post Phase 1b. The commercial milestones amount to a total of $50.0 million for the HBV program, and $65.0 million for the HIV program. Additionally, Gilead is obligated to pay royalties on net sales for each program. Payments from Gilead generally have a 60 day payment term.

The $10.0 million upfront payment, the $15.0 million initiation fee and $8.0 million in milestone payments were initially recorded as deferred revenue in the consolidated balance sheet and are recognized as revenue when revenue recognition criteria are met. As of December 31, 2022 December 31, 2023, $14.3 $7.5 million of such payments were still recorded as a liability in deferred revenues, current and non-current. As of December 31, 2021 December 31, 2022, $4.3 $14.3 million of upfront and milestone payments were included as a liability in deferred revenues, current. current and non-current. Approximately 29% 55.2% of deferred revenue is expected to be recognized as revenue in 2023, 34% in 2024, 25% 36.8% in 2025 and the remaining 12% 8.0% in 2026.

As of December 31, 2022, no cost reimbursements for research and development services were included as a liability in deferred revenues. As of December 31, 2021, $1.2 million of cost reimbursements for research and development services were included as a liability in deferred revenues. Reimbursements for external costs are recognized as revenues as progress is achieved.

In the year ended December 31, 2022 December 31, 2023, the Company recognized $3.7 $7.1 million of the milestone and initiation payments that were originally recorded as deferred revenue. Furthermore, the Company recognized $5.2 $1.4 million revenue from cost reimbursements for research and development services. In addition, the year ended December 31, 2022, the Company fully recognized $3.7 million of the upfront and milestone payments that were originally recorded as deferred revenue, $5.2 million revenue from cost reimbursements for a research and development services and $5.0 million milestone payment for revenue from a milestone achieved in December 2022. In the year ended December 31, 2021, the Company recognized $2.1 million of the upfront and milestone payments that were originally recorded as deferred

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revenue. Furthermore, the Company recognized revenue and $16.3 million revenue from cost reimbursements for research and development services. No revenue has been recognized for another $4.0 million milestone payment that was recorded as deferred revenue in December 2021. For the year ended December 31, 2020, the Company recognized $4.4 million of the upfront and milestone payments that were originally recorded as deferred revenue. Furthermore, the Company recognized $13.0 million revenue from cost reimbursements for research and

development services. In addition, the Company fully recognized revenue for $2.2 million milestone payments for milestones achieved in the year ended December 31, 2020.

Sublicense fees payable to certain licensors of technologies upon the receipt of the deferred upfront and milestone payments, were capitalized as a contract asset and will be amortized over the period in which the revenue from

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the triggering payment is recognized. As of December 31, 2022, December 31, 2023 and 2022, the contract asset relating to the sublicense payment was $0.1 million and $0.2 million, respectively, and there was no liability relating to sublicense payment. As of December 31, 2021, the contract asset and the liability relating to the sublicense payment was $0.3 million, respectively.

Roche Collaboration and License Agreement

In October 2022, the Company entered into the Roche Collaboration Agreement whereby the Company and Roche agreed to collaborate with respect to the development of novel arenaviral immunotherapies for KRAS-mutated cancers and, potentially, a second, novel arenaviral immunotherapeutic program targeting specific undisclosed cancer antigens. In January 2024, Roche provided written notice of the termination of the collaboration and licensing agreement to the Company (see Note 18. “Subsequent Events”).

Under the terms of the terminated Roche Collaboration Agreement, the Company granted Roche an exclusive, royalty-bearing license to the Company’s technology platforms. platforms for KRAS-mutated cancers, and an option right to exclusively license a second, novel arenaviral immunotherapeutic program targeting undisclosed cancer antigens. Pursuant to the terms of the Collaboration Agreement, following the termination notice, the Collaboration Agreement will end on April 25, 2024. The Company remains eligible for a final milestone payment associated with an IND submission. Effective April 25, 2024, the Company will regain full control of the associated intellectual property portfolio and will have full collaboration and licensing rights for the KRAS program.

Upon signing the Roche Collaboration Agreement in October 2022, the Company received a non-refundable upfront payment of $25.0 million.

This upfront payment, and a $10.0 million and Roche will be obliged to pay an additional $15.0 million milestone payment if the option for the UCA program is exercised. The Company is also eligible for event-based milestone payments of up to an aggregate of $335.0 million during the research and development phase of the HB-700 program for up to four oncology indications and up to an aggregate of $250.0 million in payments related to the achievement of sales-based milestones. For the additional UCA program, subject to option-exercise, the Company is eligible for up to an aggregate of $173.0 million in event-based milestone payments during research and development for up to four oncology indications as well as up to an aggregate of $160.0 million in sales-based milestones. Upon commercialization, the Company is eligible to receive tiered royalties on the worldwide net sales of HB-700 and, subject to option exercise, the UCA program. The royalty payments are subject to reduction under specified conditions set forth received in the Roche Collaboration Agreement. Payments from Roche generally have payment terms between 30 days and 60 days.

The $25.0 million upfront payment was twelve months ended December 31, 2023 were initially recorded as deferred revenue in the consolidated balance sheet and is are recognized as revenue when revenue recognition criteria are met. As of December 31, 2023, $26.8 million of such payments were still recorded as a liability in deferred revenues, current and non-current. As of December 31, 2022, $27.0 million of the upfront payment was included as a liability in deferred revenues, current and non-current. The deferred revenues related to the $25.0 million upfront payment and the $10.0 million milestone payment are subject to foreign currency exchange rate fluctuations in future accounting periods. Approximately 43%

In the year ended December 31, 2023, the Company recognized $11.1 million of the upfront and milestone payments that were originally recorded as deferred revenue. Furthermore, the Company recognized $0.5 million revenue is expected from cost reimbursements for

activities related to be recognized as revenue the preparation of a first in 2023, 17% in 2024, 16% in 2025, 15% in 2026 and the remaining 9% in 2027.

human trial. In the year ended December 31, 2022, the Company recognized $0.3 million of the upfront payment that was originally recorded as deferred revenue.

Sublicense fees payable to certain licensors of technologies upon the receipt of the deferred upfront and milestone payments, were capitalized as a contract asset and will be amortized over the period in which the revenue from the triggering payment is recognized. As of December 31, 2023, the contract asset relating to the sublicense payment was $2.0 million and there was no liability relating to sublicense payment. As of December 31, 2022 the contract asset and the liability relating to the sublicense payment was $1.5 million and $1.2 million, respectively.

4. Impairment

On January 29, 2024, the Company announced its decision to prioritize the clinical development of its HB-200 program for the treatment of HPV16+ head and neck cancers and its two Gilead-partnered infectious disease programs and to pause development activities related to HB-300 and most of its preclinical research activities (see Note 18. “Subsequent Events”). In connection with this strategic refocus, the Company’s board of directors approved a Restructuring Plan to rebalance the Company’s cost structure, which includes a reduction of the Company’s workforce

by approximately 30% and the discontinuation of the Company’s GMP manufacturing facility project. The Company expects the Restructuring Plan to be implemented and substantially completed by the end of the first quarter of 2024.

As a result of the strategic considerations preceding the adoption of the Restructuring Plan, the Company assessed the recoverability of the long-lived assets relating to the GMP manufacturing project at December 31, 2023, and determined that the undiscounted cash flows of the asset group were below the carrying values, indicating impairment. The assets were written down to their estimated fair value, which was determined based on the cost approach. The resulting impairment charges were included within Impairment expense in the Consolidated Statements of Operations and Comprehensive Loss.

The following table summarizes the effect of non-cash impairment charges (in thousands):

	December 31, 2023	December 31, 2022
Non-cash impairment charges		
Asset write-offs	$ (12,766)	$ —
Total non-cash charges	$ (12,766)	$ —

4. 5. 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, 2022 Using				Fair Value Measurement at December 31, 2023 Using			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Cash equivalents:								
Money market funds	$ 85,491	$ —	$ —	$ 85,491	$ 91,084	$ —	$ —	$ 91,084
Total	$ 85,491	$ —	$ —	$ 85,491	$ 91,084	$ —	$ —	$ 91,084

	Fair Value Measurement at December 31, 2021 Using				Fair Value Measurement at December 31, 2022 Using			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Cash equivalents:								
Money market funds	$ 35,403	$ —	$ —	$ 35,403	$ 85,491	$ —	$ —	$ 85,491
Total	$ 35,403	$ —	$ —	$ 35,403	$ 85,491	$ —	$ —	$ 85,491

During the year ended December 31, 202 20232, , there were no transfers between Level 1, Level 2 and Level 3.

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HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

5. 6. Property, plant and equipment, net

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

	December 31, 2022	December 31, 2021	December 31, 2023	December 31, 2022
Land	$ 1,959	$ 2,072	$ 2,025	$ 1,959
Leasehold improvements	3,164	3,348	3,300	3,164
Construction in progress	10,567	7,746	212	10,567
Laboratory equipment	7,403	7,025	8,722	7,403
Furniture and fixtures	622	651	654	622
Computer equipment and software	2,034	1,876	2,652	2,034
Property and equipment, gross	25,749	22,718	17,565	25,749
Less: Accumulated depreciation	(7,779)	(6,366)	(9,823)	(7,779)
Property and equipment, net	$ 17,970	$ 16,352	$ 7,742	$ 17,970

Depreciation expense for the years ended December 31, 2022 December 31, 2023, 2022 and 2021 and 2020 was $2.0 million, $1.9 million $2.1 million and $1.7 $2.1 million, respectively. Construction-in-progress as of December 31, 2022 and December 31, 2021 mainly related to investments in connection with the Company's GMP manufacturing facility project.

6. As a result of the strategic considerations preceding the adoption of the Restructuring Plan (see Note 4. and Note 18.) the Company determined that the estimated undiscounted future cash flows for its asset group related to the GMP manufacturing facility project were less than their carrying values. The Company therefore recognized an impairment loss of $12.8 million related to the GMP manufacturing facility project for the year ended December 31, 2023, which reduced the carrying value of this asset group to zero. Impairment charges are included within Impairment expense in the Consolidated Statements of Operations and Comprehensive Loss.

There were no impairments in the years ended December 31, 2022 and 2021.

7. Receivable research incentive

The Company participates in a research incentive program provided by the Austrian government under which it is entitled to reimbursement of a percentage of qualifying research and development expenses and capital expenditures incurred in Austria. Submissions for reimbursement under the program are submitted annually. Incentive amounts are generally paid out during the calendar year that follows the year of the expenses but remain subject to subsequent examinations by the responsible authority. Reimbursements received in excess of the recognized receivable research incentive for a certain period are recorded within other long term liabilities for potential repayment until such time that an audit has taken place, upon expiration of the potential reclaim period, or when it is no longer probable that a reclaim will happen. The years 2018 to present remain open to examination by the authorities.

Furthermore, the Company participated in the life sciences research and development program provided by the New York State government under which it was entitled to reimbursement of a percentage of qualifying research and development expenses in New York State up to $0.5 million per year for the years 2019 to 2021. Incentive amounts are generally paid out six to nine months after amended tax returns including a certificate of tax credit issued by Empire State Development are filed.

