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Filed Pursuant to Rule 424(b)4  
Registration No. 333-230451

**PROSPECTUS**

**6,000,000 Shares**



**Common Stock**

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This is HOOKIPA Pharma Inc.'s initial public offering. We are selling 6,000,000 shares of our common stock.

The public offering price is \$14.00 per share. Currently, no public market exists for the shares. Our common stock has been approved for listing on the Nasdaq Global Select Market under the symbol "HOOK."

**We are an "emerging growth company" under the federal securities laws and are subject to reduced public company disclosure standards. See "Prospectus Summary—Implications of Being an Emerging Growth Company."**

**Investing in the common stock involves risks that are described in the "Risk Factors" section beginning on page 11 of this prospectus.**

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|                                  | <u>Per Share</u> | <u>Total</u>  |
|----------------------------------|------------------|---------------|
| Public offering price            | \$ 14.00         | \$ 84,000,000 |
| Underwriting discount(1)         | \$ 0.98          | \$ 5,880,000  |
| Proceeds, before expenses, to us | \$ 13.02         | \$ 78,120,000 |

(1) See "Underwriting" beginning on page 188 for additional information regarding underwriting compensation.

Following the closing of this offering, we will have two classes of common stock: common stock and Class A common stock. The common stock and Class A common stock will be economically equivalent to each other. The rights of the holders of our common stock and Class A common stock will be identical, except with respect to voting and conversion. Each share of common stock will be entitled to one vote and will not be convertible into any other class of our share capital. The shares of Class A common stock will not have associated voting rights and each share of Class A common stock will be convertible at any time following the closing of this offering at the election of the holder into one share of common stock. See "Description of Capital Stock—Common Stock" for more information on the rights of the holders of our common stock and Class A common stock.

The underwriters may also exercise their option to purchase up to an additional 900,000 shares from us, at the public offering price, less the underwriting discount, for 30 days after the date of this prospectus.

Certain of our existing stockholders, directors and their affiliated entities have indicated an interest in purchasing an aggregate of up to approximately \$55.0 million in shares of our common stock in this offering at the initial public offering price per share and on the same terms as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares in this offering. The underwriters will receive the same underwriting discount and commissions on these shares as they will on any other shares sold to the public in this offering.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The shares will be ready for delivery on or about April 23, 2019.

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*Joint Book-Running Managers*

**BofA Merrill Lynch**

**SVB Leerink**

**RBC Capital Markets**

*Co-Manager*

**Kempen**

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The date of this prospectus is April 17, 2019.

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You should rely only on the information contained in this prospectus or in any free writing prospectus we file with the Securities and Exchange Commission. Neither we nor the underwriters have authorized anyone to provide you with information other than that contained in this prospectus or any free writing prospectus prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are offering to sell, and seeking offers to buy, common stock, but only under circumstances and only in jurisdictions where it is lawful to do so. The information contained in this prospectus is accurate only as of the date on the front cover page of this

prospectus, or other earlier date stated in this prospectus, regardless of the time of delivery of this prospectus or of any sale of our common stock.

**For investors outside the United States:** We have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside the United States.

This prospectus includes our trademarks and trade names, including, without limitation, VAXWAVE™ and THERAT™, which are our property and are protected under applicable intellectual property laws. This prospectus also includes trademarks and trade names that are the property of other organizations. Solely for convenience, trademarks and trade names referred to in this prospectus appear without the ® and ™ 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 this prospectus are the property of their respective owners.

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

## PROSPECTUS SUMMARY

*This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our common stock, you should carefully read this entire prospectus, including our consolidated financial statements and the related notes included elsewhere in this prospectus. You should also consider, among other things, the matters described under "Risk Factors," "Business," and "Management's Discussion and Analysis of Financial Condition and Results of Operations," in each case appearing elsewhere in this prospectus.*

### Overview

We are a clinical-stage biopharmaceutical company developing a new class of immunotherapeutics targeting infectious diseases and cancers based on our proprietary arenavirus platform that is designed to reprogram the body's immune system. We are using our "off-the-shelf" technologies, VaxWave and TheraT, to elicit directly within patients a powerful and durable response of antigen-specific killer T cells and antibodies, thereby activating essential immune defenses against infectious diseases and cancers. We believe that our technologies can meaningfully leverage the human immune system for prophylactic and therapeutic purposes by eliciting killer T cell response levels previously not achieved by other published immunotherapy approaches. Our lead infectious disease product candidate, HB-101, is in a randomized, double-blinded Phase 2 clinical trial in cytomegalovirus-negative patients awaiting kidney transplantation from cytomegalovirus-positive donors. Our lead oncology product candidates, HB-201 and HB-202, are in development for the treatment of human papillomavirus-positive cancers. We plan to file an investigational new drug application with the U.S. Food and Drug Administration for HB-201 and HB-202 in the first half of 2019 and 2020, respectively. We have also entered into a strategic partnership with Gilead Sciences, Inc. to accelerate building a pipeline of additional infectious disease product candidates in a cost efficient manner.

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

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

We believe we are the first to reengineer arenaviruses for therapeutic purposes. We have created two technologies capable of delivering disease-specific antigens for the prevention and treatment of disease. Our first technology, VaxWave, is a replication-defective arenavirus which induces a strong immune response for prophylactic use against infectious disease. Our second technology, TheraT, is a replication-attenuated arenavirus which produces an even more powerful immune response that we believe is more appropriate for use in oncology. In preclinical studies, our TheraT technology was able to reprogram the immune system such that more than half of the body's CD8+ T cells

focused on a specific cancer antigen target of our choice without observed serious adverse events. We have designed our platform to be modular in nature in order to allow substitution of antigens to target a broad range of infectious diseases and cancers. We have a robust intellectual property portfolio for our suite of arenaviruses with exclusive rights in issued patents and patent applications related to our VaxWave technology and exclusive and joint rights in patent applications related to our TheraT technology. These platform technologies can be used with a broad spectrum of antigens in therapeutic applications in immunotherapy ranging from infectious diseases to oncology. We believe the breadth and depth of our intellectual property is a strategic asset that has the potential to provide us with a significant competitive advantage.

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

**Our Pipeline**

|                     | Compound              | Antigen      | Target          | Development Stage                                       |         |         |         | Anticipated Milestones                 | Global Rights |
|---------------------|-----------------------|--------------|-----------------|---|---------|---------|---------|--|---------------|
|                     |                       |              |                 | Preclinical   | Phase 1 | Phase 2 | Phase 3 |  |               |
| Infectious Diseases | HB-101 (VaxWave™)     | gB/pp65      | CMV             | [Progress bar across Preclinical, Phase 1, and Phase 2] |         |         |         | Preliminary data H1 2020               |               |
|                     | HBV Therapy           | Undisclosed  | HBV             | [Progress bar in Preclinical]                           |         |         |         |  |               |
|                     | HIV Therapy           | Undisclosed  | HIV             | [Progress bar in Preclinical]                           |         |         |         |  |               |
| Immuno-Oncology     | HB-201 (TheraT™ LCMV) | E6/E7        | HPV16* Cancer   | [Progress bar in Preclinical]                           |         |         |         | IND H1 2019 Data late 2020/ early 2021 |               |
|                     | HB-202 (TheraT™ PICV) | E6/E7        | HPV16* Cancer   | [Progress bar in Preclinical]                           |         |         |         | IND H1 2020 Data mid-2021              |               |
|                     | HB-301 (TheraT™)      | PSA/PSMA/PAP | Prostate Cancer | [Progress bar in Preclinical]                           |         |         |         |  |               |

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

Our lead product candidate in infectious diseases, utilizing VaxWave technology, is HB-101 for the prevention of cytomegalovirus infections. A majority of the worldwide human population is latently infected with cytomegalovirus and can transmit the infection through bodily fluids. While infection in immunocompetent persons typically presents as mild or asymptomatic, cytomegalovirus remains a major cause of morbidity and mortality in persons with a compromised immune system and in patients undergoing solid organ or hematopoietic stem cell transplants. Current therapies to prevent the transmission of cytomegalovirus during organ transplants utilize antiviral prophylactic and therapeutic strategies. However, these therapies are only partially protective in preventing viral disease while also being hampered by toxicity and resistance. HB-101 delivers two clinically validated antigens, phosphoprotein 65 to induce cytomegalovirus-specific CD8+ T cells and glycoprotein B to elicit cytomegalovirus-neutralizing antibodies.

In our Phase 1 clinical trial, HB-101 was well tolerated and elicited a strong cytomegalovirus-specific immune responses in all 42 of the treatment arm volunteers. Importantly, we observed robust CD8+ and CD4+ T cell responses as well as cytomegalovirus-neutralizing antibody responses, without meaningful vector-neutralizing antibody responses. These responses increased in a statistically significant manner upon repeat administration. We believe these results demonstrate the differentiating features of our arenavirus platform. In the fourth quarter of 2018, we commenced a Phase 2 clinical trial for HB-101 in cytomegalovirus-negative patients awaiting kidney transplantation from living cytomegalovirus-positive donors. We expect safety and immunogenicity data from the first cohorts enrolled in this trial in the first half of 2020, and preliminary efficacy data to follow in the second half of 2020.

We are developing our lead oncology product candidates, HB-201 and HB-202, both utilizing TheraT technology, for cancers caused by human papilloma virus, or HPV. These cancers account for approximately 5% of the total worldwide cancer prevalence and recent studies have shown that approximately 70% of cancers of the tonsil and tongue base and the majority of cervical and anal cancers, in addition to several other cancers including head and neck may be linked to HPV. Tumors caused by HPV are referred to as HPV-positive tumors, or HPV+, and can be characterized by their expression of proteins from the HPV genome, particularly the viral E6 and E7 proteins. These two proteins are expressed in tumors but absent in normal cells, which makes them ideal target candidates for immunotherapy, however, to date, there are no therapeutically approved agents directed against these targets.

In preclinical studies, HB-201 as a monotherapy was effective at suppressing tumor growth and eliminated up to 40% of HPV+ tumors. HB-201 generated a strong and durable T cell and antibody response with successfully treated animals demonstrating resistance to a tumor re-challenge. Based on these preliminary results, we believe that treating patients with HB-201 has the potential to both control metastatic disease and prevent relapse. We intend to file an investigational new drug application for HB-201 in treatment refractory HPV16+ cancers in the first half of 2019. Our first planned Phase 1/2 clinical trial will assess the safety and efficacy of HB-201 both as a monotherapy and in combination with a checkpoint inhibitor. Our second planned Phase 1/2 clinical trial will assess the safety and efficacy of the combination of HB-201 and HB-202 in HPV16+ cancers, with or without a checkpoint inhibitor. HB-202 similarly targets E6 and E7 of HPV16+ tumors, but uses a different arenavirus than HB-201. We believe that our preclinical studies demonstrate that the combination of HB-201 and HB-202 results in a synergistic increase in E7 immunogenicity as compared to either HB-201 or HB-202 alone. Our goal is to establish the safety of this combination approach and its superiority over monotherapy.

#### **Collaboration with Gilead**

In June 2018, we partnered with Gilead Sciences, Inc., or Gilead, a world leader in innovative therapies against infectious diseases, to develop arenavirus based therapeutics to treat hepatitis B virus, or HBV, and human immunodeficiency virus, or HIV, infections. We received a one-time upfront payment of \$10.0 million upon entering into the agreement. We are also eligible to receive milestone payments based upon the achievement of specified development, regulatory, and commercial milestones potentially amounting to approximately \$400 million, as well as tiered royalties ranging from high single-digit to mid-teens percentage on net sales. In December 2018, we achieved the first research milestone under the HIV program, entitling us to a payment of \$2.8 million from Gilead, which we received in January 2019.

## **Our Strategy**

Our goal is to transform the prevention and treatment of infectious diseases and cancers to significantly improve the lives of patients by developing and commercializing a new class of "off-the-shelf" immunotherapeutics.

The key elements of our strategy are:

- Advance our lead infectious disease product candidate through clinical development and regulatory approval.
- Simultaneously progress our lead immuno-oncology product candidates through clinical development and regulatory approval.
- Apply our arenavirus platform to develop additional novel immuno-oncology product candidates.
- Selectively collaborate to realize the full potential of our arenavirus platform.
- Strengthen and scale our manufacturing capabilities and ultimately operate our own manufacturing facility.

## **Management and Investors**

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, Jörn Aldag, was previously the Chief Executive Officer of uniQure N.V., a company that under his leadership pioneered the approval of the first gene therapy product. Igor Matushansky, M.D., Ph.D., our Chief Medical Officer and Global Head of Research and Development was previously Global Head of Translational Development for Oncology at Daiichi Sankyo Company, Limited. 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 our Chief Scientific Officer.

We are supported by prominent biotechnology investors, including BioMedPartners, Boehringer Ingelheim Venture, Forbion Capital Partners, HBM, Hillhouse Capital, Redmile Group, Sofinnova Partners and Takeda Ventures, as well as Gilead, a leading biopharmaceutical company.

## **Risks Associated with Our Business**

Our ability to implement our business strategy is subject to numerous risks, as more fully described in the section entitled "Risk Factors" immediately following this prospectus summary. These risks include, among others:

- 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.
- Even if we consummate this offering, 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.
- We currently have only one product candidate, HB-101, in clinical development. A failure of this product candidate in clinical development would adversely affect our business and may require us to discontinue development of other product candidates based on the same therapeutic approach.



- If we are unable to advance our current or future product candidates into and through clinical trials, obtain marketing approval and ultimately commercialize any product candidates we develop, or experience significant delays in doing so, our business will be materially harmed.
- The regulatory approval processes of the U.S. Food and Drug Administration, the European Medicines Agency and other comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.
- Our product candidates are based on a novel approach to the treatment of cancer, which makes it difficult to predict the time and cost of product candidate development.
- Our product candidates may cause serious adverse events, undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, require expansion of the trial size, limit their commercial potential or result in significant negative consequences.
- We are fully dependent on our collaboration with Gilead for the development of our HIV and HBV programs and may depend on Gilead or additional third parties for the development and commercialization of our other programs and future product candidates. Our current and future collaborators may control aspects of our clinical trials, which could result in delays or other obstacles in the commercialization of the product candidates we develop. If our collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.
- We expect to rely on third parties to manufacture our clinical product supplies, and we may rely on third parties for at least a portion of the manufacturing process of our product candidates, if approved. Our business could be harmed if those third parties fail to provide us with sufficient quantities of clinical product supplies or product candidates or fail to do so at acceptable quality levels or prices.
- 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, 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 have identified material weaknesses in our internal control over financial reporting. If our remediation of these material weaknesses is not effective, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

#### **Indications of Interest**

Certain of our existing stockholders, directors and their affiliated entities have indicated an interest in purchasing an aggregate of up to approximately \$55.0 million in shares of our common stock in this offering at the initial public offering price per share and on the same terms as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares to any of these potential purchasers, and any of these potential purchasers could determine to purchase more,

fewer or no shares in this offering. The underwriters will receive the same underwriting discount and commissions on these shares as they will on any other shares sold to the public in this offering.

### **Implications of Being an Emerging Growth Company**

As a company with less than \$1.07 billion in revenue during our last fiscal year, we qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- reduced disclosure about our executive compensation arrangements in our periodic reports, proxy statements and registration statements;
- no non-binding advisory votes on executive compensation or golden parachute arrangements;
- exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002; and
- exemption from compliance with the requirement that the Public Company Accounting Oversight Board, or the PCAOB, has adopted regarding a supplement to the auditor's report providing additional information about the audit of the financial statements.

We may take advantage of these exemptions for up to five years following the closing of this offering or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the date of the closing of this offering, (b) in which we have total annual gross revenue of at least \$1.07 billion; or (c) in which we are deemed to be a large accelerated filer under the rules of the SEC, and (2) the date on which we have issued more than \$1.0 billion in nonconvertible debt during the previous three years. We may choose to take advantage of some but not all of these exemptions. We have taken advantage of reduced reporting requirements in this prospectus and may elect to take advantage of other reduced reporting requirements in future filings. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock.

We have irrevocably elected to "opt out" of the exemption in Section 107 of the JOBS Act that allows for the delayed adoption of certain 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.

### **Corporate Information**

We were originally incorporated as Hookipa Biotech AG under the laws of Austria in 2011. In February 2017, we reorganized to become a corporation under the laws of the State of Delaware as Hookipa Biotech, Inc., which was a fully-owned subsidiary of Hookipa Biotech AG. In June 2018, Hookipa Biotech, Inc. changed its name to HOOKIPA Pharma Inc. and acquired all of the shares of Hookipa Biotech AG, now Hookipa Biotech GmbH. Our principal executive offices are located at 350 Fifth Avenue, 72nd Floor, Suite 7240, New York, New York 10118 and our telephone number is +43 1 890 63 60. Our website address is [www.hookipapharma.com](http://www.hookipapharma.com). We have included our website address in this prospectus solely as an inactive textual reference.

**THE OFFERING**

|  |  |
|--|--|
| Common stock offered by us                                     | 6,000,000 shares.  |
| Common stock to be outstanding immediately after this offering | 21,588,756 shares (22,488,756 shares if the underwriters exercise their option to purchase additional shares in full).   |
| Class A common stock outstanding before this offering          | Zero shares.   |
| Class A common stock outstanding after this offering           | 3,819,732 shares.  |
| Underwriters' option to purchase additional shares             | We have granted a 30-day option to the underwriters to purchase up to an aggregate of 900,000 additional shares of common stock from us at the public offering price, less underwriting discounts and commissions, on the same terms as set forth in this prospectus.  |
| Use of proceeds  | We estimate that we will receive net proceeds from the sale of shares of our common stock in this offering of approximately \$74.8 million, or \$86.5 million if the underwriters exercise their option to purchase additional shares in full, based on the initial public offering price of \$14.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, to advance HB-101 through our ongoing Phase 2 clinical trial, advance HB-201 and HB-202 into and through Phase 1 clinical trials, advance HB-301 into and through a Phase 1 clinical trial, for ongoing research and development activities related to next generation programs and the remainder for working capital and other general corporate purposes. For a more complete description of our intended use of the proceeds from this offering, see "Use of Proceeds" beginning on page 68 for additional information. |

Voting Rights

Following the closing of this offering, we will have two classes of common stock: common stock and Class A common stock. Holders of our shares of common stock—the only class of common stock being sold in this offering—will be entitled to one vote and will not be convertible into any other class of our share capital. The shares of Class A common stock will not have associated voting rights and each share of Class A common stock will be convertible at any time following the closing of this offering, at the election of the holder, into one share of common stock. See "Description of Capital Stock—Common Stock" for more information on the rights of the holders of our common stock and Class A common stock.

Risk factors

You should carefully read the "Risk Factors" beginning on page 11 and the other information included in this prospectus for a discussion of factors that you should consider before deciding to invest in our common stock.

Nasdaq Global Select Market symbol

"HOOK."

The number of shares of our common stock to be outstanding after this offering is based on 15,588,756 shares of our common stock outstanding as of February 28, 2019, after giving effect to (i) the automatic conversion of 1,252,440 shares of our preferred stock into an aggregate of 14,582,161 shares of voting common stock upon closing of this offering and (ii) the automatic conversion of 328,071 shares of our preferred stock into 3,819,732 shares of non-voting Class A common stock upon the closing of this offering, and excludes:

- 1,597,638 shares of our common stock issuable upon the exercise of stock options outstanding under our 2018 Stock Option and Grant Plan, or the 2018 Plan, as of February 28, 2019, at a weighted average exercise price of \$1.94 per share;
- 440,981 shares of our common stock available for future issuance under our 2018 Plan as of February 28, 2019;
- 2,608,042 shares of our common stock that will become available for future issuance under our 2019 Stock Option and Incentive Plan, which will become effective in connection with the closing of this offering; and
- 260,804 shares of our common stock that will become available for future issuance under our 2019 Employee Stock Purchase Plan, which will become effective in connection with the closing of this offering.

Unless otherwise indicated, all information in this prospectus reflects or assumes the following:

- the filing of our amended and restated certificate of incorporation and the effectiveness of our amended and restated bylaws upon the closing of this offering;
- the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 18,401,893 shares of voting common stock upon the closing of this offering;
- no issuances of shares of non-voting Class A common stock upon the closing of this offering;
- no exercise of outstanding options after February 28, 2019;
- a 11.643-for-1 split of our common stock effected on April 5, 2019; and
- no exercise by the underwriters of their option to purchase up to 900,000 additional shares of common stock in this offering.

### Summary Consolidated Financial Data

The following tables set forth our summary consolidated financial data for the period indicated. We have derived the consolidated statement of operations data for the years ended December 31, 2017 and 2018 and the consolidated balance sheet data as of December 31, 2018 from our audited consolidated financial statements and related notes appearing at the end of this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future. You should read the following summary consolidated financial data together with our consolidated financial statements and the related notes appearing at the end of this prospectus and the "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of this prospectus.

|   | <u>Year ended December 31,</u> |                   |
|---|--------------------------------|-------------------|
|   | <u>2017</u>                    | <u>2018</u>       |
| <i>(in thousands, except share and per share data)</i>  |                                |                   |
| <b>Consolidated Statements of Operations Data:</b>  |                                |                   |
| Revenue from collaboration and licensing  | \$ —                           | \$ 7,629          |
| Operating expenses:   |                                |                   |
| Research and development  | (9,772)                        | (21,965)          |
| General and administrative  | (4,385)                        | (6,844)           |
| Total operating expenses  | <u>(14,157)</u>                | <u>(28,809)</u>   |
| Loss from operations  | <u>(14,157)</u>                | <u>(21,180)</u>   |
| Other income (expense):   |                                |                   |
| Grant income  | 2,069                          | 5,612             |
| Interest expense  | (606)                          | (778)             |
| Other income and expenses, net  | (25)                           | 133               |
| Total other income (expense), net   | <u>1,438</u>                   | <u>4,967</u>      |
| Net loss before tax   | <u>(12,719)</u>                | <u>(16,213)</u>   |
| Income tax expense  | (4)                            | (24)              |
| Net loss  | <u>(12,723)</u>                | <u>(16,237)</u>   |
| Net loss per share attributable to common stockholders—basic and diluted(1)                       | <u>\$ (13.95)</u>              | <u>\$ (17.76)</u> |
| Weighted average common shares outstanding—basic and diluted(1)                                   | <u>911,777</u>                 | <u>914,375</u>    |
| Pro forma net loss per share attributable to common shareholders—basic and diluted (unaudited)(1) |                                | <u>\$ (0.99)</u>  |
| Pro forma weighted average common shares outstanding—basic and diluted (unaudited)(1)             |                                | <u>16,324,008</u> |

- (1) See Note 2 and Note 13 to our consolidated financial statements appearing at the end of this prospectus for further details on the calculation of basic and diluted net loss per share

attributable to common shareholders and on the calculation of pro forma basic and diluted net loss per share attributable to common shareholders.

|   | As of December 31, 2018 |   |                             |
|---|-------------------------|---|-----------------------------|
|   | Actual                  | Pro Forma(2)<br>(unaudited)<br>(in thousands) | Pro Forma<br>As Adjusted(3) |
| <b>Consolidated Balance Sheet Data:</b> |                         |   |                             |
| Cash and cash equivalents               | \$ 48,580               | \$ 85,857                                     | \$ 160,856                  |
| Working capital(1)                      | 47,616                  | 84,893  | 161,200                     |
| Total assets                            | 68,251                  | 105,528                                       | 179,040                     |
| Redeemable convertible preferred stock  | 104,774                 | —   | —                           |
| Accumulated deficit                     | (59,982)                | (59,982)                                      | (59,982)                    |
| Total stockholders' equity (deficit)    | (60,375)                | 81,676  | 156,497                     |

- (1) We define working capital as current assets less current liabilities.
- (2) The pro forma balance sheet data give effect to (i) our sale of 257,000 shares of Series D redeemable convertible preferred stock in February 2019 for gross proceeds of \$37.4 million, (ii) the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 18,401,893 shares of voting common stock upon the closing of this offering, and (iii) no issuances of shares of non-voting Class A common stock upon the closing of this offering.
- (3) Reflects the pro forma adjustments described in footnote (2) above and gives further effect to our issuance and sale of 6,000,000 shares of our common stock in this offering at the initial public offering price of \$14.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Net proceeds assumed in this offering are \$74.8 million after deducting underwriting discounts and commissions and estimated offering expenses payable by us. As of December 31, 2018, deferred offering expenses classified as other non-current assets were \$1.5 million, of which \$0.2 million had been paid and \$1.3 million were accrued in current liabilities.

## 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 prospectus, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.*

### **Risks Related to Our Financial Position and Capital Needs**

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

We are a clinical-stage biopharmaceutical company with no approved products and a limited operating history. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale and have not generated any revenue from product sales. To date, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, undertaking preclinical studies and clinical trials of our product candidates, securing related intellectual property rights and conducting discovery, research and development activities for our programs. As a result, we are not profitable and have incurred losses in each period since our inception in 2011. For the years ended December 31, 2017 and 2018 we reported a net loss of \$12.7 million and \$16.2 million respectively. As of December 31, 2018, we had an accumulated deficit of \$60.0 million. We expect to continue to incur significant losses for the foreseeable future. We anticipate that our expenses will increase substantially if, and as, we:

- pursue the clinical and preclinical development of our current and future product candidates;
- leverage our technologies to advance product candidates into preclinical and clinical development;
- seek regulatory approvals for product candidates that successfully complete clinical trials, if any;
- attract, hire, and retain additional clinical, quality control and scientific personnel;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company;
- establish our manufacturing capabilities through third parties or by ourselves and scale-up manufacturing to provide adequate supply for clinical trials and commercialization;
- expand and protect our intellectual property portfolio;
- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly;
- acquire or in-license other product candidates and technologies; and

- incur additional legal, accounting and other expenses in operating our business, including the additional 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 and we may never generate revenue that is significant or large enough to achieve profitability. We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

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

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

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

As of December 31, 2018, we had approximately \$48.6 million in cash and cash equivalents. In December 2018, we achieved the first research milestone under the HIV program, entitling us to a payment of \$2.8 million from Gilead Sciences, Inc., or Gilead, which we received in January 2019. Additionally, in February 2019, we received gross proceeds of \$37.4 million from the sale of our Series D redeemable convertible preferred stock. We estimate that the net proceeds from this offering will be approximately \$74.8 million after deducting the estimated offering expenses payable by us. Based on our research and development plans, we expect that the net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect. Changes may occur beyond our control that would cause us to consume our available capital before



that time, including changes in and progress of our development activities and changes in regulation. Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing our current and future product candidates and programs, and of conducting preclinical studies and clinical trials;
- the number and development requirements of other product candidates that we may pursue, and other indications for our current product candidates that we may pursue;
- the stability, scale and yields of our future manufacturing process as we scale-up production and formulation of our product candidates for later stages of development and commercialization;
- the timing of, and the costs involved in, obtaining regulatory and marketing approvals and developing our ability to establish sales and marketing capabilities, if any, for our current and future product candidates we develop if clinical trials are successful;
- the success of our collaboration with Gilead;
- our ability to establish and maintain collaborations, strategic licensing or other arrangements and the financial terms of such agreements;
- the cost of commercialization activities for our current and future product candidates that we may develop, whether alone or with a collaborator;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the timing, receipt and amount of sales of, or royalties on, our future products, if any; and
- the emergence of competing oncology and infectious disease therapies and other adverse market developments.

We do not have any committed external source of funds or other support for our development efforts.

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

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

If we raise additional capital through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest will be diluted. If we raise additional capital through debt financing, we would be subject to fixed payment obligations and may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us.

If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, reduce or terminate our product development or future commercialization

efforts or grant rights to third parties to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

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

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

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integration;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology or products sufficient to meet our objectives in undertaking the acquisition.

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

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

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

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

## Risks Related to Our Business and Industry

***We currently have only one product candidate, HB-101, in clinical development. A failure of this product candidate in clinical development would adversely affect our business and may require us to discontinue development of other product candidates based on the same therapeutic approach.***

We recently initiated a Phase 2 clinical trial for HB-101 and it is currently our only clinical development-stage product candidate. Although we have other programs in preclinical development and we intend to develop additional product candidates in the coming years, it will take additional investment and time for such product candidates to reach the same stage of development as HB-101, and there can be no assurance that they will ever do so. If we are required to discontinue development of HB-101, or if it fails to receive regulatory approval or achieve sufficient market acceptance, if approved, we could be prevented from or significantly delayed in achieving profitability and may be required to delay or abandon the development of our other programs.

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

All of our product candidates are in early stages of development, including our lead product candidate, HB-101, that recently commenced a Phase 2 clinical trial, and as such will require extensive preclinical and clinical testing. We cannot predict with any certainty if or when we might submit an investigational new drug application, or IND, or biologics license application, or BLA, for regulatory approval for any of our product candidates or whether any such IND or BLA will be accepted for review by the FDA, or subsequently whether any such IND will go into effect or BLA will be approved upon review.

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

- successful completion of preclinical studies and clinical trials;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- acceptance of investigational new drug applications, or INDs, for our planned clinical trials or future clinical trials;
- successful enrollment and completion of clinical trials;
- successful data from our clinical program that support an acceptable risk-benefit profile of our product candidates in the intended populations;
- receipt and maintenance of regulatory and marketing approvals from applicable regulatory authorities;
- scale-up of our manufacturing processes and formulation of our product candidates for later stages of development and commercialization;

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

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

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

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

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

- the FDA, the EMA or other comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, the EMA or other comparable foreign regulatory authorities that a product candidate is safe, pure and potent or effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA, the EMA or other comparable foreign regulatory authorities for approval;

- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA, the EMA or other comparable foreign regulatory authorities may disagree with our interpretation of data from clinical trials or preclinical studies;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA to the FDA, or similar foreign submission to the EMA or other comparable foreign regulatory authority, to obtain approval in the United States, the European Union or elsewhere;
- the FDA, the EMA or other comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, the EMA or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

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

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

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

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

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

Before obtaining regulatory approvals for the commercial sale of our product candidates, including HB-101 and any other future product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe

and effective for use in each target indication. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process, and, because our product candidates are in an early stage of development, there is a high risk of failure and we may never succeed in developing marketable products.

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

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

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

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

Our product candidates HB-201, HB-202, HB-301 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, or CTAs, in Europe. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA, the EMA or other regulatory authorities will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our product candidates. As a result, we cannot be sure that submission of INDs or similar applications will result in the FDA, the EMA or other comparable foreign regulatory authorities allowing clinical trials to begin.

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

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

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

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

***Our TheraT technology has never been tested in humans and could therefore prove to be unsafe.***

TheraT is an attenuated but replicating viral vector technology. Safety and toxicity studies have so far only been conducted in animal species. If our first clinical trial for HB-201 causes unexpected side effects that are not tolerable in the treatment of the relevant patient group, the further development of the product candidate and any other potential products based on the TheraT technology may be significantly limited or become impossible.

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

We have concentrated all of our research and development efforts on product candidates based on our VaxWave and TheraT technologies, and our future success depends on the successful development of this therapeutic approach. Our VaxWave and TheraT technologies utilize arenaviruses to activate CD8+ T cells and induce pathogen-neutralizing antibodies. There are no approved products that utilize the arenavirus. Because our VaxWave and TheraT technologies are novel, regulatory agencies may lack experience with product candidates such as HB-101 and HB-201, which may

lengthen the regulatory review process, increase our development costs and delay or prevent commercialization of our product candidates. We have not yet succeeded and may not succeed in demonstrating safety and efficacy for any of our product candidates in ongoing or later-stage clinical trials or in obtaining marketing approval thereafter.

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

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

A trial design that is considered appropriate for regulatory approval includes a sufficiently large sample size with appropriate statistical power, as well as proper control of bias, to allow a meaningful interpretation of the results. In our planned Phase 1 trial for HB-201, we expect to enroll 20 patients and future trials for HB-201 or other product candidates may similarly enroll a small number of patients. The preliminary results of trials with smaller sample sizes, such as our planned Phase 1 trial for HB-201, can be disproportionately influenced by the impact the treatment had on a few individuals, which limits the ability to generalize the results across a broader community, making the trial results less reliable than trials with a larger number of patients. As a result, there may be less certainty that such product candidates would achieve a statistically significant effect in any future clinical trials. If we conduct any future clinical trials, we may not achieve a statistically significant result or the same level of statistical significance, if any, that would have been possible to achieve in a larger trial.

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

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

If unacceptable toxicities arise in the development of our product candidates, we could suspend or terminate our trials or the FDA, the EMA or other comparable foreign regulatory authorities, or local regulatory authorities such as IRBs, could order us to cease clinical trials. Competent national health authorities, such as the FDA, could also deny approval of our product candidates for any or all targeted indications. Even if the side effects presented do not preclude the product from obtaining or



maintaining marketing approval, treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our product candidates, if approved, to understand the side effect profile of these technologies for both our planned clinical trials and upon any commercialization of any product candidates, if approved. Inadequate training in recognizing or managing the potential side effects of our technologies could result in patient deaths. Any of these occurrences may harm our business, financial condition and prospects significantly.

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

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

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before the manufacturing and infusion of our product candidates or trial completion.

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

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

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

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

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

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

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

Cancer therapies are characterized as first line, second line, or third line, and the FDA often approves new therapies initially only for a particular line of use. When cancer is detected early enough, first line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first line therapy, usually chemotherapy, antibody drugs, tumor-targeted small molecules, hormone therapy, radiation therapy, surgery, or a combination of these, proves unsuccessful, second line therapy may be administered. Second line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor-targeted small molecules, or a combination of these. Third line therapies can include hematopoietic stem cell transplantation in certain cancers, chemotherapy, antibody drugs, and small molecule tumor-targeted therapies, more invasive forms of surgery, and new revolutionary technologies. We expect to initially seek approval of our product candidates in most instances at least as a third line therapy, for use in patients with relapsed or refractory metastatic cancer. Subsequently, for those product candidates that prove to be sufficiently safe and beneficial, if any, we would expect to seek approval as a second line therapy and potentially as a first line therapy, but there is no guarantee that our product candidates, even if approved as a third or subsequent line of therapy, would be approved for an earlier line of therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

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

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

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

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

- the clinical indications for which our product candidates are approved;
- physicians, hospitals, cancer treatment centers and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- the prevalence and severity of any side effects for virus-based therapeutic products, in particular, other prime-boost therapies;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

In addition, although we are not utilizing fully replication competent live virus vectors, our TheraT technology uses a replication attenuated vector and adverse publicity due to the ethical and social controversies surrounding the therapeutic use of such technologies, and reported side effects from any clinical trials using these technologies or the failure of such trials to demonstrate that these therapies are safe and effective may limit market acceptance of our product candidates. If our product candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals,

cancer treatment centers or others in the medical community, we will not be able to generate significant revenue.

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

Our HB-201 and HB-202 product candidates are being developed to be used in combination with nivolumab, a currently approved cancer therapy. In the future, we may develop other product candidates to be used with one or more currently approved cancer therapies. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or similar regulatory authorities outside of the United States could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. Combination therapies are commonly used for the treatment of cancer, and we would be subject to similar risks if we develop any of our product candidates for use in combination with other drugs or for indications other than cancer. This could result in our own products being removed from the market or being less successful commercially.

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

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

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

The commercial success of TheraT-based product candidates will depend in part on public acceptance of the use of cancer immunotherapies. Adverse events in clinical trials of HB-201 or our other TheraT-based product candidates or in clinical trials of others developing similar products and the resulting publicity, as well as any other negative developments in the field of immuno-oncology that may occur in the future, including in connection with competitor therapies, could result in a decrease in demand for any TheraT-based product candidates that we may develop. These events could also result in the suspension, discontinuation, or clinical hold of or modification to our clinical trials. If public perception is influenced by claims that the use of cancer immunotherapies is unsafe, whether related to our therapies or those of our competitors, our product candidates may not be accepted by the general public or the medical community and potential clinical trial subjects may be discouraged from enrolling in our clinical trials. In addition, responses by national or state governments to negative public perception may result in new legislation or regulations that could limit our ability to develop or commercialize any product candidates, obtain or maintain regulatory approval or otherwise achieve profitability. More restrictive statutory regimes, government regulations or negative public opinion would have an adverse effect on our business, financial condition, prospects and results of operations and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop. As a result, we may not be able to continue or may be delayed in conducting our development programs.

Our product candidates consist of a modified virus. Adverse developments in clinical trials of other immunotherapy products based on viruses, like oncolytic viruses, may result in a

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

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

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

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

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

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

We may choose to focus our efforts on and allocate resources to a potential product candidate that ultimately proves to be unsuccessful, or to license or purchase a marketed product that does not meet our financial expectations. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases that may later prove to have greater commercial potential, or

relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we are unable to evaluate the commercial potential or target market for a particular product candidate, identify and successfully commercialize additional suitable product candidates, this would adversely impact our business strategy and our financial position.

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

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

Specifically, we face significant competition in cytomegalovirus management, companies such as Helocyte, Inc., VBI Vaccines, Inc., Moderna, Inc., SL VaxiGen, Inc., Merck & Co., GlaxoSmithKline plc and Pfizer, Inc. In immuno-oncology for human papilloma virus-16 positive, or HPV16+, cancers, we face competition from companies such as Kite Pharma, a Gilead company, Advaxis, Inc., ISA Pharmaceuticals B.V., in collaboration with Regeneron Pharmaceuticals, Inc. and BioNtech AG. Even if we obtain regulatory approval of our product candidates, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our product candidates. In addition, other immuno-oncology companies are developing the following technologies, including, but not limited to, neoantigens, bispecific antibodies, engineered cell therapies and tumor specific antigens in areas outside of cytomegalovirus 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. For additional information regarding our competition, see "Business—Competition."

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

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

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

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

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

We plan to seek regulatory approval of our product candidates outside of the United States and, accordingly, we expect that we, and any potential collaborators in those jurisdictions, will be subject to additional risks related to operating in foreign countries, including:

- differing regulatory requirements in foreign countries;

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

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

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

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



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

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

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

We also expect that operating as a public company will make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

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

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

**Risks Related to Our Reliance on Third Parties**

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

In June 2018, we entered into a research collaboration and license agreement with Gilead, or the Collaboration Agreement, which is focused on researching, developing and commercializing therapies for the treatment, cure, diagnosis and prevention of HIV and hepatitis B virus, or HBV. Pursuant to the Collaboration Agreement, we granted Gilead a worldwide exclusive license to research, develop, manufacture and commercialize vaccine products for HIV and HBV using our VaxWave and TheraT technologies. The collaboration involves a complex allocation of rights, provides for milestone payments to us based on the achievement of specified clinical development, regulatory and commercial milestones, and provides us with royalty-based revenue if certain product candidates are successfully commercialized. Gilead is solely responsible for the preclinical and clinical development of the programs. Our lack of control over the clinical development under the Collaboration Agreement could result in delays or other difficulties in the development and commercialization of product candidates,

which may prevent completion of intended IND filings in a timely fashion, if at all. Additionally, Gilead has the right to terminate the Collaboration Agreement at any time for convenience. In the event Gilead terminates the Collaboration Agreement, we would be prevented from receiving any milestone payments, royalty payments and other benefits under that agreement, which would have a materially adverse effect on our results of operations. We cannot provide any assurance with respect to the success of the Collaboration Agreement.

In the future, we may form or seek other strategic alliances, joint ventures, or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to product candidates we develop.

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

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs or license arrangements based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as a strategic transaction that may divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, including technology we in-license, products that compete directly or indirectly with our products or product candidates;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- collaborators may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;
- collaborators may not properly enforce, maintain or defend our intellectual property rights or may use our proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation, or other intellectual property proceedings;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- disputes may arise between a collaborator and us that cause the delay or termination of the research, development or commercialization of the product candidate, or that result in costly litigation or arbitration that diverts management attention and resources;
- if a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated;
- collaboration agreements may restrict our right to independently pursue new product candidates. For example, under the Collaboration Agreement, we are prohibited from,

directly or indirectly, researching, developing, manufacturing or commercializing product candidates targeted to HIV or HBV; and

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

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

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

The advancement of our product candidates and development programs and the potential commercialization of our current and future product candidates will require substantial additional cash to fund expenses. For some of our programs, we may decide to collaborate with additional biotechnology and pharmaceutical companies with respect to development and potential commercialization. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business. We will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of any product candidates we may seek to develop with them. We cannot predict the success of any collaboration that we have entered into or will enter into.

We face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for other collaborations will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the progress of our clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Further, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for future product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view them as having the requisite potential to demonstrate safety and efficacy.

We may also be restricted under existing collaboration agreements from entering into future agreements on certain terms with potential collaborators. For example, under the Collaboration Agreement, we have granted worldwide exclusive rights to Gilead for using our technologies to develop

treatments for HIV and HBV, and during the term of the agreement we will be restricted from granting similar rights to other parties. This exclusivity could limit our ability to enter into strategic collaborations with future collaborators.