The Company also participates in the New York City biotechnology tax credit program, according to which certain expenses for business in the biotechnology field in New York City limited to $0.25 million per year for three

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consecutive years from January 1, 2023 to December 31, 2025 are incentivized. The biotechnology tax credit can be refunded or applied against the next year's tax if it exceeds the current year's tax liability.

As of December 31, 2022 December 31, 2023, the Company recognized receivables of $15.5 $18.8 million from the research incentive program, programs, which are reported in research incentive receivables in the Company's consolidated balance sheet. $17.3 million relate to the Austrian research incentive program, $1.4 million relate to the New York State life sciences research and development program and $0.1 million relate to the New York City biotechnology tax credit program. As of December 31, 2021 December 31, 2022, the receivables from the research incentive program were $14.3 million. $15.5 million and related to the Austrian research incentive program.

During the years ended December 31, 2022 December 31, 2023, 2021 2022 and 2020, 2021, the Company recorded $10.9 million, $7.3 million $8.9 million and $5.8 $8.9 million, respectively, of income related to the incentive program programs within the Company's consolidated statements of operations and comprehensive loss as part of the grant income. Income for the year ended December 31, 2023 included $9.4 million related to the Austrian incentive program, $1.4 million related to the New York State life sciences research and development program and $0.1 million related to the New York City biotechnology tax credit program. Income for the years ended December 31, 2022 and 2021 related to the Austrian incentive program. Research incentives depend on the eligible research and development expenses of the respective period.

7. 8. Leases

The Company leases real estate, including office and laboratory space and has entered into various other agreements with respect to assets used in conducting its business. The Company's leases have remaining lease terms ranging from less than 1 year to 3 5.2 years. Some of the lease agreements contain rent holidays and rent escalation clauses that were included in the calculation of the right of use assets and lease liabilities. The Company's current leases qualify as operating leases. The Company is required to maintain a cash balance of $0.4 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, 2022 December 31, 2023.

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 effect of lease costs in the Company's consolidated balance sheets statements of operations and comprehensive loss (in thousands):

	Balance sheet location	December 31, 2022	December 31, 2021
Assets			
Operating lease assets, net	Operating lease right of use assets	$ 4,006	$ 5,673
Finance lease assets, net	Finance lease right of use assets	—	90
Total lease assets		4,006	5,763
Liabilities			
Current operating lease liability	Operating lease liabilities, current	1,688	1,682
Current finance lease liability	Accrued expenses and other current liabilities	—	21
Total current lease liabilities		1,688	1,703
Non-current operating lease liability	Operating lease liabilities, non-current	2,310	3,911
Non-current finance lease liability	Other non-current liabilities	—	—
Total non-current lease liabilities		2,310	3,911
Total lease liabilities		$ 3,998	$ 5,614

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

	Income statement location	Year ended December 31, 2023	Year ended December 31, 2022	Year ended December 31, 2021
Operating lease expenses	Research and development expenses	$ 1,347	$ 1,430	1,910
	General and administrative expenses	242	219	203
Finance lease amortization expenses	Research and development expenses	—	89	425
	General and administrative expenses	—	—	7
Interest on finance lease liabilities	Interest expenses	—	0	5
Sublease income	Other income (expense)	—	—	(40)
Net lease expense		$ 1,589	$ 1,738	2,510

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HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

The following table summarizes the effect of lease costs in the Company's consolidated statements of operations and comprehensive loss (in thousands):

	Income statement location	Year ended December 31, 2022	Year ended December 31, 2021	Year ended December 31, 2020
Operating lease expenses	Research and development expenses	$ 1,430	$ 1,910	1,654
	General and administrative expenses	219	203	376
Finance lease amortization expenses	Research and development expenses	89	425	395

	General and administrative expenses	—	7	21
Interest on finance lease liabilities	Interest expenses	0	5	8
Sublease income	Other income (expense)	—	(40)	(155)
Net lease expense		$ 1,738	$ 2,510	2,299

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

	December 31, 2022	December 31, 2023
	Operating lease	Operating lease
2023	1,570	
2024	1,316	1,655
2025	1,174	1,627
2026	—	1,351
2027	—	1,213
2028		4
Thereafter	—	1
Total lease payments	4,060	5,851
Less: interest	62	412
Present value of lease liabilities	$ 3,998	$ 5,439

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

	December 31, 2022	December 31, 2021	December 31, 2023	December 31, 2022
Weighted average remaining lease term in years	2.8	3.7	3.7	2.8
Weighted average discount rate (1)	1.3 %	1.3 %	4.1 %	1.3 %

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

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

	December 31, 2022	December 31, 2021
Weighted average remaining lease term in years	—	0.2
Weighted average discount rate (1)	— %	0.4 %

(1) The contracts are denominated in euros. The discount rate was determined During the year ended December 31, 2023, the Company agreed on a currency-equivalent basis.

Table lease amendment, which extended the term of Contents

HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

In December 2021 the lease for its corporate headquarters in New York City by approximately 2.2 years ending at the end of August 2026. The Company also extended the estimated lease term of existing operating leases for the office and laboratory space in Vienna, Austria. Austria, by approximately 2.0 years ending at the end of December 2027. Furthermore, the Company signed a lease amendment, which extended the term of the lease for certain parking spaces in its Vienna Office by approximately 5.5 years ending at the end of February 2029. These lease amendments did not include additional right-of-use other than the extended lease term. There is no additional renewal term

included in the lease amendments to consider in the estimate of the lease term. The respective lease liabilities were remeasured and the amounts resulting from the remeasurement of the lease liability were recognized as an adjustment to the corresponding right of use asset. Also in December 2021, the Company reduced the lease term for existing operating and finance leases related to an agreement with a contract manufacturing organization for the production

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

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

8. 9. Accrued expenses and other current liabilities

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

	December 31, 2022	December 31, 2021	December 31, 2023	December 31, 2022
Salaries and bonuses	4,481	4,754	5,665	4,481
Social security contributions	267	250	340	267
Unearned grant income (current)	300	693	52	300
Sublicense fees	1,220	304	—	1,220
Accrued external research and development expenses	3,458	2,165	4,594	3,458
Accrued external general and administration expenses	898	629	292	898
Accrued for property and equipment acquisitions	—	7	14	—
Finance lease liabilities	—	21		
Income taxes	230	—	367	230
Other accruals and liabilities	324	57	777	324
	$ 11,178	$ 8,880	$ 12,101	$ 11,178

9. 10. Loans payable

As of December 31, 2022 December 31, 2023 and December 31, 2021 December 31, 2022, loans payable consisted of the following (in thousands):

	December 31, 2022	December 31, 2021	December 31, 2023	December 31, 2022
Loans from FFG	$ 2,855	$ 6,074	$ 1,172	$ 2,855
Unamortized debt discount	(350)	(1,063)	(52)	(350)
Total loans payable, net	$ 2,505	$ 5,011	$ 1,120	$ 2,505

In connection with the funding agreements with the Austrian Research Promotion Agency, (*Österreichische Forschungsförderungsgesellschaft,* or "FFG"), the Company has received various loans ("FFG Loans"). The FFG Loans were made on a project-by-project basis. Amounts due under the FFG Loans bear interest at a rate of 0.75% per annum and mature at various dates between March 2023 and in 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

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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 $0.3 million, $0.6 million $0.8 million and $0.7 $0.8 million during the years ended December 31, 2022 December 31, 2023, 2021 2022 and 2020, 2021, 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 $0.3 less than $0.1 million and $0.7 $0.3 million as of December 31, 2022 December 31, 2023 and 2021, respectively, and unearned 2022, respectively. Unearned income (non-current) presented under loans payable non-current related to such benefit was $0.1 million and $0.4 million as of December 31, 2022 , and 2021, respectively. no non-current unearned income as of December31, 2023.

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, 2022 December 31, 2023 and 2021, 2022, the unamortized debt discount related to FFG Loans was $0.1 million and $0.4 million, and $1.1 million, respectively.

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The Company recognized interest expense of $0.3 million, $0.7 million $0.9 million and $0.8 $0.9 million during the years ended December 31, 2022 December 31, 2023, 2021 2022 and 2020, 2021, respectively, related to the FFG Loans, which included interest expense related to the amortization of debt discount of $0.3 million, $0.7 million $0.8 million and $0.7 $0.8 million during the years ended December 31, 2022 December 31, 2023, 2022 and 2021, and 2020, respectively. A principal repayment Principal repayments of $1.8 million, and $2.8 million and no principal repayment was were made in the years ended December 31, 2022 December 31, 2023 and 2021, 2022, respectively.

The Company uses an estimated market rate of 20%, which was determined based on an average of the available interest rates on unsecured loans to comparable companies. A 10% increase or decrease in the estimated market rate of interest would have no material impact on grant income or liabilities.

In the event that the underlying program research results in a scientific or technical failure, the principal then outstanding under any loan may be forgiven by FFG on a project-by-project basis. The FFG Loans contain no financial covenants and are not secured by any of the Company's assets.

As of December 31, 2022 December 31, 2023, the aggregate minimum future principal payments due in connection with the FFG Loans are summarized as follows (in thousands):

Payments Due by Calendar Year	Amount	Amount
2023	1,721	
2024	1,134	1,172
2025	—	—
2026	—	—
2027	—	—
2028		—
Thereafter	—	—
Total	$ 2,855	$1,172

10. 11. Common stock, Class A common stock and convertible preferred stock

The Company's capital structure consists of common stock, Class A common stock and preferred stock. As of December 31, 2022 December 31, 2023, the Company was authorized to issue 200,000,000 shares of common stock, 3,900,000 shares of Class A common stock and 10,000,000 shares of preferred stock. The Company has designated 2,978 of the 10,000,000 authorized shares of preferred stock as non-voting Series A convertible preferred stock, and 15,800 of the 10,000,000 authorized shares of preferred stock as non-voting Series A-1 convertible preferred stock and 15,268 of the 10,000,000 authorized shares of preferred stock as non-voting Series A-2 convertible preferred stock. As of December 31, 2022 December 31, 2023, the Company had 52,317,138 96,550,590 shares of common stock, 2,399,517 shares of Class A common stock,, 1,697 370 shares of Series A convertible preferred stock, and 15,800 10,800 shares of Series A-1 convertible preferred stock and 15,268 shares of Series A-2convertible preferred stock outstanding and issued.

Table On June 5, 2023, the Company closed a public offering of Contents22,900,768 shares of its common stock and 15,268 shares of Series A-2 convertible preferred stock at a public offering price of $1.31 and $1,310.00 per share, respectively, for net proceeds of $46.2 million after deducting underwriting discounts and commissions and offering expenses.

In July 2022 and August 2022 certain of the Company's stockholders elected to convert an aggregate of 1,420,215 shares (769,734 and 650,481 shares, respectively) of Class A common stock owned by such holders into an aggregate of 1,420,215 shares of the Company's common stock.

On February 15, 2022, the Company entered into a stock purchase agreement with Gilead ("Stock Purchase Agreement (the "Stock Purchase Agreement") with Gilead, , that requires Gilead, at the Company's option, to purchase up to $35.0 million of the Company's common stock. On February 15, 2022, Gilead purchased an initial amount of 1,666,666 shares of the Company's common stock

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in exchange for $5.0 million in cash at a purchase price per share equal to $3.00. On December 20, 2023, the parties amended and restated the Stock Purchase Agreement (the "Amended Stock Purchase Agreement") and Gilead purchased 15,000,000 shares of the Company's common stock in exchange for approximately $21.3 million in cash at a purchase price per share equal to $1.4167. Pursuant to the terms of the Amended Stock Purchase Agreement, the Company may require Gilead to purchase the balance of the $30.0 $8.7 million of common stock at the discretion of the Company, as pro-rata participation in one or two subsequent purchases at a price equal to the volume weighted average purchase price preceding such purchase, as defined in the Stock Purchase Agreement, plus, for the first subsequent purchase, which can be up to the full $30.0 million balance, a premium of 30%. potential future equity raises. The Company's right to sell shares of its common stock to Gilead is subject to specified limitations, including a limitation that prevents the Company from requesting purchases of shares of common stock by Gilead that would result in a beneficial ownership of more than 19.9% of the total number of outstanding shares of common stock by Gilead. At December 31, 2022, this limitation would have prevented the Company from requesting that Gilead purchase the full $30.0 million balance of the investment commitment. The Company agreed to file a registration statement on Form S-3 to register for resale any additional shares of common stock issued to Gilead within four months from issuance.

On March 4, 2022, the Company closed a public offering of 21,700,000 shares of its common stock and of 15,800 shares of Series A-1 convertible preferred stock at a public offering price of $2.00 and $2,000.00 per share, respectively, for net proceeds of $70.2 million after deducting underwriting discounts and commissions and offering expenses including pro-rata ATM expenses.

The Company has two three series of preferred stock authorized, issued and outstanding as of December 31, 2022 December 31, 2023: Series A convertible preferred stock, Series A-1 convertible preferred stock, and Series A-1 A-2 convertible preferred stock. Shares of Series A, Series A-1 and Series A-1 A-2 convertible preferred stock may be independently converted into common stock. Holders of Series A, Series A-1 and Series A-1 A-2 convertible preferred stock have equal rights, powers and privileges.

Holders of common stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. The holders of Class A common stock and Series A, Series A-1 and Series A-1 A-2 convertible preferred stock are not entitled to vote, except as required by law. The holders of common stock and Class A common stock do not have any cumulative voting rights.

Each holder of Class A common stock has the right to convert each share of Class A common stock into one share of common stock at such holder's election. Each holder of Series A, Series A-1 and Series A-1 A-2 convertible preferred stock has the right to convert each share of Series A, Series A-1 and Series A-1 A-2 convertible preferred stock into 1,000 shares of common stock at any time at the holder's option, provided that the holder will be prohibited, subject to certain exceptions, from converting Series A, Series A-1 and Series A-1 A-2 preferred stock into shares of our common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 9.99% of the total number of shares of the Company's common stock then issued and outstanding outstanding.

Holders of common stock and Class A common stock are entitled to receive ratably any dividends declared by the board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Holders of Series A A. Series A-1 and Series A-1 A-2 preferred stock will be entitled to receive dividends at a rate equal to (on an as-if-converted-to-common stock basis), and in the same form and manner as, dividends actually paid on shares of the Company's common stock. Holders of common stock and Class A common stock have no preemptive rights, conversion rights, or other subscription rights or redemption or sinking fund provisions.

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In the event of a liquidation, dissolution, or winding up of the Company, holders of our Series A, Series A-1 and Series A-1 A-2 preferred stock will receive a payment equal to $0.001 per share of Series A, Series A-1 and Series A-1 A-2 preferred stock before any proceeds are distributed to the holders of common stock. Then, holders of common stock and Class A common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities.

There were 370 and 1,697 shares of Series A convertible preferred stock, 10,800 and 15,800 shares of Series A-1 convertible preferred stock and 15,268 and no shares of Series A-2 convertible preferred stock outstanding as of

December 31, 2023 and December 31, 2022 and December 31, 2021, respectively. In October 2021 and December 2021 May 2023 certain of the Company's stockholders elected to convert an aggregate of 1,281 1,327 shares (55 and 1,226 shares, respectively) of Series A convertible preferred stock and an aggregate of 5,000 shares of Series A-1 convertibles preferred stock owned by such holders into an aggregate of 1,281,000 6,327,000 shares of the Company's common stock.

11. 12. Stock-based compensation

2018 Stock Option and Grant Plan

In June 2018, the Board of Directors approved the 2018 Stock Option and Grant Plan. Options granted under the 2018 Stock Option and Grant Plan generally vest over four years, with 25% of the options vesting upon the first anniversary of the grant date and the remaining 75% of the options vesting in 12 equal quarterly installments following the first anniversary of the grant date, provided the option holder continues to have an employment or service relationship with the Company on each vesting date. The options expire on the 10th anniversary of the grant date. As of December 31, 2022 December 31, 2023, 900,796 782,176 options granted under the 2018 Stock Option and Grant Plan remained outstanding. Any authorization to issue new options under the 2018 Stock Option and Grant Plan was cancelled upon the effectiveness of the 2019 Stock Option and Incentive Plan and no further awards will be granted under the 2018 Plan.

2019 Stock Option and Incentive Plan

On April 1, 2019, the Company's stockholders approved the 2019 Stock Option and Incentive Plan, which became effective as of the effective date of the registration statement in connection with the Company's IPO. The plan provides for the grant of shares of restricted stock, long term incentive awards, stock options or other equity-based awards. As of December 31, 2022 December 31, 2023, the maximum number of shares of the Company's common stock that may be issued under the Company's 2019 Stock Option and Incentive Plan was 5,878,814 8,067,480 shares which shall be cumulatively increased each year by up to 4.0% of the then outstanding number of shares of common stock and Class A common stock. Options granted under the 2019 Stock Option and Incentive Plan generally vest over four years, with 25% of the options vesting upon the first anniversary of the grant date and the remaining 75% of the options vesting in 12 equal quarterly installments following the first anniversary of the grant date, provided the option holder continues to have an employment or service relationship with the Company on each vesting date. Initial options granted to non-executive directors upon their election generally vest over a three-year term with 33% of the options vesting upon the first anniversary of the grant date and the remaining 67% of the options vesting in eight equal quarterly installments following the first anniversary of the grant date. 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.

In addition, there were 500,000 shares reserved for stock options issued as inducement grants to new employees granted outside of the Company's equity-based compensation plans under Rule 5635(c)(4) of the Nasdaq Listing Rules.

On August 7, 2023, the Company's board of directors approved a one-time offer to eligible non-executive, non-director employees to exchange certain outstanding stock options for new stock options with modified terms. Under the stock option exchange program (the "Offer"), the Company offered to exchange certain out-of-the-money stock options for new stock options at an exchange ratio of between 1.75 and 2.50 surrendered options for one new option exercisable for shares of common stock with a lower exercise price and extended vesting terms. Pursuant to the Offer, a total of 82 eligible participants tendered, and the Company accepted for cancellation, stock options to purchase an aggregate of 543,228 shares of the Company's common stock with exercise prices between $6.90 and $14.00. The eligible options that were accepted for cancellation represented approximately 86.6% of the total shares of common stock underlying all of the eligible options. In accordance with the terms and conditions of the Offer, on September 12, 2023, the Company issued new options to

purchase an aggregate of 274,485 shares of common stock in exchange for the cancellation of the tendered eligible options. The exercise price per share of each new option granted in the Offer is $1.00. New options

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HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

issued for previously vested stock options vest on the first anniversary of the grant date and new options issued for previously unvested stock options vest over a three-year term in twelve equal quarterly installments. The stock option exchange offer resulted in incremental stock-based compensation expense of $0.1 million, which will be recognized using the graded-vesting method over the remaining requisite service period of the new stock options.

The following table presents a summary of awards outstanding:

	As of December 31, 2023			
	2018 Plan	2019 Plan	Inducement Awards	Total
Granted and outstanding awards:				
Stock options	782,176	7,099,399	230,000	8,111,575
Total	782,176	7,099,399	230,000	8,111,575

Stock option valuation

The Company estimates the option's fair value on the date of grant using the Black-Scholes option-pricing model. Black-Scholes utilizes assumptions related to expected term, volatility, the risk-free interest rate, the dividend and employee exercise behavior. Forfeitures are accounted for when they occur. Expected volatilities utilized in the Black-Scholes model are based on historical volatilities of a group of comparable companies. The group of representative companies have characteristics similar to the Company, including the stage of product development and focus on the life science industry. Management believes that this represents the most accurate basis for estimating expected future volatilities under the current conditions. The risk-free interest rate is derived from the yields for

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HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

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,	Year ended December 31,

	2022	2021	2020	2023	2022	2021
Risk-free interest rate	3.09 %	1.07 %	0.44 %	3.70 %	3.09 %	1.07 %
Expected term (in years)	6.0	6.1	6.1	5.7	6.0	6.1
Expected volatility	85.4 %	85.5 %	80.2 %	93.6 %	85.4 %	85.5 %
Expected dividends	— %	— %	— %	— %	— %	— %

For the 2020, 2021, 2022 and 2022 2023 grants, the Company used the simplified method in developing an estimate of the expected term due to a lack of historical exercise data.

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HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

Stock option activity

The following table summarizes the Company's stock option activity since January 1, 2022 January 1, 2023 (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	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2021	4,231,178	$ 9.21	7.5	$ 1,640				
Outstanding as of December 31, 2022					6,532,523	$ 6.19	7.7	$ 490
Granted	2,709,523	1.55			2,880,985	1.00		
Exercised	(34,223)	0.10			(5,684)	0.10		
Forfeited	(373,955)	7.31			(1,296,249)	6.63		
Outstanding as of December 31, 2022	6,532,523	$ 6.19	7.7	$ 490				
Outstanding as of December 31, 2023					8,111,575	$ 4.28	7.4	$ 486
Options exercisable as of December 31, 2022	3,182,724	$ 8.47	6.3	$ 489				
Options unvested as of December 31, 2022	3,349,799	$ 4.01	9.0	$ 1				
Options exercisable as of December 31, 2023					4,101,520	$ 6.83	6.1	$ 486
Options unvested as of December 31, 2023					4,010,055	$ 1.67	8.8	$ —

The aggregate intrinsic value of stock options was calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock. The fair value per common stock used for calculating the intrinsic values as of December 31, 2022 December 31, 2023, December 31, 2021 December 31, 2022 and December 31, 2020 December 31, 2021, was $0.81, $2.33 $0.81 and $11.09, $2.33, respectively.

The aggregate intrinsic value of options exercised during the years ended December 31, 2022 December 31, 2023, 2022 and 2021 and 2020 was less than $0.1 million, $1.0 $0.1 million and $2.9 $1.0 million, respectively.