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

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

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

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

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

Any third parties conducting our clinical trials are and will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing, clinical and nonclinical programs. These third parties may also have relationships with other commercial entities, including our

competitors, for whom they may also be conducting clinical studies or other drug development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

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

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

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

The manufacture of biological drug products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of biologic products often encounter difficulties in production, particularly in scaling up or out, validating the production process and assuring high reliability of the manufacturing process, including the absence of contamination. These problems include logistics and shipping, difficulties with production costs and yields, quality control, including lot consistency, stability of the product, product testing, operator error and availability of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if contaminants are discovered in our supply of our product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability failures or other issues relating to the manufacture of our product candidates will not occur in the future.

Although we do intend to develop our own manufacturing facility, we currently rely on third parties as part of our manufacturing process and may, in any event, never be successful in developing our own manufacturing facility. Our reliance on a limited number of third-party manufacturers exposes us to the following risks:

- the production process for our product candidates is complex and requires specific know-how that only a limited number of CMOs can provide, as a result, we compete with other companies in the field for the scarce capacities of these organizations and may not be able to secure sufficient manufacturing capacity when needed;
- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA and comparable foreign regulatory authorities must inspect any manufacturers for cGMP compliance as part of our marketing application;

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

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

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

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by our manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and

interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

### **Risks Related to Government Regulation**

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

Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a risk evaluation and mitigation strategy in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA, the EMA or another comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for any such approved product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or our or our distributors', licensees' or co-marketers' failure to comply with changes to regulatory requirements, may result in, among other things:

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

The FDA's, the EMA's and other comparable foreign regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

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

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

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability, or the ability of our collaborators, to profitably sell any products for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or our collaborators, may receive for any approved products.

For example, legislative and regulatory changes have been proposed and adopted since the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, was enacted in 2010. These changes include, among other things, aggregate reductions to Medicare Part B payments to providers of up to 2% per fiscal year, which became effective on April 1, 2013 and will remain in effect through 2027 unless additional congressional action is taken. Additionally, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Changes imposed by recent legislative actions are further described in the section of this prospectus titled "Business—Government Regulation."

While Congress has not passed repeal legislation to date, the 2017 Tax Cuts and Jobs Act includes a provision repealing the individual insurance coverage mandate included in the Affordable Care Act, effective January 1, 2019. Since January 20, 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Further, on June 14, 2018, the U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay to third-party payors more than \$12 billion in ACA risk corridor payments that they argued were owed to them. The effects of this gap in reimbursement on third-party payors, the viability of the ACA marketplace, providers, and our business, are not yet known.

Recent regulatory changes may also affect our business. In 2016, the Centers for Medicare and Medicaid Services, or CMS, issued a final rule regarding the Medicaid drug rebate program. The final rule, effective April 1, 2016, among other things, extended manufacturer rebate obligations to U.S. territories, revised the manner in which the "average manufacturer price" is to be calculated by manufacturers participating in the program, and implements certain amendments to the Medicaid rebate statute created under the ACA. In 2017, CMS issued a final Medicare rule limiting payment for outpatient drugs purchased by hospitals under the 340B program. In addition, CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. In addition, increased scrutiny by the U.S. 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.

Moreover, there have been a number of other legislative and regulatory changes in recent years aimed at the biopharmaceutical industry. For instance, the Drug Quality and Security Act imposes obligations on manufacturers of biopharmaceutical products related to product tracking and tracing. Among the requirements of this legislation, manufacturers are required to provide certain information



regarding the product to individuals and entities to which product ownership is transferred, will be required to label products with a product identifier, and are required keep certain records regarding the product. The transfer of information to subsequent product owners by manufacturers will eventually be required to be done electronically. Manufacturers are also required to verify that purchasers of the manufacturers' products are appropriately licensed. Further, manufacturers have product investigation, quarantine, disposition, and FDA and trading partner notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products that could result in serious adverse health consequences or death to humans, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

We expect federal, state and national healthcare reform measures that may be adopted in the United States or other foreign jurisdictions in the future may result in more rigorous coverage criteria, increased regulatory burdens and operating costs, decreased net revenue from our pharmaceutical products, decreased potential returns from our development efforts, and in additional downward pressure on the price that we receive for any approved product. Compliance with new requirements may increase our operational expenses and impose significant administrative burdens. As a result of these and other new proposals, we may need to change our current manner of operation, which could have a material adverse effect on our business, financial condition, and results of operations. Any reduction in reimbursement from Medicare or other government healthcare programs may result in a similar reduction in payments from private payors.

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

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

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

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. We cannot be sure that any evaluation we may make of our product candidates as qualifying for breakthrough therapy designation will meet the FDA's expectations. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure

ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that such product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

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

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

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

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

Similarly, in Europe, the European Commission grants Orphan Drug Designation after receiving the opinion of the EMA Committee for Orphan Medicinal Products on an Orphan Drug Designation application. Orphan Drug Designation is intended to promote the development of drugs that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than 5 in 10,000 persons in Europe and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or the product would be a significant benefit to those affected). Additionally, designation is granted for drugs intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in Europe would be sufficient to justify the necessary investment in developing the drug. In Europe, Orphan Drug Designation entitles a party to a number of incentives, such as protocol assistance and scientific advice specifically for designated orphan medicines, and potential fee reductions depending on the status of the sponsor.

Generally, if a drug with an Orphan Drug Designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same drug and indication for that time period, except in limited circumstances. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity

period can be reduced to six years if a drug no longer meets the criteria for Orphan Drug Designation or if the drug is sufficiently profitable such that market exclusivity is no longer justified.

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

***Our business operations and current and future relationships with investigators, health care professionals, consultants, third-party payors and customers will be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.***

Although we do not currently have any products on the market, if we obtain FDA approval for our product candidates, and begin commercializing those products in the United States, our operations may be directly, or indirectly through our prescribers, customers and third-party payors, subject to various U.S. federal and state healthcare laws and regulations, including, without limitation, the U.S. federal Anti-Kickback Statute, the U.S. federal civil and criminal false claims laws and the Physician Payments Sunshine Act and regulations. Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. These laws may impact, among other things, our current business operations, including our clinical research activities, and proposed sales, marketing and education programs and constrain the business of financial arrangements and relationships with healthcare providers, physicians and other parties through which we market, sell and distribute our products for which we obtain marketing approval. In addition, we may be subject to patient data privacy and security regulation by both the U.S. federal government and the states in which we conduct our business. Finally, we may be subject to additional healthcare, statutory and regulatory requirements and enforcement by comparable foreign regulatory authorities in jurisdictions in which we conduct our business. The laws that may affect our ability to operate include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe, or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal false claims and civil monetary penalties laws, including the civil False Claims Act, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting,

or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, and as amended again by the Modifications to the HIPAA Privacy, Security, Enforcement and Breach Notification Rules Under HITECH and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules, commonly referred to as the Final HIPAA Omnibus Rule, published in January 2013, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the Final HIPAA Omnibus Rule, i.e. health plans, healthcare clearinghouses and healthcare providers, as well as their business associates that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information;
- the U.S. Federal Food, Drug and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices; the U.S. federal legislation commonly referred to as Physician Payments Sunshine Act, enacted as part of the ACA, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the CMS information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- analogous state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and
- European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers.

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

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the delay, reduction, termination or 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.

***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. The regulatory approval process and other regulations we may be subject to in other jurisdictions in which we may operate are further described in the section of this prospectus titled "Business—Government Regulation."

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

The collection and use of personal health data in the European Union is governed by the provisions of the Data Protection Directive, and as of May 2018 the General Data Protection Regulation, or GDPR. These directives impose several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, notification of data processing obligations to the competent national data protection authorities and the security and confidentiality of the personal data. The Data Protection Directive and GDPR also impose strict rules on the transfer of personal data out of the European Union to the United States. Failure to comply with the requirements of the Data Protection Directive, the GDPR, and the related national data protection laws of the European Union Member States may result in fines and other administrative penalties. The GDPR introduces new data protection requirements in the European Union and substantial fines for breaches of the data protection rules. The GDPR regulations may impose additional responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with these and/or new data protection rules. This may be onerous and adversely affect our business, financial condition, prospects and results of operations.

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

Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the U.K. Bribery Act. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. The anti-bribery provisions of the FCPA are enforced primarily by the Department of Justice, or DOJ, and the Securities and Exchange Commission, or the SEC, in conjunction with enforcement of the books and records provisions of the FCPA and may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions. Recently the SEC and DOJ have increased their FCPA enforcement activities with respect to pharmaceutical companies. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA.

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

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

On December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act, or TCJA, that significantly reforms the Internal Revenue Code of 1986, as amended. The TCJA, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate

from a top marginal rate of 35% to a flat rate of 21%; limitation of the tax deduction for interest expense; limitation of the deduction for net operating losses and elimination of net operating loss carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such tax losses may be carried forward indefinitely); and modifying or repealing many business deductions and credits, including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as "orphan drugs". We continue to examine the impact this tax reform legislation may have on our business in the future. However, the TCJA did not have an impact on us and our affiliates due to our loss making situation. You are urged to consult your tax adviser regarding the implications of the TCJA on an investment in our common stock.

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

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

**Risks Related to Our Intellectual Property**

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

We are dependent on patents, know-how and proprietary technology, both our own and licensed from others. We license patents related to our VaxWave and TheraT technologies and certain other intellectual property rights from third parties, including from the University of Geneva, the University of Basel and the University of Zurich and expect in the future to be party to other material license or collaboration agreements. These agreements typically impose numerous obligations, such as diligence and payment obligations, including in relation to revenues we may receive from any sublicenses we grant in respect of the licensed patents. If we fail to comply with our obligations under these agreements, our licensors may have the right to terminate our licenses, in which event we might not be able to develop, manufacture or market any product that is covered by the intellectual property we in-license from such licensor and may face other adverse consequences. See "Business—License Agreements" for additional information regarding our license agreements. These licenses do and future licenses may also include provisions that impose obligations and restrictions on us that could delay or otherwise negatively impact a transaction that we may wish to enter into.

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

- the proper interpretation of the license agreement terms, including with respect to our right to sublicense patent rights and any other intellectual property rights to third parties and the amount of fees owed to the licensors as a result of such sublicenses;

- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how created by us and our partners using a combination of our own intellectual property and that licensed from our licensors.

In particular, we utilize the intellectual property rights we license from each of the University of Geneva, the University of Basel and the University of Zurich in connection with the development of our product candidates as well as in connection with our obligations under the Collaboration Agreement with Gilead. Those in-licensed intellectual property rights are also part of the rights that we license to Gilead pursuant to the Collaboration Agreement. We recently entered into a written agreement with each of the University of Geneva, the University of Basel and the University of Zurich to resolve a disagreement regarding the interpretation of certain provisions in the respective license agreements and the calculation of sublicense fees payable to the Universities in respect of the payments we receive from Gilead under the Collaboration Agreement. If we fail to comply with, or if we contest, the terms of this agreement, the Universities may seek to terminate the respective license agreements, which could materially and adversely affect our business operations.

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

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

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

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

Our success depends in large part on our ability to obtain and maintain patent protection with respect to our VaxWave technology, including our HB-101 product candidate, obtain patent protection with respect to our TheraT technology, including our HB-201, HB-202 and HB-301 product candidates, the vaccine product candidates we are developing with Gilead for HBV and HIV, and other proprietary product candidates. Although we own or license from others certain patent applications that cover the foregoing technologies and product candidates, we do not currently own or license from others issued patents covering all of the foregoing. Our reliance on patent applications carries certain risks associated with pending patent applications prior to the issuance of patents, as described below. If we do not adequately obtain and protect our intellectual property rights, competitors may be able to erode, negate or preempt any competitive advantage we may have, which could harm our business and ability to



achieve profitability. To protect our proprietary position, we file patent applications in the United States and abroad related to our product candidates that are important to our business. The patent application and approval process is expensive and time-consuming and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We cannot predict:

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

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

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

If we enter into additional collaboration agreements and strategic partnerships or license our product candidates, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects.

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

We and these third parties rely extensively on information technology systems to conduct and manage our business. Despite the implementation of security measures, our internal computer systems and those of our current and future CROs and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. The risk of a security breach or disruption, particularly through cyber attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, such as the loss of clinical trial data from completed or future clinical trials. Such loss could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. Any breach in our information technology systems could lead to the unauthorized access, disclosure and use of non-public information, including information from our patient registry or other patient information, which is protected by HIPAA, and other laws. Any such access, disclosure, or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, damage to our reputation and the further development and commercialization of our product candidates could be delayed.

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

Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates. Furthermore, for U.S. applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third-party or instituted by the USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. Various post grant review proceedings, such as *inter partes* review and post grant review, are available for any interested third party to challenge the patentability of claims issued in patents to us. These procedures are relatively new and can be unpredictable. It is also possible for third parties to file observations with various patent offices during the patent application process. In our European

patent application directed to our VaxWave technology, an unknown third party submitted such an observation. Despite that submission, the European Patent Office proceeded to grant our patent.

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

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

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

Third parties may assert that we are employing their proprietary technology without authorization. Generally, conducting clinical trials and certain other development activities in the United States is not considered an act of infringement. If and when HB-101 or another product candidate is approved by the FDA, a third party may then seek to enforce its patent by filing a patent infringement lawsuit against us. While we are aware of certain third party patents and applications that relate to similar subject matter as our technologies, we do not believe that any patent claims that could otherwise materially adversely affect commercialization of our product candidates, if approved, are valid and enforceable. We may be incorrect in this belief, or we may not be able to prove it in a litigation. In this regard, patents issued in the United States by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof. There may be third-party patents of which we are currently unaware which cover materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, we may fail to identify relevant patents or incorrectly conclude that a patent is invalid, not enforceable, exhausted, or not infringed by our activities. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process, or any final

product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license, which may not be available on commercially reasonable terms, if at all, or until such patent expires or is determined to be invalid or unenforceable. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business.

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

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

Presently we have rights to certain intellectual property, through licenses from third parties and under patent applications that we own or will own, related to HB-101 and certain other product candidates. Because additional product candidates may require the use of proprietary rights held by third parties, such as the rights to use certain antigens, specific to future disease targets, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights. In addition, while we have patent rights directed to certain VaxWave and TheraT technologies we may not be able to obtain intellectual property to all uses of VaxWave and TheraT technologies. Our product candidates may also require specific formulations to work effectively and efficiently and these rights may be held by others. Similarly, efficient production or delivery of our product candidates may also require specific compositions or methods, and the rights to these may be owned by third parties. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify. Even if we are able to obtain a license to use such intellectual property, it may be non-exclusive, which would not restrict the licensor party from giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. Moreover, the specific antigens that will be used with our product candidates may be covered by the intellectual property rights of others.

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

may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

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

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

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

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an

event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

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

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

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

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

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

Certain of our key patent families have been filed in the United States, as well as in numerous jurisdictions outside the United States. However, our intellectual property rights in certain jurisdictions outside the United States may be less robust. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and

state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may export otherwise infringing products to territories where we have patent protection. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Most of our patent portfolio is at the very early stage. We will need to decide whether and in which jurisdictions to pursue protection for the various inventions in our portfolio prior to applicable deadlines.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, and contractors. These agreements generally provide that inventions conceived by an employee, consultant, or contractor, as applicable, in the course of rendering services to us will be our exclusive property. However, those agreements may not be honored and may not effectively assign intellectual property rights to us. We may face claims by third parties that our agreements with employees, contractors or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such intellectual property. Moreover, there may be some circumstances, where we are unable to negotiate for such ownership rights. Disputes regarding ownership or inventorship of intellectual property can also arise in other contexts, such as collaborations and sponsored research. We may be subject to claims that former collaborators or other third parties have an ownership interest in our patents or other intellectual property. If we are subject to a dispute challenging our rights in or to patents or other intellectual property, such a dispute could be expensive and time-consuming. If we are unsuccessful, we could lose valuable rights in intellectual property that we regard as our own.

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

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers or our consultants' or contractors' current or former clients or customers. Litigation may be

necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees from their normal responsibilities. If we are not successful, in addition to paying monetary damages, we could lose access or exclusive access to valuable intellectual property and personnel.

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

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

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

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

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

***The contractual obligations of our Chief Scientific Officer to the University of Basel may present conflicts of interest.***

Daniel Pinschewer, M.D., our Chief Scientific Officer, provides research services to us pursuant to a consulting agreement. Dr. Pinschewer is also an employee of the University of Basel where he engages in, among other activities, academic research related to *Arenaviruses* and our technology



platform. Pursuant to a separate research service agreement with the University of Basel, the university provides us with on-going services with respect to our technologies, and employs the services of Dr. Pinschewer to perform some of these services. As an employee of the University of Basel, Dr. Pinschewer is subject to the university's rules of conduct, such as confidentiality, academic objectivity and transparency of research with respect to his academic research. As a result of Dr. Pinschewer's obligations to the University of Basel and his role as our Chief Scientific 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. See the section titled "Certain Relationships and Related Party Transaction—Agreements with the University of Basel."

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

We are highly dependent on members of our executive team. The loss of the services of any of them may adversely impact the achievement of our objectives. Although we have formal employment agreements with our executive officers, any of our executive officers could leave our employment at any time, or within a contractual termination period that is too short to find an adequate replacement. We currently do not have "key person" insurance on any of our employees. The loss of the services of one or more of our current employees might impede the achievement of our research, development and commercialization objectives.

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

To induce valuable employees to join and remain at our company, in addition to salary and cash incentives, we have provided, and intend to continue to provide, stock options that vest over time. The value of these equity grants that vest over time to our employees may be significantly affected by movements in the fair market value of our capital stock that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies.

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

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

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

As of February 28, 2019, we had 60 full-time employees. As our development and commercialization plans and strategies develop, and as we transition into operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel, as well as additional facilities to expand our operations. Future growth would impose significant added responsibilities on members of management, including:

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

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

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

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

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

We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee 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.

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

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

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

## **Risks Related to This Offering and Ownership of Our Common Stock**

***We do not know whether an active, liquid and orderly trading market will develop for our common stock or what the market price of our common stock will be and as a result it may be difficult for you to sell your shares of our common stock.***

Prior to this offering, there was no public trading market for shares of our common stock. Although we have been approved for listing on The Nasdaq Global Select Market, an active trading market for our shares may never develop or be sustained following this offering. 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. The initial public offering price may not be indicative of the market price of the common stock after the offering. As a result of these and other factors, you may be unable to resell your shares of our common stock at or above the initial public offering price. 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.

***If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.***

The initial public offering price is substantially higher than the net tangible book value per share of our common stock. Investors purchasing common stock in this offering will pay a price per share that substantially exceeds the book value of our tangible assets after subtracting our liabilities. As a result, investors purchasing common stock in this offering will incur immediate dilution of \$7.84 per share, based on the initial public offering price of \$14.00 per share. Further, investors purchasing common stock in this offering will contribute approximately 37% of the total amount invested by stockholders since our inception, but will own only approximately 24% of the total number of shares of our common stock outstanding after this offering.

This dilution is due to our investors who purchased shares prior to this offering having paid substantially less when they purchased their shares than the price offered to the public in this offering and the exercise of stock options granted to our employees. To the extent that outstanding stock options are exercised, there will be further dilution to new investors. As a result of the dilution to investors purchasing common stock in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of our liquidation. For a further description of the dilution that you will experience immediately after this offering, see "Dilution."

***The price of our stock may be volatile, and you could lose all or part of your investment.***

The trading price of our common stock following this offering is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this prospectus, these factors include:

- the commencement, enrollment or results of the clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- adverse results or delays in clinical trials;

- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- our inability to establish collaborations if needed;
- our failure to commercialize our product candidates;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- the size and growth of our initial cancer target markets;
- our ability to successfully treat additional types of cancers or at different stages;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or immunotherapy in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and The Nasdaq Global Select Market and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. If the market price of our common stock after this offering does not exceed the initial public offering price, you may not realize any return on your investment in us and may lose some or all of your investment. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition.

***If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.***

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, 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 will be able to 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 will be decided by the vote of holders of our common stock. Prior to this offering, our executive officers, directors, and 5% stockholders beneficially owned approximately 77.8% of our voting stock as of February 28, 2019, and, based on the initial public offering price of \$14.00 per share, that same group will hold approximately 60.0% of our outstanding voting stock (assuming no exercise of the underwriters' option to purchase additional shares and that all outstanding shares of our preferred stock convert into shares of voting common stock upon the closing of this offering). These stockholders may be able to determine all 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 that you may feel are in your best interest as one of our stockholders.

Certain of our existing stockholders, directors and their affiliated entities have indicated an interest in purchasing an aggregate of up to approximately \$55.0 million in shares of our common stock in this offering at the initial public offering price per share and on the same terms as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares in this offering. The foregoing discussion does not reflect any potential purchases by these potential purchasers.

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

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

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

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

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which will require, among other things, that we file with the SEC, annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and The Nasdaq Global Select Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices.

Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years from the pricing of this offering. We intend to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

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

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up and other legal restrictions on resale discussed in this prospectus lapse, the trading price of our common stock could decline. Based on the number of shares of common stock outstanding as of February 28, 2019 upon the closing of this offering, we will have outstanding a total of 25,408,488 shares of common stock (without giving effect to the conversion of 328,071 shares of preferred stock in to 3,819,732 shares of Class A common stock upon the closing of this offering). Of these shares, only the shares of common stock sold in this offering by us, plus any shares sold upon exercise of the underwriters' option to purchase additional shares, will be freely tradable without restriction in the public market immediately following this offering, unless purchased by our affiliates. Merrill Lynch, Pierce, Fenner & Smith Incorporated and SVB Leerink LLC, however, may, in their sole discretion, permit our officers, directors, and other stockholders who are subject to these lock-up agreements to sell shares prior to the expiration of the lock-up agreements.

Certain of our existing stockholders, directors and their affiliated entities have indicated an interest in purchasing an aggregate of up to approximately \$55.0 million in shares of our common stock in this offering at the initial public offering price per share and on the same terms as the other purchasers in this offering. Any such shares purchased by stockholders who are considered to be our affiliates cannot be resold in the public market immediately following this offering as a result of restrictions under securities laws, but will be able to be sold following the expiration of these restrictions as described in the "Shares Eligible for Future Sale" section of this prospectus.

The lock-up agreements pertaining to this offering will expire 180 days from the date of this prospectus. In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our 2019 Stock Option Incentive Plan will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up



agreements and Rule 144 and Rule 701 under the Securities Act of 1933, as amended, or the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

After this offering, the holders of 18,401,893 shares of our common stock as of December 31, 2018 will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the 180-day lock-up agreements described above. See "Description of Capital Stock—Registration Rights." Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

***We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.***

Our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in the section entitled "Use of Proceeds," and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our management might not apply our net proceeds in ways that ultimately increase or maintain the value of your investment. We expect to use the net proceeds from this offering, together with our existing cash and cash equivalents, to advance the development of our clinical and preclinical product candidates and to fund working capital, including general operating expenses. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from this offering in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest or apply the net proceeds from this offering in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

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

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

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

- the timing and cost of, and level of investment in, research and development activities relating to our current and any future product candidates, which will change from time to time;
- the timing and outcomes of clinical trials for our current and any other future product candidates;
- the cost of manufacturing our current and any future product candidates, which may vary depending on FDA guidelines and requirements, the quantity of production and the terms of our agreements with manufacturers;

- our ability to adequately support our future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic environment.

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

***We 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, which are to become effective upon the closing of this offering and upon the effectiveness of the registration statement of which this prospectus is a part, respectively, will contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

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

outstanding shares of our voting stock to amend specific provisions of our certificate of incorporation; and

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

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

***Our amended and restated bylaws will designate the Court of Chancery of the State of Delaware, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.***

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

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

Upon the closing of this offering, we will become subject to the periodic reporting requirements of the Exchange Act. We are continuing to refine our disclosure controls and procedures to provide reasonable assurance that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed,

summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

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

***We have identified material weaknesses in our internal control over financial reporting. If our remediation of these material weaknesses is not effective, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.***

Prior to this offering, we have been a private company with limited accounting personnel and other resources with which to address our internal control over financial reporting. In connection with our preparation and the audits of our financial statements as of and for the years ended December 31, 2017 and 2018, we and our independent registered public accounting firm identified two material weaknesses as defined under the Exchange Act and by the Public Company Accounting Oversight Board (United States) in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual financial statements will not be prevented or detected on a timely basis. We did not maintain a sufficient complement of resources with an appropriate level of accounting knowledge, experience, and training, which would allow for appropriate monitoring, presentation and disclosure, and internal control over financial reporting. Specifically, we have not designed and implemented a sufficient level of formal accounting policies and procedures. Additionally, the limited personnel resulted in our inability to consistently establish appropriate authorities and responsibilities in pursuit of our financial reporting objectives, as demonstrated by, amongst other things, our insufficient segregation of duties in their finance and accounting functions. In connection with the preparation and the audit of our financial statements as of and for the year ended December 31, 2018, we determined that the two previously identified material weaknesses had not been remediated.

Neither our management nor an independent registered public accounting firm has performed an evaluation of our internal control over financial reporting in accordance with the provision of the Sarbanes-Oxley Act because no such evaluation has been required. Had we or our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, additional material weaknesses may have been identified.

Once public, we will be subject to reporting obligations under U.S. securities laws and the Sarbanes-Oxley Act. Section 404 of the Sarbanes-Oxley Act will require that we include a report from management on the effectiveness of our internal control over financial reporting in our annual report on Form 10-K beginning with our annual report for the fiscal year ending December 31, 2020. If we fail to remediate the material weaknesses identified above, our management may conclude that our internal control over financial reporting is not effective. This conclusion could adversely impact the market price of our shares due to a loss of investor confidence in the reliability of our reporting processes.

We have begun taking measures and plan to continue to take measures to remediate these material weaknesses. However, the implementation of these measures may not fully address these material weaknesses in our internal control over financial reporting, and therefore we would not be

able to conclude that it has been fully remedied. Our failure to correct these material weaknesses or our failure to discover and address any other control deficiencies could result in inaccuracies in our financial statements and could also impair our ability to comply with applicable financial reporting requirements and make related regulatory filings on a timely basis. As a result, our business, financial condition, results of operations and prospects, as well as the trading price and listing of our shares, may be materially and adversely affected. We cannot assure you that all of our existing material weaknesses have been identified, or that we will not in the future identify additional material weaknesses.

***If we fail to establish and maintain proper and effective internal control over financial reporting, our operating results and our ability to operate our business could be harmed.***

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. In connection with this offering, we intend to begin the process of documenting, reviewing and improving our internal controls and procedures for compliance with Section 404 of the Sarbanes-Oxley Act, which will require annual management assessment of the effectiveness of our internal control over financial reporting. We have begun recruiting additional finance and accounting personnel with certain skill sets that we will need as a public company. Our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting until the later of our second annual report or the first annual report required to be filed with the SEC following the date we are no longer an emerging growth company, depending on whether we choose to rely on certain exemptions set forth in the JOBS Act.

Implementing any appropriate changes to our internal controls, including compliance with the requirements of Section 404 of the Sarbanes-Oxley Act, may distract our officers and employees, entail substantial costs to modify our existing processes and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and harm our business. In addition, investors' perceptions that our internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis may harm our stock price, make it more difficult for us to effectively market and sell our service to new and existing customers and subject us to sanctions or investigations by The Nasdaq Stock Market LLC, the SEC or other regulatory authorities. In addition, our common stock may not be able to remain listed on The Nasdaq Global Select Market or any other securities exchange.

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections entitled "Prospectus Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and "Business," contains express or implied forward-looking statements that are based on our management's belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this prospectus include, but are not limited to, statements about:

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

- our expectations regarding use of the proceeds from this offering.

In some cases, forward-looking statements can be identified by terminology, such as "may," "will," "should," "expects," "intends," "project," "target," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue," or the negative of these terms or other comparable terminology. These statements are only predictions and are based largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under "Risk Factors" and elsewhere in this prospectus. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance. You should read this prospectus and the documents that we reference in this prospectus and have filed with the Securities and Exchange Commission as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

The forward-looking statements in this prospectus represent our views as of the date of this prospectus. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this prospectus.

## **INDUSTRY AND MARKET DATA**

We obtained the industry, statistical and market data in this prospectus from our own internal estimates and research as well as from industry and general publications and research, surveys and studies conducted by third parties. Industry publications, studies and surveys generally state that they have been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. All of the market data used in this prospectus involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such data. While we believe our internal company research as to such matters is reliable and the market definitions are appropriate, neither such research nor these definitions have been verified by any independent source. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of important factors, including those described in the section titled "Risk Factors." These and other factors could cause results to differ materially from those expressed in the estimates made by third parties and by us.

## USE OF PROCEEDS

We estimate that our net proceeds from the sale of shares of our common stock in this offering will be approximately \$74.8 million, or \$86.5 million if the underwriters exercise in full their option to purchase additional shares, based on the initial public offering price of \$14.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

We currently estimate that we will use the net proceeds from this offering, together with our existing cash and cash equivalents, as follows:

- approximately \$20.0 million to advance HB-101 through completion of our ongoing Phase 2 clinical trial;
- approximately \$40.0 million to advance HB-201 and HB-202 into and through completion of Phase 1 clinical trials;
- approximately \$27.0 million to advance HB-301 into and through completion of a Phase 1 clinical trial;
- approximately \$20.0 million for ongoing research and development activities related to next generation programs; and
- the remainder for working capital and other general corporate purposes.

Based on our current plans, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to fund our operations for at least the next 12 months. We have based this estimate on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect.

This expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the closing of this offering or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual expenditures and the extent of clinical development may vary significantly depending on numerous factors, including the progress of our development, the status of and results from preclinical studies or clinical trials we may commence in the future, as well as any collaborations that we may enter into with third parties for our product candidates, and any unforeseen cash needs. We may also use a portion of the net proceeds to in-license, acquire, or invest in additional businesses, technologies, products or assets, although currently we have no specific agreements, commitments or understandings in this regard. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

Pending our use of proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation instruments, including short-term, investment-grade, interest-bearing instruments and U.S. government securities.



## **DIVIDEND POLICY**

We have never declared or paid cash dividends on our common stock. We intend to retain all available funds and any future earnings to fund the growth and development of our business. We do not intend to pay cash dividends to our stockholders in the foreseeable future. In addition, any future financing instruments could preclude us from paying dividends. Any future determination to pay dividends will be made at the discretion of our board of directors subject to applicable laws, and will depend upon, among other factors, our results of operations, financial condition, contractual restrictions and capital requirements. Investors should not purchase our common stock with the expectation of receiving cash dividends.

## CAPITALIZATION

The following table sets forth our cash and cash equivalents and our capitalization as of December 31, 2018:

- on an actual basis;
- on a pro forma basis to give effect to:
  - our sale of 257,000 shares of Series D redeemable convertible preferred stock in February 2019 for gross proceeds of \$37.4 million;
  - the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 18,401,893 shares of common stock upon the closing of this offering; and
  - the filing and effectiveness of our amended and restated certificate of incorporation, which will occur upon the closing of this offering; and
- on a pro forma as adjusted basis to give further effect to our issuance and sale of 6,000,000 shares of our common stock in this offering at the initial public offering price of \$14.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

Net proceeds assumed in this offering are \$74.8 million after deducting underwriting discounts and commissions and estimated offering expenses payable by us. As of December 31, 2018, deferred offering expenses classified as other non-current assets were \$1.5 million, of which \$0.2 million had been paid and \$1.3 million were accrued in current liabilities. You should read this table together with our consolidated financial statements and the related notes appearing elsewhere in this prospectus and the "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of this prospectus.

|  | As of December 31, 2018                            |           |                          |
|--|--|-----------|--------------------------|
|  | Actual   | Pro Forma | Pro Forma As<br>Adjusted |
|  | (in thousands, except share and per<br>share data) |           |                          |
| Cash and cash equivalents  | \$ 48,580  | \$ 85,857 | \$ 160,856               |
| Loans payable, net of discount   | \$ 4,392   | \$ 4,392  | \$ 4,392                 |
| Redeemable convertible preferred stock (Series A, B and C), par value \$0.0001 per share; 1,323,506 shares authorized, issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted  | 104,774  | —         | —                        |
| Stockholders' equity (deficit):  |  |           |                          |
| Preferred stock, \$0.0001 par value per share; no shares authorized, issued or outstanding, actual; 10,000,000 shares authorized, no shares issued or outstanding, pro forma and pro forma as adjusted   | —  | —         | —                        |
| Common stock, par value \$0.0001 per share; 18,454,860 shares authorized, 1,006,595 shares issued and outstanding, actual; 25,614,706 shares authorized, 19,408,488 shares issued and outstanding, pro forma; 100,000,000 shares authorized, 25,408,488 shares issued and outstanding, pro forma as adjusted | 0  | 2         | 3                        |
| Class A common stock, par value \$0.0001 per share, no shares authorized, no shares issued and outstanding, actual; 1,632,466 shares authorized, no shares issued and outstanding, pro forma; 3,900,000 shares authorized, no shares issued and outstanding, pro forma as adjusted                           | —  | —         | —                        |
| Additional paid-in capital   | 3,327  | 145,377   | 220,196                  |
| Accumulated other comprehensive (loss) income  | (3,720)  | (3,720)   | (3,720)                  |
| Accumulated deficit  | (59,982)   | (59,982)  | (59,982)                 |
| Total stockholders' equity (deficit)   | (60,375)   | 81,676    | 156,497                  |
| Total capitalization   | \$ 48,791  | \$ 86,068 | \$ 160,889               |

The table above does not include:

- 1,606,325 shares of our common stock issuable upon the exercise of stock options under our 2018 Stock Option and Grant Plan, or the 2018 Plan, outstanding as of December 31, 2018, at a weighted average exercise price of \$1.95 per share;
- 432,294 shares of our common stock available for future issuance under our 2018 Plan as of December 31, 2018;
- 2,608,042 shares of our common stock that will become available for future issuance under our 2019 Stock Option and Incentive Plan, which will become effective in connection with the closing of this offering;
- 260,804 shares of our common stock that will become available for future issuance under our 2019 Employee Stock Purchase Plan, which will become effective in connection with the closing of this offering; and
- the conversion of 328,071 shares of our preferred stock into 3,819,732 shares of Class A common stock upon the closing of this offering.

## DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

Our historical net tangible book value (deficit) as of December 31, 2018 was \$(61.9) million, or \$(61.53) per share of common stock. Our historical net tangible book value (deficit) is the amount of our total tangible assets less our total liabilities and the carrying value of our preferred stock, which is not included within stockholders' equity (deficit). Historical net tangible book value (deficit) per share represents historical net tangible book value (deficit) divided by 1,006,595 shares of common stock outstanding as of December 31, 2018.

Our pro forma net tangible book value as of December 31, 2018 was \$80.1 million, or \$4.13 per share of common stock. Pro forma net tangible book value represents the amount of our total tangible assets less our total liabilities, after giving effect to (i) our sale of 257,000 shares of Series D redeemable convertible preferred stock in February 2019 for gross proceeds of \$37.4 million, (ii) the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 18,401,893 shares of voting common stock upon the closing of this offering and (iii) no issuances of shares of Class A common stock upon the closing of this offering. Pro forma net tangible book value per share represents pro forma net tangible book value divided by the total number of shares outstanding as of December 31, 2018, after giving effect to the pro forma adjustment described above.

After giving further effect to our issuance and sale of 6,000,000 shares of our common stock in this offering at the initial public offering price of \$14.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of December 31, 2018 would have been \$156.4 million, or \$6.16 per share of common stock. This represents an immediate increase in pro forma as adjusted net tangible book value per share of \$2.03 to existing stockholders and immediate dilution of \$7.84 in pro forma as adjusted net tangible book value per share to new investors purchasing common stock in this offering. Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the initial public offering price per share paid by new investors. The following table illustrates this dilution on a per share basis:

|  |                |
|--|----------------|
| Initial public offering price per share  | \$ 14.00       |
| Historical net tangible book value (deficit) per share as of December 31, 2018   | \$ (61.53)     |
| Increase (decrease) per share attributable to the pro forma adjustment described above   | 65.66          |
| Pro forma net tangible book value (deficit) per share as of December 31, 2018  | 4.13           |
| Increase in pro forma as adjusted net tangible book value per share attributable to new investors purchasing common stock in this offering | 2.03           |
| Pro forma as adjusted net tangible book value per share after this offering  | 6.16           |
| Dilution per share to new investors purchasing common stock in this offering   | <u>\$ 7.84</u> |

If the underwriters exercise their option to purchase additional shares in full, our pro forma as adjusted net tangible book value per share after this offering would be \$6.39, representing an immediate increase in pro forma as adjusted net tangible book value per share of \$0.23 to existing stockholders and immediate dilution in pro forma as adjusted net tangible book value per share of \$0.23 to new investors purchasing common stock in this offering, based on the initial public offering price of \$14.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The following table summarizes, as of December 31, 2018, on the pro forma as adjusted basis described above, the total number of shares purchased from us on an as converted to common stock basis (assuming all of the outstanding preferred stock convert into shares of voting common stock), the total consideration paid or to be paid, and the average price per share paid or to be paid by existing stockholders and by new investors in this offering, based on the initial public offering price of \$14.00 per share, before deducting underwriting discounts and commissions and estimated offering expenses payable by us. As the table shows, new investors purchasing common stock in this offering will pay an average price per share substantially higher than our existing stockholders paid.

|                       | Shares Purchased |         | Total Consideration |            | Average Price Per Share |
|-----------------------|------------------|---------|---------------------|------------|-------------------------|
|                       | Number           | Percent | Amount              | Percentage |                         |
| Existing stockholders | 19,408,488       | 76.4%   | \$ 142,567,049      | 62.9%      | \$ 7.35                 |
| New investors         | 6,000,000        | 23.6    | 84,000,000          | 37.1       | \$ 14.00                |
| Total                 | 25,408,488       | 100.0%  | \$ 226,567,049      | 100.0%     |                         |

Certain of our existing stockholders, directors and their affiliated entities have indicated an interest in purchasing an aggregate of up to approximately \$55.0 million in shares of our common stock in this offering at the initial public offering price per share and on the same terms as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares in this offering. The table above does not reflect any potential purchases by these potential purchasers.

The table above assumes no exercise of the underwriters' option to purchase additional shares in this offering. If the underwriters' option to purchase additional shares is exercised in full, the number of shares of our common stock held by existing stockholders would be reduced to 73.8% of the total number of shares of our common stock outstanding after this offering, and the number of shares of common stock held by new investors purchasing common stock in this offering would be increased to 26.2% of the total number of shares of our common stock outstanding after this offering.

The number of shares purchased from us by existing stockholders is based on 19,408,488 shares of our common stock outstanding as of December 31, 2018, after giving effect to (i) our sale of 257,000 shares of Series D redeemable convertible preferred stock in February 2019 for gross proceeds of \$37.4 million, (ii) the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 18,401,893 shares of voting common stock upon the closing of this offering and (iii) no issuances of shares of Class A common stock upon the closing of this offering, and excludes:

- 1,606,325 shares of our common stock issuable upon the exercise of stock options outstanding under our 2018 Stock Option and Grant Plan, or the 2018 Plan, as of December 31, 2018, at a weighted average exercise price of \$1.95 per share;
- 432,294 shares of our common stock available for future issuance under our 2018 Plan as of December 31, 2018;
- 2,608,042 shares of our common stock that will become available for future issuance under our 2019 Stock Option and Incentive Plan, which will become effective in connection with the closing of this offering;
- 260,804 shares of our common stock that will become available for future issuance under our 2019 Employee Stock Purchase Plan, which will become effective in connection with the closing of this offering; and

- the conversion of 328,071 shares of our preferred stock into 3,819,732 shares of Class A common stock upon the closing of this offering.

To the extent that outstanding stock options are exercised, new stock options are issued, or we issue additional shares of common stock in the future, there will be further dilution to new investors. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

## SELECTED CONSOLIDATED FINANCIAL DATA

We have derived the consolidated statement of operations data for the years ended December 31, 2017 and 2018 and the consolidated balance sheet data as of December 31, 2017 and 2018 from our audited consolidated financial statements appearing at the end of this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future. You should read the following selected consolidated financial data together with our consolidated financial statements and the related notes appearing elsewhere in this prospectus and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this prospectus.

| (in thousands, except share and per share data)   | Year ended<br>December 31, |            |
|---|----------------------------|------------|
|   | 2017                       | 2018       |
| <b>Consolidated Statements of Operations Data:</b>  |                            |            |
| Revenue from collaboration and licensing  | \$ —                       | \$ 7,629   |
| Operating expenses:   |                            |            |
| Research and development  | (9,772)                    | (21,965)   |
| General and administrative  | (4,385)                    | (6,844)    |
| Total operating expenses  | (14,157)                   | (28,809)   |
| Loss from operations  | (14,157)                   | (21,180)   |
| Other income (expense):   |                            |            |
| Grant income  | 2,069                      | 5,612      |
| Interest expense  | (606)                      | (778)      |
| Other income and expenses, net  | (25)                       | 133        |
| Total other income (expense), net   | 1,438                      | 4,967      |
| Net loss before tax   | (12,719)                   | (16,213)   |
| Income tax expense  | (4)                        | (24)       |
| Net loss  | (12,723)                   | (16,237)   |
| Net loss per share attributable to common stockholders—basic and diluted(1)                       | \$ (13.95)                 | \$ (17.76) |
| Weighted average common shares outstanding—basic and diluted(1)                                   | 911,777                    | 914,375    |
| Pro forma net loss per share attributable to common shareholders—basic and diluted (unaudited)(1) |                            | \$ (0.99)  |
| Pro forma weighted average common shares outstanding—basic and diluted (unaudited)(1)             |                            | 16,324,008 |

- (1) See Note 2 and Note 13 to our consolidated financial statements appearing at the end of this prospectus for further details on the calculation of basic and diluted net loss per share attributable to common shareholders and on the calculation of basic and diluted net loss per share attributable to common shareholders.

|   | As of December 31, |           |
|---|--------------------|-----------|
|   | 2017               | 2018      |
|   | (in thousands)     |           |
| <b>Consolidated Balance Sheet Data:</b> |                    |           |
| Cash and cash equivalents               | \$ 61,362          | \$ 48,580 |
| Working capital(1)                      | 65,923             | 47,616    |
| Total assets                            | 73,732             | 68,251    |
| Redeemable convertible preferred stock  | 104,774            | 104,774   |
| Accumulated deficit                     | (43,745)           | (59,982)  |
| Total stockholders' equity (deficit)    | (42,656)           | (60,375)  |

- (1) We define working capital as current assets less current liabilities.