The weighted average grant-date fair value per share of stock options granted during the years ended December 31, 2022 December 31, 2023, 2022 and 2021 was $0.55, $1.55 and 2020 was $1.55, $11.46, and $8.95, respectively.

The total fair value of stock options vested during the years ended December 31, 2022 December 31, 2023 and 2021 2022 was $5.1 million and $7.9 million, and $6.0 million, respectively.

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Cash received from stock option exercise under share-based payment arrangements for the years ended December 31, 2022 December 31, 2023, 2022 and 2021 and 2020 was $1 thousand, $3 thousand and $203 thousand, and $63 thousand, respectively.

Restricted Stock Units

In the year ended December 31, 2020, the Company granted 43,700 restricted stock units to officers, employees and a consultant to compensate them for a temporary salary or fee reduction in response to the coronavirus pandemic. The restricted stock units were subject to time-based vesting conditions and generally vested between March 2021 and November 2021. Expenses were recorded using the graded-vesting method. In the years ended December 31, 2022 and 2021, the Company has not issued restricted stock units.

Common Stock Awards

In the year ended December 31, 2022 the Company issued unrestricted shares of common stock to members of its executive team. The Company's executive team who agreed to convert a portion of their base salaries, for the six months ended June 30, 2022, for shares of the Company's fully vested common stock having a value equal to their foregone salary. The number of shares of fully vested common stock was salary, determined based on a value of $3.00 per share, resulting share. This resulted in the issuance of 112,551 shares of common stock. The stock with a total fair value of common stock awards issued during the three months ended March 31, 2022 was $0.2 million. The grant date fair value per share of common stock was $1.50 and was measured at the closing price of the common stock on the date of grant. Expenses were recorded immediately and were are included in stock based compensation in the three months year ended March 31, 2022 December 31, 2022. No unrestricted shares of common stock were issued in the year ended December 31, 2021 December 31, 2023. In the year ended December 31, 2020, the Company issued 36,249 unrestricted shares

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Table of common stock to the non-executive members of its Board of Directors. Contents

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,			Year ended December 31,		
	2022	2021	2020	2023	2022	2021
Research and development expenses	$ 2,074	$ 3,200	$ 3,084	$ 861	$2,074	$3,200
General and administrative expenses	2,969	4,444	5,573	1,484	2,969	4,444
	$ 5,043	$ 7,644	$ 8,657	$2,345	$5,043	$7,644

As of December 31, 2022 December 31, 2023 total unrecognized compensation cost related to the unvested stock-based awards was $4.7 $1.5 million, which is expected to be recognized over a weighted average period of 1.5 years.

12. Income taxes

Income tax expense during the years ended December 31, 2022 resulted from US federal and state income tax as well as minimum tax obligations in Austria. From inception through December 31, 2021, we have not been required to pay U.S. federal and state income taxes because of current and accumulated net operating losses. Income tax expense during the years ended December 31, 2021 and 2020 resulted from minimum tax obligations. During the years ended December 31, 2022, 2021 and 2020, the Company recorded no income tax benefits for the net operating losses incurred

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HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

13. Income taxes

Income tax expense during the years ended December 31, 2023 and December 31, 2022 resulted from US federal and state income tax as well as minimum tax obligations in Austria. From inception through December 31, 2021, we have not been required to pay U.S. federal and state income taxes because of current and accumulated net operating losses. Income tax expense during the year ended December 31, 2021 resulted from minimum tax obligations. During the years ended December 31, 2023, 2022 and 2021, 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, 2022 December 31, 2023, 2021 2022 and 2020 2021 consisted of the following (in thousands):

	Year ended December 31,			Year ended December 31,		
	2022	2021	2020	2023	2022	2021
United States	$ (7,222)	$ (11,403)	$ (11,603)	$ 1,710	$ (7,222)	$(11,403)
Foreign (Austria)	(57,463)	(64,261)	(32,479)	(82,922)	(57,463)	(64,261)
Net loss before tax	$ (64,685)	$ (75,664)	$ (44,082)	$(81,212)	$(64,685)	$(75,664)

The components of the consolidated income tax provision for the years ended December 31, 2022 December 31, 2023, 2021 2022 and 2020 2021 were as follows (in thousands):

	Year ended December 31,			Year ended December 31,		
	2022	2021	2020	2023	2022	2021
Current						
Federal	$ 217	$ —	$ —	$ 145	$ 217	$ —
State	12	—	—	222	12	—
Foreign (Austria)	1	1	0	1	1	1

Total current tax expense	230	1	0	368	230	1
Deferred						
Federal	—	—	—	—	—	—
State	—	—	—	—	—	—
Foreign (Austria)	—	—	—	—	—	—
Total deferred tax expense	—	—	—	—	—	—
Total income tax expense	$ 230	$ 1	$ 0	$ 368	$ 230	$ 1

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The Company's worldwide effective tax rate for the years ended December 31, 2022 December 31, 2023, 2022 and 2021 and 2020 was 0.3% 0.5%, 0.0% 0.3% 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

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items had the most significant impact on the difference between the statutory U.S. federal income tax rate of 21% for the years ended December 31, 2022 December 31, 2023, 2021 2022 and 2020 2021 and the effective tax rate:

	Year ended December 31,			Year ended December 31,		
	2022	2021	2020	2023	2022	2021
U.S. federal statutory income tax rate	(21.0)%	(21.0)%	(21.0)%	(21.0)%	(21.0)%	(21.0)%
State income taxes, net of federal benefit	—	—	—	(0.3)	—	—
Foreign tax rate differential(1)	(4.0)	(4.0)	(4.0)	(2.7)	(4.0)	(4.0)
Not taxable government grants(2)	(3.8)	(3.8)	(4.7)	(6.8)	(3.8)	(3.8)
Stock-based compensation(3)	0.5	(1.5)	(1.0)	0.6	0.5	(1.5)
Global intangible low-taxed income(4)	1.4	—	—	2.3	1.4	—
Other	0.1	0.1	0.5	0.2	0.1	0.1
Change in deferred tax asset valuation allowance(5) (3)	27.1	30.2	30.2	28.2	27.1	30.2
Effective income tax rate	0.3 %	— %	— %	0.5 %	0.3 %	— %

(1) The 2.7% increase for the year ended December 31, 2023, and the 4% increase for the years ended December 31, 2022, and 2021, and 2020, respectively, resulted from tax rate differences between U.S. and non-U.S. jurisdictions. Net loss before tax was principally generated in

Austria, where the statutory tax rate is 24% for the year ended December 31, 2023, and 25%. for the years ended December 31, 2022 and 2021, respectively.

(2) For the years ended December 31, 2022 December 31, 2023, 2022 and 2021, and 2020, 3.8% 6.8%, 3.8% and 4.7% 3.8% increase, respectively, resulted from non-taxable research subsidies received from Austrian government agencies.

(3) For the years ended December 31, 2022 December 31, 2023, 2022 and 2021, and 2020, 0.5% decrease, 1.5% and 1.0% increase, respectively, resulted from non-taxable Stock-based compensation expense.

(4) For the years ended December 31, 2022, 2021 and 2020, 1.4% decrease, and no change, respectively, resulted from global intangible low-taxed income taxes.

(5) For the years ended December 31, 2022, 2021 and 2020, 28.2% reduction, 27.1% reduction, 30.2% reduction and 30.2% reduction, respectively, resulted from changes in valuation allowance on deferred tax assets. Deferred tax assets will only be recovered when the generation of future taxable income is more likely than not. Due to the nature of the Company's research activities and the inherent uncertainties the deferred tax assets are fully offset by a valuation allowance.

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HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

Components of the net deferred tax assets or liabilities as of the years ended December 31, 2022 December 31, 2023 and 2021 2022 consisted of the following (in thousands):

	Year ended December 31,		Year ended December 31,	
	2022	2021	2023	2022
Deferred tax assets:				
Net operating loss carryforwards	$ 66,201	$ 55,752	$ 87,445	$ 66,201
Capitalized R&D expenses	1,354	—	2,657	1,354
Credit carryforwards	64	64	1,265	64
Accrued expenses and other	366	357	317	366
Stock-based compensation	1,251	1,209	1,421	1,251
Operating lease liabilities	918	1,378	1,254	918
Finance lease liabilities	—	5		
Total deferred tax assets	70,154	58,765	94,359	70,154
Valuation allowance	(65,774)	(53,728)	(89,309)	(65,774)
Total deferred tax assets	4,380	5,037	5,050	4,380
Deferred tax liabilities:				
Accrued expenses and other	(3,450)	(3,604)	(3,774)	(3,450)
Fixed assets	(10)	(11)	(14)	(10)
Operating lease right of use asset	(920)	(1,400)	(1,262)	(920)
Finance lease right of use asset	—	(22)		
Total deferred tax liabilities	(4,380)	(5,037)	(5,050)	(4,380)
Net deferred tax assets	$ —	$ —	$ —	$ —

As of December 31, 2022 December 31, 2023, 2021 2022 and 2020, 2021, the Company had Austrian net operating loss carryforwards of $378.1 million, $275.3 million and $219.7 million, respectively, that do not expire, however these carryforwards are limited to 75% of the taxable income in any one tax period. As of December 31, 2023, 2022 and $163.2 million, respectively. The 2021, the Company had federal net

operating loss carryforwards as of December 31, 2021 that were generated after December 31, 2017 of $2.2 million, $13.8 million and $17.9 million, respectively, that do not expire, however these carryforwards are limited to 80% of the taxable income in any one tax period. The Company generated US taxable income in the current year and was able to offset 80% the taxable income utilizing net operating loss carryforwards which gave rise to current taxes during 2022. 2023. The federal net operating loss carryforward as of December 31, 2022 December 31, 2023 were $13.8 $2.2 million, and US Federal net operating loss carryforwards as of December 31, 2020 December 31, 2022 were $8.3 $13.8 million. The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets resulting from its net operating loss carryforwards. Management has considered the Company's history of cumulative net losses incurred since inception and the uncertainties related to the long period necessary to achieve profits from commercialization of any products and has concluded that it is more likely than not that the Company will not realize the benefits of its deferred tax assets. Accordingly, a full valuation allowance has been established against the deferred tax assets as of December 31, 2022 December 31, 2023, 2021 2022 and 2020. 2021. According to a tax reform in Austria in 2022, the corporate income tax rate will be reduced from 25.0% to 24.0% in 2023 and to 23.0% in 2024. The future tax rate of 23.0% was used to determine deferred taxes and the valuation allowance for the Austrian business. Management reevaluates the positive and negative evidence at each reporting period.

The amount of the deferred tax asset considered realizable, however, could be adjusted if estimates of future taxable income during the carryforward period are reduced or increased or if objective negative evidence in the form of

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HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

losses is no longer present and additional weight may be given to subjective evidence. The tax years in which the tax carryforwards were generated may still be adjusted upon examination by the tax authorities.

Changes in the valuation allowance for deferred tax assets during the years ended December 31, 2022 December 31, 2023, 2021 2022 and 2020 2021 related primarily to the increases in net operating loss carryforwards as follows (in thousands):

	Year ended December 31,			Year ended December 31,		
	2022	2021	2020	2023	2022	2021
Valuation allowance at beginning of period	$ (53,728)	$ (46,064)	$ (32,583)	$(65,774)	$(53,728)	$(46,064)
Increases	(12,046)	(7,664)	(13,481)	(23,535)	(12,046)	(7,664)
Valuation allowance at end of period	$ (65,774)	$ (53,728)	$ (46,064)	$(89,309)	$(65,774)	$(53,728)

On December 22, 2017, the United States enacted the Tax Cuts and Jobs Act (“Tax Reform Legislation” or “TCJA”). The Tax Reform Legislation introduced section 951A, a new tax on so-called “global intangible low-taxed income”. GILTI applies to income of a controlled foreign corporation (“CFC”) that is not otherwise subpart F income, and consists of the excess "tested income" over a 10% return on the CFC's “qualified business asset investment,” or “QBAI”. QBAI is the total tax basis of the CFC's depreciable, tangible property used in the production of tested income. The full amount of GILTI is included in taxable income. The GILTI inclusion is then reduced by 50% (reduced to 37.5% after 2025). However, that reduction in GILTI may be limited based on the level of U.S. taxable income. A limited allowance for foreign tax credits is allowed that would reduce the U.S. tax cost. GILTI foreign tax credits can only reduce U.S. taxes owed on GILTI and are not eligible for carryforward. The Company's Austrian subsidiary falls under the category of a CFC and due to the nature of its business model as a technology company, there may not be a material amount of tangible assets if this subsidiary starts to generate profits. GILTI taxation therefore may be applicable. The Company recognized $3.6 estimated approximately $8.8 million of GILTI inclusion for the year ended December 31, 2022 and no GILTI December 31, 2023. The Company previously estimated $3.6 million for the tax year ended December 31, 2021 December 31, 2022, but did not recognize any GILTI inclusion upon filing of the December 31, 2022 statements. The U.S. tax on GILTI, net of research credits, was $0.4 million and $0.2 million for the years ended December 31, 2023 and 2022, respectively.

The Company files income tax returns in the U.S. federal jurisdiction as well as in New York. The tax years from 2018 to present remain open to examination by the jurisdictions in which the Company is subject to tax. There are currently no pending income tax

examinations in the U.S. Furthermore, the Company files income tax returns in Austria. The tax years 2018 to present remain open to examination by the jurisdiction. There are currently no pending income tax examinations in Austria.

The Company evaluates tax positions for recognition using a more likely than not recognition threshold, and those tax positions eligible for recognition are measured as the largest amount of tax benefit that is greater than 50% likely of being realized upon the effective settlement with a taxing authority that has full knowledge of all relevant information. As of December 31, 2022 December 31, 2023 and 2021, 2022, the Company had no unrecognized income tax benefits that would affect the Company's effective tax rate if recognized.

13. 14. 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, 2022 December 31, 2023, the Company's total non-cancellable obligations under contracts with CMOs were $9.3 $7.4 million, of which $9.2 million relate to 2023 deliverables and $0.1 $0.9 million relate to 2024 deliverables and $6.5 million relate to 2025 deliverables.

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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, 2022 December 31, 2023, 2021 2022 and 2020, 2021, the Company recorded $1.6 million, $1.0 million $1.3 million and $1.2 $1.3 million, respectively, in licensing fees related to intellectual property licenses as research and development expenses. The amounts amount for the years year ended December 31, 2021 and 2020 mainly related to the upfront payment and milestone payments received by the Company under the Gilead Collaboration Agreement. The amount for the year years ended December 31, 2023 and December 31, 2022 mainly related to the upfront payment and milestone payments received by the Company under the Gilead Collaboration Agreement and the Roche Collaboration 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, 2022 December 31, 2023 or December 31, 2021 December 31, 2022.

Legal proceedings

At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company is currently was recently a party to a patent proceeding opposing European Patent No. 3218504 (the "EP '504 Patent"), which was granted to the University of Geneva in July 2020 and is exclusively licensed to the Company. While it is not feasible to predict In a decision that has become final, the outcome Opposition Division of these matters with certainty, and some lawsuits, claims or proceedings may be disposed or decided unfavorably, the Company does not expect that European Patent Office ("EPO") dismissed the pending patent opposition, and any asserted or unasserted legal claims or proceedings, individually or in maintained the aggregate, will have a material adverse effect on the Company. However, if, patent as a result of the current patent proceeding, the Company would lose all, or at least part, of the protection under the opposed patent, such loss could erode the Company's competitive position and harm its business and ability to achieve profitability. granted. The Company expenses the costs related to the pending this case and other such legal proceedings as incurred.

14. 15. 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, 2022 December 31, 2023, December 31, 2021 December 31, 2022 and December 31, 2020 December 31, 2021 expenses recognized for the 401(k) Plan were $0.6 million, $0.6 million and $0.4 million, and $0.2 million, respectively.

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15. 16. 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,			Year ended December 31,		
	2022	2021	2020	2023	2022	2021
Numerator:						
Net loss	$ (64,915)	$ (75,665)	$ (44,082)	$ (81,580)	$ (64,915)	$ (75,665)
Denominator:						
Weighted-average common shares outstanding, basic and diluted	50,743,080	29,945,954	25,876,376	72,422,676	50,743,080	29,945,954
Weighted-average Series A convertible preferred shares outstanding, basic and diluted, presented as if converted into common stock(1)	1,697,000	2,887,636	162,732	835,359	1,697,000	2,887,636
Weighted-average Series A-1 convertible preferred shares outstanding, basic and diluted, presented as if converted into common stock(1)	13,072,877	—	—	12,526,027	13,072,877	—

Weighted-average Series A-2 convertible preferred shares outstanding, basic and diluted, presented as if converted into common stock(1)				8,742,499	—	—
Total number of shares used to calculate net loss per share, basic and diluted	65,512,957	32,833,590	26,039,108	94,526,561	65,512,957	32,833,590
Net loss per share, basic and diluted	$ (0.99)	$ (2.30)	$ (1.69)	$ (0.86)	$ (0.99)	$ (2.30)

(1) Class A common stock, Series A, Series A-1 and Series A-1 A-2 convertible preferred stock are participating securities that have substantially the same terms and features as the Company's common stock. The Class A common stock, Series A, Series A-1 and Series A-1 A-2 convertible preferred stock is therefore included in the weighted-average number of shares outstanding to calculate net loss per share, basic and diluted as if converted in common stock. Each share of Class A common stock, Series A, Series A-1 and Series A-1 A-2 convertible preferred stock is independently convertible into one and 1,000 shares of common stock, respectively. 2,399,517 shares of the Company's common stock are issuable upon conversion of the Class A common stock, 1,697,000 370,000 shares of the Company's common stock are issuable upon conversion of Series A convertible preferred stock, and 15,800,000 10,800,000 shares of the Company's common stock are issuable upon conversion of Series A-1 convertible preferred stock and 15,268,000 shares of the Company's common stock are issuable upon conversion of Series A-2 convertible preferred stock (see Note 10) 11).

Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share for all periods as the inclusion of all potential common shares (common stock and Class A common stock) outstanding would have been anti-dilutive. Potentially dilutive securities that were not included in the diluted per share calculations because they would be anti-dilutive were as follows:

	Year ended December 31,			Year ended December 31,		
	2022	2021	2020	2023	2022	2021
Options issued and outstanding	6,532,523	4,231,178	3,555,945	8,111,575	6,532,523	4,231,178
Unvested restricted stock units	—	—	43,700			
Total	6,532,523	4,231,178	3,599,645	8,111,575	6,532,523	4,231,178

16. Related parties

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

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The Company is party to research and service arrangements with the University of Basel. Daniel Pinschewer, formerly Chief Scientific Officer, and his spouse are employees

17. Related parties

Effective September 15, 2023, Malte Peters, a member of the University Company's board of Basel and both involved in providing directors, agreed to lead the services under these arrangements. Payments Company's clinical activities ad interim as Senior Clinical Advisor. During the year ended December 31, 2023, the Company recorded expense of $0.1 million related to the University of Basel during

Daniel Pinschewer's term as Chief Scientific Officer were reported as related party transactions but payments following the expiry of that role in March 2020 were no longer considered related party transactions.

a consulting agreement entered into with Dr. Peters, effective September 15, 2023. In the years ended December 31, 2022 and December 31, 2021, the Company did not record any related party transactions. In the year ended December 31, 2020

18. Subsequent events

Roche Collaboration and License Agreement

On January 25, 2024, the Company received written notice of termination from Roche of the Roche Collaboration Agreement (see Note 3.). The termination was made according to Roche's right to terminate without cause, acknowledging that, to date, the Company had met all go-forward criteria under the agreement. The Company remains eligible for a final milestone payment of $10.0 million associated with an IND submission for the HB-700 program. Upon the termination effective date April 25, 2024, the Company will regain full control of the associated intellectual property portfolio and have full collaboration and licensing rights for this program. At December 31, 2023, $26.8 million of non-refundable upfront and milestone payments received from Roche were still recorded $0.3 million as deferred revenue and may be early recognized as revenue as a result of the termination in the first half of 2024.

January 2024 Restructuring Plan

On January 29, 2024, the Company announced its decision to prioritize the clinical development of its HB-200 program for the treatment of HPV16+ head and neck cancers and its two Gilead-partnered infectious disease programs and to pause development activities related to HB-300 and most of its preclinical research activities. In connection with this strategic refocus, the Company's Board of Directors approved to reduce the Company's workforce by 55 fulltime employees, or approximately 30% of the Company's then-current employee base and to rebalance the Company's cost structure in alignment with the new prioritization of research and development expenses for service fees paid programs (together, the "Restructuring Plan"). The Company expects the Restructuring Plan to the University of Basel, which represented related party transactions.

The University of Basel is also entitled to receive de minimis royalties on the net sales of any product that is based on a patent created be implemented and substantially completed by the Company's Scientific Advisor to end of the Chief Executive Officer in first quarter of 2024.

In connection with the course Restructuring Plan, the Company estimates that it will incur cash charges of his consulting services to the Company. In the years ended December 31, 2022, 2021 approximately $1.6 million for severance and 2020, no royalties were paid pursuant to the terms of this arrangement. other personnel and restructuring related costs.

Exhibit 10.28 4.3

DESCRIPTION OF SECURITIES REGISTERED UNDER

AMENDMENT NO. 1 TO LICENSE AGREEMENT SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

This Amendment The following description of the registered capital stock of HOOKIPA Pharma Inc. ("Amendment" 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 a modification the only security of the License Agreement by and between **University Company registered under Section 12 of Basel**, having its principal offices located at Petersgraben 35, 4001 Basel, Switzerland ("UNIBAS" 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 200,000,000 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 **Hookipa Biotech GmbH**, having its principal offices located at Helmut-Qualtinger-Gasse 2, 1030 Vienna, Austria ("Hookipa" 10,000,000 shares of undesignated preferred stock, par value $0.0001 per share (the "preferred stock"), made effective on October 15, 2020 ("Agreement" of which 2,978 shares are designated as Series A convertible preferred stock (the "Series A preferred stock"), 15,800 shares are designated as Series A-1 convertible preferred stock (the "Series A-1 preferred stock") and 15,268 shares are designated as Series A-2 convertible preferred stock (the "Series A-2 preferred stock").