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read the following discussion and analysis of our financial condition and results of operations together with the section titled "Selected Consolidated Financial Data" and our audited consolidated financial statements and related notes included elsewhere in this prospectus. This discussion and other parts of this prospectus contain forward-looking statements that involve risks and uncertainties, such as our plans, objectives, expectations, intentions and beliefs. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in the section titled "Risk Factors" included elsewhere in this prospectus. For convenience of presentation, some of the numbers have been rounded in the text below.*

### Overview

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

Our lead infectious disease product candidate, HB-101, is in a Phase 2 clinical trial in cytomegalovirus-negative patients awaiting kidney transplantation from living cytomegalovirus-positive donors. Our lead oncology product candidates, HB-201 and HB-202, are in development for the treatment of human papillomavirus-positive cancers. We plan to file an investigational new drug application, or IND, with the U.S. Food and Drug Administration, or the FDA, for HB-201 and HB-202 in the first half of 2019 and 2020, respectively. We have also entered into a strategic partnership with Gilead Sciences, Inc., or Gilead, to accelerate building a pipeline of additional infectious disease product candidates in a cost efficient manner.

We have funded our operations to date primarily from private placements of our redeemable convertible preferred stock, with aggregate gross proceeds of approximately \$105.0 million, grant funding and loans from an Austrian government agency, and \$12.8 million in upfront and milestone payments from Gilead in connection with a research collaboration and license agreement. We do not expect to generate revenue from any product candidates that we develop until we obtain regulatory approval for one or more of such product candidates, if at all, and commercialize our products or enter into additional collaboration agreements with third parties. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

All of our product candidates, including our most advanced product candidate, HB-101, will require substantial additional development time and resources before we would be able to apply for and receive regulatory approvals and begin generating revenue from product sales. Before launching our first products, if approved, we plan to establish our own manufacturing facility to minimize or eliminate our reliance on contract manufacturing organizations, or CMOs, which will require substantial capital expenditures and cause additional operating expenses. We currently have no marketing and sales organization and have no experience in marketing products; accordingly, we will incur significant expenses to develop a marketing organization and sales force in advance of generating any commercial product sales. As a result, we will need substantial additional capital to support our operating activities. In addition, upon the closing of this offering we expect to incur additional legal, accounting and other



expenses in operating our business, including the additional costs associated with operating as a public company.

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

We have incurred net losses each year since inception, including net losses of \$12.7 million for the year ended December 31, 2017 and \$16.2 million for the year ended December 31, 2018. As of December 31, 2017 and 2018, we had an accumulated deficit of \$43.7 million and \$60.0 million, respectively, and we do not expect positive cash flows from operations in the foreseeable future. We expect to continue to incur net operating losses for at least the next several years as we advance our product candidates through clinical development, seek regulatory approval, prepare for and, if approved, proceed to commercialization, continue our research and development efforts and invest to establish a commercial manufacturing facility.

## **Components of Our Operating Results**

### ***Revenue from collaboration and licensing***

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

On June 4, 2018, we entered into a Research Collaboration and License Agreement, or the Collaboration Agreement, with Gilead to evaluate potential vaccine products using or incorporating our TheraT technology and VaxWave technology for the treatment, cure, diagnosis or prevention of hepatitis B virus, or HBV, and the human immunodeficiency virus, or HIV.

Under the Collaboration Agreement, we granted Gilead an exclusive, royalty-bearing license to our technology platform for researching, developing, manufacturing or commercializing products for HIV or HBV. We received a non-refundable \$10.0 million upfront payment upon entering the Collaboration Agreement. Gilead is also obligated to reimburse us for our cost, including all benefits, travel, overhead, and any other expenses, of performing research and development under the agreement and to make additional payments to us upon the achievement of preclinical, development and commercial milestones. We are eligible for up to \$140.0 million in developmental milestone payments for each of the HBV and HIV programs and up to \$50.0 million in commercialization milestone payments for each of the HBV and HIV programs. Additionally, Gilead is obligated to pay royalties of a high single-digit to low-teens percentage on the worldwide net sales of each HBV product, and royalties of a mid-single-digit to low-teens percentage of worldwide net sales of each HIV product.

We determined that our performance obligations under the terms of the Collaboration Agreement included one combined performance obligation for each of the HBV and HIV research programs, comprised of the transfer of intellectual property rights and providing research and development services. Accordingly, we recognize these amounts as revenue over the performance period of the respective services on a percent of completion basis using total estimated research and development labor hours for each of the performance obligations.

Through December 31, 2018, we have received from Gilead the non-refundable upfront payment of \$10.0 million discussed above and \$0.9 million of cost reimbursements for research and development services performed during the period. In December 2018, we achieved the first pre-clinical

milestone under the HIV program, entitling us to a payment of \$2.8 million from Gilead, which we received in January 2019. During the year ended December 31, 2018 we recognized revenue of \$7.6 million under the Collaboration Agreement, which included recognition of \$2.8 million of the upfront payment from collaboration and licensing, \$2.0 million in cost reimbursements for research and development services and \$2.8 million for the achievement of the first pre-clinical milestone.

### ***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 and conducting a Phase 1 clinical trial for HB-101. Research and development activities account for a significant portion of our operating expenses. Research and development costs are expensed as incurred. These costs include:

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

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

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

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

- successful completion of preclinical studies and clinical trials;

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

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

#### ***General and Administrative Expenses***

Our general and administrative expenses consist primarily of personnel costs in our executive, finance, business development and administrative functions. Other general and administrative expenses include consulting fees and professional service fees for auditing, tax and legal services, rent expenses related to our offices, 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 support our operations as a public company, including increased expenses related to legal, accounting,

regulatory and tax-related services associated with maintaining compliance with requirements of the Nasdaq Global Select Market and the Securities and Exchange Commission, or the SEC, directors and officers liability insurance premiums and investor relations activities.

### **Grant Income**

Since inception, we have received grants from an Austrian government agency, either under funding agreements or under research incentive programs. In addition, we have received loans under funding agreements that bear interest at below market interest rate. We account for the grants received as other income and for the imputed benefits arising from the difference between a market rate of interest and the rate of interest as additional grant income, and record interest expense for the loans at a market rate of interest.

### **Interest Expense**

Interest expense results primarily from loans under funding agreements with the Austrian Research Promotion Agency, recorded at a market rate of interest. The difference between interest payments payable pursuant to the loans, which rates are at below market interest rates, and the market interest rate, is accounted for as grant income.

### **Income Taxes**

Income tax expense results from foreign minimum income tax and profit on a legal entity basis. The losses that we have incurred since inception result primarily from the losses of our Austrian subsidiary. As of December 31, 2018, we had foreign net operating loss carryforwards of \$76.0 million with no expiry date, resulting in a deferred tax asset of \$19.2 million. We have considered that it is more likely than not that we will not realize the benefits of the deferred tax asset, and accordingly, established a full valuation allowance as of December 31, 2018.

### **Results of Operations**

The following table sets forth the significant components of our results of operations (in thousands):

|  | <u>Year ended December 31,</u> |                    |
|--|--------------------------------|--------------------|
|  | <u>2017</u>                    | <u>2018</u>        |
| Revenue from collaboration and licensing | \$ —                           | \$ 7,629           |
| Operating expenses:                      |                                |                    |
| Research and development                 | (9,772)                        | (21,965)           |
| General and administrative               | (4,385)                        | (6,844)            |
| Total operating expenses                 | <u>(14,157)</u>                | <u>(28,809)</u>    |
| Loss from operations                     | (14,157)                       | (21,180)           |
| Other income (expense):                  |                                |                    |
| Grant income                             | 2,069                          | 5,612              |
| Interest expense                         | (606)                          | (778)              |
| Other income and expenses, net           | (25)                           | 133                |
| Total other income (expense), net        | <u>1,438</u>                   | <u>4,967</u>       |
| Net loss before tax                      | (12,719)                       | (16,213)           |
| Income tax expense                       | (4)                            | (24)               |
| Net loss                                 | <u>\$ (12,723)</u>             | <u>\$ (16,237)</u> |

**Revenue from collaboration and licensing**

We had no revenue for the year ended December 31, 2017.

Revenue for the year ended December 31, 2018 was \$7.6 million, which resulted from collaboration and licensing under the Collaboration Agreement. This included \$2.0 million from reimbursement of research and development expenses, \$2.8 million from partial recognition of revenue related to the upfront payment of \$10.0 million that we received in June 2018 and \$2.8 million of revenue that was recognized upon the achievement of a research milestone in December 2018.

**Research and Development Expenses**

For the year ended December 31, 2017, our research and development expenses were \$9.8 million, compared to \$22.0 million for the year ended December 31, 2018. Direct expenses for outside services, consultants and materials due to the preparations for the Phase 2 clinical trials for our HB-101 program and due to the increased costs for manufacturing of clinical trial material for our HB-201 and HB-202 programs. The primary driver of the increase was direct research and development expenses of \$9.3 million. In addition, costs related to the start of our collaboration with Gilead and the expansion of earlier stage projects, also contributed to the increase in direct expenses.

Personnel related research and development expenses for the years ended December 31, 2017 and 2018 were \$3.8 million and \$5.7 million, respectively. This increase of \$1.9 million was primarily a result of our increased research and development headcount. Facility related research and development expenses and other internal costs increased by \$0.4 million and \$0.6 million, respectively in the year ended December 31, 2018 and were due to the expansion of laboratory space and our increased research and development headcount.

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

|   | <u>Year ended December 31,</u> |                  |
|---|--------------------------------|------------------|
|   | <u>2017</u>                    | <u>2018</u>      |
| <b>Direct research and development expenses by program:</b> |                                |                  |
| HB-101  | \$ 1,185                       | \$ 4,232         |
| HB-201/202  | 1,695                          | 6,445            |
| Gilead partnered programs(1)                                | —                              | 761              |
| Other and earlier-stage programs                            | 1,637                          | 2,377            |
| Sub-total direct expenses                                   | <u>4,517</u>                   | <u>13,815</u>    |
| <b>Internal research and development expenses:</b>          |                                |                  |
| Personnel related (including stock-based compensation)      | 3,789                          | 5,660            |
| Facility related  | 779                            | 1,190            |
| Other internal costs  | 687                            | 1,300            |
| Sub-total internal expenses                                 | <u>5,255</u>                   | <u>8,150</u>     |
| Total research and development expenses                     | <u>\$ 9,772</u>                | <u>\$ 21,965</u> |

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

**General and Administrative Expenses**

General and administrative expenses for the years ended December 31, 2017 and 2018 were \$4.4 million and \$6.8 million, respectively. The increase in general and administrative expenses in the year ended 2018 was primarily due to an increase in personnel related expenses of \$0.7 million and an

increase in professional and consulting fees of \$1.3 million. Personnel related expenses increased mainly due to the growth in headcount in our general and administrative functions. The increase in professional and consulting fees resulted from an increase in accounting, audit and legal fees as well as costs associated with ongoing business activities and our preparations to operate as a public company.

### **Grant Income**

In the years ended December 31, 2017 and 2018, we recorded grant income of \$2.1 million and \$5.6 million, respectively, from grants, research incentives and imputed benefits from below market interest rates on loans from governmental agencies. A significant part of our grant income is linked to the amount of qualifying research and development expenses, which have increased substantially in the year ended December 31, 2018 and thus our grant income has also increased.

### **Interest Expense**

Interest expenses for loans from government agencies in the years ended December 31, 2017 and 2018 were \$0.6 million and \$0.8 million, respectively, and included \$0.5 million and \$0.7 million, respectively, in interest representing the difference between contractual interest and the market rate of interest. Contractual interest was \$0.1 million in both of the years ended December 31, 2017 and 2018.

## **Liquidity and Capital Resources**

### **Sources of Liquidity**

Since our inception, we have funded our operations primarily through private placements of our convertible preferred stock as well as from grants, research incentives and borrowings under various agreements with public funding agencies, and most recently, from an upfront payment and service reimbursement of fees received pursuant to the Collaboration Agreement. Through December 31, 2018, we had received gross proceeds of approximately \$105.0 million from the issuance of our convertible preferred stock and \$10.9 million pursuant to the Collaboration Agreement. In February 2019, we raised an additional gross proceeds of \$37.4 million from the issuance of our Series D convertible preferred stock. As of December 31, 2018, the principal amount outstanding under loans from government agencies was \$8.3 million and we had cash and cash equivalents of \$48.6 million. Key financing and corporate milestones include:

- In November 2011, we raised gross proceeds of approximately \$9.5 million from the issuance of our Series A convertible preferred stock.
- Between November 2013 and June 2015, we raised gross proceeds of \$25.6 million from the issuance of our Series B convertible preferred stock.
- In December 2016, we raised gross proceeds of \$5.2 million from the issuance of a second tranche of our Series B convertible preferred stock.
- In March 2017, we raised gross proceeds of \$5.3 million from an extension of the issuance of a second tranche of our Series B convertible preferred stock.
- In December 2017, we raised gross proceeds of \$59.3 million from the issuance of our Series C convertible preferred stock.
- In February 2019, we raised gross proceeds of \$37.4 million from the issuance of our Series D convertible preferred stock.

We entered into various funding agreements with the Austrian Research Promotion Agency, or FFG. The loans by FFG, or the FFG Loans, were made on a project-by-project basis and bear interest at rates ranging from 0.75% to 1.0% per annum. In the event that the underlying program research

results in a scientific or technical failure, the principal then outstanding under any loan may be forgiven by FFG and converted to non-repayable grant funding on a project-by-project basis. The FFG Loans contain no financial covenants and are not secured by any of our assets.

Because the FFG Loans bear interest at below market rates we account for the imputed benefit arising from the difference between an estimated market rate of interest and the contractual interest rate as grant funding from FFG, which is included in grant income. On the date that FFG Loan proceeds are received, we recognize the portion of the loan proceeds allocated to grant funding as a discount to the carrying value of the loan and as unearned income. As of December 31, 2018, the unamortized debt discount related to FFG Loans was \$3.9 million.

We do not expect positive cash flows from operations in the foreseeable future, if at all. Historically, we have incurred operating losses as a result of ongoing efforts to develop our arenavirus technology platform and our product candidates, including conducting ongoing research and development, preclinical studies, clinical trials, providing general and administrative support for these operations and developing our intellectual property portfolio. We expect to continue to incur net operating losses for at least the next several years as we progress clinical development, seek regulatory approval, prepare for and, if approved, proceed to commercialization of our most advanced product candidates HB-101, HB-201 and HB-202, continue our research and development efforts relating to our other and future product candidates, and invest in our manufacturing capabilities and our own manufacturing facility.

### ***Future Funding Requirements***

We have no products approved for commercial sale. To date, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, undertaking preclinical studies and clinical trials of our product candidates. As a result, we are not profitable and have incurred losses in each period since our inception in 2011. As of December 31, 2017 and 2018, we had an accumulated deficit of \$43.7 million and \$60.0 million, respectively. We expect to continue to incur significant losses for the foreseeable future. We anticipate that our expenses will increase substantially as we:

- pursue the clinical and preclinical development of our current and future product candidates;
- leverage our technologies to advance product candidates into preclinical and clinical development;
- seek regulatory approvals for product candidates that successfully complete clinical trials, if any;
- attract, hire and retain additional clinical, quality control and scientific personnel;
- establish our manufacturing capabilities through third parties or by ourselves and scale-up manufacturing to provide adequate supply for clinical trials and commercialization;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company;
- expand and protect our intellectual property portfolio;
- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly;
- acquire or in-license other product candidates and technologies; and
- incur additional legal, accounting and other expenses in operating our business, including the additional costs associated with operating as a public company.

Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

Even if we consummate this offering, we will require substantial additional financing and a failure to obtain this necessary capital could force us to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations.

Since our inception, we have invested a significant portion of our efforts and financial resources in research and development activities for our VaxWave and TheraT technologies and our product candidates derived from these technologies. Preclinical studies and clinical trials and additional research and development activities will require substantial funds to complete. We believe that we will continue to expend substantial resources for the foreseeable future in connection with the development of our current product candidates and programs as well as any future product candidates we may choose to pursue, as well as the gradual gaining of control over our required manufacturing capabilities and other corporate uses. These expenditures will include costs associated with conducting preclinical studies and clinical trials, obtaining regulatory approvals, and manufacturing and supply, as well as marketing and selling any products approved for sale. In addition, other unanticipated costs may arise. Because the outcome of any preclinical study or clinical trial is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our current or future product candidates.

Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing our current and future product candidates and programs, and of conducting preclinical studies and clinical trials;
- the number and development requirements of other product candidates that we may pursue, and other indications for our current product candidates that we may pursue;
- the stability, scale and yields of our future manufacturing process as we scale-up production and formulation of our product candidates for later stages of development and commercialization;
- the timing of, and the costs involved in, obtaining regulatory and marketing approvals and developing our ability to establish sales and marketing capabilities, if any, for our current and future product candidates we develop if clinical trials are successful;
- the success of our collaboration with Gilead;
- our ability to establish and maintain collaborations, strategic licensing or other arrangements and the financial terms of such agreements;
- the cost of commercialization activities for our current and future product candidates that we may develop, whether alone or with a collaborator;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the timing, receipt and amount of sales of, or royalties on, our future products, if any; and
- the emergence of competing oncology and infectious disease therapies and other adverse market developments.



A change in the outcome of any of these or other variables with respect to the development of any of our current and future product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plans may change in the future, and we will need additional funds to meet operational needs and capital requirements associated with such operating plans.

We do not have any committed external source of funds or other support for our development efforts. Until we can generate sufficient product and royalty revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements as well as grant funding. Based on our research and development plans, we expect that the net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. These estimates are based on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect.

If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest will be diluted. If we raise additional capital through debt financing, we would be subject to fixed payment obligations and may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we 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<br>December 31, |                    |
|--|----------------------------|--------------------|
|  | 2017                       | 2018               |
| Net cash used in operating activities                | \$ (11,913)                | \$ (14,998)        |
| Net cash used in investing activities                | (1,297)                    | (2,150)            |
| Net cash provided by financing activities            | 58,892                     | 6,873              |
| Net increase (decrease) in cash and cash equivalents | <u>\$ 45,682</u>           | <u>\$ (10,275)</u> |

### **Cash Used in Operating Activities**

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

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

#### ***Cash Used in Investing Activities***

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

#### ***Cash Provided by Financing Activities***

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

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

#### ***Options Granted***

The following table sets forth by grant date the number of shares underlying options granted between January 1, 2017 and December 31, 2018, the per share exercise price of the options, the fair value of common stock per share on each grant date, and the per share estimated fair value of the options on each grant date:

| <u>Grant Date</u> | <u>Number of Shares Subject to Options Granted</u> | <u>Per Share Exercise Price of Options</u> | <u>Fair Value per Share of Common Stock on Option Grant Date</u> | <u>Per Share Estimated Fair Value of Option on Grant Date</u> |
|-------------------|--|--|--|---|
| February 20, 2017 | 188,314  | \$ 0.10                                    | \$ 1.62  | \$ 1.64   |
| June 13, 2017     | 74,224   | \$ 0.10                                    | \$ 1.62  | \$ 1.64   |
| December 30, 2017 | 283,874  | \$ 0.10 - 2.93                             | \$ 2.93  | \$ 2.64   |
| December 6, 2018  | 283,305  | \$ 10.33                                   | \$ 10.33   | \$ 6.31   |

In determining the compensation expense in our consolidated statements of operations and comprehensive loss for option grants in the year ended December 31, 2017, we retrospectively estimated the fair value of our common stock as of the date of each option grant. For option grants during the year ended December 31, 2018 the estimated fair value of our common stock has been determined by our board of directors considering the most recently available third-party valuation of common stock. See "—Critical Accounting Policies and Use of Estimates—Stock-based compensation."

**Off-Balance Sheet Arrangements**

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

**Contractual Obligations and Commitments****Operating leases**

As of December 31, 2018, our future annual minimum lease payments under non-cancellable operating leases and debt obligations were as follows (in thousands):

|                                | Payments Due by Period |                     |                  |                 |                      |
|--------------------------------|------------------------|---------------------|------------------|-----------------|----------------------|
|                                | Total                  | Less Than<br>1 Year | 1 - 3<br>Years   | 4 - 5<br>Years  | More than<br>5 Years |
| Operating lease commitments(1) | \$ 895                 | \$ 520              | \$ 321           | \$ 54           | \$ —                 |
| CMO commitments(2)             | 19,578                 | 9,222               | 10,356           | —               | —                    |
| Debt obligations(3)            | 8,316                  | —                   | 2,168            | 3,720           | 2,428                |
| Total                          | <u>\$ 28,789</u>       | <u>\$ 9,742</u>     | <u>\$ 12,845</u> | <u>\$ 3,774</u> | <u>\$ 2,428</u>      |

- (1) Our lease obligations relate primarily to the rent of our office and laboratory facilities in Vienna, Austria, which expire in 2020 and 2023.
- (2) Reflects our non-cancellable obligations under arrangements with CMOs including an embedded lease in one of these arrangements commencing in February 2019.
- (3) Reflects the contractually required principal and interest payments payable under the FFG Loans.

The contractual obligations table does not include any potential contingent payments upon the achievement by us of specified clinical, regulatory and commercial events, as applicable, or patent prosecution or royalty payments we may be required to make under license agreements we have entered into with various universities or partners pursuant to which we have in-licensed certain intellectual property, including our license agreements with the University of Zurich, the University of Basel and the University of Geneva. We have excluded these potential payments in the contractual obligations table because the timing and likelihood of these contingent payments are not known. See "Business—License Agreements" for additional information about these license agreements, including with respect to potential payments thereunder.

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

**Intellectual property licenses**

In October 2011, we entered into a license agreement with University of Zurich for an exclusive, worldwide, royalty-bearing license for a propagation-deficient arenavirus vector. Pursuant to the license agreement, we are obligated to pay the University of Zurich low single-digit royalties on aggregate net sales of products licensed under the agreement, and to pay percentages ranging from the mid-single digits to 20% of the sublicense fees that we may receive from sublicensing, depending on the amount of fees received from sublicensees.

In January 2017, we entered into a license agreement with University of Basel for an exclusive, worldwide, royalty-bearing license for a tri-segmented Pichinde virus vector. We are required to use reasonable efforts to make commercially available licensed products. Pursuant to the license agreement, we are obligated to pay nominal milestone payments for each licensed product upon the achievement of certain development and regulatory milestones and to pay royalties of low single digits of net sales of licensed products. We are also obligated to pay a low- to high-single digit percentage of the sublicense fees that we may receive from sublicensing.

In February 2017, we entered into a license agreement with the University of Geneva for an exclusive, worldwide, royalty-bearing license for a tri-segmented arenavirus vector. Pursuant to the license agreement, we are obligated to pay the University of Geneva an annual fee which is fully deductible from any milestone, royalty or sublicense payments. We are also obligated to pay milestone nominal payments for each licensed product upon the achievement of certain development and regulatory milestones and to pay low single-digit royalties on aggregate net sales of products licensed under the agreement, and to pay percentages ranging from the low-single digits to 10% of the sublicense fees that we may receive from sublicensing.

In the year ended December 31, 2018, we recorded \$0.1 million in licensing fees from intellectual property licenses as research and development expenses. At December 31, 2018, \$0.5 million payable from sublicensing fees were included in accrued expenses and other current liabilities.

For additional information on these license agreements, please see "Business—License Agreements."

### **Critical Accounting Policies and Use of Estimates**

This discussion and analysis of financial condition and results of operation is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of financial statements requires management to make estimates and judgments that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities as of the date of the financial statements and the reported amounts of expenses during the reporting period. On an ongoing basis, management evaluates its estimates, including those related to accruals for external manufacturing of clinical trial material as well as clinical study conduct, fair value of assets and liabilities, and the fair value of common stock and stock-based compensation. Management bases its estimates on historical experience and on various other market-specific and relevant assumptions that management believes to be reasonable under the circumstances. Actual results could differ from those estimates.

While our significant accounting policies are more fully described in the notes to our audited financial statements included elsewhere in this prospectus, we believe that the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our financial statements and understanding and evaluating our reported financial results.

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

We have entered into the Collaboration Agreement with Gilead for the development and commercialization of certain of its product candidates. Our performance obligations under the terms of this agreement include one combined performance obligation for each research program comprised of the transfer of intellectual property rights (licenses) and providing research and development services. Payments by Gilead to us under this agreement included a non-refundable up-front payment, payments for research and development activities, and may include payments based upon the achievement of defined pre-clinical development and commercial milestones and royalties on product sales if certain future conditions are met.

We evaluate our collaboration and licensing arrangements pursuant to Accounting Standards Codification 606, or ASC 606. To determine the recognition of revenue from arrangements that fall within the scope of ASC 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when, or as, the Company satisfies a performance obligation. We present revenues from collaboration and licensing arrangements separately from other sources of revenue.

Amounts received by us as non-refundable upfront payment under the collaboration and licensing agreement prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in our consolidated balance sheets. Such amounts are recognized as revenue over the performance period of the respective services on a percent of completion basis for each of the obligations. Reimbursement of costs for or services under the collaboration and licensing agreement are presented as revenue and not deducted from expenses. Amounts of consideration allocated to the performance of research or manufacturing services are recognized over the period in which services are performed. Contingent milestone payments related to specified preclinical and clinical development milestones are not initially recognized within the transaction price as they are fully constrained under the guidance in ASC 606. The collaboration and licensing arrangement also includes certain sales-based milestone and royalty payments upon successful commercialization of a licensed product which we anticipate recognizing if and when sales from a licensed product are generated.

#### ***Research and development costs***

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including salaries and bonuses, stock-based compensation, employee benefits, facilities costs, laboratory supplies, depreciation, manufacturing expenses and external costs of vendors engaged to conduct preclinical development activities and clinical trials as well as the cost of licensing technology. Advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed.

All patent-related costs incurred in connection with filing and prosecuting patent applications are classified as research and development expenses and expensed as incurred due to the uncertainty about the recovery of the expenditure. Upfront payments, milestone payments and annual payments made for the licensing of technology are generally expensed as research and development in the period in which they are incurred. Incremental sublicense fees triggered by contracts with customers are capitalized and expensed as research and development expenses over the period in which the relating revenue is recognized.

#### ***Stock-based compensation***

We measure stock options and other stock-based awards granted to employees, directors, consultants or advisors of the company or its affiliates based on their fair value on the date of the grant and recognize compensation expense of those awards, net of estimated forfeitures, 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. Compensation expense for those awards is recognized, net of forfeitures, over the requisite service period, which is generally the vesting period of the respective award. We use the straight-line method to record the expense of awards with service-based vesting conditions.

We measure 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. The fair value of options granted before the year ended December 31, 2018 were determined retrospectively as no independent third party valuation was performed at the time of such grants. Black-Scholes utilizes assumptions related to expected term, forfeitures, volatility, the risk-free interest rate, the dividend yield (which is assumed to be zero, as we have not paid any cash dividends) and employee exercise behavior. The assumptions used in the Black-Scholes model to determine fair value for the 2017 stock option grants were:

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

In the year ended December 31, 2018, we granted an aggregate of 283,305 options at a per share exercise price of \$10.33.

As there is no public market for our common stock to date, we estimated fair value of our common stock as of the date of each option grant, considering third-party valuations. These valuations considered both objective and subjective factors, including:

- the prices at which we sold preferred stock and the superior rights and preferences of the preferred stock relative to our common stock at the time of each grant;
- the progress of our research and development programs, including the status of preclinical studies and planned clinical trials for our product candidates;
- our stage of development and our business strategy;
- external market conditions affecting the biotechnology industry, and trends within the biotechnology industry;
- our financial position, including cash on hand, and our historical and forecasted performance and operating results;
- the lack of an active public market for our common stock and our preferred stock; and
- the likelihood of achieving a liquidity event, such as an initial public offering or a sale of our company in light of prevailing market conditions.

The fair value of options granted for the year ended December 31, 2018 were determined in December 2018 in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. The fair value of options granted before the year ended December 31, 2018 were determined retrospectively as no independent third party valuation was performed at the time of such grants. The methods used to derive total equity value varied, depending on the availability of objective valuation-related information. Inputs used in our retrospective valuations include the issue prices of our periodic investment rounds, Return-on-R&D-Spend, and market factors based on recent mergers and acquisitions within the biotechnology and pharmaceutical industries. An option pricing allocation method, or OPM, was selected to allocate the total equity value. The OPM treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the common stock has value only if the funds available for

distribution to stockholders exceeded the value of the preferred stock liquidation preference at the time of the liquidity event, such as a strategic sale or a merger.

The assumptions underlying these valuations represented management's best estimate, which involved inherent uncertainties and the application of management's judgment. As a result, if we had used significantly different assumptions or estimates, the fair value of our common stock and our stock-based compensation expense could have been materially different.

Once a public trading market for our common stock has been established in connection with the closing of this offering, it will no longer be necessary for our board of directors to estimate the fair value of our common stock in connection with our accounting for granted stock options and other such awards we may grant, as the fair value of our common stock will be determined based on the quoted market price of our common stock.

#### ***Recognition of other income under government grant agreements and research incentives***

We recognize income from grants, research incentives and the imputed benefit arising from the difference between an estimated market rate of interest and the contractual interest rate on loans received from Austrian government agencies. Income from grants and incentives is recognized in the period during which the related qualifying expenses are incurred, provided that the conditions under which the grants or incentives were provided have been met. For grants under funding agreements and for proceeds under research incentive programs, we recognize grant and incentive income in an amount equal to the qualifying expenses incurred in each period multiplied by the applicable reimbursement percentage.

Grant income that we have received in advance of incurring qualifying expenses is recorded in the consolidated balance sheets as deferred income. Grant and incentive income recognized upon incurring qualifying expenses in advance of receipt of grant funding or proceeds from research and development incentives is recorded in the consolidated balance sheets as prepaid expenses and other current assets.

We have received loans under funding agreements that bear interest below market rates. We account for the imputed benefit arising from the difference between an estimated market interest rate and the actual interest rate charged on such loans as additional grant income, and record interest expense for the loans at a market interest. On the date that loan proceeds are received, we recognize the portion of the loan proceeds allocated to grant funding as a discount to the carrying value of the loan and as unearned income, which is subsequently recognized as additional grant income over the term of the funding agreement.

#### **JOBS Act**

We are an emerging growth company under the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act. As an emerging growth company, we may delay the adoption of certain accounting standards until those standards would otherwise apply 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 will remain an emerging growth company until the earliest of (1) the last day of the fiscal year (a) following the fifth anniversary of the consummation of this offering, (b) in which we have total annual gross revenue of at least \$1.07 billion, or (c) in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded \$700.0 million as of the prior June 30th, and (2) the date

on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period.

## **Quantitative and Qualitative Disclosures About Market Risk**

### ***Foreign currency and currency translation***

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 and cash equivalents as of December 31, 2018 consisted primarily of cash balances held by Hookipa Biotech GmbH in euros.

Assets and liabilities of Hookipa Biotech GmbH are translated into U.S. dollars at the exchange rate in effect on the balance sheet date. Income items and expenses are translated at the average exchange rate in effect during the period. Unrealized translation gains and losses are recorded as a cumulative translation adjustment, which is included in the consolidated Statements of Stockholders' Equity as a component of accumulated other comprehensive loss. Adjustments that arise from exchange rate changes on transactions denominated in a currency other than the local currency are included in other income and expenses, net in the consolidated Statements of Operations and Comprehensive Loss as incurred.

### ***Interest Rate Sensitivity***

We are exposed to market risk related to changes in interest rates. We had cash and cash equivalents of \$48.6 million as of December 31, 2018, which were primarily held as account balances with foreign banks. A hypothetical 10% relative change in interest rates during any of the periods presented would not have had a material impact on our financial statements.

## **Internal Control over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with GAAP. As a result of becoming a public company, we will be required, pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, as amended, to furnish a report by our management on, among other things, the effectiveness of our internal control over financial reporting for the first fiscal year beginning after the effective date of the registration statement of which this prospectus is a part or the date we are no longer an "emerging growth company" as defined in the JOBS Act, if we take advantage (as we expect to do) of the exemptions contained in the JOBS Act. This assessment will need to include disclosures of any material weaknesses identified by our management in our internal control over financial reporting. The SEC defines a material weakness as a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be detected or prevented on a timely basis.

In connection with our preparation and the audits of our financial statements as of and for the years ended December 31, 2017 and 2018, we and our independent registered public accounting firm identified two material weaknesses, as defined under the Exchange Act and by the Public Company Accounting Oversight Board (United States), in our internal control over financial reporting. We did not maintain a sufficient complement of resources with an appropriate level of accounting knowledge, experience, and training, which would allow for appropriate monitoring, presentation and disclosure, and internal control over financial reporting. Specifically, we have not designed and implemented a sufficient level of formal accounting policies and procedures. Additionally, the limited personnel resulted in our inability to consistently establish appropriate authorities and responsibilities in pursuit of



our financial reporting objectives, as demonstrated by, amongst other things, our insufficient segregation of duties in their finance and accounting functions. These kinds of control deficiencies could result in a misstatement of these accounts or disclosures that would result in a material misstatement of our annual or interim consolidated financial statements that would not be prevented or detected, and accordingly, it was determined that these control deficiencies constituted material weaknesses. In connection with the preparation and the audit of our financial statements as of and for the year ended December 31, 2018, we determined that the two previously identified material weaknesses had not been remediated.

#### ***Plan for Remediation of the Material Weaknesses***

We are implementing measures designed to improve our internal control over financial reporting to remediate these material weaknesses, including the following:

- we are in the process of hiring additional qualified accounting personnel and segregating duties among accounting personnel; and
- we are formalizing our internal controls documentation and strengthening supervisory reviews by our management.

These additional resources and procedures are designed to enable us to broaden the scope and quality of our internal review of underlying information related to financial reporting and to formalize and enhance our internal control procedures. With the oversight of senior management and our audit committee, we have begun taking steps and plan to take additional measures to remediate the underlying causes of the material weaknesses.

We intend to complete the implementation of our remediation plan during fiscal year 2019. Although we believe that our remediation plan will improve our internal control over financial reporting, additional time may be required to fully implement it and to make conclusions regarding the effectiveness of our internal controls over financial reporting. Our management will closely monitor and modify, as appropriate, the remediation plan to eliminate the identified material weakness.

If our remediation of the material weaknesses is not effective, or if we experience additional material weaknesses or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations. Accordingly, there could continue to be a reasonable possibility that a material misstatement of our financial statements would not be prevented or detected on a timely basis. We cannot assure you that the measures we have taken to date, or any measures we may take in the future, will be sufficient to remediate the material weaknesses we have identified or avoid potential future material weaknesses.

#### **Recent Accounting Pronouncements**

See Note 2 to our audited consolidated financial statements and related notes included elsewhere in this prospectus.

## BUSINESS

### Overview

We are a clinical-stage biopharmaceutical company developing a new class of immunotherapeutics targeting infectious diseases and cancers based on our proprietary arenavirus platform that is designed to reprogram the body's immune system. We are using our "off-the-shelf" technologies, VaxWave and TheraT, to elicit directly within patients a powerful and durable response of antigen-specific killer T cells and antibodies, thereby activating essential immune defenses against infectious diseases and cancers. We believe that our technologies can meaningfully leverage the human immune system for prophylactic and therapeutic purposes by eliciting killer T cell response levels previously not achieved by other published immunotherapy approaches. Our lead infectious disease product candidate, HB-101, is in a randomized, double-blinded Phase 2 clinical trial in cytomegalovirus-negative patients awaiting kidney transplantation from cytomegalovirus-positive donors. Our lead oncology product candidates, HB-201 and HB-202, are in development for the treatment of human papillomavirus-positive cancers. We plan to file an investigational new drug application with the U.S. Food and Drug Administration for HB-201 and HB-202 in the first half of 2019 and 2020, respectively. We have also entered into a strategic partnership with Gilead Sciences, Inc. to accelerate building a pipeline of additional infectious disease product candidates in a cost efficient manner.

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

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

We believe we are the first to reengineer arenaviruses for therapeutic purposes. We have created two technologies capable of delivering disease-specific antigens for the prevention and treatment of disease. Our first technology, VaxWave, is a replication-defective arenavirus which induces a strong immune response for prophylactic use against infectious disease. Our second technology, TheraT, is a replication-attenuated arenavirus which produces an even more powerful immune response that we believe is more appropriate for use in oncology. In preclinical studies, our TheraT technology was able to reprogram the immune system such that more than half of the body's CD8+ T cells focused on a specific cancer antigen target of our choice without observed serious adverse events. We have designed our platform to be modular in nature in order to allow substitution of antigens to target a broad range of infectious diseases and cancers. We have a robust intellectual property portfolio for our suite of arenaviruses with exclusive rights in issued patents and patent applications related to our VaxWave technology and exclusive and joint rights in patent applications related to our TheraT technology. These platform technologies can be used with a broad spectrum of antigens in therapeutic applications in immunotherapy ranging from infectious diseases to oncology. We believe the breadth

and depth of our intellectual property is a strategic asset that has the potential to provide us with a significant competitive advantage.

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

Our lead product candidate in infectious diseases, utilizing VaxWave technology, is HB-101 for the prevention of cytomegalovirus infections. A majority of the worldwide human population is latently infected with cytomegalovirus and can transmit the infection through bodily fluids. While infection in immunocompetent persons typically presents as mild or asymptomatic, cytomegalovirus remains a major cause of morbidity and mortality in persons with a compromised immune system and in patients undergoing solid organ or hematopoietic stem cell transplants. In a cytomegalovirus-negative patient receiving an organ or stem cells from a cytomegalovirus-positive donor, the spread of the virus through the bloodstream, known as viremia, can cause end-organ disease, such as hepatitis, pneumonitis, gastroenteritis and retinitis, and can result in transplant rejection and death. In this high risk patient group, approximately 80% of kidney transplant recipients develop active cytomegalovirus infections. Cytomegalovirus disease in the transplant setting varies according to the type of transplant, the immunosuppressive drugs used and the presence of any other comorbidity risk factors. Symptomatic cytomegalovirus infections develop in patients in between 8% and 32% of kidney transplants, 22% and 29% of liver transplants, 9% and 23% of heart transplants and 50% and 75% of lung transplants. Based on a recent market research study we commissioned from an independent third party and reviewed by management, we believe that approximately 110,000 patients are added to the solid organ transplant waiting list annually in developed countries, with kidney transplantation representing approximately 60% of cases. Furthermore, more than 20,000 allogeneic cell transplants, in which cell and tissue donors are matched with transplant recipients, are carried out annually worldwide. In this group, the incidence of cytomegalovirus infection is approximately 30% as a result of the donor being cytomegalovirus positive. Current therapies to prevent the transmission of cytomegalovirus during organ transplants utilize antiviral prophylactic and therapeutic strategies. However, these therapies are only partially protective in preventing viral disease while also being hampered by toxicity and resistance.

HB-101 delivers two clinically validated antigens, phosphoprotein 65, or pp65, to induce cytomegalovirus-specific CD8+ T cells and glycoprotein B, or gB, to elicit cytomegalovirus-neutralizing antibodies. In our Phase 1 clinical trial, HB-101 was well tolerated and elicited a strong cytomegalovirus-specific immune responses in all 42 of the treatment arm volunteers. Importantly, we observed robust CD8+ and CD4+ T cell responses as well as cytomegalovirus-neutralizing antibody responses, without meaningful vector-neutralizing antibody responses. These responses increased in a statistically significant manner upon repeat administration. We believe these results demonstrate the differentiating features of our arenavirus platform. In the fourth quarter of 2018, we commenced a Phase 2 clinical trial for HB-101 in cytomegalovirus-negative patients awaiting kidney transplantation from living cytomegalovirus-positive donors. We expect safety and immunogenicity data from the first cohorts enrolled in this trial in the first half of 2020, and preliminary efficacy data to follow in the second half of 2020.

We are developing our lead oncology product candidates, HB-201 and HB-202, both utilizing TheraT technology, for cancers caused by human papilloma virus, or HPV. These cancers account for

approximately 5% of the total worldwide cancer prevalence and recent studies have shown that approximately 70% of cancers of the tonsil and tongue base and the majority of cervical and anal cancers may be linked to HPV. Tumors caused by HPV are referred to as HPV-positive tumors, or HPV+, and can be characterized by their expression of proteins from the HPV genome, particularly the viral E6 and E7 proteins. These two proteins are expressed in tumors but absent in normal cells, which makes them ideal target candidates for immunotherapy, however, to date, there are no therapeutically approved agents directed against these targets.

HB-201 utilizes our TheraT replication-attenuated viral vector technology to target E6 and E7 proteins on HPV16+ cancer cells. In preclinical studies, HB-201 as a monotherapy was effective at suppressing tumor growth and eliminated up to 40% of HPV+ tumors. HB-201 generated a strong and durable T cell and antibody response with successfully treated animals demonstrating resistance to a tumor re-challenge. Based on these preliminary results, we believe that treating patients with HB-201 has the potential to both control metastatic disease and prevent relapse. HPV16+ cancers include cancers of the head, neck, anus, vagina, cervix and penis. Based on a recent market research study we commissioned from an independent third party, we believe that in developed countries, approximately 70,000 patients annually are newly diagnosed with HPV16+ head and neck cancer. Each year, approximately 30,000 of these patients present with metastatic disease and an additional 10,000 patients progress to the recurrent and metastatic stages of the disease. We intend to file an investigational new drug application, or IND, for HB-201 in patients with treatment-refractory HPV16+ cancers in the first half of 2019. Our first planned Phase 1/2 clinical trial will assess the safety and efficacy of HB-201 both as a monotherapy and in combination with a checkpoint inhibitor. Our second planned Phase 1/2 clinical trial will assess the safety and efficacy of the combination of HB-201 and HB-202 in HPV16+ cancers, with or without a checkpoint inhibitor. HB-202 is also based on our TheraT technology and similarly targets E6 and E7 of HPV16+ tumors, but uses a different arenavirus than HB-201. We believe that our preclinical studies demonstrate that the combination of HB-201 and HB-202 results in a synergistic increase in E7 immunogenicity as compared to either HB-201 or HB-202 alone. Our goal is to establish the safety of this combination approach and its superiority over monotherapy.

In June 2018, we partnered with Gilead Sciences, Inc., or Gilead, a world leader in innovative therapies against infectious diseases, to develop arenavirus based therapeutics to treat hepatitis B virus, or HBV, and human immunodeficiency virus, or HIV, infections. We received a one-time upfront payment of \$10.0 million upon entering into the agreement. We are also eligible to receive milestone payments based upon the achievement of specified development, regulatory, and commercial milestones potentially amounting to approximately \$400 million, as well as tiered royalties ranging from high single-digit to mid-teens percentage on net sales. In December 2018, we achieved the first research milestone under the HIV program, entitling us to a payment of \$2.8 million from Gilead, which we received in January 2019.

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, Jörn Aldag, was previously the Chief Executive Officer of uniQure, a company that under his leadership pioneered the approval of the first gene therapy product. Igor Matushansky, M.D., Ph.D., our Chief Medical Officer and Global Head of Research and Development was previously Global Head of Translational Development for Oncology at Daiichi Sankyo. The fundamental discoveries underlying our arenavirus platform originated with our co-founders, Nobel laureate Rolf Zinkernagel, M.D., and Daniel Pinschewer, M.D., an internationally recognized arenavirus expert who serves as our Chief Scientific Officer.

We are supported by prominent biotechnology investors, including BioMedPartners, Boehringer Ingelheim Venture Fund, Forbion Capital Partners, HBM, Hillhouse Capital, Sofinnova Partners and Takeda Ventures, as well as Gilead, a leading biopharmaceutical company.

## Our Pipeline

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

|                     | Compound              | Antigen      | Target          | Development Stage                             |         |         |         | Anticipated Milestones                | Global Rights |
|---------------------|-----------------------|--------------|-----------------|---|---------|---------|---------|---------------------------------------|---------------|
|                     |                       |              |                 | Preclinical                                   | Phase 1 | Phase 2 | Phase 3 |                                       |               |
| Infectious Diseases | HB-101 (VaxWave™)     | gB/pp65      | CMV             | [Progress bar: Preclinical, Phase 1, Phase 2] |         |         |         | Preliminary data H1 2020              |               |
|                     | HBV Therapy           | Undisclosed  | HBV             | [Progress bar: Preclinical]                   |         |         |         |                                       |               |
|                     | HIV Therapy           | Undisclosed  | HIV             | [Progress bar: Preclinical]                   |         |         |         |                                       |               |
| Immuno-Oncology     | HB-201 (TheraT™ LCMV) | E6/E7        | HPV16+ Cancer   | [Progress bar: Preclinical]                   |         |         |         | IND H1 2019 Data late 2020/early 2021 |               |
|                     | HB-202 (TheraT™ PICV) | E6/E7        | HPV16+ Cancer   | [Progress bar: Preclinical]                   |         |         |         | IND H1 2020 Data mid-2021             |               |
|                     | HB-301 (TheraT™)      | PSA/PSMA/PAP | Prostate Cancer | [Progress bar: Preclinical]                   |         |         |         |                                       |               |

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

## Our Strategy

Our goal is to transform the prevention and treatment of infectious diseases and cancers to significantly improve the lives of patients by developing and commercializing a new class of "off-the-shelf" immunotherapeutics.

The key elements of our strategy are:

- Advance our lead infectious disease product candidate through clinical development and regulatory approval.** Our lead product candidate, HB-101, is being developed for the prevention of cytomegalovirus infection in patients receiving a solid organ transplant. Our Phase 1 clinical trial of HB-101 demonstrated the ability of our VaxWave technology to elicit both robust CD8+ T cell and antibody responses, while being well tolerated, which we believe supports the broad therapeutic potential of our technologies. In the fourth quarter of 2018, we commenced a randomized, double-blinded Phase 2 clinical trial of HB-101 in cytomegalovirus negative patients receiving a kidney transplant from cytomegalovirus positive donors, and we expect immunogenicity data from the first cohorts enrolled in this trial in the first half of 2020, and preliminary efficacy data to follow in the second half of 2020.
- Simultaneously progress our lead immuno-oncology product candidates through clinical development and regulatory approval.** Our lead immuno-oncology product candidates are HB-201 and HB-202, which are based on our TheraT technology. Both of these product candidates are in development for the treatment of HPV16+ cancers, including cancers of the head, neck, anus, vagina, cervix and penis. In preclinical models, HB-201 as a monotherapy was active in suppressing the tumor growth, and eliminated up to 40% HPV antigen positive tumors. We intend to file an IND with the U.S. Food and Drug Administration, or the FDA, for HB-201 and HB-202 in the first half of 2019 and 2020, respectively. We plan to initiate a Phase 1/2 clinical trial for HB-201 in patients with treatment-refractory HPV16+ cancers in the second half of 2019 and expect preliminary results in late 2020 or early 2021. We also plan to combine HB-201 with a checkpoint

inhibitor and to commence a Phase 1/2 trial combining HB-201 and HB-202, both with and without a checkpoint inhibitor, in patients with treatment-refractory HPV16+ cancers in late 2020.

- **Apply our arenavirus platform to develop additional novel immuno-oncology product candidates.** We believe that our technologies have broad potential within the field of immuno-oncology. We plan to utilize the potential of our platform to develop additional product candidates for the treatment of a broad range of cancers, starting with our HB-301 program in prostate cancer. Beyond our current pipeline of preclinical assets, which includes viral and self-antigen targets, we intend to invest in our research and development activities in order to expand the potential of our platform to target a new class of antigens, which are shared across a subpopulation of patients. To accelerate the development of this new class of therapeutics, we are collaborating with DarwinHealth, a company which is pioneering novel bioinformatics, to identify the next generation of cancer-testis antigens and develop "off-the-shelf" cancer therapies. We believe that our technologies have the potential to be applied in any cancer associated with specific antigens.
- **Selectively collaborate to realize the full potential of our arenavirus platform.** We are building a broad pipeline of product candidates using our arenavirus platform. Beyond our current collaboration with Gilead, we plan to pursue strategic collaborations with additional leading biopharmaceutical companies with specialized capabilities or know-how, including development and commercial expertise. We may pursue partnerships that may allow us to expedite the discovery and development of product candidates for the prevention and treatment of infectious diseases and tumors, and provide us opportunities to combine our technologies with other modalities. We believe this approach may further broaden the therapeutic reach of our technologies, provide non-dilutive financing, and complement and expand our internal development expertise while allowing us to strategically retain rights to our product candidates.
- **Strengthen and scale our manufacturing capabilities and ultimately operate our own manufacturing facility.** We believe the quality, reliability, scalability and timing of our manufacturing activities will be an important factor in successfully developing and commercializing our product candidates and therefore, we intend to invest in manufacturing capabilities. We recently secured access to a dedicated good manufacturing practice, or GMP, suite to control the manufacturing capacity required to conduct a broad range of upcoming clinical trials for our product candidates. In the future, we intend to establish and operate our own current good manufacturing practice, or cGMP, facility for multi-product manufacturing of our commercial products.

## Background

### *Immune System Function: Antigen Presentation by Dendritic Cells*

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

The innate immune system is the body's first line of defense and enables a rapid, short-lived and non-specific response. In contrast, the adaptive immune system utilizes highly specialized immune cells called lymphocytes that have been selected to recognize specific foreign antigens. Although it takes longer to mobilize, the adaptive immune system is capable of providing long-term, more effective

immunity against specific pathogens by being able to recall prior antigen exposure and mounting a very powerful and specific response.

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

### ***Immunotherapy and Current Limitations***

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

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

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

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

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

*Clinical Application.* Two common limiting factors of many immunotherapies are the inability to deliver full length proteins directly to dendritic cells and the inability to be administered

systemically. The former limitation restricts these therapies to being patient-specific as they can only deliver smaller proteins such as neoantigens and it furthermore prevents an "off-the-shelf" approach. The latter restricts their application only to tumors that are amenable to intratumoral administration, as is the case for oncolytic viruses.

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

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

## **Our Technology Platform**

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

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

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

The arenavirus family is comprised of 24 currently known species, many of which we believe have potential prophylactic and therapeutic applications. We believe we are the first to reengineer arenaviruses for the prevention and treatment of disease. We have created two types of viral technologies capable of delivering disease-specific antigens: VaxWave, a replication-defective vector, and TheraT, a replication-competent but attenuated vector.

Our VaxWave and TheraT technologies utilize both lymphocytic choriomeningitis, or LCMV, and Pichinde virus, or PICV, two of the 24 species of arenaviruses, as a backbone of the product candidates we are developing. LCMV is principally carried and secreted by wild mice, with human infection being secondary to such exposure and uncommon. Approximately 2% to 5% of individuals in industrialized countries have circulating antibodies against LCMV, which indicates prior exposure in these individuals. Individuals infected with LCMV typically remain asymptomatic or may present with a non-specific and self-resolving flu-like illness. PICV is principally carried and secreted by Colombian rice rats (*oryzomys albigularis*) and is a nonpathogenic virus that does not cause disease in humans.



### ***VaxWave Overview***

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

### ***Advantages of VaxWave***

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

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

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

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

### ***TheraT Overview***

Our proprietary TheraT technology is replication-competent but attenuated. The intent of designing a replicating vector was to allow it to retain all of the beneficial properties of VaxWave but to induce an even more robust immune response. Unlike naturally occurring arenaviruses which have two genomic segments, our TheraT constructs were engineered to have three segments in order to allow for the introduction of genomic space in which to insert additional target antigens of choice. As a result of the larger genome the virus' ability to replicate is naturally attenuated.

### ***Advantages of TheraT***

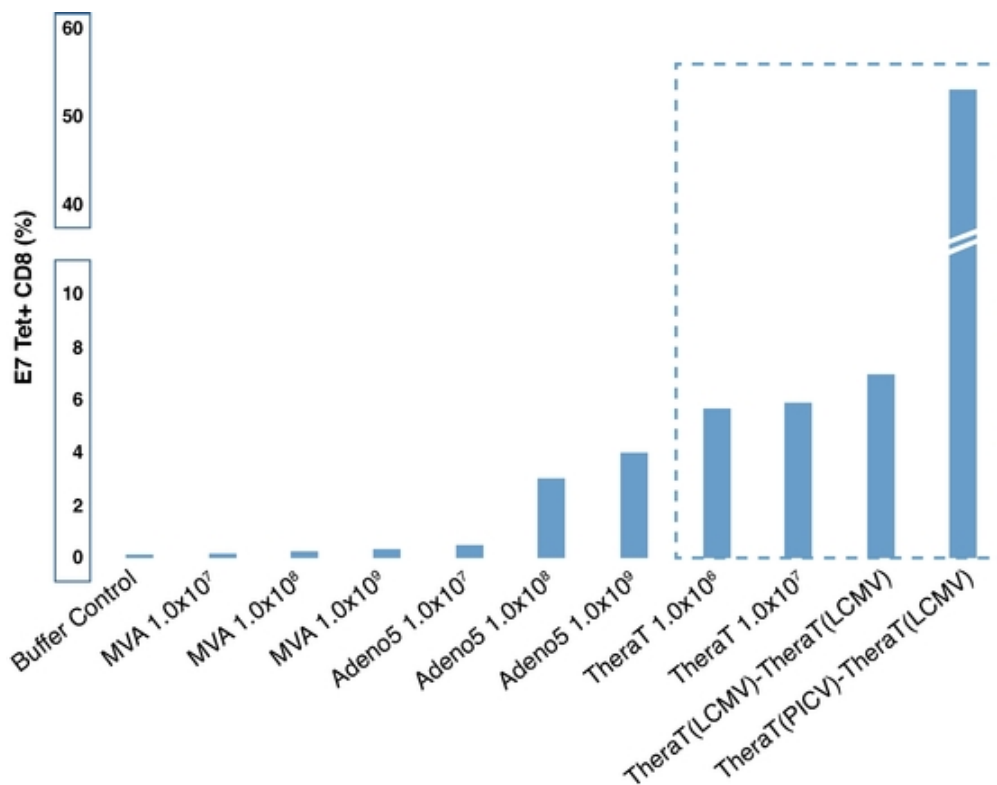
Based on the preclinical data that we have generated to date, we believe our TheraT technology supports the benefits of our arenavirus platform approach. In addition to having the advantages of VaxWave technology, in preclinical studies TheraT has shown the following additional benefits:

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

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

The additional benefits of TheraT are attributable to its ability to replicate. This allows it to infect not only dendritic cells but also lymphoid stromal cells, which are immune support cells found in lymph nodes and the spleen. Infection of lymphoid stromal cells results in the release of a signaling protein which further drives the proliferation and differentiation of CD8+ T cells. This mechanism has the potential to generate ten-fold more antigen-specific CD8+ T cells as compared to viral delivery systems that are unable to trigger this pathway. Furthermore, we believe TheraT-induced CD8+ T cells do not need the addition of commonly used checkpoint inhibitors to function at optimal potency, as they are able to establish long-lasting interactions with their target cells inside solid tissues and kill them.

To demonstrate the superior properties of our approach, we performed a head-to-head comparison in mice of our TheraT LCMV and PICV E7 constructs versus modified vaccinia virus Ankara, or MVA, and adenovirus 5, or Adeno5, each expressing E7 antigens for their ability to induce E7-specific CD8+ T cells. As shown below, our TheraT constructs were superior to MVA and Adeno5, despite being dosed at concentrations 1,000 times lower than the latter two vectors. Furthermore, sequential dosing of TheraT(PICV) followed by administration of TheraT(LCMV) resulted in over 50% of CD8+ T cells being targeted against E7.



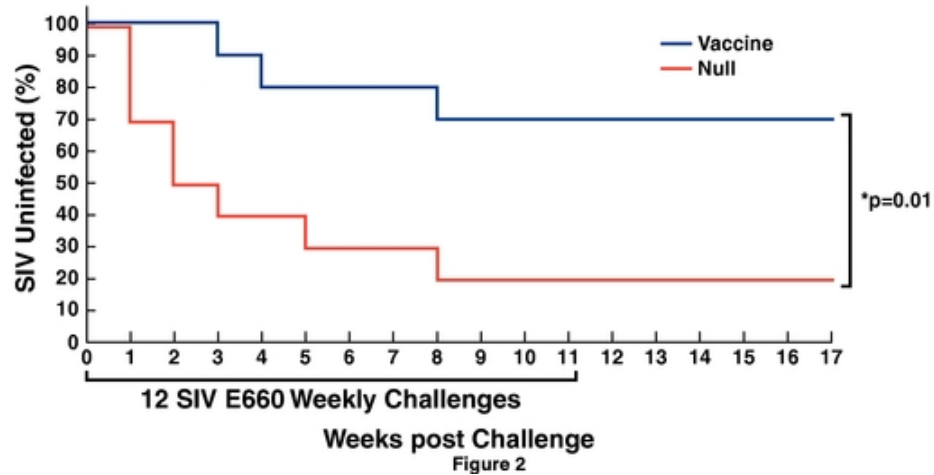
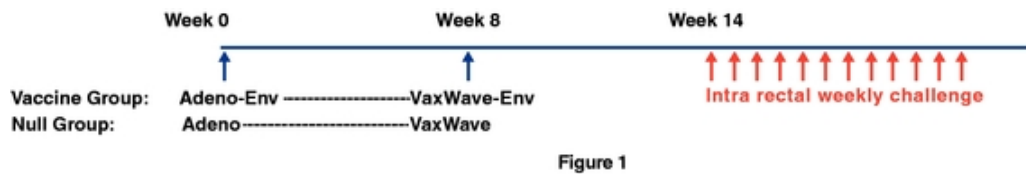
In additional preclinical models, including a mouse melanoma model and a cancer-testis self-antigen cancer model, we again demonstrated the ability of sequential administration of TheraT PICV and LCMV constructs to direct up to 50% of a body's T cells to focus on a single target of choice.

#### ***VaxWave Preclinical Data***

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

*HIV Model*

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



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

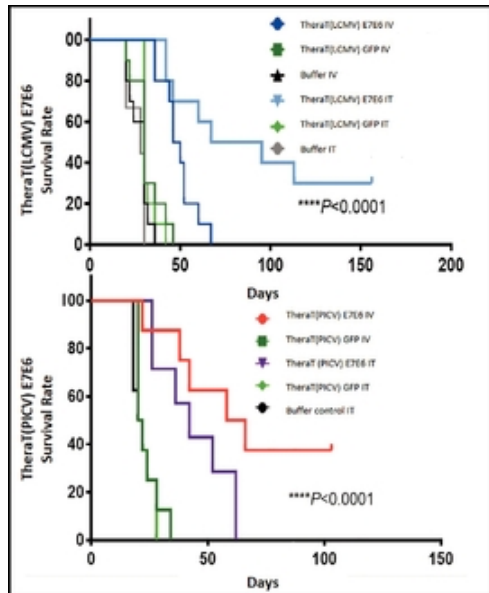
*HBV Model*

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

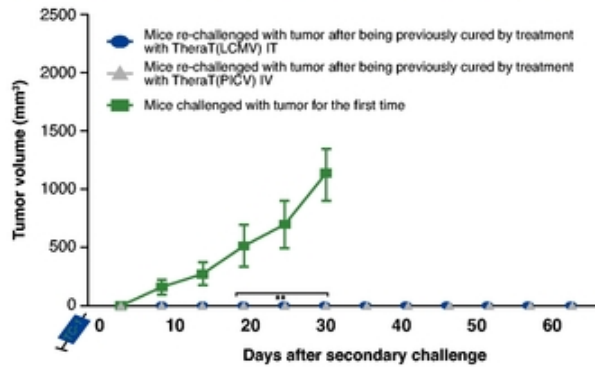
We believe that the combination of our HIV and HBV preclinical and subsequent VaxWave clinical data facilitated our Gilead collaboration.

**TheraT Preclinical Data**

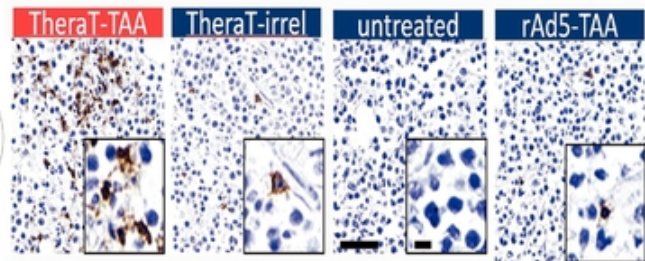
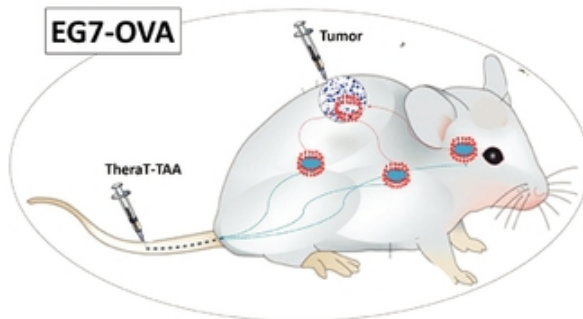
We have conducted several preclinical studies assessing the efficacy of our TheraT technology, for both LCMV and PICV constructs, carrying the HPV specific E7/E6 fusion protein through intravenous, or IV, and intratumoral, or IT, administration. Mice treated with the replication-attenuated TheraT vectors showed no evidence of toxicity. In a mouse model of HPV-induced cancer (TC1), we observed that a single intravenous administration of TheraT(LCMV) significantly suppressed and delayed tumor growth while a single intratumoral administration of TheraT(LCMV) eliminated the tumor in approximately half of the mice (top left panel). Intravenous administration of TheraT(PICV) eliminated the tumor in approximately half of the mice, by the same definition, while intratumoral administration of TheraT(PICV) significantly suppressed and delayed tumor growth (bottom left panel). These mice had complete remission without recurrence for at least six months, which represents over 25% of a mouse's lifetime (right panel). In contrast, TheraT vectors carrying non-tumor specific antigens, such as GFP, demonstrated no anti-tumor activity. In these studies, we also observed resistance to a tumor re-challenge after six months (right panel).



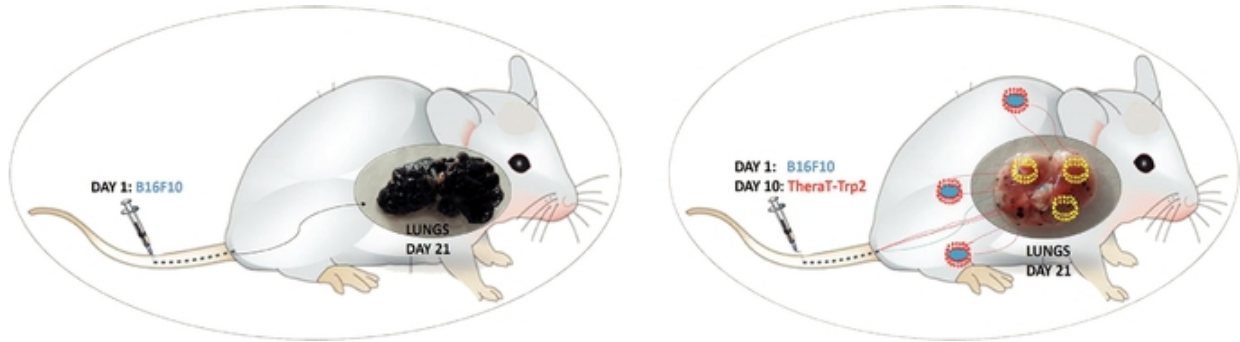
**TC1 Re-Challenge: no recurrence**  
(inject tumor cells a second time after 150 days)



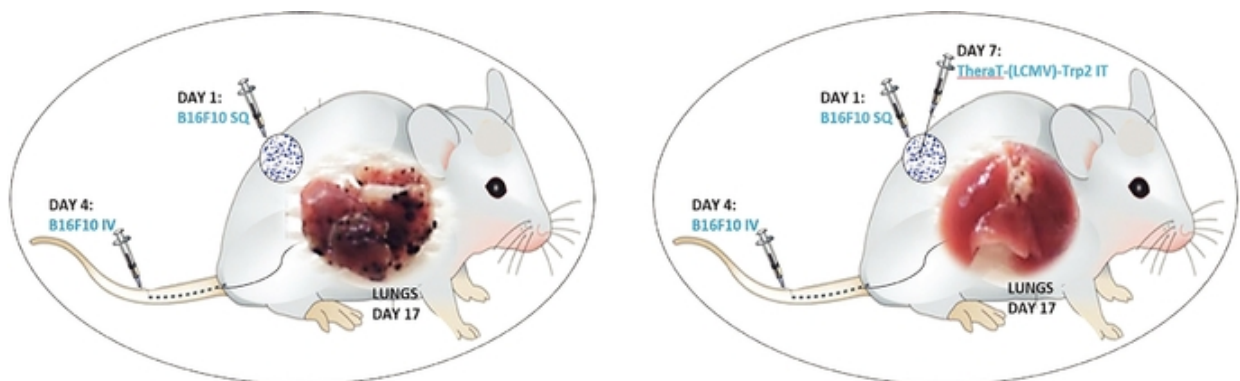
We have also performed "tracking" experiments wherein we observed that while our intravenous TheraT vectors travel to dendritic cells, the reprogrammed antigen CD8+ T cells travel to tumors. We illustrated this in an EG7-OVA model, which analyzed subcutaneous tumors for the presence of antigen specific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



We observed similar results in a more aggressive B16F10 melanoma mouse model. In this experiment B16F10 malignant cells were introduced into the tail vein of mice, resulting in lung metastases within three weeks. Ten days after the introduction of B16F10, a TheraT vector expressing Trp2, a melanoma antigen, was introduced intravenously leading to a significant delay in disease progression. Similarly, in subcutaneously growing B16F10 tumors treated intravenously, histopathology showed clear evidence of strong CD8+ T cell infiltration.



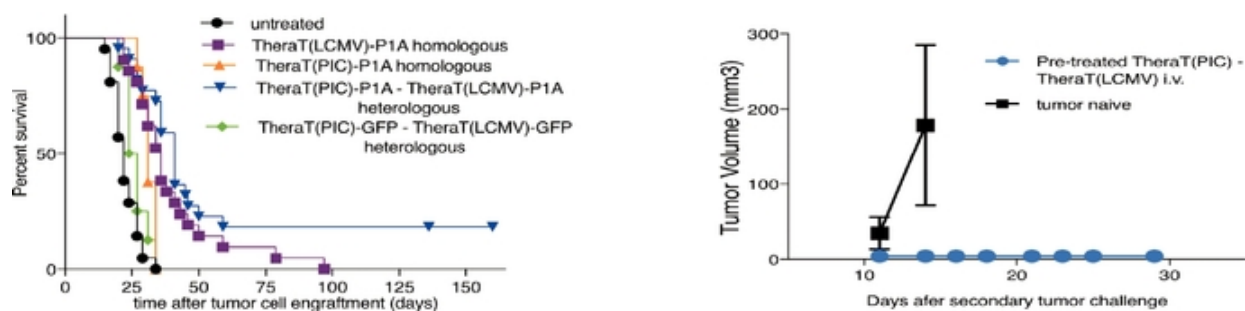
When we combined the above two experiments, by initially introducing B16F10 malignant cells subcutaneously, and then intravenously, we achieved both a localized subcutaneous tumor and metastatic lung lesions. Subsequent administration of our intratumoral TheraT vector demonstrated both a localized response,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



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

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

survived beyond the 160 days of the study. Furthermore, and as seen in our other studies, mice with eliminated tumors demonstrated resistance to a tumor re-challenge (right panel below).



## Our Product Candidates

### *HB-101, a Prophylactic Vaccine for Cytomegalovirus*

HB-101 is a VaxWave product candidate that delivers two clinically validated antigens: pp65, to induce cytomegalovirus-specific CD8<sup>+</sup> T cells, and gB, to elicit cytomegalovirus-neutralizing antibodies. Cytomegalovirus infections present a serious risk for patients with suppressed immune systems, such as solid organ and stem cell transplant recipients. In our Phase 1 clinical trial, HB-101 was well tolerated and elicited strong and durable cytomegalovirus-specific immune responses in all 42 volunteers in the treatment arm. Importantly, we observed robust CD8<sup>+</sup> and CD4<sup>+</sup> T cell responses as well as cytomegalovirus-neutralizing antibody responses. As anticipated, the LCMV vector did not elicit clinically meaningful vector-neutralizing antibodies, as only one volunteer developed a transient neutralizing antibody response against the vector after three administrations. Furthermore, upon repeat administration, the pp65 CD8<sup>+</sup> T cell levels achieved by VaxWave increased in a statistically significant manner. In the fourth quarter of 2018, we commenced a randomized, double-blinded Phase 2 clinical trial for HB-101 in cytomegalovirus-negative patients awaiting kidney transplantation from living cytomegalovirus-positive donors. We expect immunogenicity data from the first cohorts enrolled in this trial in the first half of 2020, and efficacy data to follow in the second half of 2020. We intend to pursue regulatory approval for HB-101 for the prevention of cytomegalovirus in all solid organ transplants regardless of cytomegalovirus status of the recipient. In the future, and in the event of successful proof of concept of HB-101 in the Phase 2 clinical trial, we may pursue additional indications such as stem cell transplantation and congenital cytomegalovirus infection.

### *Cytomegalovirus*

Cytomegalovirus is a virus that is commonly transmitted in childhood and early adulthood. Approximately 60% of the U.S. population has been exposed, and as such, is latently infected. Worldwide data indicate that while half the people in industrialized countries have been exposed, up to 99% of people in developing countries, including China and India, have been exposed. Infections result in lifelong latent persistence of the virus with few symptoms, if any. However, in immunosuppressed patients, such as transplant recipients, primary cytomegalovirus infection or reactivation generally causes significant morbidity, mortality and graft rejection. There are two scenarios in which cytomegalovirus infections are relevant in the transplant setting. In one case, the recipient could be cytomegalovirus negative, or previously uninfected, and the donor cytomegalovirus positive. In this case, introduction of cytomegalovirus into the immunocompromised recipient can lead to rapid virus spread and development of serious complications. In the other case, the recipient is already cytomegalovirus positive, but the immunosuppressive treatments required as part of the transplant procedure lead to reactivation of latent virus. Based on a recent market research study we commissioned from an independent third party, we believe that approximately 110,000 patients are added to the solid organ

transplant waiting list annually in developed countries, with kidney transplantation representing approximately 60% of cases. Furthermore, more than 20,000 allogeneic cell transplants, in which cell and tissue donors are matched with transplant recipients, are carried out annually worldwide. In this group, the incidence of cytomegalovirus infection is approximately 30% as a result of the donor being cytomegalovirus positive. Current therapies to prevent the transmission of cytomegalovirus during organ transplants utilize antiviral prophylactic and therapeutic strategies. However, these therapies are only partially protective in preventing viral disease while also being hampered by toxicity and resistance.

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

### ***Cytomegalovirus in Kidney Transplant Patients***

In 2015, approximately 85,000 of the approximately 126,000 solid organ transplants performed worldwide were kidney transplants, an increase of 5.5% over the previous year. Approximately 80% of high risk kidney transplant recipients develop active cytomegalovirus infections. High risk recipients are defined as cytomegalovirus-negative patients receiving kidney transplants from cytomegalovirus-positive donors. In most solid organ transplant patients, complications from cytomegalovirus develop between 30 and 90 days after transplantation and rarely after 180 days.

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

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

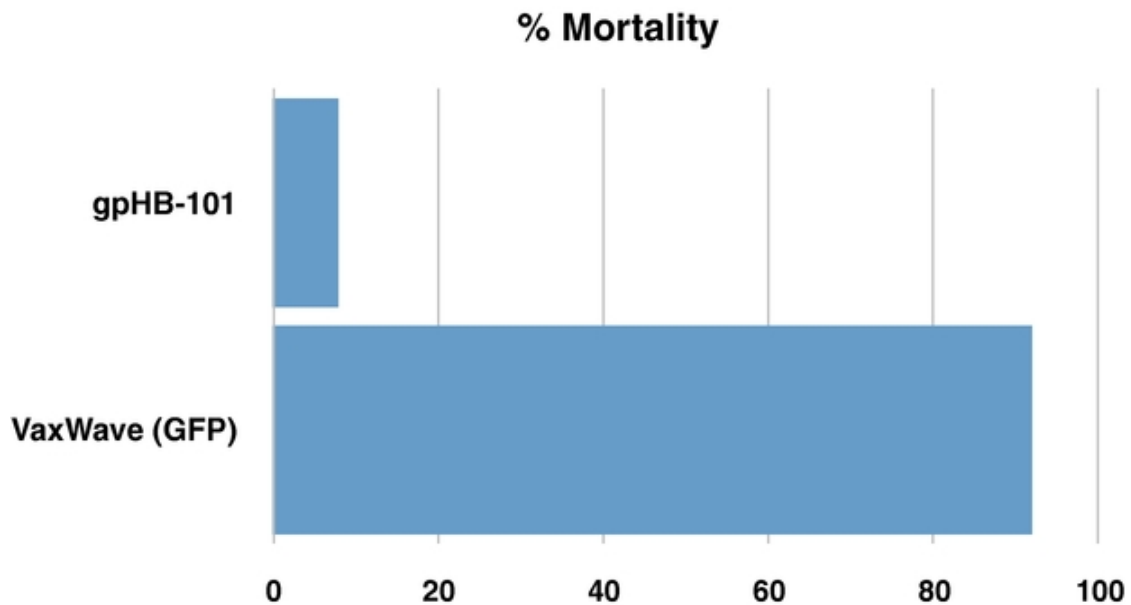
- one vector expresses the gene encoding the cytomegalovirus 65 kD pp65 protein; and
- another vector expresses the gene encoding the cytomegalovirus gB protein.

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



### HB-101 Preclinical Results

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



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

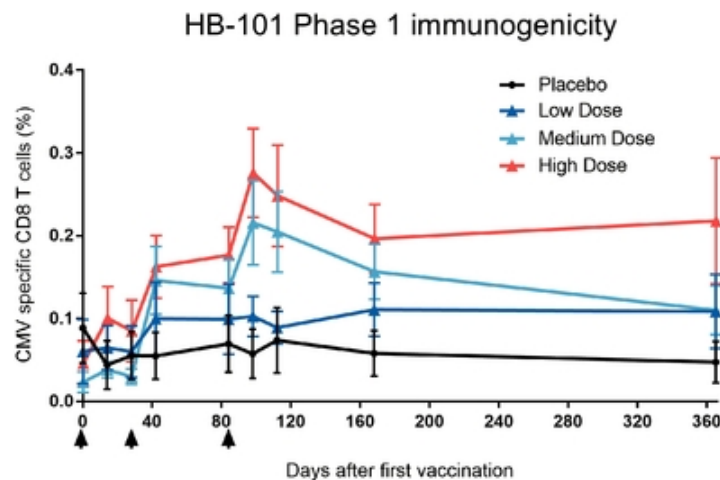
We conducted a placebo-controlled, randomized double-blinded dose escalating Phase 1 clinical trial of HB-101 to assess the vaccine's safety and immunogenicity. In this trial, 54 healthy volunteers aged 18 to 45 were administered three consecutive doses of either HB-101 or placebo by intramuscular injection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

We observed that HB-101 was well-tolerated with no dose limiting toxicities and no serious adverse events. Symptoms by volunteers were of mild to moderate intensity and 93.5% of reported symptoms were of short duration (1-8 days). The maximum duration of any symptom was 10 days. Pain at the injection site was the predominant solicited local adverse event. Malaise, fatigue and generalized myalgia were the most common solicited general symptoms. The percentage of subjects reporting unsolicited causally related adverse events of mild to moderate intensity was similar for placebo and the vaccine groups. Upper respiratory tract infections were the predominant adverse event, occurring at rates in the low dose group that were twice as high as those seen in all three other groups (placebo, middle and high dose). The percentage of volunteers reporting related adverse events of mild to



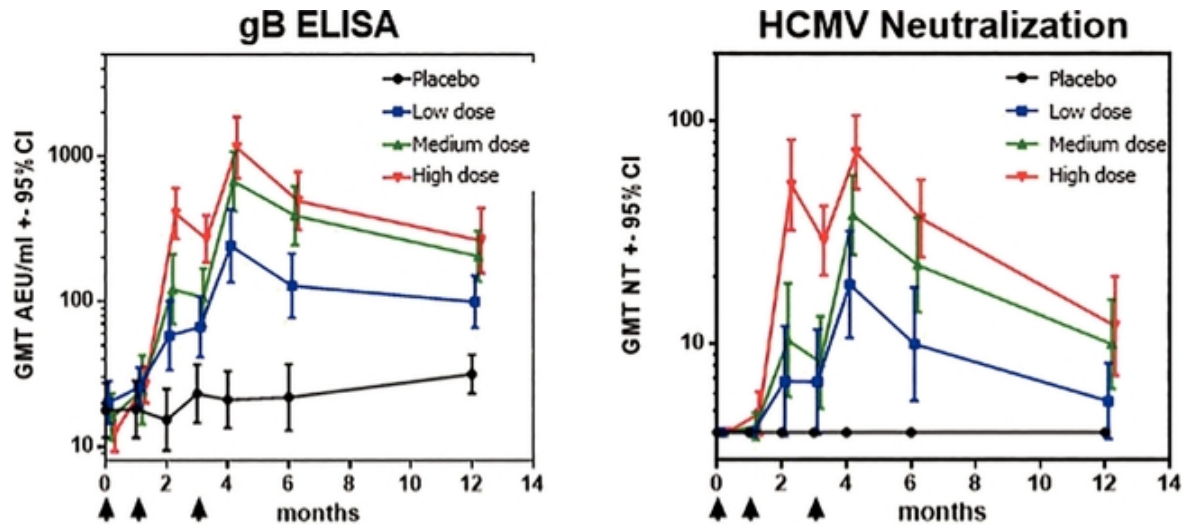
moderate intensity was similar for placebo and vaccine groups. None of the adverse events appeared to be treatment related.

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



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

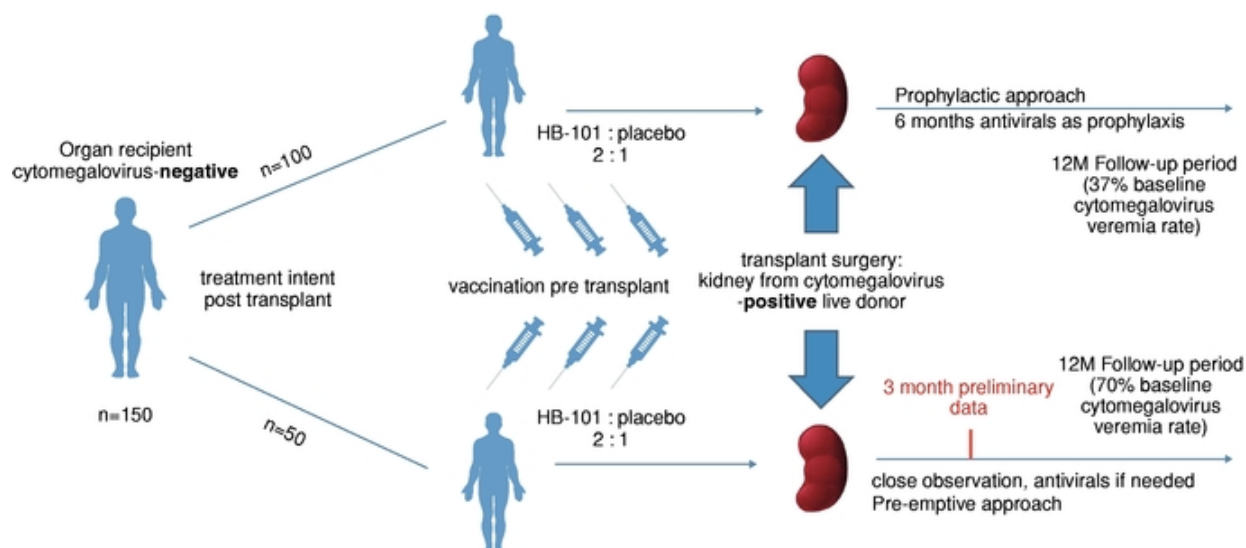
administration of the vaccine in all 42 of these volunteers could have resulted in an additional antibody response, if desired.



*HB-101 Clinical Development Plan*

In the fourth quarter of 2018, pursuant to an IND filed by us with the FDA in July 2018, we initiated a randomized, double-blinded Phase 2 trial of HB-101 to assess the safety, reactogenicity, immunogenicity and efficacy of HB-101 in cytomegalovirus-negative patients receiving a kidney transplant from living cytomegalovirus-positive donors. The primary endpoint of this trial will evaluate safety and immunogenicity of HB-101. The secondary endpoint will evaluate efficacy, which is defined as the reduction of viremia, as well as the decreased need to use antivirals. We plan to enroll a total of 150 patients, randomized 2:1 between the study drug and placebo, in two treatment groups. The first group will be randomized to receive two to three administrations of either HB-101 or placebo prior to transplant and then treated with standard preemptive anti-viral therapy post-transplant. The second group will be randomized to receive two to three administrations of either HB-101 or placebo before transplant, and will then receive three to six months of anti-viral prophylaxis therapy post-transplant. Patients will be monitored for twelve months post-transplant to assess safety and T cell and antibody

responses to pp65, gB and the LCMV vector, as well as cytomegalovirus viremia and the need for use of antivirals. The trial design is depicted in the figure below.