Common Stock

This Amendment is made according*Annual Meeting*. Annual meetings of our stockholders are held on the date designated in accordance with our Bylaws. Written notice must be mailed to Article 10.6 each stockholder entitled to vote not less than ten (10) nor more than sixty (60) days before the date of the Agreement. This Amendment 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 construed consistently insofar 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 possible with provided by law or in our Certificate of Incorporation, dividends may be declared and paid or set aside for payment on the Agreement, but 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 a conflict, this Amendment shall control. Any capitalized terms used herein shall have our liquidation, dissolution or winding up, our net assets will be distributed pro rata to the same meaning as set forth for such terms 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 Agreement. 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 Parties hereby agree transfer agent and registrar for our common stock is Equiniti 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.

32,820 shares of preferred stock are outstanding as follows: of the date of our Annual Report on Form 10-K with which this Exhibit 4.3 is filed as an exhibit, consisting of 1,752 shares of Series A preferred stock, 15,800 shares of Series A-1 preferred stock and 15,268 shares of Series A-2 preferred stock.

Series A Preferred Stock

Rank. The Series A preferred stock will rank:

1. ● Article 3.2(c) shall be deleted in on parity with our common stock, Class A common stock, Series A-1 preferred stock and Series A-2 preferred stock;
- on parity with any class or series of capital stock hereafter created specifically ranking by its entirety and replaced terms on parity with the following: Series A preferred stock;
- senior to any class or series of our capital stock hereafter created specifically ranking by its terms junior to the Series A preferred stock; and
- junior to any class or series of capital stock hereafter created specifically ranking by its terms senior to the Series A preferred stock;

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

Conversion. Each share of the Series A preferred stock is convertible into 1,000 shares of our common stock (subject to adjustment as provided in the related certificate of designation of preferences rights and limitations) at any time at the option of the holder, provided that the holder will be prohibited, subject to certain exceptions, from converting Series A preferred stock into shares of our common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 9.99% of the total number

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of shares of our common stock then issued and outstanding, which percentage may be changed at the holder's election to any other number less than or equal to 19.99% upon 61 days' notice to us.

LICENSEE Liquidation Preference. In the event of our liquidation, dissolution or winding up, holders of the Series A preferred stock will receive a payment equal to $0.001 per share of Series A preferred stock *pari passu* with the common stock, Class A common stock, Series A-1 preferred stock and Series A-2 preferred stock.

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

A "Fundamental Transaction" means:

- we effect any merger or consolidation with or into another person or any stock sale to, or other business combination (including, without limitation, a reorganization, recapitalization, spin-off, share exchange or scheme of arrangement) with or into another person (other than such a transaction in which we are the surviving or continuing entity and our common stock is not exchanged for or converted into other securities, cash or property);
- we effect any sale of all or substantially all of our assets in one transaction or a series of related transactions;

- any tender offer or exchange offer (whether by us or another person) is completed pursuant to which more than 50% of the common stock not held by us or such person is exchanged for or converted into other securities, cash or property; or
- we effect any reclassification of our common stock or any compulsory share exchange pursuant (other than specified dividends, subdivisions or combinations) to which our common stock is effectively converted into or exchanged for other securities, cash or property.

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

Dividends. Shares of Series A preferred stock will be entitled to receive dividends at a rate equal to (on an as-if-converted-to-common stock basis), and in the same form and manner as, dividends actually paid on shares of common stock.

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

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

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

Series A-1 Preferred Stock

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

- on parity with our common stock, Class A common stock, Series A preferred stock and Series A-2 preferred stock;
- on parity with any class or series of capital stock hereafter created specifically ranking by its terms on parity with the Series A-1 preferred stock;
- senior to any class or series of our capital stock hereafter created specifically ranking by its terms junior to the Series A-1 preferred stock; and
- junior to any class or series of capital stock hereafter created specifically ranking by its terms senior to the Series A-1 preferred stock;

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

Conversion. Each share of the Series A-1 preferred stock is convertible into 1,000 shares of our common stock (subject to adjustment as provided in the related certificate of designation of preferences rights and limitations) at any time at the option of the holder, provided that the holder will be prohibited, subject to certain exceptions, from converting Series A-1 preferred stock into shares of our common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 9.99% of the total number of shares of our common stock then issued and outstanding, which percentage may be changed at the holder's election to any other number less than or equal to 19.99% upon 61 days' notice to us.

Liquidation Preference. In the event of our liquidation, dissolution or winding up, holders of the Series A-1 preferred stock will receive a payment equal to $0.001 per share of Series A-1 preferred stock *pari passu* with the common stock, Class A common stock, Series A preferred stock and Series A-2 preferred stock.

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

A “Fundamental Transaction” means:

- we effect any merger or consolidation with or into another person or any stock sale to, or other business combination (including, without limitation, a reorganization, recapitalization, spin-off, share exchange or scheme of arrangement) with or into another person (other than such a transaction in which we are the surviving or continuing entity and our common stock is not exchanged for or converted into other securities, cash or property);

- we effect any sale of all or substantially all of our assets in one transaction or a series of related transactions;
- any tender offer or exchange offer (whether by us or another person) is completed pursuant to which more than 50% of the common stock not held by us or such person is exchanged for or converted into other securities, cash or property; or
- we effect any reclassification of our common stock or any compulsory share exchange pursuant (other than specified dividends, subdivisions or combinations) to which our common stock is effectively converted into or exchanged for other securities, cash or property.

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

Dividends. Shares of Series A-1 preferred stock will be entitled to receive dividends at a rate equal to (on an as-if-converted-to-common stock basis), and in the same form and manner as, dividends actually paid on shares of common stock.

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

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

The transfer agent and registrar for shares of our Series A-1 preferred stock (and the underlying shares of common stock) is Equiniti Trust Company, LLC

Series A-2 Preferred Stock

Rank. The Series A-2 preferred stock will rank:

- on parity with our common stock, Class A common stock, Series A preferred stock and Series A-1 preferred stock;
- on parity with any class or series of capital stock hereafter created specifically ranking by its terms on parity with the Series A-2 preferred stock;
- senior to any class or series of our capital stock hereafter created specifically ranking by its terms junior to the Series A-2 preferred stock; and
- junior to any class or series of capital stock hereafter created specifically ranking by its terms senior to the Series A-2 preferred stock;

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

Conversion. Each share of the Series A-2 preferred stock is convertible into 1,000 shares of our common stock (subject to adjustment as provided in the related certificate of designation of preferences rights and limitations) at any time at the option of the holder, provided that the holder will be prohibited, subject to certain exceptions, from converting Series A-2 preferred stock into shares of our common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 9.99% of the total

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number of shares of our common stock then issued and outstanding, which percentage may be changed at the holder's election to any other number less than or equal to 19.99% upon 61 days' notice to us.

Liquidation Preference. In the event of our liquidation, dissolution or winding up, holders of the Series A-2 preferred stock will receive a payment equal to $0.001 per share of Series A-2 preferred stock *pari passu* with the common stock, Class A common stock, Series A preferred stock and Series A-1 preferred stock.

Fundamental Transaction. Upon consummation of a Fundamental Transaction (as defined below) pursuant to which holders of shares of our common stock are entitled to receive securities, cash or property, then upon any subsequent conversion of the Series A-2 preferred stock, the holder thereof shall have the right to receive, in lieu of the right to receive the shares of our common stock underlying the Series A-2 preferred stock, for each share of common stock that it would have otherwise been entitled to receive upon such conversion immediately prior to the occurrence of such Fundamental Transaction, the same kind and amount of securities, cash or property as it would have been entitled to receive upon the occurrence of such Fundamental Transaction if it had been, immediately prior to such Fundamental Transaction, the holder of one share of our common stock. If holders of our common stock are given a choice as to the securities, cash or property to be received in a Fundamental Transaction, then the holder of the Series A-2 preferred stock shall be given the same choice as to the consideration it receives upon any exercise of the Series A-2 preferred stock following such Fundamental Transaction.

A "Fundamental Transaction" means:

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

Voting Rights. Shares of Series A-2 preferred stock will generally have no voting rights, except as required by law and except that the consent of the holders of a majority of the outstanding shares of Series A-2 preferred stock will be required to amend the terms of the Series A-2 preferred stock.

Dividends. Shares of Series A-2 preferred stock will be entitled to receive dividends at a rate equal to (on an as-if-converted-to-common stock basis), and in the same form and manner as, dividends actually paid on shares of common stock.

Redemption. We are not obligated to redeem or repurchase any shares of Series A-2 preferred stock. Shares of Series A-2 preferred stock are not otherwise entitled to any redemption rights or mandatory sinking fund or analogous fund provisions.

Exchange Listing. We do not plan on making an application to list the Series A-2 preferred stock on The Nasdaq Global Select Market, any national securities exchange or other nationally recognized trading system. We expect the common stock issuable upon conversion of the Series A-2 preferred stock to be listed on the Nasdaq Global Select Market.

The transfer agent and registrar for shares of our Series A-2 preferred stock (and the underlying shares of common stock) is Equiniti Trust Company, LLC.

Registration Rights

Pursuant to the terms of our shareholders' agreement, dated as of February 15, 2019, certain of our stockholders are entitled to rights with respect to the registration of their shares under Securities Act of 1933, as amended (the "Securities Act").

Demand Registration Rights. Pursuant to the terms of our shareholders' agreement, certain holders of shares of our common stock are entitled to demand registration rights.

Short-Form Registration Rights. Pursuant to the terms of our shareholders' agreement, certain holders of shares of our common stock are entitled to short-form registration rights. If we are eligible to file a registration statement on Form S-3, upon the written request of a majority of our stockholders to sell securities at an anticipated aggregate price of at least $10.0 million, we will be required to use commercially reasonable efforts to effect a registration of such shares.

Piggyback Registration Rights. Pursuant to the terms of our shareholders' agreement, certain holders of shares of our common stock are entitled to piggyback registration rights. If we register any of our securities either for our own account or for the account of other security holders, the holders of these shares are entitled to include their shares in the registration.

Expiration of Registration Rights. The demand registration rights and short form registration rights will terminate as to a given stockholder at such time as Rule 144 or another similar exemption under the Securities Act is available for the sale of all of such stockholder's shares without limitation during a three-month period without registration.

Provisions of Our Certificate of Incorporation and Bylaws and Delaware Law That May Have Anti-Takeover Effects

The provisions of Delaware law and our Certificate of Incorporation and Bylaws could discourage or make it more difficult to accomplish a proxy contest or other change in our management or the acquisition of control by a holder of a substantial amount of our voting stock. It is possible that these provisions could make it more difficult to accomplish, or could deter, transactions that stockholders may otherwise consider to be in their best interests or in our best interests. These provisions are intended to enhance the likelihood of continuity and stability in the composition of our board of directors and in the policies formulated by the board of directors and to discourage certain types of transactions that may involve an actual or threatened change of our control. These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy fights. Such provisions also may have the effect of preventing changes in our management.