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

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

We are currently developing two immunotherapeutics targeting HPV16+ cancers.

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

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

We plan to initiate a Phase 1/2 clinical trial for HB-201 in patients with treatment-refractory HPV16+ cancers in the second half of 2019 and expect preliminary results in the second half of 2020. We also plan to combine HB-201 with a checkpoint inhibitor and to commence a Phase 1/2 trial combining HB-201 and HB-202, both with and without a checkpoint inhibitor, in patients with treatment-refractory HPV16+ cancers in the first half of 2020.

### ***HPV-Positive Cancers***

HPV is estimated to cause about 5% of cancers worldwide, including approximately 99% of cervical cancers, 25% to 60% of HNSCC, 70% of vaginal cancers and 88% of anal cancers, the majority of which are caused by the HPV serotype 16. While most infections with HPV are cleared from the body with no lasting consequences, in some cases, HPV DNA becomes integrated into chromosomal DNA. When host cells take up this DNA, they express the HPV E6 and E7 proteins. The expression of these proteins can potentially cause cancer because they can lead to alterations in cell cycle control, which in turn predisposes these cells to become cancerous.

While the rates of HNSCC from causes such as smoking and alcohol are decreasing, the rates of HPV16+ HNSCC are increasing. HNSCC is the fifth most common form of cancer. Each year, HNSCC is diagnosed in more than 600,000 people worldwide, with 65,000 new cases and more than 13,700 deaths occurring in the United States alone. HNSCC includes tumors of the oral cavity, oropharynx, larynx and hypopharynx. The current standard of care for HNSCC is the same regardless of HPV status. Treatment typically involves a combination of chemotherapy, radiation and surgery. These treatments are associated with acute and long-term effects including mucositis, swallowing dysfunction, dry mouth, and dental problems. The overall survival rate for patients with advanced metastatic HNSCC progressing on platinum and checkpoint based therapies is less than six months. While there is no T cell therapy approved for HNSCC, retrospective analyses have shown that patients with high levels of CD8+ T cells in tumors have a much better prognosis. In many cases, the survival rate of these patients is more than double that of patients with lower levels of CD8+ T cells.

We believe that evaluating the potential of our product candidates for the treatment of HPV16+ HNSCC is a rational clinical development strategy as there is precedent data supporting the efficacy of immunotherapy in this patient population. In developed countries, HPV16+ HNSCC accounts for only 13% of the approximately 120,000 annual cases of HPV+ cancers. In contrast, in less developed countries, HPV+ HNSCC accounts for just 1% of 490,000 annual HPV-related cancer cases. Proof of concept in either HPV16+ HNSCC or HPV16+ non-HNSCC could support the potential of our product candidates to be effective for all HPV16+ cancers, regardless of the cancer's tissue of origin.

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

Both HB-201(LCMV) and HB-202(PICV) are TheraT-based product candidates expressing a non-oncogenic but highly antigenic E6/E7 fusion protein from HPV16. In animal models, HB-201 was observed to be highly immunogenic, resulting in a robust CD8+ T cell response. Based on the levels of antigen-specific CD8+ T cells induced by HB-201 in preclinical models, notably when compared to therapeutic levels induced by other published approaches including adoptive cell therapies, as observed in separately designed and conducted third-party clinical trials, we believe that HB-201 monotherapy has the potential to provide therapeutic benefit to patients across the broader HPV16+ cancer setting. We have observed strong immunogenicity and robust anti-tumor activity in mouse models for HB-201 alone as well as for the sequential administration of HB-201 and HB-202.

#### ***Relevance of E6 and E7 as Tumor Antigens***

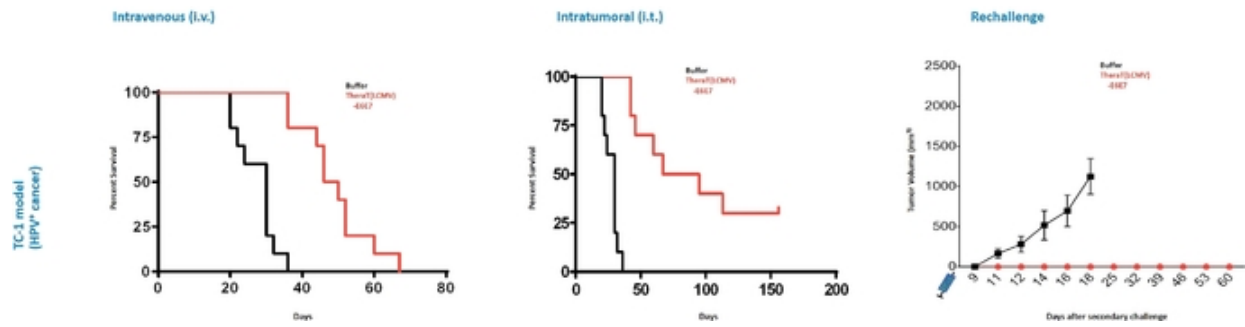
Integration of HPV viral sequences into the genome of a cell can result in the introduction of E6 and E7 oncoproteins. They are present in cells that become cancerous and play a critical role in interfering with cellular processes and interrupting normal tumor suppressor functions.

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

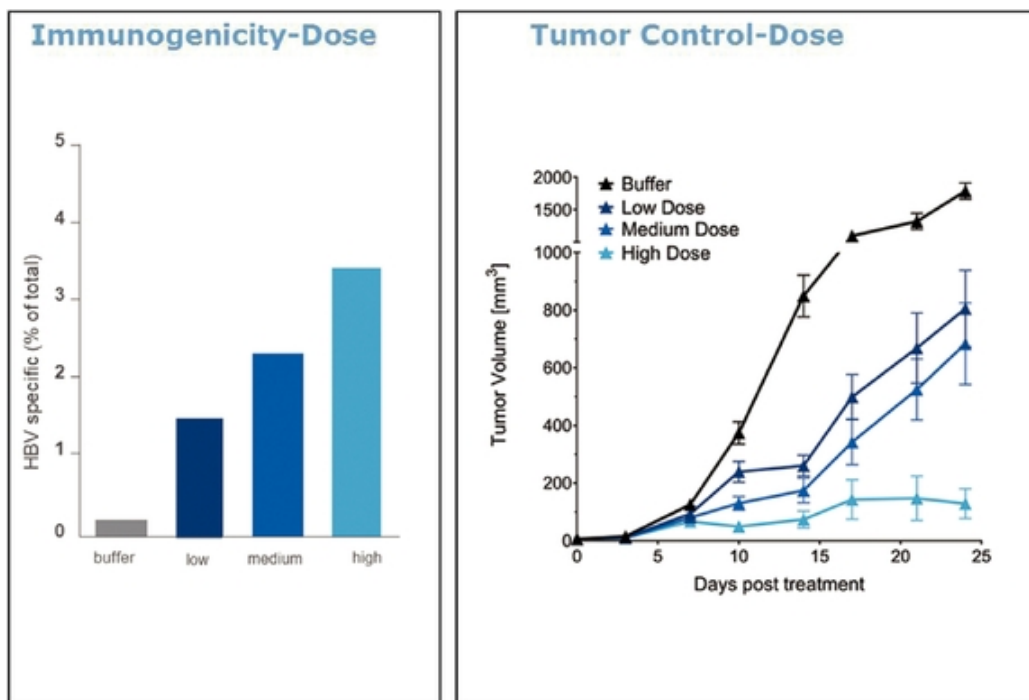
#### ***HB-201 Preclinical Results***

The ability of HB-201 to suppress tumor growth was tested in a TC1 mouse model of a transplantable HPV16+ E6/E7 expressing tumor. HB-201 was administered either intravenously or intratumorally to animals when tumor volume was approximately 100mm<sup>3</sup>. In both cases, as depicted in the figures below, single doses of HB-201 led to suppression of tumor growth in a statistically significant manner ( $p < 0.05$ ) in all treated mice, and intratumoral administrations resulted in an

approximately 40% long term survival rate. When these long term survivor mice were re-challenged with the same tumor six months later, no new tumor growth was detected. We believe that these results demonstrate the potential for HB-201 to be active both in treating primary tumors and also controlling metastatic and recurring disease.



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



*HB-201 Clinical Plans*

We intend to initiate an open label, dose escalating Phase 1/2 clinical trial to evaluate HB-201 in HPV16+ cancers, alone and in combination with nivolumab, an approved checkpoint inhibitor that

is marketed as Opdivo by Bristol-Myers Squibb Company as a current second line standard of care therapy in patients with HPV16+ HNSCC with disease progression on or after platinum-based therapy.

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

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

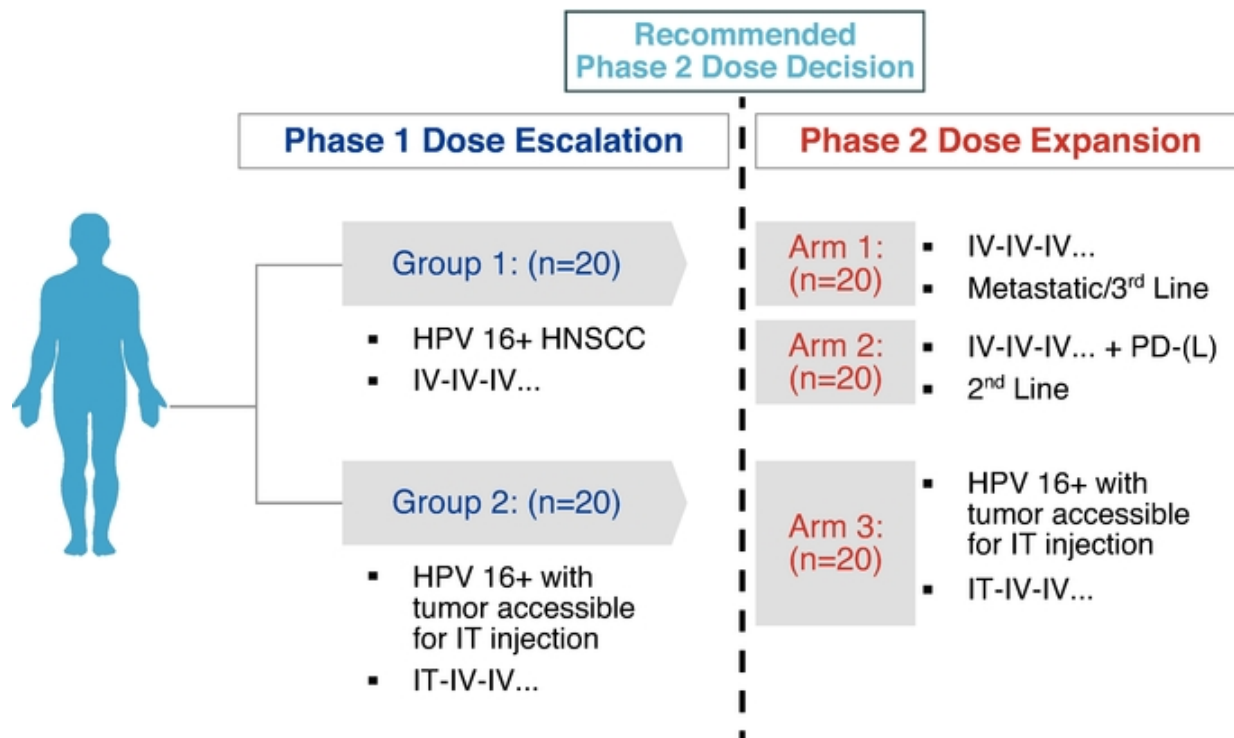
- Group 1 (intravenous, or IV, administration HB-201): patients with HPV16+ cancers with tumor progression or recurrence on standard of care therapy, or for whom standard of care therapy is contraindicated.
- Group 2 (intratumoral, or IT, administration of HB-201 followed by IV administration of HB-201): patients with HPV16+ cancers with a safe and accessible tumor site amenable for IT administration who had tumor progression or recurrence on standard of care therapy or for whom standard of care therapy is contraindicated.

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

- Arm 1 (IV administration of HB-201): patients with HPV16+ cancers with tumor progression or recurrence on standard of care therapy, or for whom standard of care therapy is contraindicated.
- Arm 2 (IV administration of HB-201 with nivolumab): patients with HPV16+ cancers with tumor progression or recurrence on standard of care therapy, or for whom standard of care therapy is contraindicated.
- Arm 3 (IT administration of HB-201 followed by IV administration of HB-201): patients with HPV16+ cancers with a safe and accessible tumor site amenable for IT administration who had tumor progression or recurrence on standard of care therapy or for whom standard of care therapy is contraindicated.

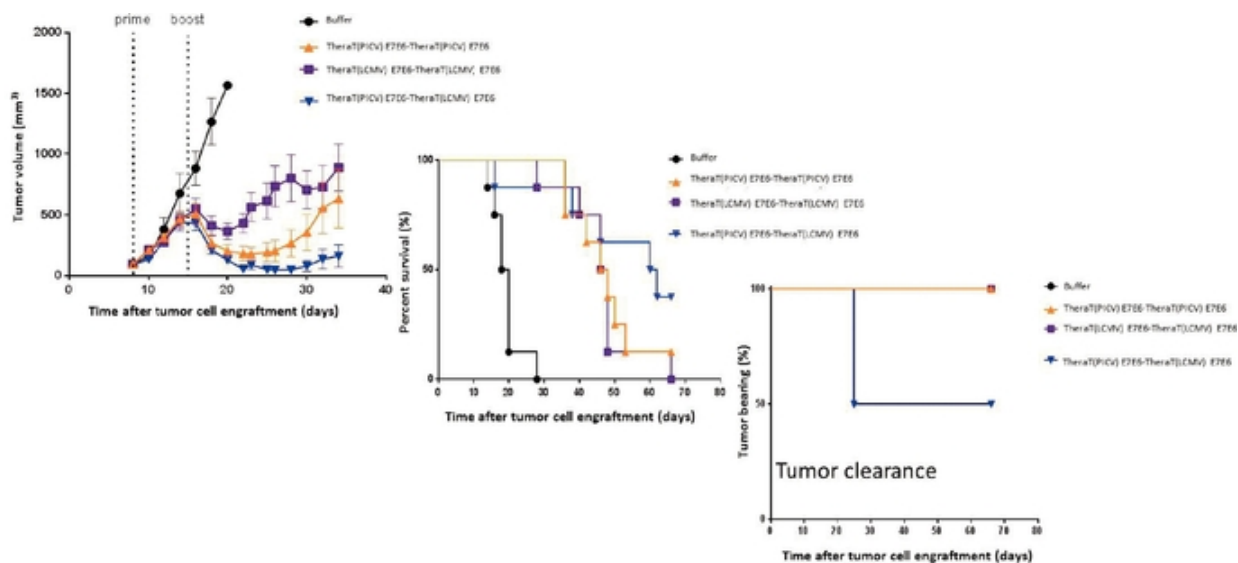
The primary endpoint of the Phase 1 portion of this trial will be to evaluate safety and tolerability to determine the recommended dose for the Phase 2 portion. Secondary endpoints will evaluate anti-tumor activity and immunogenicity. The Phase 2 groups of the trial will also investigate the efficacy of HB-201 alone and in combination with nivolumab. We anticipate commencing the initial

Phase 1/2 clinical trial in the second half of 2019 with preliminary data expected to be available in late 2020 or early 2021.



*HB-202 Preclinical Studies*

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



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

#### *HB-201 and HB-202 Clinical Plans*

Based on preclinical data observed with HB-201, we intend to commence an open label dose escalating Phase 1/2 trial to evaluate HB-201 alone and in combination with nivolumab. Based on our preclinical experience, we anticipate that this combination approach may deliver significantly more robust anti-tumor activity in patients than nivolumab alone. The design of the trial will be the same as that of the single agent trial for HB-201. The primary endpoint of the Phase 1 portion of this trial will be to evaluate safety and tolerability to determine the recommended dose for the Phase 2 portion of the trial. Secondary endpoints will evaluate anti-tumor activity and immunogenicity. We anticipate commencing the initial Phase 1/2 trial in the second half of 2019 with preliminary data expected to be available in late 2020 or early 2021. Subsequent trials will also investigate the potential of HB-201 and HB-202 together and in combination with nivolumab.

#### **Targeting Self-Antigens**

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

#### **Additional Product Opportunities: Tumor Self-Antigens**

Our HB-101, HB-201 and HB-202 programs target viral antigens associated with virally-induced tumors. In these programs, the viral, or non-self nature of the antigens, makes them a natural target for an immunotherapy approach. In addition, we are pursuing the development of product candidates based on our arenavirus platform to target self-antigens, non-viral antigenic proteins that are highly overexpressed in solid tumors or only minimally expressed in normal cells. Because these self-antigens are found in certain normal cells as well as tumor cells, the immune system does not typically recognize them as foreign proteins and does not respond to them. This protection of self-antigens from immune system attack is known as immune tolerance. The results obtained by earlier-generation marketed products such as sipuleucel-T, developed as Provenge by Dendreon Pharmaceuticals, Inc. and currently marketed by Sanpower Group Co., Ltd. have proven that it is possible to overcome immune tolerance and activate the immune system to produce an anti-tumor response.

#### ***HB-301 in Prostate Cancer***

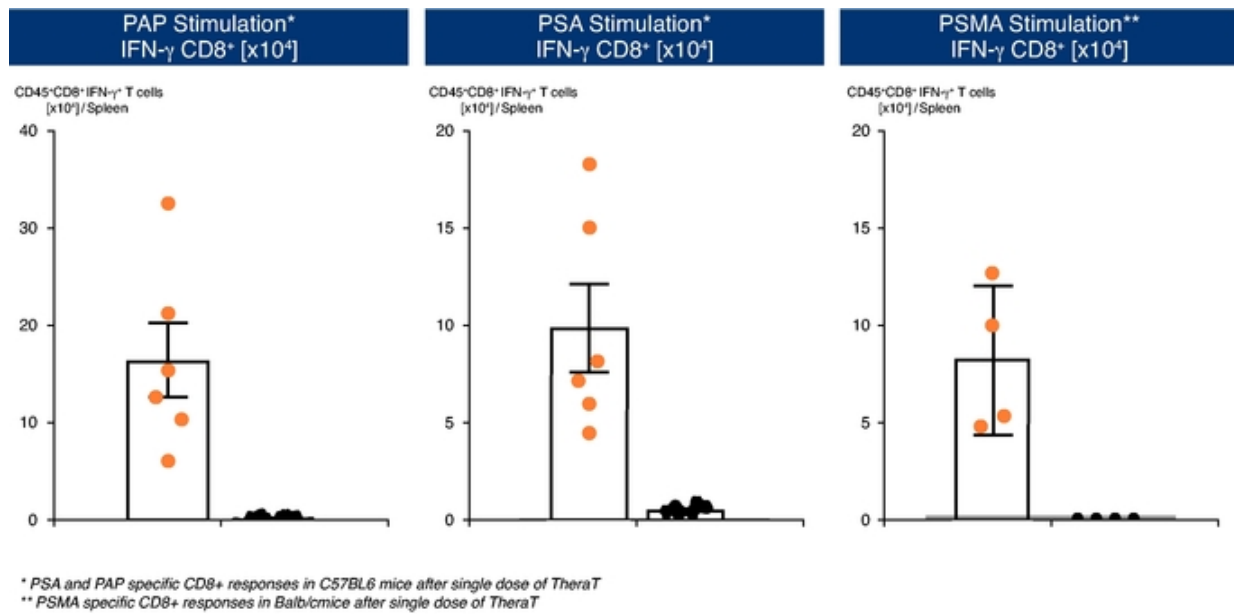
We are developing our most advanced self-antigen project in this area, HB-301, as a TheraT product candidate in metastatic, hormone-resistant prostate cancer. Prostate cancer provides a unique treatment opportunity for immunotherapy because prostate cancer cells express a number of tumor-specific antigens that serve as potential targets. HB-301 targets three of these antigens: prostatic acid phosphatase, or PAP, prostate specific antigen, or PSA, and prostate-specific membrane antigen, or PSMA.

Direct evidence for the ability to induce a therapeutically relevant immune response to one of these antigens, PAP, comes from Provenge. To create Provenge, a personalized treatment, clinicians remove dendritic cells from the body, load them with PAP and then reintroduce them to the patient. The use of Provenge has been shown to increase survival in patients with metastatic, hormone-resistant prostate cancer. Other companies are developing dendritic cell therapies similar to Provenge by using



other tumor antigens. All of these dendritic cell therapies require a complex, patient-specific therapeutic manufacturing process involving isolating cells from patients, loading them *ex vivo* with tumor antigens and then re-administering the cells to patients.

Our TheraT technology has been engineered to hold two additional genes compared to the natural form of the arenavirus. This allows us to express multiple antigens in one construct. In HB-301, we are including the coding sequences for PAP, PSA and PSMA antigens. Since it is a TheraT-based product candidate, we can deliver HB-301 by simple infusion and it can target dendritic cells in the body without the need for cellular isolation or *ex vivo* processing. We have shown in preclinical experiments that TheraT vectors can lead to robust CD8<sup>+</sup> T cell responses to the encoded antigens. We intend to maximize these CD8<sup>+</sup> T cell responses using a combination of TheraT vectors based on both LCMV and PICV in a sequential dosing regimen.



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

#### Next Generation Product Candidates

A critical advantage of our technology is that it is designed to deliver full length proteins directly to dendritic cells for endogenous expression and direct presentation to CD8<sup>+</sup> T cells. Having the dendritic cell express and present full length proteins rather than fragments overcomes the major difficulty of attempting to predict which part of the protein, or epitope, will be presented by the patient's individual major histocompatibility complex, or MHC, class I alleles. This presentation is important in immunotherapy because T cells will only recognize and respond to the antigen when it is bound to the individual's MHC class I molecules, of which several hundred different versions exist in the population. While this approach overcomes the major issue faced by neo-epitope-based personalized antigen approaches, it also has limitations in that the repertoire of known tumor-associated proteins that could be used for targets is limited. The best example of full length proteins that are, to a degree, cancer specific and immunogenic include the cancer-testis antigens, examples of which include NY-ESO-1, MAGE and CAGE. These cancer-testis antigens have been known for decades, and many of them are currently being pursued by other companies. For many tumor types the cancer-testis type of antigens remains unknown. Furthermore, most of the known tumor-associated

antigens are not commonly expressed or are not sufficiently specific to tumor tissue, making them suboptimal targets for clinical development.

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

### **Intellectual Property**

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

As of February 28, 2019, we are the owner or exclusive licensee to five issued U.S. patents and seven pending U.S. patent applications, 22 issued foreign patents and approximately 58 foreign patent applications, and two international Patent Cooperation Treaty, or PCT, applications. These patents and patent applications are related to our technologies concerned with the arenavirus-based immunization systems, VaxWave and TheraT, our product candidates and various development programs, which are directed to the use of these immunization systems for the treatment and/or prevention of various infectious diseases or cancer, and certain clinical uses of our current or future product candidates in oncology. The issued patents and pending patent applications contain claims directed to various aspects of our work, including compositions of matter, methods of treatment and prevention, methods of producing certain compositions, and use of our product candidates in combination with certain other therapeutics.

#### ***VaxWave Technology Portfolio***

Our patent portfolio related to our VaxWave technology includes a patent family exclusively licensed to us from the University of Zurich. This patent family includes three patents granted in the United States and patents granted in Europe (validated in Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, Netherlands, Poland, Spain, Sweden, Switzerland and the United Kingdom), Canada, China, India, Hong Kong and Japan. This patent family also includes pending applications in the United States, Europe, China, Hong Kong and India. The granted patents and pending applications related to our VaxWave technology are expected to expire no earlier than 2028, not giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other

governmental fees. Our VaxWave technology is being employed or may be employed in one or more of the product candidates or programs described herein.

### ***TheraT Technology Portfolio***

We are the owner or exclusive licensee to proprietary patent positions related to our TheraT technology. Our patent portfolio related to our TheraT technology includes a patent family exclusively licensed from the University of Geneva. This patent family includes pending applications in the United States, Europe, Canada, Australia, Japan, India, China and Hong Kong. The second patent family in our TheraT platform portfolio is jointly owned by us and the University of Basel. The rights of the University of Basel under this patent family are exclusively licensed to us. This second patent family includes pending applications in various countries, including in the United States, Europe, Canada, Australia, New Zealand, Mexico, Japan, Brazil, Singapore, India, and Israel. The pending applications related to our TheraT technology are expected to expire between 2035 and 2037, not giving effect to any potential patent term extensions or patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. Our TheraT technology is being employed or may be employed in one or more of the product candidates or programs described herein.

### ***Oncology Technology Portfolio***

For the application of our VaxWave and TheraT technologies in oncology, we own three patent families. These patent families include pending applications in the United States, Europe, Australia, Canada, China, India and Japan, as well as two pending PCT applications. These patent families relate to potential clinical uses of our product candidates, such as combination treatments and modes of administration. The pending applications are expected to expire between 2036 and 2038, not giving effect to any potential patent term extensions or patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

### ***HB-101 (Cytomegalovirus)***

Our HB-101 product candidate relies on our VaxWave technology. In addition to the VaxWave patent portfolio, we own one patent family that more specifically relates to our HB-101 product candidate. This patent family includes one patent granted in the United States with claims directed to pharmaceutical compositions. This patent family also includes pending applications in the United States, Europe, Australia, Canada, China, Hong Kong, India and Japan. Excluding the VaxWave patent portfolio, the granted patent and pending applications specifically related to our HB-101 product candidate are expected to expire in 2034, not giving effect to any potential patent term extensions or patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

### ***HBV***

Our HBV program, co-developed with Gilead, is in the discovery phase and is being built on either our VaxWave or TheraT technologies. In addition to the VaxWave and TheraT patent portfolios, we own one patent family that relates to the use of our platform technologies for prevention and treatment of HBV. This patent family includes pending applications in the United States, Europe, Australia, Brazil, Canada, China, India, Israel, Japan, Korea, Mexico, New Zealand and Singapore. Excluding the VaxWave and TheraT patent portfolios, the pending applications related to the HBV program are expected to expire in 2036, not giving effect to any potential patent term extensions or patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

### **HIV**

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

### **HB-201 (HPV)**

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

### **HB-202 (HPV)**

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

### **HB-301**

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

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

Our ability to maintain and solidify our proprietary position for our product candidates and technologies will depend on our success in obtaining effective patent claims and enforcing those claims once granted. We do not know whether any of our patent applications will result in the issuance of any patents, or what the scope of the claims in any future issued patents may be. Our issued patents and those that may issue in the future, or those licensed to us, may be challenged, invalidated, narrowed, rendered unenforceable or circumvented, which could limit our ability to stop competitors from marketing identical or substantially similar products or could reduce the length of term of patent protection that we may have for our products. With respect to patents and patent applications licensed to us, our licensors may have the right to terminate our licenses if we fail to comply with our obligations under the applicable license agreement. In addition, the claims granted in any of our issued

patents may not provide us with advantages against competitors with similar products or technology. Furthermore, our competitors may independently develop technologies that are similar or identical to technology developed by us but that do not infringe our patents or other intellectual property. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, by the time that any of our product candidates or those developed by our collaborators can be commercialized, our key patent may have expired or may only continue to remain in force for a short period following commercialization, thereby reducing the usefulness of the patent.

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

## **Gilead Collaboration Agreement**

### ***Overview***

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

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

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

### ***Governance***

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

### ***Research on HBV and HIV products***

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

### ***Development and Commercialization of HBV and HIV products***

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

### ***Non-Compete***

We may not, directly or indirectly, conduct, participate in or fund any research, development, manufacture, or commercialization of, or with respect to products utilizing arenavirus-based vectors for the treatment, cure, diagnosis, or prevention of HBV or HIV, except for the activities we are expressly permitted to perform under the Collaboration Agreement.

### ***Right of First Negotiation***

Pursuant to the Collaboration Agreement, in the event we offer a license or other rights to the Licensed Technology to a third party to research, develop, manufacture or commercialize a Licensed Product outside of the Field before June 4, 2028, we are required to offer Gilead a right of first negotiation for the same rights to the Licensed Technology in such field offered to the third party.

### ***Financial Terms***

Upon execution of the Collaboration Agreement, Gilead paid us a one-time upfront fee of \$10.0 million. For each of the HBV and the HIV program, Gilead is obligated to pay us a one-time, low six-digit dollar amount upon the delivery by us of each research grade vector specified in the applicable program and a one-time mid seven-digit dollar amount after initiation of the IND-enabling studies for such program. In addition we are eligible for up to \$140.0 million in developmental milestone payments for each of the HBV and HIV programs and \$50.0 million in commercialization milestone payments for each of the HBV and HIV programs. Upon the commercialization of a Licensed Product, we are eligible to receive tiered royalties of a high single-digit to mid-teens percentage on the worldwide net sales of each HBV Licensed Product, and royalties of a mid-single-digit to low-teens percentage of worldwide net sales of each HIV Licensed Product. The royalty payments are subject to reduction under specified conditions set forth in the Collaboration Agreement. In December 2018, we achieved the first research milestone under the HIV program, entitling us to a payment of \$2.8 million from Gilead.

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

### ***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. Gilead may terminate at any time in its entirety for convenience or on a product-by-product or a country-by-country basis upon prior written notice. If the Collaboration Agreement is not otherwise terminated prior to the expiration of the last-to-expire royalty term, upon such expiration the license granted to Gilead will continue in effect, but will be fully paid-up, royalty-free, perpetual, and irrevocable.

### **License Agreements**

#### ***University of Geneva License Agreement***

In February 2017, we entered into an Exclusive License Agreement with the University of Geneva, or 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 Arenavirus 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, sale, or importation 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. Beginning on March 31, 2019 and for as long as the University of Geneva has not received any milestone, royalty or sublicense payments pursuant to the Geneva Agreement, we are required to provide the University of Geneva with an annual report detailing our efforts and progress to develop Geneva Licensed Products. We are 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. The University of Geneva can terminate the Geneva Agreement if we fail to provide such report, such report shows that we have stopped the development and/or exploitation of the technology licensed by the University of Geneva to us, or if we fail to provide proof of filing of such IND within such seven year period.

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

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

University of Geneva may terminate the Geneva Agreement if we cease to carry on our business or become insolvent.

### ***University of Basel License Agreement***

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

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

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

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

### ***University of Zurich License Agreement***

In October 2011, we entered into a License Agreement with the University of Zurich, or 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," or the Zurich Licensed Patent Rights, to make and have made, use, sell, offer for sale, and import products that fall within the scope of the Zurich Licensed Patent Rights, each a Zurich Licensed Product and to practice the Zurich Licensed Patent Rights and methods that fall within the scope of the Zurich Licensed Patent Rights, each a Zurich Licensed Method.

Pursuant to the terms of the Zurich Agreement, we are obligated to diligently proceed with the development, manufacture, and sale of, and the obtaining of government approvals for the manufacture, use and sale of, suitable Zurich Licensed Products in the United States, Japan and certain European countries. If we fail to use commercially reasonable efforts to do the foregoing, the University of Zurich can demand a written development and marketing plan. Failure of the parties to



agree on a development and marketing plan entitles the University of Zurich to terminate the Zurich Agreement. Beginning on January 1, 2012 and ending on the date of the first commercial sale of a Zurich Licensed Product, we are required to provide the University of Zurich with an annual report detailing our efforts to develop and test Zurich Licensed Products and to use the Zurich Licensed Patent Rights and Zurich Licensed Methods.

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

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

#### ***National Institutes of Health License Agreement***

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

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

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

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

default within a specified period upon notice thereof. We may terminate the NIH Agreement for convenience upon prior notice.

## Competition

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

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

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

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

- In cytomegalovirus management, companies such as Helocyte, Inc., VBI Vaccines Inc., Moderna, Inc., SL VaxiGen Inc., Merck & Co., GlaxoSmithKline plc and Pfizer Inc.
- In immuno-oncology for HPV+ cancers, companies such as Kite Pharma, a Gilead company, Advaxis, Inc., ISA Pharmaceuticals B.V., in collaboration with Regeneron Pharmaceuticals, Inc. and BioNtech AG;

On the technology level, other direct competitors which can potentially develop competing product candidates in areas in and outside of HPV16+ cancers and cytomegalovirus infection such as neoantigens, oncolytic viruses, bispecific antibodies, engineered cell therapies and tumor specific antigens, and other active immunization technologies, include, among others, Gritstone Oncology, Inc., in collaboration with bluebird bio, Inc., Neon Therapeutics, Inc., Replimune Group, Inc., in collaboration with Bristol-Myers Squibb Company, Immune Design Corp., in collaboration with MedImmune LLC, Turnstone Biologics Inc., Adaptimmune PLC, Achilles Therapeutics Ltd., CureVac AG, Roche Holdings AG, Five Prime Therapeutics, Inc., Novartis International AG and Juno Therapeutics, Inc.

Many of our competitors, either alone or in combination with their respective strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, the regulatory approval process, and marketing than we do. Mergers and acquisition activity in the pharmaceutical, biopharmaceutical and biotechnology sector is likely to result in greater resource concentration among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through sizeable collaborative arrangements with established companies. These competitors also compete with us in recruiting and retaining

qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

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

## **Manufacturing**

We are establishing manufacturing processes and supply agreements for all of the components used in our product candidates to support ongoing and planned clinical trials. These include the components for our VaxWave-based and TheraT-based product candidates. We rely on CMOs to produce our product candidates for clinical use and currently do not own or operate manufacturing facilities beyond laboratory scale 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 before the launch of our first commercial product, we may continue to rely on CMOs for parts of the process, like filling and labelling of our products for commercial sale. We maintain agreements with potential and existing manufacturers that include confidentiality and intellectual property provisions to protect our proprietary rights related to our product candidates.

We plan to ultimately establish our own manufacturing facility. By establishing our own manufacturing facility, we aim to minimize or eliminate our reliance on CMOs, which typically have limited capacity at commercial scale and quality. We believe that having control over the whole manufacturing process will allow us to reduce cycle times, increase the robustness and consistency of the process and reduce cost of goods for commercial production. We expect that control over our own manufacturing facility will also help to shorten overall timelines for new product candidates in our development pipeline, as well as help us develop drug formulations or presentations to simplify distribution as well as administration of future immunotherapeutics. We also believe that having a dedicated manufacturing facility will allow us to optimize commercial-scale processes and to develop a suitable workforce capable of supporting market launch.

As an intermediate step between utilizing different CMOs for production of clinical trial material, depending on their availability at the required times, and establishing our own manufacturing facility, we have recently entered into an agreement with Valneva Sweden AB, or Valneva, a commercial vaccine manufacturer, by which we gain exclusive access to a dedicated GMP facility including qualified workforce for the manufacture of clinical trial material according to our specifications. We expect that through this agreement, the necessary capacity for manufacture of Phase 1 and Phase 2 clinical trial material will largely be covered from 2020 onwards. In addition, we will avoid technology transfer activities to different CMOs and will benefit from increases in experience and efficiency with each additional run performed under the Valneva agreement.

## **Government Regulation**

Government authorities in the United States at the federal, state and local level and in other countries regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of biological products, such

as those developed from our VaxWave and TheraT technologies and any other product candidates we develop. Generally, before a new drug or biologic can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority.

### ***U.S. Biological Product Development***

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

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

- Completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with GLP requirements;
- Submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- Approval by an Institutional Review Board, or IRB, or independent ethics committee at each clinical trial site before each trial may be initiated;
- Performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, good clinical practice, or GCP, requirements and other clinical trial-related regulations to establish the safety and efficacy of the investigational product for each proposed indication;
- Submission to the FDA of a BLA;
- A determination by the FDA within 60 days of its receipt of a BLA to accept the filing for review;
- Satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the biologic will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the biologic's identity, strength, quality and purity;
- Potential FDA audit of the clinical trial sites that generated the data in support of the BLA; and

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

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

### ***Preclinical Studies and IND***

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

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

### ***Clinical Trials***

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

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

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

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the product candidate.
- Phase 2 clinical trials involve studies in disease-affected patients to determine the dose required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, possible adverse effects and safety risks are identified and a preliminary evaluation of efficacy is conducted.
- Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product labeling.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of a BLA.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse events, findings from other studies or animal or in vitro testing that suggest a significant risk for human subjects and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure.

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

#### ***FDA Review Process***

Following completion of the clinical trials, data are analyzed to assess whether the investigational product is safe and effective for the proposed indicated use or uses. The results of preclinical studies and clinical trials are then submitted to the FDA as part of a BLA, along with proposed labeling, chemistry and manufacturing information to ensure product quality and other relevant data. The BLA may include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources,

including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety, purity and potency of the investigational product to the satisfaction of FDA. FDA approval of a BLA must be obtained before a biologic may be marketed in the United States.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each BLA must be accompanied by a user fee. The FDA adjusts the PDUFA user fees on an annual basis. According to the FDA's fee schedule, effective through September 30, 2019, the user fee for an application requiring clinical data, such as a BLA, is \$2,588,478. The sponsor of an approved BLA is also subject to an annual prescription drug program fee, which for fiscal year 2019 is \$309,915. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

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

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

### ***Orphan Drug Designation***

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

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

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

### ***Expedited Development and Review Programs***

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

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

A product may also be eligible for accelerated approval, if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, or IMM, that is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA may require that a sponsor of a drug or biologic receiving accelerated approval perform



adequate and well-controlled post-marketing clinical trials. If the FDA concludes that a drug or biologic shown to be effective can be safely used only if distribution or use is restricted, it will require such post-marketing restrictions, as it deems necessary to assure safe use of the product. If the FDA determines that the conditions of approval are not being met, the FDA can withdraw its accelerated approval for such drug or biologic.

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

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

### ***Pediatric Information***

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

### ***Post-Marketing Requirements***

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

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

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

#### ***U.S. Healthcare Reform and Other U.S. Healthcare Laws***

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

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

- The federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under the Medicare and Medicaid programs, or other federal healthcare programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, the government may

assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;

- The federal civil and criminal false claims laws and civil monetary penalty laws, including the FCA, which prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to, or approval by, the federal government or knowingly making, using or causing to be made or used a false record or statement, including providing inaccurate billing or coding information to customers or promoting a product off-label, material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the federal government. In addition, manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;
- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose, among other things, specified requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities and their business associates. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- The federal legislation commonly referred to as the Physician Payments Sunshine Act, created under the Patient Protection and Affordable Care Act, or ACA, and its implementing regulations, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

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

Pricing and rebate programs must comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the ACA. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws.

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

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

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

The failure to comply with any of these laws or regulatory requirements subjects companies to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause a pharmaceutical company to incur significant legal expenses and divert management's attention from the operation of the business.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the ACA was passed, which substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, subjects biological products to potential

competition by lower-cost biosimilars, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and creates a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (70% commencing January 1, 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition to coverage under Medicare Part D for the manufacturer's outpatient drugs.

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

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2027 unless additional congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers.

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

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

### ***U.S. Patent-Term Restoration and Marketing Exclusivity***

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

An abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA-licensed reference biological product was created by the Biologics Price Competition and Innovation Act of 2009 as part of the ACA. This amendment to the PHS Act, in part, attempts to minimize duplicative testing. Biosimilarity, which requires that the biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, animal studies and a clinical trial or trials. Interchangeability requires that a biological product be biosimilar to the reference product and that the product can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times to an individual, that the product and the reference product may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product without such alternation or switch. A reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. "First licensure" typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity, or potency. Therefore, one must determine whether a new product includes a modification to the structure of a previously licensed product that results in a change in safety, purity, or potency to assess whether the licensure of the new product is a first licensure that triggers its own period of exclusivity. Whether a subsequent application, if approved, warrants exclusivity as the "first licensure" of a biological product is determined on a case-by-case basis with data submitted by the sponsor.

Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing regulatory exclusivity periods. This

six-month exclusivity may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

### ***European Union Drug Development***

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

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

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

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

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

- The Community MA is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the EMA and is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced-therapy medicines such as gene-therapy, somatic cell-therapy or tissue-engineered medicines and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.
- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a member state of the EEA, this National MA can be recognized in other member states through the Mutual Recognition Procedure. If the product has not received a National MA in any member state at the time of application, it can be approved simultaneously in various member state through the Decentralized Procedure. Under the Decentralized Procedure an identical dossier is submitted to the

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

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

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

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

In the European Union, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity is granted following medicinal product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. Orphan drug designation must be requested before submitting an application for MA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

#### ***European Union Drug Marketing***

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

Payments made to physicians in certain EU member states must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization as well as the regulatory authorities of the individual EU member states. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU member states. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

#### ***European Data Collection***

The collection and use of personal health data in the EU is governed by the provisions of the Data Protection Directive, and as of May 2018 the General Data Protection Regulation, or GDPR. This directive imposes several requirements relating to the consent of the individuals to whom the



personal data relates, the information provided to the individuals, notification of data processing obligations to the competent national data protection authorities and the security and confidentiality of the personal data. The Data Protection Directive and GDPR also impose strict rules on the transfer of personal data out of the EU to the United States. Failure to comply with the requirements of the Data Protection Directive, the GDPR, and the related national data protection laws of the EU member states may result in fines and other administrative penalties. The GDPR introduces new data protection requirements in the EU and substantial fines for breaches of the data protection rules. The GDPR regulations may impose additional responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. This may be onerous and adversely affect our business, financial condition, results of operations and prospects.

### ***Rest of the World Regulation***

For other countries outside of the EU and the United States, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. Additionally, the clinical trials must be conducted in accordance with GCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

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

### ***Reimbursement***

Sales of our products, when and if approved, will depend, in part, on the extent to which our products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. In the United States, no uniform policy of coverage and reimbursement for drug or biological products exists. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of our products will be made on a payor-by-payor basis. As a result, coverage determination is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

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

The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the Department of Health and Human Services as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. The ACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs from 15.1% of average manufacturer price, or AMP, to 23.1% of AMP and adding a new rebate calculation for "line extensions" (i.e., new

formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The ACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by enlarging the population potentially eligible for Medicaid drug benefits.

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

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

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

In addition, in most foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may

approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

## **Employees**

As of February 28, 2019, we had 60 full-time employees and 18 part-time employees. Of our 78 full and part-time employees, 22 have Ph.D. or M.D. degrees and 65 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.

## **Facilities**

Our principal executive offices are located in New York, New York, pursuant to a lease that expires in February 2024. Our European research and preclinical development operations are located in Vienna, Austria, where we lease and occupy approximately 30,638 square feet of office and laboratory space. Our first facility is leased pursuant to two operating leases, comprised of (i) a lease of unlimited duration for approximately 15,198 square feet of office and laboratory space and (ii) a lease set to expire in September 2028 and with no option to extend for approximately 2,357 square feet of storage space. In January 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. We believe that our current facilities are adequate to meet our ongoing needs, and that, if we require additional space, we will be able to obtain additional facilities on commercially reasonable terms.

## **Legal Proceedings**

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

**MANAGEMENT****Executive Officers and Directors**

The following table sets forth the name, age, and position of each of our current executive officers and directors as of February 28, 2019:

| <b>Name</b>                                     | <b>Age</b> | <b>Position</b>   |
|---|------------|---|
| <i>Executive Officers:</i>                      |            |   |
| Jörn Aldag                                      | 60         | Chief Executive Officer, Director                                 |
| Reinhard Kandra                                 | 49         | Chief Financial Officer, Director                                 |
| Igor Matushansky, M.D., Ph.D.                   | 46         | Chief Medical Officer and Global Head of Research and Development |
| Daniel Pinschewer, M.D.                         | 44         | Chief Scientific Officer  |
| Anders Lilja, Ph.D.                             | 46         | Senior Vice President Technical Development                       |
| Klaus Orlinger, Ph.D.                           | 41         | Senior Vice President Research                                    |
| <i>Non-Employee Directors:</i>                  |            |   |
| Jan van de Winkel, Ph.D. <sup>(2)(3)</sup>      | 57         | Chairman of the Board, Director                                   |
| Christoph Lengauer, Ph.D. <sup>(3)</sup>        | 53         | Director  |
| Sander van Deventer, M.D., Ph.D. <sup>(1)</sup> | 64         | Director  |
| Paul-Henri Lambert, M.D. <sup>(4)</sup>         | 80         | Director  |
| Graziano Seghezzi <sup>(2)</sup>                | 50         | Director  |
| Julie O'Neill <sup>(1)</sup>                    | 53         | Director  |
| Michael A. Kelly <sup>(1)</sup>                 | 62         | Director  |
| David R. Kaufman, M.D., Ph.D. <sup>(5)</sup>    | 47         | Director  |

(1) Member of the audit committee.

(2) Member of the compensation committee.

(3) Member of the nominating and corporate governance committee.

(4) Dr. Lambert will resign from our board of directors effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

(5) Dr. Kaufman has been appointed to our board of directors effective immediately following the effectiveness of the registration statement of which this prospectus forms a part.

**Executive Officers**

**Jörn Aldag** has served as our Chief Executive Officer and a member of our board of directors since HOOKIPA Pharma's inception to date. Mr. Aldag served as the Chief Executive Officer at uniQure N.V. (Nasdaq: QURE, formerly, Amsterdam Molecular Therapeutics N.V.), or uniQure, from October 2009 to December 2015 and as an advisor to the board from January 2016 to May 2016. Prior to his tenure at uniQure, Mr. Aldag was President and Chief Executive Officer of Evotec AG from November 1997 to December 2008. Mr. Aldag serves as a non-executive director on the board of Unum Therapeutics, Boston, USA, since January 2016. Mr. Aldag also served as the Chairman of Molecular Partners AG, Zurich, Switzerland (SWIX: MOLN) from 2007 to 2018. He co-founded G7 Therapeutics AG in 2014, which was acquired by Heptares Therapeutics Ltd. in 2016. Mr. Aldag received business degrees from the Harvard Business School (Advanced Management Program) in 1994

and from the European Business School (Diplom Betriebswirt) in 1982. Our board of directors believes that Mr. Aldag's experience gained from serving as our Chief Executive Officer, combined with his previous qualifications and the skills and experience he has developed during his extensive career in the life sciences industry, qualify him to serve as a member of our board of directors.

**Reinhard Kandra** has served as our Chief Financial Officer since April 2017 and as a member of our board of directors since June 2018. Mr. Kandra served as the Chief Financial Officer and Member of the Management Board of Valneva SE, or Valneva, from May 2013 to March 2017. Prior to Valneva, he served as Chief Financial Officer of Intercell AG, or Intercell, from March 2009 to May 2013 and as Member of Intercell's Management Board from November 2011 to May 2013, which merged with Vivalis SA to become Valneva in May 2013. Mr. Kandra received doctorate degrees in Business Administration and in Law from the Vienna University. Our board of directors believes that Mr. Kandra's experience gained from serving as our Chief Financial Officer, combined with his previous qualifications and the skills and experience he has developed during his extensive career in the life sciences industry, qualify him to serve as a member of our board of directors.

**Igor Matushansky, M.D., Ph.D.**, has served as our Chief Medical Officer and Global Head of Research and Development since February 2017. Dr. Matushansky served as the Global Head of Translational Development for Oncology at Daiichi Sankyo from 2015 to 2017, where he led Daiichi Sankyo's international research unit that focused on early oncology therapeutic programs, strategy and development and was also responsible for a range of development activities, including post-target identification, clinical trials and proof-of-concept research. Before this, Dr. Matushansky worked at Novartis from 2012 to 2015 as both Global Head for Clinical and Scientific Development in the Gene & Cell Therapy Unit and as Global Clinical Program Lead within the Oncology Translational Medicine Unit. Prior to this, he was a Professor at Columbia University Medical Center from 2007 to 2012 where he ran an independent laboratory that focused on the molecular biology of sarcomas, including translational opportunities and clinical trials. Dr. Matushansky received a B.A. degree, summa cum laude, from Columbia University, and a M.D. and Ph.D. in Molecular Biology from the Albert Einstein College of Medicine. He performed his internal medicine residency at New York Presbyterian Hospital/Weill Cornell Medical Center and then completed a fellowship in Medical Oncology as well as a post-doctoral research fellowship in Cancer Biology at the Memorial Sloan Kettering Cancer Center. He is currently a Clinical Assistant Professor of Medical Oncology at Columbia University. He has also been a non-executive director on the board of directors of Crescendo Biologics Ltd since June 2018.

**Daniel Pinschewer, M.D.**, has served as our Chief Scientific Officer since January 2017 and is our founder. Since 2013, he has served as a professor of virology at the University of Basel Medical School. From 2007 to 2013, Dr. Pinschewer served as associate professor of immunology at the University of Geneva Medical School. Dr. Pinschewer received his M.D. from the University of Zurich.

**Anders Lilja, Ph.D.**, has served as our Senior Vice President of Technical Development since January 2019. He began leading the technological development of our products in 2016, and previously served as project leader for our HB-101 program from 2014 to 2016. From 2013 to 2014, Dr. Lilja served as director of Virology and Molecular Biology at Batavia Bioservices, Inc. He previously served at Novartis Vaccines and Diagnostics, Inc. as research investigator from 2009 to 2013 and associate research project leader from 2010 to 2013. He received his M.Sc. in chemical engineering from Chalmers University of Technology and a Ph.D. in biochemistry from the University of Maryland. He also did postdoctoral training in molecular virology at Princeton University.

**Klaus Orlinger, Ph.D.**, has served as our Senior Vice President of Research since January 2019. He began leading our research and preclinical departments in 2017, and previously served as our head of virology from 2012 to 2016. From 2008 to 2012, Dr. Orlinger previously led a research team in the Molecular Vaccines Department of Baxter AG. He received his M.Sc. and Ph.D. in genetics and microbiology from the University of Vienna.

## Non-Employee Directors

**Jan van de Winkel, Ph.D.**, has served as Chairman of our board of directors since October 2017. Dr. van de Winkel is a co-founder of Genmab A/S and has served as the company's President and Chief Executive Officer since June 2010. Prior to June 2010, he served as Genmab's President Research & Development and Chief Scientific Officer. Dr. van de Winkel serves on the board of directors of Celdara Medical Inc. and LEO Pharma, as well as the scientific advisory board of Thuja Capital Healthcare Fund and the advisory board of Capricorn Healthtech Fund. Our board of directors believes that Dr. van de Winkel's experience in biopharmaceutical research and development and his experience in managerial and director roles in life sciences companies qualify him to serve on our board of directors.

**Christoph Lengauer, Ph.D.**, has served as a member of our board of directors since June 2018. Dr. Lengauer is currently a venture partner at Third Rock Ventures and President of Celsius Therapeutics, Cambridge, USA. He was the Chief Scientific Officer and Chief Drug Hunter at Blueprint Medicines from January 2012 to November 2016, the Vice President and Global Head of Oncology Drug Discovery and Preclinical Development at Sanofi S.A., a multinational pharmaceutical company, from May 2008 to January 2012 and Executive Director and Senior Unit Head of Oncology Discovery at the Novartis Institutes for Biomedical Research from 2005 to 2008. Prior to his experience at Novartis, Dr. Lengauer was a member of the faculty at the Sidney Kimmel Comprehensive Cancer Center at the Johns Hopkins University School of Medicine from 1997 to 2005. Dr. Lengauer received an M.Sc. from the University of Salzburg, Austria, a Ph.D. in biology from the University of Heidelberg, Germany and an M.B.A. in medical services management from The Johns Hopkins University. Our board of directors believes that Dr. Lengauer's experience in biopharmaceutical research and development and his experience in venture capital qualify him to serve on our board of directors.

**Sander van Deventer, M.D., Ph.D.**, has served as a member of our board of directors since October 2011. Dr. van Deventer has been a general partner of Forbion Capital Partners (formerly ABN AMRO Capital) since 2006. He has also been the Chief Scientific Officer of uniQure since August 2018. From 2008 to 2009, he served as the Chief Executive Officer of Amsterdam Molecular Therapeutics, or AMT, a gene therapy company that he co-founded in 1998. From 2012 to 2013, he was the Chief Executive Officer of Dezima Pharma, which was acquired by Amgen Inc. In addition, Dr. van Deventer has also served as a member of AMT's board of directors since 2007. He previously served as a member of the board of directors of Argos Therapeutics, Inc. from 2001 until 2018 and a member of the board of directors of uniQure from February 2014 until August 2018. Dr. van Deventer has also served as a professor of translational gastroenterology at Leiden University since 2008. He received an M.D. and Ph.D. from the University of Amsterdam. Our board of directors believes that Dr. van Deventer's experience serving on the boards of directors of life science companies and his experience in venture capital qualify him to serve on our board of directors.

**Paul-Henri Lambert, M.D.**, has served as a member of our board of directors since December 2011. Dr. Lambert currently serves as senior advisor and honorary professor within the Center of Vaccinology in the Department of Pathology and Immunology at the University of Geneva and is a director of the International Advanced Course of Vaccinology. He also serves as a member of the governing board of the Tuberculosis Vaccine Initiative. He previously served as chairman of the Human Vaccine Committee of the International Association for Biologicals and chairman of the Global Advisory Committee on Vaccine Safety of the World Health Organization. From 1987 to 1999, he was Chief of Microbiology and Immunology and of Vaccine Research and Development at the World Health Organization. Our board of directors believes that Dr. Lambert's extensive experience in the healthcare industry qualify him to serve on our board of directors. Dr. Lambert will resign from our board of directors effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

**Graziano Seghezzi** has served as a member of our board of directors since March 2011. Mr. Seghezzi is currently Managing Partner of Sofinnova Partners, which he joined in 2006. Previously, he seed funded and was a member of the board of directors of GlycoVaxyn (Switzerland), which was sold to GlaxoSmithKline in 2015, and Omthera Pharmaceuticals, which went public on Nasdaq in 2013 and was then sold to AstraZeneca later that year. Mr. Seghezzi was a principal at Index Ventures in Geneva, Switzerland from 2003 to 2006, and previously began his career at Sofinnova Partners from 2001 to 2003. Mr. Seghezzi also serves as a member of the board of directors of Creabilis Therapeutics (Italy), Crescendo Biologics (United Kingdom) and BiovelocITA (Milan). Mr. Seghezzi holds a degree in genetics and microbiology from the University of Pavia (Italy) and an M.B.A. from the RSM-Erasmus University (Netherlands). Our board of directors believes that Mr. Seghezzi's experience as a venture capital investor in biopharmaceutical companies and his training in both business and biology qualify him to serve as a member of our board of directors.

**Julie O'Neill** has served as a member of our board of directors since November 2018. Ms. O'Neill previously served as the Executive Vice President, Global Operations of Alexion Pharmaceuticals, Inc., a position she held from 2015 to September 2018. From 2014 to 2015, Ms. O'Neill was Senior Vice President of Global Manufacturing Operations and General Manager of Alexion Pharma International Trading. Prior to joining Alexion, Ms. O'Neill served in various leadership positions at Gilead Sciences, Inc., or Gilead, from 1997 to 2014 including Vice President of Operations and General Manager of Ireland from 2011 to 2014. Prior to Gilead, Ms. O'Neill held leadership positions at Burnil Pharmacies and Helsinn Birex Pharmaceuticals. She was previously Chairperson for the National Standards Authority of Ireland and is a member of the board and chairs the audit committee of the National Institute for Bioprocessing Research & Training. Ms. O'Neill serves as member of the board of directors of DBV Technologies S.A. (Nasdaq: DBVT). Ms. O'Neill received a Bachelor of Science in Pharmacy from University of Dublin, Trinity College and a Masters of Business Administration from University College Dublin (Smurfit School of Business) and is a Chartered Director. The board of directors believes that Ms. O'Neill's experience in the life sciences industry and her knowledge of corporate development matters qualify her to serve on our board of directors.

**Michael A. Kelly** has served as a member of our board of directors since February 2019. Mr. Kelly is currently the President of Sentry Hill Partners, LLC, a consulting firm in the global life sciences industry that he founded in 2018. He previously served in various leadership positions at Amgen, Inc., or Amgen, from 2003 to 2017, including Senior Vice President, Global Business Services from 2014 to 2017, Acting Chief Financial Officer in 2010 and 2014 and Vice President, Corporate Planning & Control and Chief Accounting Officer from 2005 to 2010. Prior to joining Amgen, Mr. Kelly previously served as Chief Financial Officer of Tanox, Inc. from 2000 to 2003 and as Vice President, Finance and Corporate Controller of Biogen, Inc. from 1998 to 2000 and Vice President, Finance and Chief Financial Officer of NutraSweet Kelco Company, a division of Monsanto Life Sciences Company from 1996 to 1998. Mr. Kelly received a B.A. from Florida A&M University. The board of directors believes that Mr. Kelly's experience in the life sciences industry and his financial background qualify him to serve on our board of directors.

**David R. Kaufman, M.D., Ph.D.**, will begin to serve as a member of our board of directors immediately following the effectiveness of this registration statement of which this prospectus forms a part. Dr. Kaufman is currently the Chief Medical Officer of The Bill & Melinda Gates Medical Research Institute, where he has served since January 2018. Dr. Kaufman previously held several positions at Merck Research Laboratories from June 2011 to December 2018, including Head of Translational Oncology from 2017 to 2018, Executive Director, Clinical Oncology from 2015 to 2017 and Associate Director, Merck Drug Development and Leadership Program from 2011 to 2014. Dr. Kaufman serves a member of the board of directors of the Society for Immunotherapy of Cancer. Dr. Kaufman received a Ph.D. in molecular virology/immunology from The Rockefeller University and

a M.D. from Weill Medical College of Cornell University. The board of directors believes that Dr. Kaufman's extensive background in pharmaceutical research and development and his experience in managerial and executive roles qualify him to serve on our board of directors.

### **Family Relationships**

There are no family relationships among any of our executive officers or directors.

### **Composition of Our Board of Directors**

Our board of directors currently consists of nine members, each of whom are members pursuant to the board composition provisions of our amended and restated certificate of incorporation and agreements with our stockholders, which agreements are described under "Certain Relationships and Related Party Transactions." These board composition provisions will terminate upon the closing of this offering. Upon the termination of these provisions, there will be no further contractual obligations regarding the election of our directors. Our nominating and corporate governance committee and our board of directors may therefore consider a broad range of factors relating to the qualifications and background of nominees, which may include diversity, which is not only limited to race, gender, or national origin. Our nominating and corporate governance committee's and our board of directors' priority in selecting board members is identification of persons who will further the interests of our stockholders through his or her established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business, understanding of the competitive landscape, and professional and personal experiences and expertise relevant to our growth strategy. Our directors hold office until their successors have been elected and qualified or until the earlier of their resignation or removal. Our amended and restated certificate of incorporation and amended and restated bylaws that will become effective upon the closing of this offering also provide that our directors may be removed only for cause by the affirmative vote of the holders of at least 66.67% of the votes that all our stockholders would be entitled to cast in an annual election of directors, and that any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

### ***Director Independence***

The Nasdaq Stock Market LLC, or Nasdaq, Marketplace Rules, or the Nasdaq Listing Rules, require a majority of a listed company's board of directors to be comprised of independent directors within one year of listing. In addition, the Nasdaq Listing Rules require that, subject to specified exceptions and phase in periods following the initial public offering, each member of a listed company's audit, compensation and nominating and corporate governance committees be independent under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act and compensation committee members must also satisfy the independence criteria set forth in Rule 10C-1 under the Exchange Act. Under the Nasdaq Listing Rules, a director will only qualify as an "independent director" if, in the opinion of the listed company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee: (1) accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries; or (2) otherwise be an affiliated person of the listed company or any of its subsidiaries. In order to be considered independent for purposes of Rule 10C-1, the board must consider, for each member of a



compensation committee of a listed company, all factors specifically relevant to determining whether a director has a relationship to such company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: (1) the source of compensation of the director, including any consulting, advisory or other compensatory fee paid by such company to the director; and (2) whether the director is affiliated with the company or any of its subsidiaries or affiliates.

In January and February of 2019, our board of directors undertook a review of the composition of our board of directors and its committees and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment, and affiliations, including family relationships, our board of directors has determined that each of our directors, with the exception of Messrs. Aldag and Kandra, is an "independent director" as defined under the Nasdaq Listing Rules. In making such determination, our board of directors considered the relationships that each such non-employee director has with our company and all other facts and circumstances that our board of directors deemed relevant in determining his or her independence, including the beneficial ownership of our capital stock by each non-employee director.

### ***Staggered Board***

In accordance with the terms of our amended and restated certificate of incorporation and amended and restated bylaws that will become effective upon the closing of this offering, will provide that the number of our directors shall be fixed from time to time by a resolution of the majority of our board of directors and that our board of directors will be divided into three staggered classes of directors and each director will be assigned to one of the three classes. At each annual meeting of the stockholders, a class of directors will be elected for a three-year term to succeed the directors of the same class whose terms are then expiring. The terms of the directors will expire upon the election and qualification of successor directors at the annual meeting of stockholders to be held during the years 2020 for Class I directors, 2021 for Class II directors and 2022 for Class III directors.

- Our Class I directors will be Jörn Aldag, Jan van de Winkel and David R. Kaufman (whose appointment to the board will be effective immediately following the effectiveness of the registration statement of which this prospectus forms a part);
- Our Class II directors will be Sander van Deventer, Graziano Seghezzi and Michael A. Kelly; and
- Our Class III directors will be Julie O'Neill, Christoph Lengauer and Reinhard Kandra.

The division of our board of directors into three classes with staggered three-year terms may delay or prevent stockholder efforts to effect a change of our management or a change in control. We expect that additional directorships resulting from an increase in the number of directors, if any, will be distributed among the three classes so that, as nearly as possible, each class shall consist of one third of the board of directors.

## **Board Leadership Structure and the Role of the Board in Risk Oversight**

### ***Board Leadership Structure***

The positions of our chairperson of the board and chief executive officer are separated, with Mr. Aldag serving as our chief executive officer and Dr. van de Winkel serving as the chairperson of our board of directors. Separating these positions allows Mr. Aldag, as our chief executive officer, to focus on our day-to-day business, while allowing the chairperson of the board to lead the board of directors in its fundamental role of providing advice to and independent oversight of management. Our board of directors recognizes the time, effort, and energy that Mr. Aldag, as our chief executive officer, must devote to his position in the current business environment, as well as the commitment required to

serve as our chairperson, particularly as the board of directors' oversight responsibilities continue to grow. Our board of directors also believes that this structure ensures a greater role for the independent directors in the oversight of our company and active participation of the independent directors in setting agendas and establishing priorities and procedures for the work of our board of directors. Our board of directors believes its administration of its risk oversight function has not affected its leadership structure. Our board of directors believes that having separate positions is the appropriate leadership structure for us at this time and demonstrates our commitment to good corporate governance.

### ***Role of the Board in Risk Oversight***

Risk is inherent with every business, and how well a business manages risk can ultimately determine its success. We face a number of risks, including those described under the section titled "Risk Factors" in this prospectus. Our board of directors is actively involved in oversight of risks that could affect us. This oversight is conducted primarily by our full board of directors, which has responsibility for general oversight of risks.

Following the closing of this offering, our board of directors will satisfy this responsibility through full reports by each committee chair regarding the committee's considerations and actions, as well as through regular reports directly from officers responsible for oversight of particular risks within our company. Our board of directors believes that full and open communication between management and the board of directors is essential for effective risk management and oversight.

### **Committees of Our Board of Directors**

Our board of directors has established an audit committee, a compensation committee, and a nominating and corporate governance committee, each of which will operate pursuant to a charter to be adopted by our board of directors and will be effective upon the effectiveness of the registration statement of which this prospectus is a part. Our board of directors may establish other committees to facilitate the management of our business. Upon the effectiveness of the registration statement of which this prospectus is a part, the composition and functioning of all of our committees will comply with all applicable requirements of the Sarbanes-Oxley Act of 2002, Nasdaq and the Securities and Exchange Commission's, or the SEC, rules and regulations.

#### ***Audit Committee***

Michael Kelly, Sander van Deventer and Julie O'Neill, will serve on the audit committee, which will be chaired by Michael Kelly. Our board of directors has determined that Michael Kelly and Sander van Deventer are "independent" for audit committee purposes as that term is defined in the rules of the SEC and the applicable Nasdaq rules, and each has sufficient knowledge in financial and auditing matters to serve on the audit committee. Our board of directors has designated Michael Kelly as an "audit committee financial expert," as defined under the applicable rules of the SEC. The audit committee's responsibilities upon closing of this offering include:

- appointing, approving the compensation of, and assessing the independence of our independent registered public accounting firm;
- pre-approving auditing and permissible non-audit services, and the terms of such services, to be provided by our independent registered public accounting firm;
- reviewing the overall audit plan with our independent registered public accounting firm and members of management responsible for preparing our financial statements;
- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures as well as critical accounting policies and practices used by us;

- coordinating the oversight and reviewing the adequacy of our internal control over financial reporting;
- establishing policies and procedures for the receipt and retention of accounting-related complaints and concerns;
- recommending based upon the audit committee's review and discussions with management and our independent registered public accounting firm whether our audited financial statements shall be included in our Annual Report on Form 10-K;
- monitoring the integrity of our financial statements and our compliance with legal and regulatory requirements as they relate to our financial statements and accounting matters;
- preparing the audit committee report required by SEC rules to be included in our annual proxy statement;
- reviewing all related person transactions for potential conflict of interest situations and approving all such transactions; and
- reviewing quarterly earnings releases.

Under the applicable Nasdaq rules, a company listing in conjunction with its initial public offering is permitted to phase in its compliance with the independent committee requirements set forth in Nasdaq Rules §5605(d) and (e) as follows: (1) one independent member at the time of listing; (2) a majority of independent members within 90 days of listing; and (3) all independent members within one year of listing.

#### ***Compensation Committee***

Jan van de Winkel and Graziano Seghezzi will serve on the compensation committee, which will be chaired by Jan van de Winkel. Our board of directors has determined that Jan van de Winkel and Graziano Seghezzi are "independent" as defined in the applicable Nasdaq rules. The compensation committee's responsibilities upon closing of this offering include:

- annually reviewing and approving corporate goals and objectives relevant to the compensation of our chief executive officer;
- evaluating the performance of our chief executive officer in light of such corporate goals and objectives and determining the compensation of our chief executive officer;
- reviewing and approving the compensation of our other executive officers;
- reviewing and establishing our overall management compensation, philosophy, and policy;
- overseeing and administering our compensation and similar plans;
- evaluating and assessing potential and current compensation advisors in accordance with the independence standards identified in the applicable Nasdaq rules;
- retaining and approving the compensation of any compensation advisors;
- reviewing and approving our policies and procedures for the grant of equity-based awards;
- evaluating director compensation and making recommendations on director compensation to the Board;
- preparing the compensation committee report required by SEC rules, if and when required, to be included in our annual proxy statement; and

- reviewing and approving the retention or termination of any consulting firm or outside advisor to assist in the evaluation of compensation matters.

#### ***Nominating and Corporate Governance Committee***

Jan van de Winkel and Christoph Lengauer will serve on the nominating and corporate governance committee, which will be chaired by Jan van de Winkel. Our board of directors has determined that Jan van de Winkel and Christoph Lengauer are "independent" as defined in the applicable Nasdaq rules. The nominating and corporate governance committee's responsibilities upon closing of this offering include:

- developing and recommending to the board of directors criteria for board and committee membership;
- establishing procedures for identifying and evaluating board of director candidates, including nominees recommended by stockholders;
- reviewing the size and composition of the board of directors to ensure that it is composed of members containing the appropriate skills and expertise to advise us;
- identifying individuals qualified to become members of the board of directors;
- recommending to the board of directors the persons to be nominated for election as directors and to each of the board's committees;
- developing and recommending to the board of directors a code of business conduct and ethics and a set of corporate governance guidelines; and
- overseeing the evaluation of our board of directors and management.

Our board of directors may from time to time establish other committees.

#### **Compensation Committee Interlocks and Insider Participation**

None of the members of our compensation committee has at any time during the prior three years been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving on our board of directors or compensation committee. For a description of transactions between us and members of our compensation committee and affiliates of such members, please see "Certain Relationships and Related Party Transactions."

#### **Code of Business Conduct and Ethics**

We have adopted a written code of business conduct and ethics that applies to all of our employees, officers, and directors, including those officers responsible for financial reporting, which will become effective upon closing of this offering. Upon the closing of this offering, our code of business conduct and ethics will be available on the Corporate Governance section of our website at [www.hookipharma.com](http://www.hookipharma.com). We intend to disclose any amendments to the code, or any waivers of its requirements, on our website or in a Current Report on Form 8-K as may be required by SEC or Nasdaq rules. We do not incorporate the information on or accessible through our website into this prospectus, and you should not consider any information on, or that can be accessed through, our website as part of this prospectus.

**EXECUTIVE COMPENSATION****Overview**

This section provides an overview of the compensation awarded to, earned by, or paid to our principal executive officer and our next two most highly compensated executive officers in respect of their service to us for our fiscal years ended December 31, 2018 and 2017. We refer to these individuals as our named executive officers. We are an "emerging growth company" within the meaning of the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act, and have elected to comply with the reduced compensation disclosure requirements available to emerging growth companies under the JOBS Act. Our named executive officers are:

- Jörn Aldag, our Chief Executive Officer;
- Reinhard Kandra, our Chief Financial Officer; and
- Igor Matushansky, our Chief Medical Officer.

This section contains certain forward-looking statements that are based on our current intentions and expectations regarding compensatory plans or arrangements we may adopt in the future. Actual plans or arrangements that we adopt following the closing of this offering may be materially different from those described in this section.

Our executive compensation program is based on a pay for performance philosophy. Compensation for our executive officers is composed primarily of the following components: base salary, cash bonus, and long-term equity incentives. Our executive officers, like all full-time employees, are eligible to participate in our retirement and health and welfare benefit plans.

**Summary Compensation Table**

The following table presents information regarding the total compensation awarded to, earned by, and paid to our named executive officers for services rendered to us in all capacities for the years ended December 31, 2018 and 2017.

| <b>Name and Principal Position</b> | <b>Year</b> | <b>Salary (\$)</b> | <b>Option Awards (\$)(1)</b> | <b>Non-Equity Incentive Plan Compensation (\$)(2)</b> | <b>All Other Compensation (\$)</b> | <b>Total (\$)</b> |
|------------------------------------|-------------|--------------------|------------------------------|---|------------------------------------|-------------------|
| Jörn Aldag(3)                      | 2018        | 361,600            | —                            | 212,706   | —                                  | 574,306           |
| <i>Chief Executive Officer</i>     | 2017        | 339,007            | —                            | 203,400   | —                                  | 542,407           |
| Reinhard Kandra(3)                 | 2018        | 295,307            | —                            | 98,436  | 13,613(4)                          | 407,356           |
| <i>Chief Financial Officer</i>     | 2017        | 195,725            | 224,547                      | 94,129  | 8,678                              | 523,079           |
| Igor Matushansky                   | 2018        | 357,000            | 279,186                      | 158,280   | 11,438(5)                          | 805,904           |
| <i>Chief Medical Officer</i>       | 2017        | 262,500            | 326,427                      | 140,000   | 9,518                              | 738,445           |

- (1) Amounts reflect the grant-date fair value of option awards granted during the applicable fiscal year as computed in accordance with ASC Topic 718. Such grant-date fair value does not take into account any estimated forfeitures related to service-vesting conditions. For information regarding assumptions underlying the valuation of equity awards, see Note 10 to our consolidated financial statements. These amounts do not correspond to the actual value that may be recognized by the executives upon vesting.
- (2) Amounts represent incentive compensation earned by our named executive officers for fiscal year performance, based upon achievement of corporate and individual goals.
- (3) The compensation paid to Messrs. Aldag and Kandra in Euro have been converted to USD at exchange rates of 1 Euro to 1.13 USD for 2017, and 1 Euro to 1.18 USD for 2018, based on the average exchange rates published by the Federal Reserve Bank for such years.

- (4) Mr. Kandera was provided with a car for his business and personal use, and reimbursement of all related insurance, maintenance, and fuel expenses for the car. The value of these automobile benefits provided to Mr. Kandera is equal to \$13,613.
- (5) Amount represents a \$11,000 Company matching 401(k) plan contribution, and \$438 in life insurance and disability insurance premium payments.

### **Narrative Disclosure to Summary Compensation Table**

**Base Salary.** Each named executive officer's base salary is a fixed component of annual compensation for performing specific duties and functions, and has been established by our board of directors taking into account each individual's role, responsibilities, skills, and expertise. In 2018, we paid annual base salaries of €306,000 to Mr. Aldag, €249,900 to Mr. Kandera, and \$357,000 to Dr. Matushansky. Our named executive officers will enter into employment agreements with us, effective upon the closing of this offering, that will increase their annual base salary to €460,000 for Mr. Aldag, €338,000 for Mr. Kandera and \$410,000 for Dr. Matushansky, which may be increased by our compensation committee during the annual redetermination of base salaries. For additional information regarding the employment agreements of our named executive officers, see subsection entitled "Employment Arrangements with our Named Executive Officers."

**Cash Bonus.** Our annual bonus program is intended to reward our named executive officers for meeting individual or corporate performance goals for a fiscal year. For 2018, the target bonus for Mr. Aldag was equal to 50% of his base salary and the target bonus for each of Mr. Kandera and Dr. Matushansky was equal to 40% of his respective base salary.

**Long-Term Equity Incentives.** Our equity grant program is intended to align the interests of our named executive officers with those of our stockholders and to motivate them to make important contributions to our performance. Generally, all stock option awards vest over four years, with 25% of each option award vesting upon the first anniversary of a vesting commencement date, and the remaining shares vesting in 12 equal quarterly installments thereafter, subject to the executive officer's continuing service relationship.

#### ***Employment Arrangements with our Named Executive Officers***

We anticipate entering into new employment agreements with each of Mr. Aldag, Mr. Kandera, and Dr. Matushansky, which will become effective upon the closing of this offering and will amend and restate each named executive officer's existing employment arrangement, as described below.

#### ***Amended and Restated Employment Agreements with our Named Executive Officers***

*Jörn Aldag.* Under the amended and restated employment agreement effective upon the closing of this offering, Mr. Aldag's base salary will be €460,000, which will be redetermined annually by our compensation committee, and he will be eligible to earn annual incentive compensation with a target amount equal to 50% of his base salary. Mr. Aldag is also eligible to participate in the employee benefit plans available to our employees, including our stock option plan, subject to the terms of those plans. Additionally, Mr. Aldag is provided with a Company laptop and mobile phone, and entitled to receive reimbursement for business travel expenses between his place of employment in Hamburg, Germany and other Company office locations. Additionally, in the event that Mr. Aldag is liable for and pays social security costs in both Germany and Austria, without any corresponding credit, the Company has agreed to reimburse Mr. Aldag for up to €25,000 of social security costs per year.

Mr. Aldag's amended and restated employment agreement contains standard confidentiality, assignment of intellectual property work product and twelve months' post-termination noncompetition, non-solicitation of employee, and non-solicitation of customer covenants.

Mr. Aldag's amended and restated employment agreement provides that, in the event that his employment is terminated by us without "cause" or Mr. Aldag resigns for "cause" (as defined with respect to each party in his amended and restated employment agreement), subject to the execution and effectiveness of a separation agreement, including a general release of claims in our favor, he will be entitled to receive (1) an amount equal to 100% of his then annual base salary, payable in substantially 12 equal installments over 12 months following his termination, and (ii) up to 12 months of continued participation in our benefit plans at active employee rates. In lieu of the payments described in the preceding sentence, in the event that Mr. Aldag's employment is terminated by us without cause or Mr. Aldag resigns for cause, in either case within 12 months following a "change in control" (as defined in his amended and restated employment agreement), subject to the execution and effectiveness of a separation agreement, including a general release of claims in our favor, he will be entitled to receive (i) a lump sum in cash an amount equal to 1.5 times the sum of (A) Mr. Aldag's then current annual base salary (or Mr. Aldag's base salary in effect immediately prior to the change in control, if higher) plus (B) Mr. Aldag's target annual incentive compensation, (ii) up to 18 months of continued participation in our benefit plans at active employee rates, and (iii) full acceleration of vesting of all stock options and other stock-based awards held by Mr. Aldag.

*Reinhard Kandra.* Under the amended and restated employment agreement effective upon the closing of this offering, Mr. Kandra's base salary will be €338,000, which will be redetermined annually by our compensation committee, and he will be eligible to earn an annual incentive compensation with a target amount equal to 40% of his base salary. Mr. Kandra will also be provided a company car with a maximum monthly leasing rate equal to €1,000, and will be reimbursed for all expenses relating to the company car. Mr. Kandra is also eligible to participate in the employee benefit plans available to our employees, including our stock option plan, subject to the terms of those plans. Additionally, Mr. Kandra is provided with a car for his business and personal use, and reimbursement of all related insurance, maintenance, and fuel expenses for the car. Mr. Kandra is provided with a Company laptop and mobile phone, and is also entitled to receive reimbursement for business travel expenses.

Mr. Kandra's amended and restated employment agreement contains standard confidentiality, assignment of intellectual property work product and twelve months' post-termination noncompetition, non-solicitation of employee, and non-solicitation of customer covenants.

Mr. Kandra's amended and restated employment agreement provides that, in the event that his employment is terminated by us without "cause" or Mr. Kandra resigns for "cause" (as defined with respect to each party in his amended and restated employment agreement), subject to the execution and effectiveness of a separation agreement, including a general release of claims in our favor, (i) he will be entitled to receive an amount equal to 100% of his then annual base salary, payable in 14 equal installments over 12 months following his termination, and (ii) up to 12 months of continued participation in our benefit plans at active employee rates. In lieu of the payments described in the preceding sentence, in the event that Mr. Kandra's employment is terminated by us without cause or Mr. Kandra resigns for cause, in either case within 12 months following a "change in control" (as defined in his amended and restated employment agreement), subject to the execution and effectiveness of a separation agreement, including a general release of claims in our favor, he will be entitled to receive (i) a lump sum in cash an amount equal to 1.0 times the sum of (A) Mr. Kandra's then current base salary (or Mr. Kandra's base salary in effect immediately prior to the change in control, if higher) plus (B) Mr. Kandra's target annual incentive compensation, (ii) up to 12 months of continued participation in our benefit plans at active employee rates, and (iii) full acceleration of vesting of all stock options and other stock-based awards held by Mr. Kandra.

*Igor Matushansky.* Under the amended and restated employment agreement effective upon the closing of this offering, Dr. Matushansky's base salary will be \$410,000, which will be redetermined annually by our compensation committee, and he will be eligible to earn an annual bonus with a target

amount equal to 40% of his base salary. Dr. Matushansky is also eligible to participate in the employee benefit plans available to our employees, subject to the terms of those plans. Additionally, Dr. Matushansky is eligible to receive reimbursement for (i) premiums paid on a \$700,000 life insurance policy, (ii) expenses incurred to maintain his professional liability insurance in the amount of \$25,000 and his medical license, (iii) the cost of automobile tolls and parking incurred from commuting to the Company's principal offices, and (iv) the costs of premium payments for long-term disability insurance in an amount up to 200 percent of his base salary.

Dr. Matushansky's amended and restated employment agreement contains standard confidentiality, assignment of intellectual property work product and twelve months' post-termination noncompetition, non-solicitation of employee, and non-solicitation of customer covenants.

Dr. Matushansky's amended and restated employment agreement provides that, in the event that his employment is terminated by us without "cause" or Dr. Matushansky resigns for "good reason" (as each term is defined in his amended and restated employment agreement), subject to the execution and effectiveness of a separation agreement, including a general release of claims in our favor, he will be entitled to receive (i) an amount equal to 12 months of his base salary, payable in substantially equal installments over 12 months following his termination, and (ii) if Dr. Matushansky is participating in our group health plan immediately prior to his termination and elects to continue COBRA health coverage, a monthly cash payment until the earlier of 12 months following termination or the end of Dr. Matushansky's COBRA health continuation period in an amount equal to the amount that we would have paid to provide health insurance to Dr. Matushansky had he remained employed with us. In lieu of the payments and benefits described in the preceding sentence, in the event that Dr. Matushansky's employment is terminated by us without cause or Dr. Matushansky resigns for good reason, in either case within 12 months following a "change in control" (as defined in his amended and restated employment agreement), subject to the execution and effectiveness of a separation agreement, including a general release of claims in our favor, he will be entitled to receive (i) a lump sum in cash an amount equal to 1.0 times the sum of (A) Dr. Matushansky's current base salary (or Dr. Matushansky's base salary in effect immediately prior to the change in control, if higher) plus (B) Dr. Matushansky's target annual incentive compensation, (ii) if Dr. Matushansky is participating in our group health plan immediately prior to his termination and elects to continue COBRA coverage, a monthly cash payment until the earlier of 12 months following termination or the end of Dr. Matushansky's COBRA health continuation period in an amount equal to the amount that we would have paid to provide health insurance to him had he remained employed with us, and (iii) full acceleration of vesting of all stock options and other stock-based awards held by Dr. Matushansky.

The payments and benefits provided to Dr. Matushansky under his amended and restated employment agreement in connection with a change in control may not be eligible for a federal income tax deduction for the Company pursuant to Section 280G of U.S. Internal Revenue Code of 1986, as amended, or the Code, or may subject Dr. Matushansky to an excise tax under Section 4999 of the Code. If the payments or benefits payable to Dr. Matushansky in connection with a change in control would be subject to the excise tax on golden parachutes imposed under Section 4999 of the Code, then those payments or benefits will be reduced if such reduction would result in a higher net after-tax benefit to Dr. Matushansky.

#### ***Prior Employment Arrangements with our Named Executive Officers***

*Jörn Aldag.* In May 2016, we entered into a management contract with Mr. Aldag, which provided for an annual base salary of €300,000. For the year ended December 31, 2018, the annual base salary for Mr. Aldag was increased to €306,000. For 2018, Mr. Aldag was eligible to earn an annual cash incentive bonus of up to 50 percent of his base salary. Additionally, Mr. Aldag was provided with a Company laptop and mobile phone, and entitled to receive reimbursement for business



travel expenses between his place of employment in Hamburg, Germany and other Company office locations.