Board of Directors. Our Certificate of Incorporation and Bylaws provide for a board of directors divided into three classes. Each class is elected to a term expiring at the annual meeting of stockholders held in the third year following the year of such election. The number of directors comprising our board of directors is fixed from time to time by the board of directors.

Removal of Directors by Stockholders. Our Certificate of Incorporation provides that members of our board of directors may only be removed for cause by a vote of the holders of at least two-thirds (2/3) of the outstanding shares entitled to vote on the election of the directors.

Issuance of Preferred Stock. Our board of directors is authorized, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one postponement 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 two milestones of Article 3.2(a)(ii) and (iii) above (i.e. only one under this paragraph) by eight (8) months against payment of a rescheduling fee of one hundred thousand Swiss Francs (CHF 100'000). If such milestone is so extended or postponed, the subsequent milestones are automatically extended or postponed by the same amount of time without additional fees.

2. ● All other terms and 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 Agreement remain unchanged and transaction which resulted in full force.

3. This Amendment shall be effective on 11 July 2022.

IN WITNESS WHEREOF, the Parties hereby have executed this Amendment the day and year herein written.

Hookipa Biotech GmbH

By: _____
Name: Reinhard Kandera
Title: CFO

Date: _____

University of Basel

By: _____
Name:
Title:

Date: _____

University of Basel

By: _____
Name:
Title:

Date: _____

Exhibit 10.29

AMENDMENT NO. 2 TO LICENSE AGREEMENT

This amendment (the "**Amendment No. 2**") is a modification of the License Agreement by and between University of Basel, having its principal place of business at Petersgraben 35, CH-4001 Basel, Switzerland ("**UNIVERSITY**"), and Hookipa Biotech GmbH, having its principal place of business at Helmut-Qualtinger-Gasse 2, 1030 Vienna, Austria ("**LICENSEE**"), effective as of October 15, 2020 (the "**Agreement**"), as first amended by and among the Parties by entering into a first amendment, effective July 11, 2022.

This Amendment No. 2 is made according to Article 10.6 of the Agreement. This Amendment No. 2 is to be construed consistently insofar as possible with the Agreement, but in the event of a conflict, this Amendment No. 2 shall take precedence. Any capitalized terms used herein shall have the same meaning as set forth for such terms in the Agreement, unless otherwise here defined.

The Parties hereby agree as follows:

1. Article 3.1 (a) the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the Agreement shall be amended so that in addition to the License Issue Fee an additional Amendment Signing Fee of one hundred fifty thousand Swiss Francs (CHF 150'000) is due upon execution of this Amendment No. 2.

2. Article 3.1(b) voting stock of the Agreement shall be amended so that corporation outstanding at the License Maintenance Fee per calendar year 2022 is increased to hundred fifty thousand Swiss Francs (CHF 150'000), 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 License Maintenance Fee per calendar year 2023 and any further calendar year is increased to two hundred thousand Swiss Francs (CHF 200'000).

3. Article 3.1(c) of the Agreement shall be amended to add further Milestone Payments in the amounts payable according to the following schedule of events:

(i-A) *Fifty thousand Swiss Francs (CHF 50'000) upon completion of the work activities performed in relation to the diligence obligation specified in Article 3.2(a)(ii-A) of this Amendment No. 2;*

(i-B) *hundred thousand Swiss Francs (CHF 100'000) upon completion of the work activities performed in relation to the diligence obligation specified in Article 3.2(a)(ii-B) of this Amendment No. 2;*

(i-C) *hundred fifty thousand Swiss Francs (CHF 150'000) upon completion of the work activities performed in relation to the diligence obligation specified in Article 3.2(a)(iii) of this Amendment No. 2;*

4. Article 3.2(a) of the Agreement shall be amended by replacing subsections 3.2(a)(ii) and 3.2(a)(iii) outstanding voting stock owned by the following amended subsections 3.2(a)(ii-A), 3.2(a)(ii-B) and 3.2(a)(iii):

(ii-A) *perform all work activities set forth in Annex C to support selection of parental virus for generation of SplitC-based third vector candidate within 12 months after the effective date of this Amendment No. 2 as evidenced by fulfilment of the relevant criteria set forth in Annex C;*
interested stockholder; or

(ii-B) at Hookipa within 12 months or after reaching the milestone time the stockholder became interested, the business combination was approved by our board of Article 3.2(a)(ii-A) as evidenced by fulfilment directors and authorized at an annual or special meeting of the relevant criteria set forth in Annex C;

(iii) *perform all work activities set forth in Annex C to render a product candidate based on stockholders by the selected SplitC vector system "development-ready" within 12 months after reaching the milestone affirmative vote of Article 3.2(a)(ii-B) as evidenced by fulfilment at least two-thirds of the relevant criteria set forth in Annex C;*

5. Article 3.2(b) of the Agreement shall be replaced in its entirety outstanding voting stock which is not owned by the following:
interested stockholder.

(b) *In addition to the progress reports according to Article 4.1(a), the LICENSEE shall inform UNIVERSITY every three months (first time on 15 December 2022) by e-mail whether the work progresses according to the plan and criteria of Annex C and whether the achievement of the set milestones can realistically be expected from the then current point of view. Should it become evident that a milestone cannot be reached, then the LICENSEE will inform the UNIVERSITY accordingly as soon as reasonably practicable. In such an event, the Parties shall discuss and within forty-five (45) days agree on a suitable amendment to subsequent work packages and milestones under the development plan. In addition LICENSEE shall notify the UNIVERSITY of the achievement of the milestones of Articles 3.2(a)(ii-A), 3.2(a)(ii-B) and 3.2(a)(iii) by written report. The LICENSEE undertakes to provide a detailed report of the achievement of the three milestones and the results achieved in accordance with the plan and criteria of Annex C. Such reports shall be provided to UNIVERSITY within fifteen (15) days from the date of the deadline for reaching the respective milestone.*

6. For the avoidance of doubt the Parties hereby acknowledge and agree that the right under Article 3.2(c) to request one postponement of any one of the two milestones of Article 3.2(a)(ii) and (iii) has already been claimed by LICENSEE and that there are no longer any rights to postponements under this Article 3.2(c).

7. For further avoidance of doubt, the Parties hereby acknowledge and agree that the right of LICENSEE under Article 3.2(d) to request a total of three (3) postponements of (any) one of the milestones of Article 3.2(a)(ii-A)- 3.2(a)(vi) by one year shall remain in full force and effect.

8. Annex B of the Agreement shall be deleted in its entirety and the Diligence Criteria laid out in Appendix 1 to this Amendment No. 2 shall be added to the Agreement as Annex C.

9. All other terms and conditions of the Agreement remain unchanged and in full force.

10. This Amendment No. 2 shall enter into force on 15 September 2022 upon execution by both Parties.

IN WITNESS WHEREOF, the Parties hereby have executed this Amendment No. 2 the day and year herein written.

Hookipa Biotech GmbH

By: _____
Name: Jörn Aldag
Title: CEO

Date: _____

University of Basel

By: _____
Name: Prof. Dr. Torsten Schwede
Title: Vice President Research

Date: _____

University of Basel

By: _____
Name: Dr. Jürgen Rümmele
Title: Director of Finances

Date: _____

Appendix 1:

ANNEX C: Diligence Criteria and Split Development Plan

Description of work Section 203 defines a business combination to be performed in order to obtain information required to enable decision making at the indicated decision points

1) **Milestone of Article 3.2(a)(ii-A): Select parental virus for SplitC development**

Work to be performed:

- Generate SplitC vectors based on Tamiami virus (TAMV) any merger or consolidation involving the corporation and Tacaribe virus (TCRV) the interested stockholder;
- Investigate immunogenicity any sale, transfer, lease, pledge or other disposition involving the interested stockholder of heterologous prime – boost regimens based on various combinations 10% or more of TAMV, TCRV, LCMV, PICV-based SplitC vectors, respectively the assets of the corporation
- Develop data package subject to allow for selection exceptions, any transaction that results in the issuance or transfer by the corporation of either TAMV or TCRV for further development (e.g., vector-neutralizing antibody induction; homologous boosting potential; antigen expression levels in human cell lines; literature search on documented human infections / associated disease) any stock of the corporation to the interested stockholder;
- Test vector growth in GMP production cell line (growth curves in production cell line at multiple MOIs)

Decision Point: Select parental virus (e.g., TAMV or TCRV) for further development of SplitC-based vector candidate OR start alternative Split R&D program (e.g., SplitE)

It is understood between the Parties that LICENSEE's diligence obligation defined in 3.2(a)(ii-A) shall also be deemed to be fulfilled if LICENSEE is able to prove by written evidence that the respective work has been diligently conducted using all resources reasonably required, however, the obtained results do not enable selection of one of the evaluated parental viruses for further development of a SplitC-based vector candidate. In such event, the Parties shall discuss 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 within forty-five (45) days agree on a suitable amendment to subsequent work packages and milestones under the development plan.

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2) **Milestone of Article 3.2(a)(ii-B): Establish selected SplitC System at Hookipa**

Work to be performed:

- **Generate research vectors encoding model antigens for immunogenicity and efficacy testing** (e.g., SplitC vectors encoding E7E6/E7E6, Trp2/Trp2, E7E6/Trp2; Trp2/E7E6 and respective artARENA controls)
  - rescue efficiency in R&D & GMP system;
  - Growth kinetics and titer determination of vectors for preclinical testing.

- **Analyze transgene expression & transgene stability**
  - Western blots; Serial passaging of vectors for 6 passages and analysis of transgene stability by double immunostaining and/or RT-PCR

- **Establish PMVS generation & test genetic stability of vectors**
  - Adapt procedure from LCMV- and PICV-based artARENA vectors; test/adapt PMVS rescue; test/adapt plaque assay;

- **Safety / Immunogenicity**
  - Safety analysis; if feasible, analysis of attenuation compared to wildtype and artARENA in mouse neurovirulence studies
  - To the extent possible: stability of attenuation in AGRAG mice
  - Immunogenicity of R&D vectors in non-tumor bearing mice to compare SplitC vectors described above to the corresponding artARENA (TAMV and TCRV) and artARENA (LCMV) controls, to verify non-inferiority.

- Compare immunogenicity of alternating prime boost regimen, e.g.,
  - TheraT(PICV)/TheraT(LCMV)/SplitC(TAMV or TCRV)
  - TheraT(PICV)/TheraT(LCMV)/TheraT(PICV)

- **Split Efficacy**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.
  - Efficacy study in relevant tumor model (e.g., TC-1 or B16F10) in comparison to artARENA (single vector treatment) to demonstrate non-inferiority of SplitC compared to corresponding artARENA vectors, with simultaneous measurement of immunogenicity in tumor-bearing mice.