Mr. Aldag's employment agreement contains standard confidentiality, assignment of intellectual property work product and twelve (12) months' post-termination noncompetition and non-solicitation of employees covenants.

Pursuant to Mr. Aldag's employment agreement with the Company, in the event that Mr. Aldag's employment is terminated by us without any fault on the part of Mr. Aldag, he is entitled to receive (i) a lump sum payment in the amount of his annual gross salary, and (ii) if such termination occurs before May 31, 2018, acceleration of 50 percent of his stock option, granted December 20, 2016. Alternatively, in the event that Mr. Aldag's employment as a member of our Management Board is terminated by his resignation for 'good cause', he is entitled to receive (i) a lump sum payment in the amount of his annual gross salary, and (ii) full acceleration of his stock option, granted December 20, 2016.

*Reinhard Kandra.* In March 2017, we entered into a management contract with Mr. Kandra, which provided for an annual base salary of €245,000. For the year ended December 31, 2018, the annual base salary for Mr. Kandra was increased to €249,900. For 2018, Mr. Kandra was eligible to earn an annual cash incentive bonus of up to 40 percent of his base salary. For 2017, payment of Mr. Kandra's base salary and annual cash incentive bonus were each pro-rated based on the date that he commenced employment with the Company. Additionally, Mr. Kandra was provided with a car for his business and personal use, and reimbursement of all related insurance, maintenance, and fuel expenses for the car. Mr. Kandra was provided with a Company laptop and mobile phone, and is also entitled to receive reimbursement for business travel expenses.

Mr. Kandra's employment agreement contains standard confidentiality, assignment of intellectual property work product and twelve (12) months' post-termination noncompetition and non-solicitation of employees covenants.

Pursuant to Mr. Kandra's employment agreement with the Company, in the event that Mr. Kandra's employment as a member of our Management Board is terminated by us without any fault on the part of Mr. Kandra, he is entitled to receive a lump sum payment in the amount of one month of his base salary.

*Igor Matushansky.* In February 2017, we entered into an employment agreement with Dr. Matushansky, which provided for an annual base salary of \$350,000. For the year ended December 31, 2018, the annual base salary for Dr. Matushansky was increased to \$357,000. For 2017, Dr. Matushansky was eligible to earn an annual cash incentive bonus of up to 40 percent of his base salary. For 2017, payment of Dr. Matushansky's base salary and annual cash incentive bonus were each pro-rated based on the date that he commenced employment with the Company. Additionally, Dr. Matushansky received reimbursement for (i) premiums paid on a life insurance policy on the life of Dr. Matushansky, (ii) expenses incurred to maintain his professional liability insurance and his medical license, (iii) the cost of automobile tolls and parking incurred from commuting to the Company's principal offices, and (iv) the costs of premium payments for long-term disability insurance in an amount up to 200 percent of his base salary.

Dr. Matushansky's employment agreement contains standard confidentiality, assignment of intellectual property work product and twelve (12) months' post-termination noncompetition and non-solicitation of employees covenants.

Pursuant to Dr. Matushansky's employment agreement with the Company, in the event that Dr. Matushansky's employment is terminated by us without "cause" or Dr. Matushansky resigns for "good reason" (as each term is defined in his employment agreement), subject to the execution and effectiveness of a general release of all claims in our favor and the continued compliance with the

restrictive covenants in his agreement, he will be entitled to receive (i) his base salary for a period of 12 months following his termination date, and (ii) a pro-rata portion of his annual bonus for the year of termination, to the extent that the applicable performance requirements have been met.

### Outstanding Equity Awards at 2018 Fiscal Year-End

The following table sets forth information concerning outstanding equity awards held by each of our named executive officers as of December 31, 2018.

| Name             | Vesting Commencement Date(1) | Number of Securities Underlying Unexercised Options (#) Exercisable | Number of Securities Underlying Unexercised Options (#) Unexercisable(1) | Option Exercise Price (\$) | Option Expiration Date(2) |
|------------------|------------------------------|---|--|----------------------------|---------------------------|
| Jörn Aldag       | 6/1/2016                     | 247,403   | 148,449  | 0.10                       | 12/31/2026                |
| Reinhard Kandra  | 6/1/2017                     | 27,839  | 46,385   | 0.10                       | 12/31/2026                |
|                  | 12/1/2017                    | 8,756   | 26,266   | 0.10                       | 12/31/2026                |
| Igor Matushansky | 3/1/2017                     | —   | 72,687   | 0.10                       | 12/31/2026                |
|                  | 1/1/2018                     | —   | 45,466   | 0.10                       | 12/31/2026                |
|                  | 1/1/2019                     | —   | 13,634   | 0.10                       | 12/31/2026                |
|                  | 10/1/2018                    | —   | 44,243   | 10.33                      | 12/31/2026                |

- (1) Each option vests with respect to 25% of the shares upon the first anniversary of the vesting commencement date, with the remaining shares vesting in 12 equal quarterly installments thereafter, subject to the executive's continuing service relationship.
- (2) All options outstanding as of December 31, 2018, except Dr. Matushansky's option for 44,243 shares with a vesting commencement date of October 1, 2018, were originally granted pursuant to the 2016 Stock Option Plan, which provided for an expiration date of December 31, 2026.

### Employee Benefit and Equity Compensation Plans

#### 2019 Stock Option and Incentive Plan

Our 2019 Stock Option and Incentive Plan, or the 2019 Plan, was adopted by our board of directors on March 14, 2019 and approved by our stockholders on March 28, 2019 and will become effective upon the date immediately preceding the date of the effectiveness of the registration statement of which this prospectus is a part. The 2019 Plan allows the board of directors' compensation committee to make equity-based incentive awards to our officers, employees, directors, and other key persons (including consultants).

We have initially reserved 2,608,042 shares of our common stock for the issuance of awards under the 2019 Plan, or the Initial Limit, which shall be cumulatively increased on January 1, 2020 and each January 1 thereafter by the lesser of (i) 4.0% of the number of shares of our common stock and Class A common stock issued and outstanding on the immediately preceding December 31, or (ii) such lesser number of shares as determined by the administrator, or the Annual Increase. These limits are subject to adjustment in the event of a stock split, stock dividend, or other change in our capitalization.

The shares we issue under the 2019 Plan will be authorized but unissued shares or shares underlying any awards that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by us prior to vesting, satisfied without the issuance of stock, expire, or are otherwise terminated (other than by exercise) under the 2019 Plan or the 2018 Plan.

The maximum number of shares that may be issued as incentive stock options may not exceed the Initial Limit, as cumulatively increased on January 1, 2020 and each January 1 thereafter by the lesser of the Annual Increase or 2,608,042 shares.

The 2019 Plan will be administered by our compensation committee. Our compensation committee has full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted and the number of shares subject to such awards, to make any combination of awards to participants, to accelerate at any time the exercisable or vesting of any award and to determine the specific terms and conditions of each award, subject to the provisions of the 2019 Plan.

The 2019 Plan permits the granting of both options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Code and options that do not so qualify. The option exercise price of each option will be determined by our compensation committee but may not be less than 100% of the fair market value of our common stock on the date of grant. The term of each option will be fixed by our compensation committee and may not exceed ten years from the date of grant. Our compensation committee will determine at what time or times each option may be exercised.

Our compensation committee may award stock appreciation rights subject to such conditions and restrictions as it may determine. Stock appreciation rights entitle the recipient to shares of common stock, or cash, equal to the value of the appreciation in our stock price over the exercise price. The exercise price may not be less than 100% of the fair market value of our common stock on the date of grant. The term of each stock appreciation right will be fixed by our compensation committee and may not exceed ten years from the date of grant. Our compensation committee will determine at what time or times each stock appreciation right may be exercised.

Our compensation committee may award restricted shares of common stock and restricted stock units to participants subject to such conditions and restrictions as it may determine. These conditions and restrictions may include the achievement of certain performance goals and/or continued employment with us through a specified vesting period. Our compensation committee may also grant shares of common stock that are free from any restrictions under the 2019 Plan. Unrestricted stock may be granted to participants in recognition of past services or for other valid consideration and may be issued in lieu of cash compensation due to such participant.

Our compensation committee may grant dividend equivalent rights to participants that entitle the recipient to receive credits for dividends that would be paid if the recipient had held a specified number of shares of common stock.

Our compensation committee may grant cash bonuses under the 2019 Plan to participants, subject to the achievement of certain performance goals.

The 2019 Plan provides that upon the effectiveness of a "sale event," as defined in the 2019 Plan, an acquirer or successor entity may assume, continue or substitute outstanding awards under the 2019 Plan. To the extent that awards granted under the 2019 Plan are not assumed or continued or substituted by the successor entity, upon the effective time of the sale event, such awards under the 2019 Plan shall terminate. In such case, except as may be otherwise provided in the relevant award certificate, all options and stock appreciation rights with time-based vesting that are not exercisable immediately prior to the sale event shall become fully exercisable as of the effective time of the sale event, all other awards with time-based vesting, conditions or restrictions shall become fully vested and non-forfeitable as of the effective time of the sale event, and all awards with conditions and restrictions relating to the attainment of performance goals may become vested and non-forfeitable in connection with a sale event in the administrator's discretion or to the extent specified in the relevant award certificate. In the event of such termination, individuals holding options and stock appreciation rights

will be permitted to exercise such options and stock appreciation rights (to the extent exercisable) within a specified period of time prior to the sale event. In addition, in connection with the termination of the 2019 Plan upon a sale event, we may make or provide for a cash payment to participants holding vested and exercisable options and stock appreciation rights equal to the difference between the per share cash consideration payable to stockholders in the sale event and the exercise price of the options or stock appreciation rights and we may make or provide for a cash payment to participants holding other vested awards.

Our board of directors may amend or discontinue the 2019 Plan, and our compensation committee may amend or cancel outstanding awards for purposes of satisfying changes in law or any other lawful purpose, but no such action may adversely affect rights under an award without the holder's consent. Certain amendments to the 2019 Plan require the approval of our stockholders.

No awards may be granted under the 2019 Plan after the date that is ten years from the date of stockholder approval of the 2019 Plan. No awards under the 2019 Plan have been made prior to the date hereof.

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

The 2018 Stock Option and Grant Plan, or the 2018 Plan, was adopted by our board of directors and approved by our stockholders on May 23, 2018. Under the 2018 Plan, we may grant equity-based incentive awards to eligible employees in order to attract, retain and motivate the employees who make important contributions to our company. The material terms of the 2018 Plan are summarized below.

*Shares Available for Awards.* The 2018 Plan has reserved for issuance an aggregate of 2,133,437 shares of our common stock. This number of shares of common stock reserved for issuance is subject to adjustment in the event of a stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, reorganization, or other similar change in our capitalization, or any dividend or distribution to holders of common stock other than an ordinary cash dividend.

The shares of common stock underlying awards that are forfeited, canceled, reacquired by us prior to vesting, satisfied without the issuance of stock or otherwise terminated (other than by exercise) are added back to the shares of common stock available for issuance under the 2018 Plan. In addition, shares of common stock that are withheld upon exercise of an option or settlement of an award to cover the exercise price or tax withholding are added back to the shares available for grant under the 2018 Plan.

*Administration; Eligibility.* Our board of directors has acted as administrator of the 2018 Plan. The administrator has full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted, and to determine the specific terms and conditions of each award, subject to the provisions of the 2018 Plan. Persons eligible to participate in the 2018 Plan are those employees, officers and directors of, and consultants and advisors to, our company as selected from time to time by the administrator in its discretion.

*Awards.* The 2018 Plan permits the granting of (1) options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Internal Revenue Code of 1986, as amended, (2) options that do not so qualify, (3) restricted stock, (4) unrestricted stock, or (5) restricted stock units. For stock options issued prior to an initial public offering, the 2018 Plan provides that the per share option exercise price will be equal to the U.S. dollar equivalent of one euro and the administrator has discretion to determine at what time or times each option may be exercised.

**Sale Event.** The 2018 Plan provides that upon the occurrence of a "sale event" (as defined in the 2018 Plan), our board of directors may take one or more of the following actions (or a combination of the following actions) as to some or any stock option awards outstanding under the 2018 Plan: (i) provide that unexercised options will be assumed or substituted by the acquiring or successor corporation, (ii) upon written notice to participants, provide that all unexercised options will terminate immediately prior to the consummation of such transaction unless exercised (to the extent exercisable) within a specified period following the date of such notice, (iii) provide that options shall become exercisable (in whole or in part) prior to or upon such transaction, or (iv) make or provide for a cash payment to holders of unexercised options equal to the number of shares subject to outstanding options being cancelled (to the extent exercisable) times the difference between the per share consideration in the transaction and the per share exercise price of the outstanding option. Similarly, upon the occurrence of a "sale event," our board of directors may take one or more of the following actions (or a combination of the following actions) as to some or any restricted stock or restricted stock unit awards outstanding under the 2018 Plan: (i) provide that unvested restricted stock and restricted stock unit awards will be assumed or substituted by the acquiring or successor corporation, (ii) provide that unvested restricted stock and restricted stock unit awards shall be forfeited, (iii) make or provide for a cash payment to holders of unvested restricted stock or restricted stock unit awards equal to the number of shares subject to such award times the per share consideration in the transaction. The 2018 Plan provides that an initial public offering and any subsequent public offering will not constitute a "sale event."

**Amendment; Termination.** Our board of directors may amend or discontinue the 2018 Plan at any time, subject to stockholder approval where such approval is required by applicable law. Our board of directors may also amend or cancel any outstanding award, provided that no amendment to an award may adversely affect a participant's rights without his or her consent.

As of December 31, 2018, options to purchase 1,606,325 shares of common stock were outstanding under the 2018 Plan. Our board of directors has determined not to make any further awards under the 2018 Plan following the closing of this offering.

#### ***Stock Option Plan 2016 of Hookipa Biotech AG***

Prior to our acquisition of all of the shares of Hookipa Biotech AG, our business provided long-term equity incentives under the Stock Option Plan 2016 of Hookipa Biotech AG, or the 2016 Plan. In connection with our acquisition of all of the shares of Hookipa Biotech AG, the 2016 Plan has been discontinued and each option granted under the 2016 Plan has been cancelled and substituted with an equivalent option award under the 2018 Plan.

#### ***2019 Employee Stock Purchase Plan***

Our 2019 Employee Stock Purchase Plan, or the ESPP, was adopted by our board of directors on March 14, 2019 and approved by our stockholders on March 28, 2019, and will become effective upon the effectiveness of the registration statement of which this prospectus is a part. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Code. The ESPP initially reserves and authorizes the issuance of up to a total of 260,804 shares of common stock to participating employees. The ESPP provides that the number of shares reserved and available for issuance will automatically increase on January 1, 2020, and each January 1 thereafter through January 1, 2029, by the least of (i) 785,905 shares of common stock, (ii) 1% of the outstanding number of shares of our common stock and Class A common stock issued and outstanding on the immediately preceding December 31, or (iii) such lesser number of shares as determined by the ESPP administrator. The number of shares reserved under the ESPP is subject to adjustment in the event of subdivision of our stock, stock dividend or other change in our capitalization.

All employees who have been employed at least 30 days and whose customary employment is for more than 20 hours per week are eligible to participate in the ESPP. However, any employee who owns 5% or more of the total combined voting power or value of all classes of stock is not eligible to purchase shares under the ESPP.

We will make one or more offerings each year to eligible employees to purchase shares under the ESPP. Each offering will begin at such time and on such dates as the administrator may determine, provided that no offering may exceed 27 months. Each eligible employee may elect to participate in any offering by submitting an enrollment form at least 15 days before the relevant offering date.

Each employee who is a participant in the ESPP may purchase shares by authorizing payroll deductions of up to 15% of his or her base compensation during an offering period. Unless the participating employee has previously withdrawn from the offering, his or her accumulated payroll deductions will be used to purchase shares on the last business day of the offering period at a price equal to 85% of the fair market value of the shares on the first business day or the last business day of the offering period, whichever is lower, subject to a cap of the number of shares equal to \$25,000 divided by the fair market value of the common stock on the first day of the offering period, or such other lesser number of shares as determined by the ESPP administrator. Under applicable tax rules, an employee may purchase no more than \$25,000 worth of shares of common stock, valued at the start of the purchase period, under the ESPP in any calendar year.

The accumulated payroll deductions of any employee who is not a participant on the last day of an offering period will be refunded. An employee's rights under the ESPP terminate upon voluntary withdrawal from the plan or when the employee ceases employment with us for any reason.

The ESPP may be terminated or amended by our board of directors at any time. Other than as already provided in the ESPP, an amendment that increases the number of shares of common stock authorized under the ESPP and certain other amendments require the approval of our stockholders.

### ***Senior Executive Incentive Bonus Plan***

On March 14, 2019, our board of directors adopted the Senior Executive Cash Incentive Bonus Plan, or the Bonus Plan. Our Bonus Plan provides for bonus payments based upon the attainment of performance targets established by our compensation committee. The payment targets will be related to financial and operational measures or objectives with respect to our company, or the Corporate Performance Goals, as well as individual performance objectives.

Our compensation committee may select Corporate Performance Goals from among the following: cash flow (including, but not limited to, operating cash flow and free cash flow); revenue; corporate revenue; earnings before interest, taxes, depreciation and amortization; net income (loss) (either before or after interest, taxes, depreciation and/or amortization); changes in the market price of our common stock; economic value-added; development, clinical, regulatory or commercial milestones; acquisitions or strategic transactions; operating income (loss); return on capital, assets, equity, or investment; stockholder returns; return on sales; gross or net profit levels; productivity; expense efficiency; margins; operating efficiency; customer satisfaction; working capital; earnings (loss) per share of our common stock; bookings, new bookings or renewals; sales or market shares; number of customers; number of new customers or customer references; operating income and/or net annual recurring revenue, any of which may be measured in absolute terms, as compared to any incremental increase, in terms of growth, as compared to results of a peer group, against the market as a whole, compared to applicable market indices and/or measured on a pre-tax or post-tax basis.

Each executive officer who is selected to participate in our Bonus Plan will have a target bonus opportunity set for each performance period. The bonus formulas will be adopted in each performance period by the compensation committee and communicated to each executive. The Corporate

Performance Goals will be measured at the end of each performance period after our financial reports have been published. If the Corporate Performance Goals and individual performance objectives are met, payments will be made as soon as practicable following the end of each performance period. Our compensation committee may adjust bonus amounts payable based on achievement of one or more performance objectives or pay bonuses to executive officers based on individual performance goals or such other terms as our compensation committee may determine. Subject to the rights contained in any agreement between the executive officer and us, an executive officer must be employed by us on the bonus payment date to be eligible to receive a bonus payment. Our Bonus Plan also permits the compensation committee to approve additional bonuses to executive officers in its sole discretion.

***Retirement Plans***

***401(k) Plan***

We maintain a tax-qualified retirement plan that provides eligible U.S. employees, including our named executive officers, with an opportunity to save for retirement on a tax-advantaged basis. All participants' interests in their contributions are 100% vested when contributed. Contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participants' directions. The retirement plan is intended to qualify under Section 401(a) of the Code. We match 100 percent of employee contributions, up to 4 percent of each employee's compensation (as defined in the plan).

**DIRECTOR COMPENSATION****2018 Director Compensation**

Except as set forth below, in the year ended December 31, 2018, we did not pay any compensation, make any equity or non-equity awards to, or pay any other compensation to any of the non-employee members of our board of directors for their service as a director in 2018. Jörn Aldag, our Chief Executive Officer and a member of our board of directors, and Reinhard Kandra, our Chief Financial Officer and a member of our board of directors, each did not receive any compensation for their service as members of our board of directors during 2018. Messrs. Aldag and Kandra's compensation for service as employees for fiscal year 2018 is presented above in the "2018 Summary Compensation Table."

| <u>Name</u>           | <u>Fees<br/>Earned or<br/>Paid in<br/>Cash \$(7)</u> | <u>Option<br/>Awards<br/>\$(1)</u> | <u>All Other<br/>Compensation (\$)</u> | <u>Total (\$)</u> |
|-----------------------|--|------------------------------------|--|-------------------|
| Paul-Henri Lambert(2) | 46,336   | —                                  | —                                      | 46,336            |
| Jan van de Winkel(3)  | 70,902   | —                                  | —                                      | 70,902            |
| John Lambert(4)       | 70,902   | —                                  | —                                      | 70,902            |
| Julie O'Neill(5)      | 6,667  | 77,437                             | 7,976(8)                               | 92,081            |
| Christoph Lengauer(6) | 23,333   | 77,437                             | —                                      | 100,770           |

- (1) Amounts reflect the grant-date fair value of option awards granted in 2018 in accordance with ASC Topic 718. Such grant-date fair value does not take into account any estimated forfeitures related to service-vesting conditions. For information regarding assumptions underlying the valuation of equity awards, see Note 9 to our consolidated financial statements. These amounts do not correspond to the actual value that may be recognized by the directors upon vesting.
- (2) In April 2012, we entered into an agreement with Dr. Lambert for his services as a member of our board of directors. For the year ended December 31, 2018, the annual compensation for his services was 45,000 Swiss Francs. As of December 31, 2018, Dr. Lambert held an unexercised option to purchase 6,450 shares.
- (3) In September 2017, we entered into an agreement with Dr. van de Winkel for his services as a member of our board of directors. For the year ended December 31, 2018, the annual compensation for his services as a member of our board of directors was 40,000 Euros, plus an additional 20,000 Euros for service as the chairman of our board of directors. As of December 31, 2018, Dr. van de Winkel held an unexercised option to purchase 81,967 shares.
- (4) In August 2014, we entered into an agreement with Mr. Lambert for his services as a member of our board of directors. For the year ended December 31, 2018, the annual compensation for his services was 60,000 Euros. As of December 31, 2018, Mr. Lambert held an unexercised option to purchase 67,239 shares.
- (5) In November 2018, we appointed Ms. O'Neill to our board of directors. For the year ended December 31, 2018, the annual compensation for her services was \$40,000 USD. Payment of Ms. O'Neill's annual compensation was pro-rated based on the date she commenced service on our board. As of December 31, 2018, Ms. O'Neill held an unexercised option to purchase 12,271 shares.
- (6) In June 2018, we appointed Dr. Lengauer to our board of directors. For the year ended December 31, 2018, the annual compensation for his services was \$40,000 USD.



Payment of Dr. Lengauer's annual compensation was pro-rated based on the date he commenced service on our board. As of December 31, 2018, Dr. Lengauer held an unexercised option to purchase 12,271 shares.

- (7) The compensation paid to Dr. Lambert in Swiss Francs was converted to Euros at the actual exchange rate as of the date of payment charged by banks (excluding bank charges), which has been converted to USD at an exchange rate of 1 Euro to 1.18 USD based on the average exchange rate published by the Federal Reserve Bank for 2018. The compensation paid to Dr. van de Winkel and Mr. John Lambert in Euro have been converted to USD at an exchange rate of 1 Euro to 1.18 USD based on the average exchange rate published by the Federal Reserve Bank for 2018.
- (8) Effective as of October 29, 2018, we entered into a Consultancy Service Agreement with Ms. O'Neill to provide us with advice and assistance in relation to manufacturing pharmaceutical products. In December 2018, we extended the term of such Consultancy Service Agreement until June 30, 2019. For the year ended December 31, 2018, Ms. O'Neill earned 6,750 Euros in consulting fees for services provided under the Consultancy Service Agreement, which has been converted to USD at an exchange rate of 1 Euro to 1.18 USD based on the average exchange rate published by the Federal Reserve Bank for 2018.

We expect to grant options to purchase an aggregate of 71,456 shares of our common stock to each of our non-employee directors in connection with this offering. These options will be issued with an exercise price per share equal to the initial public offering price in this offering, and such options will vest and become exercisable in equal installments at the end of each month following the vesting start date until the third anniversary of the vesting start date.

### Non-Employee Director Compensation Policy

Our board of directors adopted a non-employee director compensation policy, effective as of the closing of this offering, that is designed to enable us to attract and retain, on a long-term basis, highly qualified non-employee directors. Under the policy, each director who is not an employee will be paid cash compensation from and after the closing of this offering, as set forth below:

|   | <u>Annual Retainer</u> |
|---|------------------------|
| <b>Board of Directors:</b>                  |                        |
| Members                                     | \$ 40,000              |
| Additional retainer for non-executive chair | \$ 30,000              |
| <b>Audit Committee:</b>                     |                        |
| Members (other than chair)                  | \$ 15,000              |
| Retainer for chair                          | \$ 22,500              |
| <b>Compensation Committee:</b>              |                        |
| Members (other than chair)                  | \$ 10,000              |
| Retainer for chair                          | \$ 15,000              |
| <b>Corporate Governance Committee:</b>      |                        |
| Members (other than chair)                  | \$ 7,500               |
| Retainer for chair                          | \$ 11,500              |

Directors will be given the opportunity to elect to receive all or a portion of their retainer and committee fees in the form of an equity award of (a) unrestricted shares having a grant date fair value equal to the amount (or portion thereof) of such retainer and committee fees or (b) stock options to

purchase common stock based on the Black-Scholes option-pricing model as of the date of grant. Any such election shall be made (i) for any continuing non-employee director, before the start of the calendar year with respect to any cash compensation for such calendar year and (ii) for any new non-employee director, within 30 days of her or his election to the board of directors. Any such stock options shall be vested upon grant and shall expire ten years from the date of grant.

Upon his or her election to the board of directors, each non-employee director will receive an initial, one-time stock option grant to purchase 19,200 shares of our common stock, which will vest in equal monthly installments over three years, subject to continued service as a member of the board of directors, or the Initial Award. In addition, each continuing non-employee member of the board will receive, at the time of the Company's annual meeting, an annual equity grant of options to purchase 9,605 shares of our common stock, which will vest in full upon the earlier of the first anniversary of the date of grant or the date of the next annual meeting of the Company's stockholders, subject to continued service as a member of the board of directors through such date. Each of the foregoing grants will vest in full upon the death or disability of the applicable director or upon a change in control of the Company. In addition, any stock options awarded to non-employee directors pursuant to the non-employee director compensation policy will be exercisable until the earlier of one year following the termination of the director's service on the board of directors or the original expiration date of the option.

## CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Other than the compensation agreements and other arrangements described under "Executive Compensation" and "Director Compensation" in this prospectus and the transactions described below, since January 1, 2016 there has not been and there is not currently proposed, any transaction or series of similar transactions to which we were, or will be, a party in which the amount involved exceeded, or will exceed, \$120,000 and in which any director, executive officer, holder of five percent or more of any class of our capital stock or any member of the immediate family of, or entities affiliated with, any of the foregoing persons, had, or will have, a direct or indirect material interest.

We believe the terms obtained or consideration that we paid or received, as applicable, in connection with the transactions described below were comparable to terms available or the amounts that we would pay or receive, as applicable, in arm's-length transactions.

### Sales and Purchases of Securities

#### *Series B Preferred Stock Extension Financing*

In December 2016 and March 2017, we issued and sold an aggregate of 164,064 shares of our Series B preferred stock at a price of €60.95 per share. The following table sets forth the number of shares of our Series B preferred stock purchased by our directors, executive officers and five percent stockholders and their affiliates and the aggregate purchase price paid for such shares.

| <u>Purchaser</u>                            | <u>Shares of Series B Preferred Stock Purchased</u> | <u>Aggregate Purchase Price (€)</u> |
|---|---|-------------------------------------|
| Sofinnova Capital VI FCPR(1)                | 49,219  | 3,000,000.00                        |
| Forbion Capital Fund II Coöperatief U.A.(2) | 32,813  | 2,000,000.00                        |
| Boehringer Ingelheim Venture Fund GmbH      | 41,016  | 2,500,000.00                        |
| Takeda Ventures, Inc.                       | 20,508  | 1,250,000.00                        |
| BioMedInvest II LP                          | 20,508  | 1,250,000.00                        |
| Total                                       | 164,064   | 10,000,000.00                       |

- (1) Mr. Seghezzi, a member of our board of directors, is a managing partner at Sofinnova Partners, an entity affiliated with Sofinnova Capital VI FCPR.
- (2) Dr. van Deventer, a member of our board of directors, is a general partner at Forbion Capital Partners, an entity affiliated with Forbion Capital Fund II Coöperatief U.A.

#### *Series C Preferred Stock Financing*

In December 2017, we issued and sold an aggregate of 693,500 shares of our Series C preferred stock at a price of €72.10 per share. The following table sets forth the number of shares of

our Series C preferred stock purchased by our directors, executive officers and five percent stockholders and their affiliates and the aggregate purchase price paid for such shares.

| <u>Purchaser</u>                            | <u>Shares of Series C Preferred Stock Purchased</u> | <u>Aggregate Purchase Price (€)</u> |
|---|---|-------------------------------------|
| Sofinnova Capital VI FCPR(1)                | 76,283  | 5,500,004.30                        |
| Forbion Capital Fund II Coöperatief U.A.(2) | 51,318  | 3,700,027.80                        |
| Boehringer Ingelheim Venture Fund GmbH      | 20,111  | 1,450,003.10                        |
| Takeda Ventures, Inc.                       | 20,111  | 1,450,003.10                        |
| BioMedInvest II LP                          | 20,111  | 1,450,003.10                        |
| 667, L.P.(3)                                | 27,864  | 2,008,994.40                        |
| Baker Brothers Life Sciences, L.P.          | 249,536   | 17,991,545.60                       |
| HBM BioCapital II LP                        | 89,466  | 6,450,498.60                        |
| <b>Total</b>                                | <b>554,800</b>                                      | <b>40,001,080.00</b>                |

- (1) Mr. Seghezzi, a member of our board of directors, is a managing partner at Sofinnova Partners, an entity affiliated with Sofinnova Capital VI FCPR.
- (2) Dr. van Deventer, a member of our board of directors, is a general partner at Forbion Capital Partners, an entity affiliated with Forbion Capital Fund II Coöperatief U.A.
- (3) 667, L.P. is an entity affiliated with Baker Brothers Life Sciences, L.P.

### **Series D Preferred Stock Financing**

In February 2019, we issued and sold an aggregate of 257,000 shares of our Series D preferred stock at a price of \$145.65 per share. The following table sets forth the number of shares of our Series D preferred stock purchased by our directors, executive officers and five percent stockholders and their affiliates and the aggregate purchase price paid for such shares.

| <u>Purchaser</u>                      | <u>Shares of Series D Preferred Stock Purchased</u> | <u>Aggregate Purchase Price (\$)</u> |
|---------------------------------------|---|--------------------------------------|
| Takeda Ventures, Inc.                 | 14,500  | 2,111,925.00                         |
| 667, L.P.(1)                          | 5,170   | 753,010.50                           |
| Baker Brothers Life Sciences, L.P.    | 45,500  | 6,627,075.00                         |
| Redmile Biopharma Investments I, L.P. | 51,502  | 7,501,266.30                         |
| RAF, L.P.(2)                          | 34,328  | 4,999,873.20                         |
| <b>Total</b>                          | <b>151,000</b>                                      | <b>21,993,150.00</b>                 |

- (1) 667, L.P. is an entity affiliated with Baker Brothers Life Sciences, L.P.
- (2) RAF, L.P. is an entity affiliated with Redmile Biopharma Investments I, L.P.

### **Employment Agreements**

We have employment agreements or offer letters with our executive officers. For more information regarding our agreements with our named executive officers for the fiscal year ended December 31, 2018, see the section titled "Executive Compensation—Narrative Disclosure to Summary Compensation Table—Employment Arrangements With Our Named Executive Officers."

## **Agreements with the University of Basel**

### *Agreement for Services*

We are party to an agreement, effective January 1, 2014, as further amended, with the University of Basel, pursuant to which the University of Basel provides us with specified research activities and deliverables. Daniel Pinschewer, M.D., our Chief Scientific Officer, is an employee of the University of Basel and provides research services to the University of Basel pursuant to this Agreement. Dr. Pinschewer's spouse is also employed by the University of Basel and assists on the services provided to us as scientific staff. The compensation of Dr. Pinschewer's spouse is indirectly tied to the revenues the university receives from us under the terms of this agreement. During the years ended December 31, 2016, 2017 and 2018, we paid CHF 272,000, CHF 254,000 and CHF 368,000, respectively, to the University of Basel for services provided under this Agreement.

### *Agreement Regarding Consulting Services of Employee*

We are party to an agreement with the University of Basel, pursuant to which the university permits Dr. Pinschewer to provide us with part-time consulting services. Pursuant to the terms of the agreement, all patentable inventions and associated rights created by Dr. Pinschewer in the course of his consulting services ("Service IP") (except those created as a result of or in connection with resources from the University of Basel or in or under the laboratories of the University of Basel) will be assigned to us and we will be entitled to all rights related to such Service IP. As a condition to entering this agreement, we agreed to pay the University of Basel de minimis royalties on the net sales of any approved product candidate under a patent which discloses and claims Service IP. The royalty rate is to be determined based on the number of patents, the university's contribution, among other factors. As of the date hereof, we have not paid any royalties to the University of Basel pursuant to the terms of this agreement.

## **Indemnification Agreements**

Prior to the closing of this offering, we intend to enter agreements to indemnify our directors and certain executive officers. These agreements will, among other things, require us to indemnify these individuals for certain expenses (including attorneys' fees), judgments, fines and settlement amounts reasonably incurred by such person in any action or proceeding, including any action by or in our right, on account of any services undertaken by such person on behalf of our company or that person's status as a member of our board of directors to the maximum extent allowed under Delaware law.

## **Agreements with our Stockholders**

We entered into the shareholders' agreement in connection with our Series B preferred stock financing in 2013, which was further amended and restated in 2016 in connection with our Series B preferred stock extension financing, in 2017 in connection with our Series C preferred stock financing, in June 2018 in connection with our reorganization as Hookipa Biotech, Inc. and in February 2019 in connection with our Series D preferred stock financing, or the Shareholders' Agreement. The Shareholders' Agreement will automatically terminate upon the closing of this offering, other than with respect to the registration rights and board nomination rights provided for therein. See the section titled "Description of Capital Stock—Registration Rights."

The Shareholders' Agreement provides for the voting of shares with respect to the constituency of our board of directors and the voting of shares in favor of specified matters. The agreement provides these holders with certain rights relating to the registration of their shares under the Securities Act of 1933, as amended. For a more detailed description of these registration rights, see the section titled "Description of Capital Stock—Registration Rights."

The Shareholder Agreement also establishes certain board observer rights, reporting and information rights, drag-along rights and tag-along rights, and sets forth certain covenants relating to insurance, employee agreements, employee stock and related matters.

### **Participation Right**

Pursuant to the Shareholders' Agreement, we shall use commercially reasonable efforts to cause the underwriters to provide Redmile Group, Baker Bros. Advisors LP, HH HKP (HK) Limited, Takeda Ventures, Inc., Fynveur SCA, Gilead Sciences, Inc. and Samsara BioCapital, L.P., or the Series D Investors, the right to participate in this offering in such amount equal to the pro rata share of the total outstanding number of shares held by it prior to this offering. Despite our commercially reasonable efforts, the underwriters may in their sole discretion determine that the Series D Investors' participation in such proportion is not advisable and designate a reduced number of or no shares to the Series D Investors.

### **Indications of Interest to Participate in this Offering**

Certain of our existing stockholders, directors and their affiliated entities have indicated an interest in purchasing an aggregate of up to approximately \$55.0 million in shares of our common stock in this offering at the initial public offering price per share and on the same terms as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares in this offering. The underwriters will receive the same underwriting discount and commissions on these shares as they will on any other shares sold to the public in this offering.

### **Policies for Approval of Related Party Transactions**

Our board of directors reviews and approves transactions with directors, officers and holders of five percent or more of our voting securities and their affiliates, each a related party. Prior to this offering, the material facts as to the related party's relationship or interest in the transaction are disclosed to our board of directors prior to their consideration of such transaction, and the transaction is not considered approved by our board of directors unless a majority of the directors who are not interested in the transaction approve the transaction. Further, when stockholders are entitled to vote on a transaction with a related party, the material facts of the related party's relationship or interest in the transaction are disclosed to the stockholders, who must approve the transaction in good faith.

In connection with this offering, we adopted a formal written policy that our executive officers, directors, holders of more than five percent of any class of our voting securities, and any member of the immediate family of and any entity affiliated with any of the foregoing persons, are not permitted to enter into a related party transaction with us without the prior consent of our audit committee, or other independent members of our board of directors in the event it is inappropriate for our audit committee to review such transaction due to a conflict of interest. Any request for us to enter into a transaction with an executive officer, director, holders of more than 5% of any class of our voting securities, or any of their immediate family members or affiliates, in which the amount involved exceeds \$120,000 must first be presented to our audit committee for review, consideration and approval. In approving or rejecting any such proposal, our audit committee will consider the relevant facts and circumstances available and deemed relevant to our audit committee, including, but not limited to, whether the transaction will be on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related party's interest in the transaction. All of the transactions described in this section were entered into prior to the adoption of this policy.

## PRINCIPAL STOCKHOLDERS

The following table sets forth certain information known to us regarding beneficial ownership of our capital stock as of February 28, 2019, as adjusted to reflect the sale of common stock offered by us in this offering, for:

- each person or group of affiliated persons known by us to be the beneficial owner of more than five percent of our capital stock;
- each of our named executive officers;
- each of our directors; and
- all of our executive officers and directors as a group.

To the extent that the underwriters sell more than 6,000,000 shares in this offering, the underwriters have the option to purchase up to an additional 900,000 shares at the initial public offering price less the underwriting discount.

Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Under those rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power. Except as noted by footnote, and subject to community property laws where applicable, we believe, based on the information provided to us, that the persons and entities named in the table below have sole voting and investment power with respect to all common stock shown as beneficially owned by them.

The percentage of beneficial ownership prior to this offering in the table below is based on 19,408,488 shares of common stock deemed to be outstanding as of February 28, 2019, assuming the conversion of all outstanding shares of our preferred stock upon the closing of this offering into shares of our voting common stock upon the closing of this offering, and the percentage of beneficial ownership after this offering in the table below is based on 25,408,488 shares of common stock outstanding after the closing of the offering. The information in the table below assumes no exercise of the underwriters' option to purchase additional shares and does not give effect to the conversion of 328,071 shares of preferred stock into 3,819,732 shares of Class A common stock upon the closing of this offering. Options to purchase shares of common stock that are exercisable within 60 days of February 28, 2019 are deemed to be beneficially owned by the persons holding these options for the purpose of computing percentage ownership of that person, but are not treated as outstanding for the purpose of computing any other person's ownership percentage.

Certain of our existing stockholders, directors and their affiliated entities have indicated an interest in purchasing an aggregate of up to approximately \$55.0 million in shares of our common stock in this offering at the initial public offering price per share and on the same terms as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares in this offering. The following table does not reflect any potential purchases by these potential purchasers. If any shares are purchased by our existing principal stockholders, directors

or their affiliated entities, the number and percentage of shares of our common stock beneficially owned by them after this offering will differ from those set forth in the following table.

| Name and Address of Beneficial Owner(1)                             | Shares Beneficially Owned | Percentage of Shares Beneficially Owned |                |
|---|---------------------------|---|----------------|
|   |                           | Before Offering                         | After Offering |
| <b>5% Stockholders:</b>   |                           |   |                |
| Entities affiliated with Baker Bros. Advisors LP(2)                 | 3,819,732                 | 19.68%                                  | 15.03%         |
| Sofinnova Capital VI FCPR(3)  | 3,606,712                 | 18.58%                                  | 14.19%         |
| Forbion Capital Fund II Coöperatief U.A.(4)                         | 2,440,602                 | 12.57%                                  | 9.61%          |
| Boehringer Ingelheim Venture Fund GmbH(5)                           | 1,666,806                 | 8.59%                                   | 6.56%          |
| Takeda Ventures, Inc.(6)  | 1,119,303                 | 5.77%                                   | 4.41%          |
| HBM BioCapital II LP(7)   | 1,041,656                 | 5.37%                                   | 4.10%          |
| Entities affiliated with Redmile Group(8)                           | 999,322                   | 5.15%                                   | 3.93%          |
| <b>Named Executive Officers and Directors:</b>                      |                           |   |                |
| Jörn Aldag(9)   | 272,148                   | 1.38%                                   | 1.06%          |
| Reinhard Kandra(10)   | 43,417                    | *                                       | *%             |
| Igor Matushansky(11)  | 50,871                    | *                                       | *%             |
| Jan van de Winkel(12)   | 25,614                    | *                                       | *%             |
| Christoph Lengauer  | —                         | —                                       | —%             |
| Sander van Deventer   | —                         | —                                       | —%             |
| Paul-Henri Lambert(13)  | 12,271                    | *                                       | *%             |
| Graziano Seghezzi   | —                         | —                                       | —%             |
| Julie O'Neill   | —                         | —                                       | —%             |
| Michael A. Kelly  | —                         | —                                       | —%             |
| David R. Kaufman  | —                         | —                                       | —%             |
| <b>All executive officers and directors as a group (14 persons)</b> | <b>613,205</b>            | <b>3.16%</b>                            | <b>2.41%</b>   |

\* Represents beneficial ownership of less than one percent.