Decision Point: Go / No-Go Decision for Start of Development **In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the third vectorized virus for potential combination treatment (1) with either LCMV or Pichinde (in a two-vector system) or (2) with both, LCMV and Pichinde, in a three-vector system**

It is understood between the Parties that LICENSEE's diligence obligation defined in 3.2(a)(ii-B) shall also be deemed to be fulfilled if LICENSEE is able to prove by written evidence that the respective work has been diligently conducted using all resources reasonably required, however, the obtained results do not support start of development outstanding voting stock of the third vectorized virus. In such event, corporation and any entity or person affiliated with or controlling or controlled by the Parties shall discuss and within forty-five (45) days agree on a suitable amendment to subsequent work packages and milestones under the development plan.

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3) **Milestone of Article 3.2(a)(iii): Render product candidate based on selected SplitC System "Development-Ready"** (Defined as a summarization of preclinical research & an assessment of suitability of drug candidate to enter development activities designed to enable regulatory authorization to enter clinical testing)

Work to be performed:

- Select indication for 3-vector (or 2-vector) product
- Analyze manufacturability (R&D simulation of PMVS rescues and testing of genetic stability of transgene of product candidate(s))
- Qualify assays for selected SplitC System
- Analyze immunogenicity of vectors (R&D material) at multiple doses (dose response)
- Analyze efficacy of vectors (in case tumor model is available - unlikely) (dose response) Analyze recombination / reassortment of 3 vector system (pair-wise).

Decision Point: Go / No-Go Decision for Start of Development of product candidate based on selected SplitC System

It is understood between the Parties that LICENSEE's diligence obligation defined in 3.2(a)(iii) shall also be deemed to be fulfilled if LICENSEE is able to prove by written evidence that the respective work has been diligently conducted using all resources reasonably required, however, the obtained results do not support start of development of the respective product candidate. In such event, the Parties shall discuss and within sixty (60) days agree on a suitable amendment to subsequent work packages and milestones under the development plan. entity or person.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-266084, 333-266104 and 333-266104) 333-276220) and Form S-8 (No. 333-230995, 333-237285, 333-264587 and 333-264587) 333-271238) of HOOKIPA Pharma Inc. of our report dated March 15, 2023 March 22, 2024 relating to the financial statements, which appears in this Form 10-K.

Vienna, Austria
March 15, 2023 22, 2024

PwC Wirtschaftsprüfung GmbH
/s/ Stefano Mulas Gabor Kruepl
German 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 15, 2023 March 22, 2024

/s/ Joern Aldag

Joern Aldag

Chief Executive Officer

(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Reinhard Kandera, certify that:

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

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

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

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 15, 2023 March 22, 2024

/s/ Reinhard Kandera
Reinhard Kandera
Chief Financial Officer
(Principal Financial and Accounting 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, 2022 December 31, 2023, 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 15, 2023 March 22, 2024

/s/ Joern Aldag
Joern Aldag
Chief Executive Officer
(Principal Executive Officer)

Date: March 15, 2023 March 22, 2024

/s/ Reinhard Kandera
Reinhard Kandera
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 97.1

HOOKIPA PHARMA INC.

CLAWBACK POLICY

Adopted on September 20, 2023

HOOKIPA Pharma Inc., a Delaware corporation (the "Company"), has adopted a compensation recovery / clawback policy (this "Policy") as described below.

1. Overview

The Policy sets forth the circumstances and procedures under which the Company shall recover Erroneously Awarded Compensation from Covered Persons (as defined below) in accordance with rules issued by the United States Securities and Exchange Commission (the "SEC") under the Securities Exchange Act of 1934 (the "Exchange Act") and the Nasdaq Stock Market. Please refer to Section 3 below for definitions of capitalized terms used and not otherwise defined herein.

2. Compensation Recovery Requirement

In the event the Company is required to prepare a Financial Restatement, the Company shall reasonably promptly recover all Erroneously Awarded Compensation with respect to such Financial Restatement.

3. Definitions

a. "Applicable Recovery Period" means the three completed fiscal years immediately preceding the Restatement Date for a Financial Restatement. In addition, in the event the Company has changed its fiscal year: (i) any transition period of less than nine months occurring within or immediately following such three completed fiscal years shall also be part of such Applicable Recovery Period and (ii) any transition period of nine to 12 months will be deemed to be a completed fiscal year.

b. "Applicable Rules" means any rules or regulations adopted by the Exchange pursuant to Rule 10D-1 under the Exchange Act and any applicable rules or regulations adopted by the SEC pursuant to Section 10D of the Exchange Act.

c. "Board" means the Board of Directors of the Company.

d. "Committee" means the Compensation Committee of the Board or, in the absence of such committee, a majority of independent directors serving on the Board.

e. "Covered Person" means any Executive Officer. A person's status as a Covered Person with respect to Erroneously Awarded Compensation shall be determined as of the time of receipt of such Erroneously Awarded Compensation regardless of the person's current role or status with the Company (e.g., if a person began service as an Executive Officer after the beginning of an Applicable Recovery Period, that person would not be considered a Covered Person with respect to Erroneously Awarded Compensation received before the person began service as an Executive Officer, but would be

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considered a Covered Person with respect to Erroneously Awarded Compensation received after the person began service as an Executive Officer where such person served as an Executive Officer at any time during the performance period for such Erroneously Awarded Compensation).

f. "Effective Date" means October 2, 2023.

g. "Erroneously Awarded Compensation" means the amount of any Incentive-Based Compensation received by a Covered Person on or after the Effective Date and during the Applicable Recovery Period that exceeds the amount that otherwise would have been received by the Covered Person had such compensation been determined based on the restated amounts in the Financial Restatement, computed without regard to any taxes paid. Calculation of Erroneously Awarded Compensation with respect to Incentive-Based Compensation based on stock price or total shareholder return, where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in a Financial Restatement, shall be based on a reasonable estimate of the effect of the Financial Restatement on the stock price or total shareholder return upon which the Incentive-Based Compensation was received, and the Company shall maintain documentation of the determination of such reasonable estimate and provide such documentation to the Exchange in accordance with the Applicable Rules.

h. "Exchange" means The Nasdaq Stock Market LLC.

i. An "Executive Officer" means any person who served the Company in any of the following roles at any time during the performance period applicable to Incentive-Based Compensation such person received during service in such role: the president, principal financial officer, principal accounting officer (or if there is no such accounting officer the controller), any vice president in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy making function, or any other person who performs similar policy making functions for the Company. Executive officers of parents or subsidiaries of the Company may be deemed executive officers of the Company if they perform such policy making functions for the Company.

j. "Financial Reporting Measures" mean measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, any measures that are derived wholly or in part from such measures (including, for example, a non-GAAP financial measure), and stock price and total shareholder return.

k. A "Financial Restatement" means a restatement of previously issued financial statements of the Company due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required restatement to correct an error in previously-issued financial statements that is material to the previously-issued financial statements or that would result in a material

misstatement if the error were corrected in the current period or left uncorrected in the current period.

l. "Incentive-Based Compensation" means any compensation provided, directly or indirectly, by the Company or any of its subsidiaries that is granted, earned, or vested based, in whole or in part, upon the attainment of a Financial Reporting Measure. Incentive-Based Compensation is deemed received, earned or vested when the Financial Reporting Measure is attained, not when the actual payment, grant or vesting occurs.

m. "Restatement Date" means, with respect to a Financial Restatement, the earlier to occur of: (i) the date the Board or the Audit Committee of the Board concludes, or reasonably should have concluded, that the Company is required to prepare the Financial Restatement or (ii) the date a court, regulator or other legally authorized body directs the Company to prepare the Financial Restatement.

4. Exception to Compensation Recovery Requirement

The Company may elect not to recover Erroneously Awarded Compensation pursuant to this Policy if the Committee determines that recovery would be impracticable, and one or more of the following conditions, together with any further requirements set forth in the Applicable Rules, are met: (i) the direct expense paid to a third party, including outside legal counsel, to assist in enforcing this Policy would exceed the amount to be recovered, and the Company has made a reasonable attempt to recover such Erroneously Awarded

Compensation; or (ii) recovery would likely cause an otherwise tax-qualified retirement plan to fail to be so qualified under applicable regulations.

5. Tax Considerations

To the extent that, pursuant to this Policy, the Company is entitled to recover any Erroneously Awarded Compensation that is received by a Covered Person, the gross amount received (i.e., the amount the Covered Person received, or was entitled to receive, before any deductions for tax withholding or other payments) shall be returned by the Covered Person.

6. Method of Compensation Recovery

The Committee shall determine, in its sole discretion, the method for recovering Erroneously Awarded Compensation hereunder, which may include, without limitation, any one or more of the following:

a. requiring reimbursement of cash Incentive-Based Compensation previously paid;

b. seeking recovery of any gain realized on the vesting, exercise, settlement, sale, transfer or other disposition of any equity-based awards;

c. cancelling or rescinding some or all outstanding vested or unvested equity-based awards;

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d. adjusting or withholding from unpaid compensation or other set-off;

e. cancelling or setting-off against planned future grants of equity-based awards; and/or

f. any other method permitted by applicable law or contract.

Notwithstanding the foregoing, a Covered Person will be deemed to have satisfied such person's obligation to return Erroneously Awarded Compensation to the Company if such Erroneously Awarded Compensation is returned in the exact same form in which it was received; provided that equity withheld to satisfy tax obligations will be deemed to have been received in cash in an amount equal to the tax withholding payment made.

7. Policy Interpretation

This Policy shall be interpreted in a manner that is consistent with the Applicable Rules and any other applicable law. The Committee shall take into consideration any applicable interpretations and guidance of the SEC in interpreting this Policy, including, for example, in determining whether a financial restatement qualifies as a Financial Restatement hereunder. To the extent the Applicable Rules require recovery of Incentive-Based Compensation in additional circumstances besides those specified above, nothing in this Policy shall be deemed to limit or restrict the right or obligation of the Company to recover Incentive-Based Compensation to the fullest extent required by the Applicable Rules.

8. Policy Administration

This Policy shall be administered by the Committee. The Committee shall have such powers and authorities related to the administration of this Policy as are consistent with the governing documents of the Company and applicable law. The Committee shall have full power and authority to take, or direct the taking of, all actions and to make all determinations required or provided for under this Policy and shall have full power and authority to take, or direct the taking of, all such other actions and make all such other determinations not inconsistent with the specific terms and provisions of this Policy that the Committee deems to be necessary or appropriate to the administration of this Policy. The interpretation and construction by the Committee of any provision of this Policy and all determinations made by the Committee under this policy shall be final, binding and conclusive.

9. Compensation Recovery Repayments not Subject to Indemnification

Notwithstanding anything to the contrary set forth in any agreement with, or the organizational documents of, the Company or any of its subsidiaries, Covered Persons are not entitled to indemnification for Erroneously Awarded Compensation or for any claim or losses arising out of or in any way related to Erroneously Awarded Compensation recovered under this Policy.

DATE APPROVED BY BOARD OF DIRECTORS: September 20, 2023

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