- (1) Unless otherwise indicated, the address for each beneficial owner is c/o HOOKIPA Pharma Inc., 350 Fifth Avenue, 72nd Floor, Suite 7240, New York, New York 10118.
- (2) Consists of (i) 2,905,359 shares of common stock issuable upon conversion of shares of Series C preferred stock held directly by Baker Brothers Life Sciences, L.P.; (ii) 324,421 shares of common stock issuable upon conversion of shares of Series C preferred stock held by 667, L.P., (iii) 529,758 shares of common stock issuable upon conversion of shares of Series D preferred stock held directly by Baker Brothers Life Sciences, L.P.; and (iv) 60,194 shares of common stock issuable upon conversion of shares of Series D preferred stock held by 667, L.P., together with Baker Brothers Life Sciences, L.P., the Baker Funds. Upon the closing of this offering, the 328,071 shares of preferred stock held by the Baker Funds will automatically convert into 3,819,732 shares of Class A common stock. Baker Bros. Advisors LP, or BBA, is the management company and investment advisor to the Baker Funds and has sole voting and investment power with respect to the shares held by the Baker Funds. Baker Bros. Advisors (GP) LLC, or BBA-GP, is the sole general partner of BBA. Felix J. Baker and Julian C. Baker are the managing members of BBA-GP, and, as such, may be deemed to have voting and dispositive power with respect to the shares of common stock held by the Baker Funds. Julian C. Baker, Felix J. Baker, BBA and BBA-GP disclaim beneficial ownership of all shares held by the Baker Funds, except to the extent of their indirect pecuniary interest therein. The address for BBA, BBA-GP and the Baker Funds is 860 Washington Street, 3rd Floor, New York, New York 10014.



- (3) Consists of (i) 916,901 shares of common stock issuable upon conversion of shares of Series A preferred stock; (ii) 1,719,189 shares of common stock issuable upon conversion of shares of Series B preferred stock; (iii) 888,166 shares of common stock issuable upon conversion of shares of Series C preferred stock; and (iv) 82,456 shares of common stock. All shares are held directly by Sofinnova Capital VI FCPR. Sofinnova Partners SAS, a French corporation and the management company of Sofinnova Capital VI FCPR, may be deemed to have sole voting and investment power, and Dennis Lucquin, Antoine Papiernik and Monique Saulnier, the managing partners of Sofinnova Partners SAS, may be deemed to have shared voting and investment power with respect to such shares. Graziano Seghezzi is a managing partner of Sofinnova Partners SAS and is also a member of our board of directors. Mr. Seghezzi disclaims beneficial ownership of such shares, except to the extent of his proportionate pecuniary interest therein, if any. The address for Sofinnova Capital VI FCPR is 16-18 rue de 4 Septembre, 75002 Paris, France.
- (4) Consists of (i) 687,673 shares of common stock issuable upon conversion of shares of Series A preferred stock; (ii) 1,146,118 shares of common stock issuable upon conversion of shares of Series B preferred stock; and (iii) 597,497 shares of common stock issuable upon conversion of shares of Series C preferred stock; and (iv) 9,314 shares of common stock. All shares are held directly by Forbion Capital Fund II Coöperatief U.A., or Coöperatief. Forbion II Management B.V., or Forbion, the director of Coöperatief, may be deemed to have voting and dispositive power over the ordinary shares held by Coöperatief. Sander van Deventer is an operating partner of Forbion and a member of the investment committee of Forbion and is also a member of our board of directors. The address for Forbion Capital Fund II Coöperatief U.A. is Gooimeer 2-35, 1411 DC Naarden, the Netherlands.
- (5) Consists of (i) 1,432,653 shares of common stock issuable upon conversion of shares of Series B preferred stock; and (ii) 234,153 shares of common stock issuable upon conversion of shares of Series C preferred stock. All shares are held directly by Boehringer Ingelheim Venture Fund GmbH. The address for Boehringer Ingelheim Venture Fund GmbH is Binger Strasse 173, 55216 Ingelheim am Rhein, Germany.
- (6) Consists of (i) 716,326 shares of common stock issuable upon conversion of shares of Series B preferred stock; (ii) 234,153 shares of common stock issuable upon conversion of shares of Series C preferred stock; and (iii) 168,824 shares of common stock issuable upon conversion of shares of Series D preferred stock. All shares are held directly by Takeda Ventures, Inc. The address for Takeda Ventures, Inc. is 435 Tasso Street, Suite 300, Palo Alto, California 94301.
- (7) Consists of 1,041,656 shares of common stock issuable upon conversion of shares of Series C preferred stock held by HBM BioCapital II LP. The board of directors of HBM BioCapital II Management Ltd., the general partner of the HBM BioCapital II LP, has sole voting and investment power with respect to such shares. The address for HBM BioCapital II LP is c/o HBM BioCapital II Management Ltd., Aztec Group House 11-15, Seaton Place, St. Helier JE4 0QH, Jersey.
- (8) Consists of (i) 599,640 shares of common stock issuable upon conversion of shares of Series D preferred stock held directly by Redmile Biopharma Investments I, L.P.; and (ii) 399,682 shares of common stock issuable upon conversion of shares of Series D preferred stock held directly by RAF, L.P., together with Redmile Biopharma Investments I, L.P., the Redmile Funds. Redmile Group, LLC is the investment manager to the Redmile Funds and, in such capacity, exercises shared voting and dispositive power over the securities held by the Redmile Funds and may be deemed to beneficially own such securities. Jeremy Green serves as the managing member of Redmile Group, LLC and as such shares voting and dispositive power over the securities held by the Redmile Funds. Redmile Group, LLC and Mr. Green each disclaim

beneficial ownership of these securities, except to the extent of its or his pecuniary interest in such securities, if any. The address of the above person and entities is One Letterman Drive, Building D, Suite D3-300, San Francisco, California 94129.

- (9) Consists of options to purchase 272,148 shares of common stock that are exercisable within 60 days of February 28, 2019.
- (10) Consists of options to purchase 43,417 shares of common stock that are exercisable within 60 days of February 28, 2019.
- (11) Consists of (i) 28,583 shares of common stock; and (ii) options to purchase 22,288 shares of common stock that are exercisable within 60 days of February 28, 2019.
- (12) Consists of options to purchase 25,614 shares of common stock that are exercisable within 60 days of February 28, 2019.
- (13) Consists of (i) 5,821 shares of common stock; and (ii) options to purchase 6,450 shares of common stock that are exercisable within 60 days of February 28, 2019.

## DESCRIPTION OF CAPITAL STOCK

The following descriptions are summaries of the material terms of our amended and restated certificate of incorporation and amended and restated bylaws which will become effective immediately upon the closing of this offering. The descriptions of the common stock and preferred stock give effect to changes to our capital structure that will occur immediately upon the closing of this offering. We refer in this section to our amended and restated certificate of incorporation as our certificate of incorporation, and we refer to our amended and restated bylaws as our bylaws.

### General

Upon closing of this offering, our authorized capital stock will consist of 100,000,000 shares of common stock, par value \$0.0001 per share, 3,900,000 shares of Class A common stock, par value \$0.0001 per share, and 10,000,000 shares of preferred stock, par value \$0.0001 per share, all of which shares of preferred stock will be undesignated.

As of February 28, 2019, 19,408,488 shares of our common stock were outstanding and held by 23 stockholders of record. This amount assumes the conversion of all outstanding shares of our preferred stock into voting common stock and no issuances of shares of Class A common stock upon this closing of this offering. In addition, as of February 28, 2019, we had outstanding options to purchase 1,597,638 shares of our common stock under our 2018 Stock Option and Grant Plan, at a weighted average exercise price of \$1.94 per share, 736,636 of which were exercisable.

### Common Stock

Following the closing of this offering, we will have two classes of common stock: common stock and Class A common stock. The common stock is voting common stock and the Class A common stock is non-voting common stock. The holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. The holders of our common stock do not have any cumulative voting rights. Holders of both classes of our common stock are entitled to receive ratably any dividends declared by our board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock or that we may designate or issue in the future.

In the event of our liquidation, dissolution, or winding up, holders of both classes of our common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock. The shares to be issued by us in this offering will be, when issued and paid for, validly issued, fully paid and non-assessable. The rights, preferences and privileges of holders of both classes of our common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

#### *Voting Common Stock*

The shares being offered in this offering are our common stock. As of December 31, 2018, there were 1,006,595 shares of common stock issued and outstanding. All common stock is fully paid and non-assessable. Our common stock has no preemptive rights, conversion rights, or other subscription rights or redemption or sinking fund provisions.

#### *Non-Voting Class A Common Stock*

As of December 31, 2018, there were no shares of Class A common stock issued and outstanding. No Class A common stock may be issued until the effectiveness of the registration statement of which this prospectus forms a part. Following the closing of this offering, each holder of

Class A common stock may elect to convert any portion of its Class A common stock into voting common stock at any time, unless, as a result of such conversion, the holder and its affiliates would own more than 4.99% of the combined voting power of our outstanding share capital. A holder of Class A common stock may increase, decrease or waive this limitation on ownership by providing us with 61-days' notice. Our Class A common stock has no preemptive rights or other subscription rights or redemption or sinking fund provisions.

### **Preferred Stock**

Immediately upon the closing of this offering, all outstanding shares of our preferred stock will be converted into shares of our common stock. Upon the closing of this offering, our board of directors will have the authority, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our company or other corporate action. Immediately after closing of this offering, no shares of preferred stock will be outstanding, and we have no present plan to issue any shares of preferred stock.

### **Registration Rights**

Upon the closing of this offering, the holders of 18,401,893 shares of our common stock, including those issuable upon the conversion of Class A common stock into common stock, are entitled to rights with respect to the registration of such securities under the Securities Act of 1933, as amended, or the Securities Act. These rights are provided under the terms of our Shareholders' Agreement between us and certain holders our capital stock. All fees, costs and expenses of underwritten registrations under these agreements will be borne by us and all selling expenses, including underwriting discounts and selling commissions, will be borne by the holders of the shares being registered.

#### ***Demand Registration Rights***

Beginning 180 days after the closing of this offering, the holders of 18,401,893 shares of our common stock, including those issuable upon the conversion of Class A common stock into common stock, are entitled to demand registration rights.

#### ***Short-Form Registration Rights***

The holders of 18,401,893 shares of our common stock, including those issuable upon the conversion of Class A common stock into 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 the preferred stock 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. We are not obligated to file a registration statement pursuant to this provision on more than two occasions in any 12-month period.

### ***Piggyback Registration Rights***

The holders of 18,401,893 shares of our common stock, including those issuable upon the conversion of Class A common stock into 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. We and the underwriters may limit the number of shares included in the underwritten offering to the number of shares which we and the underwriters determine in our sole discretion will not jeopardize the success of the offering.

### ***Indemnification***

Our Shareholders' Agreement contains customary cross-indemnification provisions, under which we are obligated to indemnify holders of registrable securities in the event of material misstatements or omissions in the registration statement attributable to us, and they are obligated to indemnify us for material misstatements or omissions attributable to them.

### ***Expenses of Registration***

We are generally required to bear all registration and selling expenses incurred in connection with the demand, short-form and piggyback registration described above, other than underwriting discounts and selling commissions.

### ***Expiration of Registration Rights***

The demand registration rights and short form registration rights will terminate as to a given holder of registrable securities at such time as Rule 144 or another similar exemption under the Securities Act is available for the sale of all of such holder's shares without limitation during a three-month period without registration.

### **Participation and Drag Right in a Qualified Initial Public Offering**

Pursuant to the Shareholders' Agreement, we shall use commercially reasonable efforts to cause the underwriters to provide Redmile Group, Baker Bros. Advisors LP, HH HKP (HK) Limited, Takeda Ventures, Inc., Fynveur SCA, Gilead Sciences, Inc., or Gilead, and Samsara BioCapital, L.P., or the Series D Investors, the right to participate in any initial public offering we consummate in amount equal to its pro rata share of the total number of shares outstanding prior to this offering held by it. Despite our commercially reasonable efforts, the underwriters may in their sole discretion determine that the Series D Investors' participation in such proportion is not advisable and designate a reduced number of or no shares to the Series D Investors. See "Certain Relationships and Related Party Transactions—Participation Right."

In the event we consummate an initial public offering prior to December 31, 2021, in which the per share price is at least €5.66 with minimum aggregate proceeds of \$60.0 million, Gilead is required to subscribe to purchase shares in such offering in an amount of at least €5.0 million, but not to exceed either €10.0 million or such number of shares which would cause it to hold more than 9.9% of our outstanding common stock upon the consummation of the offering. Gilead's obligation to participate in the initial public offering does not obligate the underwriters to actually allocate any shares to Gilead.

### **Anti-Takeover Effects of our Certificate of Incorporation and Bylaws and Delaware Law**

Our amended and restated certificate of incorporation and amended and restated bylaws include a number of provisions that may have the effect of delaying, deferring or preventing another party from acquiring control of us and encouraging persons considering unsolicited tender offers or

other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

### ***Undesignated Preferred Stock***

Our amended and restated certificate of incorporation provides for 10,000,000 authorized shares of preferred stock. The existence of authorized but unissued shares of preferred stock may enable our board of directors to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of our stockholders, our board of directors could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our certificate of incorporation grants our board of directors broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring, or preventing a change in control.

### ***Exclusive Jurisdiction for Certain Actions***

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, or the DGCL, 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.

### ***Section 203 of the Delaware General Corporation Law***

Upon closing of this offering, we will be subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or

- at or after the time the stockholder became interested, the business combination was approved by our board of directors and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

In general, Section 203 defines a business combination to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, lease, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges, or other financial benefits provided by or through the corporation.

In general, Section 203 defines an "interested stockholder" as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

#### ***Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws***

Provisions of our amended and restated certificate of incorporation and our amended and restated bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our amended and restated certificate of incorporation and amended and restated bylaws:

- permit our board of directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate;
- provide that the authorized number of directors may be changed only by resolution adopted by a majority of the board of directors;
- provide that the board of directors or any individual director may only be removed with cause and the affirmative vote of the holders of at least 66.67% of the voting power of all of our then outstanding common stock;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law or subject to the rights of holders of preferred stock as designated from time to time, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- divide our board of directors into three classes;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent or electronic transmission;

- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder's notice;
- do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);
- provide that special meetings of our stockholders may 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; and
- provide that 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, or the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws, (iv) any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated 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.

The amendment of any of these provisions included in our amended and restated certificate of incorporation, with the exception of the ability of our board of directors to issue shares of preferred stock and designate any rights, preferences, and privileges thereto, would require the affirmative vote of the majority of all of our then outstanding common stock. The amendment of any of these provisions included in our amended and restated bylaws would require the affirmative vote of the holders of at least 66.67% of the voting power of our then outstanding common stock.

#### **Nasdaq Global Select Market Listing**

Our common stock has been approved for listing on The Nasdaq Global Select Market under the trading symbol "HOOK."

#### **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC.



## SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for shares of our common stock. Future sales of our common stock in the public market, or the availability of such shares for sale in the public market, could adversely affect market prices prevailing from time to time. As described below, only a limited number of shares will be available for sale shortly after this offering due to contractual and legal restrictions on resale. Nevertheless, sales of our common stock in the public market after such restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price at such time and our ability to raise equity capital in the future.

Based on the number of shares outstanding as of February 28, 2019, upon the closing of this offering, 25,408,488 shares of our common stock will be outstanding, based on the an initial public offering price of \$14.00 per share, and assuming no exercise of the underwriters' option to purchase additional shares and no exercise of outstanding options and that all outstanding shares of our preferred stock convert into shares of our voting common stock upon the closing of this offering. Of the outstanding shares, all of the shares sold in this offering will be freely tradable, except that any shares held by our affiliates, as that term is defined in Rule 144 under the Securities Act of 1933, as amended, or the Securities Act, may only be sold in compliance with the limitations described below. The remaining outstanding shares of our common stock will be "restricted securities" as that term is defined under Rule 144 of the Securities Act.

As a result of the lock-up agreements described below and the provisions of Rules 144 and 701 under the Securities Act, the shares of common stock that will be deemed restricted securities after this offering will be available for sale in the public market as follows:

- no shares will be available for sale until 180 days after the date of this prospectus, subject to certain limited exceptions provided for in the lock-up agreements; and
- 19,408,488 shares will be eligible for sale beginning more than 180 days after the date of this prospectus, subject, in the case of shares held by our affiliates, to the volume limitations under Rule 144.

### Rule 144

In general, under Rule 144, beginning 90 days after the date of this prospectus, a person who has beneficially owned restricted stock for at least six months would be entitled to sell their securities provided that (i) such person is not deemed to have been one of our affiliates at the time of, or at any time during the 90 days preceding, a sale and (ii) we are subject to the Securities Exchange Act of 1934, as amended, or the Exchange Act, periodic reporting requirements for at least 90 days before the sale. Additionally, a person who has beneficially owned restricted shares for at least one year and who is not deemed to have been one of our affiliates at the time of, or at any time during the 90 days before the sale, would be entitled to sell those securities subject at any time. Persons who have beneficially owned restricted shares for at least six months but who are our affiliates at the time of, or any time during the 90 days preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of securities that does not exceed the greater of either of the following:

- 1% of the number of shares then outstanding, which will equal approximately 215,887 shares of common stock immediately after this offering assuming no exercise of the underwriters' option to purchase additional shares, based on the number of shares outstanding as of February 28, 2019; or
- the average weekly trading volume of our common stock on The Nasdaq Global Select Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale;

provided, in each case, that we are subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Such sales both by affiliates and by non-affiliates must also comply with the manner of sale, current public information and notice provisions of Rule 144.

Certain of our existing stockholders, directors and their affiliated entities have indicated an interest in purchasing an aggregate of up to approximately \$55.0 million in shares of our common stock in this offering at the initial public offering price per share and on the same terms as the other purchasers in this offering. Any such shares purchased by stockholders who are considered to be our affiliates cannot be resold in the public market immediately following this offering as a result of restrictions under securities laws, but will be able to be sold following the expiration of these restrictions, as described below. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares in this offering.

#### **Rule 701**

Rule 701 under the Securities Act, as in effect on the date of this prospectus, permits resales of shares in reliance upon Rule 144 but without compliance with certain restrictions of Rule 144, including the holding period requirement. Most of our employees, executive officers or directors who purchased shares under a written compensatory plan or contract may be entitled to rely on the resale provisions of Rule 701, but all holders of Rule 701 shares are required to wait until 90 days after the date of this prospectus before selling their shares. However, substantially all Rule 701 shares are subject to lock-up agreements as described below and under "Underwriters" included elsewhere in this prospectus and will become eligible for sale upon the expiration of the restrictions set forth in those agreements.

#### **Lock-Up Agreements**

All of our directors and officers and substantially all the holders of all of our outstanding capital stock and stock options have signed lock-up agreements which prevent them from selling any of our common stock or any securities convertible into or exercisable or exchangeable for common stock for a period of not less than 180 days from the date of this prospectus without the prior written consent of Merrill Lynch, Pierce, Fenner & Smith Incorporated and SVB Leerink LLC, subject to certain exceptions. See "Underwriting."

#### **Registration Rights**

Upon closing of this offering, certain holders of our securities will be entitled to various rights with respect to registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration. See "Description of Capital Stock—Registration Rights" for additional information. Shares covered by a registration statement will be eligible for sale in the public market upon the expiration or release from the terms of the lock-up agreements described above.

#### **Equity Incentive Plans**

We intend to file one or more registration statements on Form S-8 under the Securities Act to register our shares issued or reserved for issuance under our equity incentive plans. The first such registration statement is expected to be filed soon after the date of this prospectus and will automatically become effective upon filing with the Securities and Exchange Commission. Accordingly, shares registered under such registration statement will be available for sale in the open market, unless such shares are subject to vesting restrictions with us or the lock-up restrictions described above.

**10b5-1 Plans**

After the offering, certain of our employees, including our executive officers and/or directors may enter into written trading plans that are intended to comply with Rule 10b5-1 under the Exchange Act. Sales under these trading plans would not be permitted until the expiration of the lock-up agreements relating to the offering described above.

## MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS FOR NON-U.S. HOLDERS OF COMMON STOCK

The following discussion is a summary of the material U.S. federal income tax considerations applicable to non-U.S. holders (as defined below) with respect to their ownership and disposition of shares of our common stock issued pursuant to this offering. For purposes of this discussion, a non-U.S. holder means a beneficial owner of our common stock that is for U.S. federal income tax purposes:

- a non-resident alien individual;
- a foreign corporation or any other foreign organization taxable as a corporation for U.S. federal income tax purposes; or
- a foreign estate or trust, the income of which is not subject to U.S. federal income tax on a net income basis.

This discussion does not address the tax treatment of partnerships or other pass-through entities or arrangements for U.S. federal income tax purposes or persons that hold their common stock through partnerships or other pass-through entities or arrangements. A partner in a partnership or other pass-through entity or arrangement that will hold our common stock should consult his, her or its own tax advisor regarding the tax consequences of acquiring, holding and disposing of our common stock through a partnership or other pass-through entity or arrangement, as applicable.

This discussion is based on current provisions of the U.S. Internal Revenue Code of 1986, as amended, or the Code, existing and proposed U.S. Treasury Regulations promulgated thereunder, current administrative rulings and judicial decisions, all as in effect as of the date of this prospectus and, all of which are subject to change or to differing interpretation, possibly with retroactive effect. Any such change or differing interpretation could alter the tax consequences to non-U.S. holders described in this prospectus. There can be no assurance that the Internal Revenue Service, or the IRS, will not challenge one or more of the tax consequences described herein or that a court would not sustain such challenge. We assume in this discussion that a non-U.S. holder holds shares of our common stock as a capital asset, generally property held for investment.

This discussion does not address all aspects of U.S. federal income taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder's individual circumstances nor does it address any aspects of any U.S. federal tax other than the income and estate tax, U.S. state, local or non-U.S. taxes, the alternative minimum tax, or the Medicare tax on net investment income. This discussion also does not consider any specific facts or circumstances that may apply to a non-U.S. holder and does not address the special tax rules applicable to particular non-U.S. holders, such as:

- insurance companies;
- tax-exempt or governmental organizations;
- financial institutions;
- brokers or dealers in securities;
- regulated investment companies;
- pension plans;
- "controlled foreign corporations," "passive foreign investment companies," and corporations that accumulate earnings to avoid U.S. federal income tax;
- "qualified foreign pension funds," or entities wholly owned by a "qualified foreign pension fund";

- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and partners and investors therein);
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons that hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security, or other integrated investment;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- persons for whom our stock constitutes "qualified small business stock" within the meaning of Section 1202 of the Code; and
- certain U.S. expatriates.

This discussion is for general information only and is not tax advice. Accordingly, all prospective non-U.S. holders of our common stock should consult their own tax advisors with respect to the U.S. federal, state, local, and non-U.S. tax consequences of the purchase, ownership and disposition of our common stock.

### **Distributions on Our Common Stock**

Distributions, if any, on our common stock will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder's investment, and will first reduce a Non-U.S. Holder's basis in the common stock, but not below zero and then will be treated as capital gain, subject to the U.S. federal income tax treatment described below in "Gain on sale, exchange or other disposition of our common stock." Any such distributions will also be subject to the discussions below under the sections titled "—Backup Withholding and Information Reporting" and "—Withholding and Information Reporting Requirements—FATCA."

Subject to the discussion in the following two paragraphs in this section, dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence. If we or another withholding agent apply over-withholding or if a non-U.S. holder does not timely provide us with the required certification, the non-U.S. holder may be entitled to a refund or credit of any excess tax withheld by timely filing an appropriate claim with the IRS.

Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States and, if an applicable income tax treaty so provides, that are attributable to a permanent establishment or a fixed base maintained by the non-U.S. holder within the United States, are generally exempt from the 30% withholding tax if the non-U.S. holder satisfies applicable certification requirements. To obtain this exemption, a non-U.S. holder must generally provide a properly executed IRS Form W-8ECI properly certifying such exemption. However, such U.S. effectively connected income, net of specified deductions and credits, is taxed at the same graduated U.S. federal income tax rates applicable to United States persons (as defined in the Code). Any U.S. effectively connected income received by a non-U.S. holder that is a corporation may also, under certain circumstances, be subject to an additional "branch profits tax" at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

A non-U.S. holder of our common stock who claims the benefit of an applicable income tax treaty between the United States and such holder's country of residence generally will be required to

provide a properly executed IRS Form W-8BEN or W-8BEN-E (or successor form) to the applicable withholding agent and satisfy applicable certification and other requirements. Non-U.S. holders are urged to consult their tax advisors regarding their entitlement to benefits under a relevant income tax treaty. A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim with the IRS.

Any documentation provided to an applicable withholding agent may need to be updated in certain circumstances. The certification requirements described above may also require a non-U.S. holder to provide its U.S. taxpayer identification number.

### **Gain on Sale or Other Taxable Disposition of Our Common Stock**

Subject to the discussion below under "—Backup Withholding and Information Reporting," a non-U.S. holder generally will not be subject to any U.S. federal income tax on any gain realized upon such holder's sale or other taxable disposition of shares of our common stock unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a U.S. trade or business and, if an applicable income tax treaty so provides, is attributable to a permanent establishment or a fixed-base maintained by such non-U.S. holder in the United States, in which case the non-U.S. holder generally will be taxed on a net income basis at the graduated U.S. federal income tax rates applicable to United States persons (as defined in the Code) and, if the non-U.S. holder is a foreign corporation, the branch profits tax described above in "—Distributions on Our Common Stock" also may apply;
- the non-U.S. holder is a nonresident alien individual who is present in the United States for 183 days or more in the taxable year of the disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence) on the net gain derived from the disposition, which may be offset by certain U.S. source capital losses of the non-U.S. holder, if any (even though the individual is not considered a resident of the United States), provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses; or
- we are, or have been, at any time during the five-year period preceding such sale or other taxable disposition (or the non-U.S. holder's holding period, if shorter) a "U.S. real property holding corporation," unless our common stock is regularly traded on an established securities market and the non-U.S. holder holds no more than 5% of our outstanding common stock, directly or indirectly, actually or constructively, during the shorter of the 5-year period ending on the date of the disposition or the period that the non-U.S. holder held our common stock. In such case, such non-U.S. holder generally will be taxed on its net gain derived from the disposition at the graduated U.S. federal income tax rates applicable to United States persons (as defined in the Code). Generally, a corporation is a U.S. real property holding corporation only if the fair market value of its U.S. real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we do not believe that we are, or have been, a U.S. real property holding corporation, or that we are likely to become one in the future. No assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rules described above.

### **Backup Withholding and Information Reporting**

We must report annually to the IRS and to each non-U.S. holder the gross amount of the distributions on our common stock paid to such holder and the tax withheld, if any, with respect to

such distributions. Non-U.S. holders may have to comply with specific certification procedures to establish that the holder is not a United States person (as defined in the Code) in order to avoid backup withholding at the applicable rate with respect to dividends on our common stock. Dividends paid to non-U.S. holders subject to withholding of U.S. federal income tax, as described above in "—Distributions on Our Common Stock," generally will be exempt from U.S. backup withholding.

Information reporting and backup withholding will generally apply to the proceeds of a disposition of our common stock by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the holder certifies its status as a non-U.S. holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Non-U.S. holders should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them. Copies of information returns may be made available to the tax authorities of the country in which the non-U.S. holder resides or is incorporated under the provisions of a specific treaty or agreement. Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder can be refunded or credited against the non-U.S. holder's U.S. federal income tax liability, if any, provided that an appropriate claim is filed with the IRS in a timely manner.

#### **Withholding and Information Reporting Requirements—FATCA**

The Foreign Account Tax Compliance Act (FATCA) generally imposes a U.S. federal withholding tax at a rate of 30% on payments of dividends on our common stock paid to a foreign entity unless (i) if the foreign entity is a "foreign financial institution," such foreign entity undertakes certain due diligence, reporting, withholding, and certification obligations, (ii) if the foreign entity is not a "foreign financial institution," such foreign entity identifies certain of its U.S. investors, if any, or (iii) the foreign entity is otherwise exempt under FATCA. Under certain circumstances, a non-U.S. holder may be eligible for refunds or credits of this withholding tax. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this paragraph. Non-U.S. holders should consult their tax advisors regarding the possible implications of FATCA on their investment in our common stock and the entities through which they hold our common stock, including, without limitation, the process and deadlines for meeting the applicable requirements to prevent the imposition of the 30% withholding tax under FATCA.

#### **Federal Estate Tax**

Common stock owned or treated as owned by an individual who is a non-U.S. holder (as specially defined for U.S. federal estate tax purposes) at the time of death will be included in the individual's gross estate for U.S. federal estate tax purposes and, therefore, may be subject to U.S. federal estate tax, unless an applicable estate tax or other treaty provides otherwise.

**The preceding discussion of material U.S. federal tax considerations is for general information only. It is not tax advice. Prospective investors should consult their own tax advisors regarding the particular U.S. federal, state, local and non-U.S. tax consequences of purchasing, holding and disposing of our common stock, including the consequences of any proposed changes in applicable laws.**

## UNDERWRITING

Merrill Lynch, Pierce, Fenner & Smith Incorporated, SVB Leerink LLC and RBC Capital Markets, LLC are acting as representatives of each of the underwriters named below. Subject to the terms and conditions set forth in an underwriting agreement among us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of shares of common stock set forth opposite its name below.

| <u>Underwriter</u>                                 | <u>Number of Shares</u> |
|--|-------------------------|
| Merrill Lynch, Pierce, Fenner & Smith Incorporated | 2,490,000               |
| SVB Leerink LLC                                    | 2,010,000               |
| RBC Capital Markets, LLC                           | 1,080,000               |
| Kempen & Co U.S.A., Inc.                           | 420,000                 |
| Total  | <u>6,000,000</u>        |

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933, as amended, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the shares, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officer's certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part. Sales of shares made outside of the United States may be made by affiliates of the underwriters.

Certain of our existing stockholders, directors and their affiliated entities have indicated an interest in purchasing an aggregate of up to approximately \$55.0 million in shares of our common stock in this offering at the initial public offering price per share and on the same terms as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares in this offering. The underwriters will receive the same underwriting discount and commissions on these shares as they will on any other shares sold to the public in this offering.

### Commissions and Discounts

The representatives have advised us that the underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of \$0.588 per share. After the initial offering, the public offering price, concession or any other term of the offering may be changed.



The following table shows the public offering price, underwriting discount and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional shares.

|                                  | <u>Per Share</u> | <u>Without Option</u> | <u>With Option</u> |
|----------------------------------|------------------|-----------------------|--------------------|
| Public offering price            | \$ 14.00         | \$ 84,000,000         | \$ 96,600,000      |
| Underwriting discount            | \$ 0.98          | \$ 5,880,000          | \$ 6,762,000       |
| Proceeds, before expenses, to us | \$ 13.02         | \$ 78,120,000         | \$ 89,838,000      |

The expenses of the offering, not including the underwriting discount, are estimated at \$3.3 million and are payable by us. We have also agreed to reimburse the underwriters for their expenses relating to clearance of this offering with the Financial Industry Regulatory Authority in an amount up to \$30,000.

#### **Option to Purchase Additional Shares**

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus, to purchase up to 900,000 additional shares at the public offering price, less the underwriting discount. If the underwriters exercise this option, each will be obligated, subject to conditions contained in the underwriting agreement, to purchase a number of additional shares proportionate to that underwriter's initial amount reflected in the above table.

#### **No Sales of Similar Securities**

We, our executive officers and directors and our other existing security holders have agreed not to sell or transfer any common stock or securities convertible into, exchangeable for, exercisable for, or repayable with common stock, for 180 days after the date of this prospectus without first obtaining the written consent of Merrill Lynch, Pierce, Fenner & Smith Incorporated and SVB Leerink LLC. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly:

- offer, pledge, sell or contract to sell any common stock,
- sell any option or contract to purchase any common stock,
- purchase any option or contract to sell any common stock,
- grant any option, right or warrant for the sale of any common stock,
- lend or otherwise dispose of or transfer any common stock,
- request or demand that we file or make a confidential submission of a registration statement related to the common stock,
- enter into any swap or other agreement that transfers, in whole or in part, the economic consequence of ownership of any common stock whether any such swap or transaction is to be settled by delivery of shares or other securities, in cash or otherwise, or
- publicly disclose the intention to do any of the foregoing.

This lock-up provision applies to common stock and to securities convertible into or exchangeable or exercisable for or repayable with common stock. With limited exceptions, it also applies to common stock owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition.

## Nasdaq Global Select Market Listing

Our common stock has been approved for listing on the Nasdaq Global Select Market under the symbol "HOOK."

Before this offering, there has been no public market for our common stock. The initial public offering price was determined through negotiations between us and the representatives. In addition to prevailing market conditions, the factors we considered in determining the initial public offering price were:

- the valuation multiples of publicly traded companies that the representatives believe to be comparable to us;
- our financial information;
- the history of, and the prospects for, our company and the industry in which we compete;
- an assessment of our management, its past and present operations, and the prospects for, and timing of, our future revenues;
- the present state of our development; and
- the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for the shares may not develop. It is also possible that after the offering the shares will not trade in the public market at or above the initial public offering price.

The underwriters do not expect to sell more than 5% of the shares in the aggregate to accounts over which they exercise discretionary authority.

## Price Stabilization, Short Positions and Penalty Bids

Until the distribution of the shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing our common stock. However, the representatives may engage in transactions that stabilize the price of the common stock, such as bids or purchases to peg, fix or maintain that price.

In connection with the offering, the underwriters may purchase and sell our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering. "Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares described above. The underwriters may close out any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option granted to them. "Naked" short sales are sales in excess of such option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of shares of common stock made by the underwriters in the open market prior to the closing of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the

representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. The underwriters may conduct these transactions on the Nasdaq Global Select Market, in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor any of the underwriters make any representation that the representatives will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

### **Electronic Distribution**

In connection with the offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail.

### **Other Relationships**

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial activities and services. Some of the underwriters and their affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They have received, or may in the future receive, customary fees and commissions for these transactions.

In addition, in the ordinary course of their business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

### **Notice to Prospective Investors in the European Economic Area**

In relation to each member state of the European Economic Area, no offer of ordinary shares which are the subject of the offering has been, or will be made to the public in that Member State, other than under the following exemptions under the Prospectus Directive:

- (a) to any legal entity which is a qualified investor as defined in the Prospectus Directive;
- (b) to fewer than 150 natural or legal persons (other than qualified investors as defined in the Prospectus Directive), subject to obtaining the prior consent of the representatives for any such offer; or
- (c) in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of ordinary shares referred to in (a) to (c) above shall result in a requirement for the Company or any representative to publish a prospectus pursuant to Article 3 of the Prospectus Directive, or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

Each person located in a Member State to whom any offer of ordinary shares is made or who receives any communication in respect of an offer of ordinary shares, or who initially acquires any ordinary shares will be deemed to have represented, warranted, acknowledged and agreed to and with each representative and the Company that (1) it is a "qualified investor" within the meaning of the law in that Member State implementing Article 2(1)(e) of the Prospectus Directive; and (2) in the case of any ordinary shares acquired by it as a financial intermediary as that term is used in Article 3(2) of the Prospectus Directive, the ordinary shares acquired by it in the offer have not been acquired on behalf of, nor have they been acquired with a view to their offer or resale to, persons in any Member State other than qualified investors, as that term is defined in the Prospectus Directive, or in circumstances in which the prior consent of the representatives has been given to the offer or resale; or where ordinary shares have been acquired by it on behalf of persons in any Member State other than qualified investors, the offer of those ordinary shares to it is not treated under the Prospectus Directive as having been made to such persons.

The Company, the representatives and their respective affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgments and agreements.

This prospectus has been prepared on the basis that any offer of shares in any Member State will be made pursuant to an exemption under the Prospectus Directive from the requirement to publish a prospectus for offers of shares. Accordingly any person making or intending to make an offer in that Member State of shares which are the subject of the offering contemplated in this prospectus may only do so in circumstances in which no obligation arises for the Company or any of the representatives to publish a prospectus pursuant to Article 3 of the Prospectus Directive in relation to such offer. Neither the Company nor the representatives have authorized, nor do they authorize, the making of any offer of shares in circumstances in which an obligation arises for the Company or the representatives to publish a prospectus for such offer.

For the purposes of this provision, the expression an "offer of ordinary shares to the public" in relation to any ordinary shares in any Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the ordinary shares to be offered so as to enable an investor to decide to purchase or subscribe the ordinary shares, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State, the expression "Prospectus Directive" means Directive 2003/71/EC (as amended) and includes any relevant implementing measure in each Member State.

The above selling restriction is in addition to any other selling restrictions set out below.

#### **Notice to Prospective Investors in the United Kingdom**

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are "qualified investors" (as defined in the Prospectus Directive) (i) who have professional experience in matters relating to investments falling within Article 19 (5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "Order") and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as "relevant persons"). This document must not be acted on or relied on in the United Kingdom by persons who are not relevant persons. In the United Kingdom, any investment or investment activity to which this document relates is only available to, and will be engaged in with, relevant persons.

### **Notice to Prospective Investors in Switzerland**

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange ("SIX") or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, the Company, or the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA (FINMA), and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes ("CISA"). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

### **Notice to Prospective Investors in the Dubai International Financial Centre**

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority ("DFSA"). This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

### **Notice to Prospective Investors in Australia**

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission ("ASIC"), in relation to the offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001 (the "Corporations Act"), and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons (the "Exempt Investors") who are "sophisticated investors" (within the meaning of section 708(8) of the Corporations Act), "professional investors" (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

#### **Notice to Prospective Investors in Hong Kong**

The shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or (b) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the shares has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the Securities and Futures Ordinance and any rules made under that Ordinance.

#### **Notice to Prospective Investors in Japan**

The shares have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold, directly or indirectly, in Japan, or for the benefit of any Japanese Person or to others for re-offering or resale, directly or indirectly, in Japan or to any Japanese Person, except in compliance with all applicable laws, regulations and ministerial guidelines promulgated by relevant Japanese governmental or regulatory authorities in effect at the relevant time. For the purposes of this paragraph, "Japanese Person" shall mean any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

#### **Notice to Prospective Investors in Singapore**

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the "SFA"), (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275, of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- (a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- (b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

- (a) to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- (b) where no consideration is or will be given for the transfer;
- (c) where the transfer is by operation of law;
- (d) as specified in Section 276(7) of the SFA; or
- (e) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

#### **Notice to Prospective Investors in Canada**

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 *Underwriting Conflicts* (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

#### **Notice to Prospective Investors in Israel**

This prospectus does not constitute a prospectus under the Israeli Securities Law, 5728-1968 (the "Israeli Securities Law"), and has not been filed with or approved by the Israel Securities Authority. In the State of Israel, this prospectus is being distributed only to, and is directed only at, and any offer of the shares of common stock is directed only (i) at a limited number of persons (35 investors or fewer during any given 12 month period) in accordance with Section 15A(a)(1) of the Israeli Securities Law and/or (ii) to investors listed in the first schedule to the Israeli Securities Law (the "Schedule"), consisting primarily of joint investment in trust funds, provident funds, insurance companies, banking corporations, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and high net worth individuals, each as described in the Schedule (as it may be amended from time to time), collectively referred to as "qualified investors" (in each case purchasing for their own account or, where permitted under the Schedule, for the accounts of their clients who are investors listed in the Schedule). Qualified investors will be required to submit written confirmation that they fall within the scope of the Schedule, and that they are aware of the consequences of such designation and agree thereto.

## LEGAL MATTERS

The validity of the shares of common stock offered by this prospectus will be passed upon for us by Goodwin Procter LLP, Boston, Massachusetts. Shearman & Sterling LLP, New York, New York, is acting as counsel for the underwriters in connection with this offering.

## EXPERTS

The financial statements as of December 31, 2018 and 2017 and for the years then ended included in this prospectus have been so included in reliance on the report (which contains an emphasis of matter paragraph relating to the Company's requirement for additional financing to fund future operations as described in Note 2 to the financial statements) of PwC Wirtschaftsprüfung GmbH, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

## WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 (File Number 333- ) under the Securities Act of 1933, as amended, with respect to the common stock we are offering by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all of the information included in the registration statement. For further information pertaining to us and our common stock, you should refer to the registration statement and to its exhibits. Whenever we make reference in this prospectus to any of our contracts, agreements or other documents, the references are not necessarily complete, and you should refer to the exhibits attached to the registration statement for copies of the actual contract, agreement or other document.

Upon the closing of the offering, we will be subject to the informational requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and will file annual, quarterly and current reports, proxy statements and other information with the SEC. You can read our SEC filings, including the registration statement, at the SEC's website at [www.sec.gov](http://www.sec.gov). We also maintain a website at [www.hookipapharma.com](http://www.hookipapharma.com). Upon closing of the offering, you may access, free of charge, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC.

You may also request a copy of these filings, at no cost to you, by writing or telephoning us at the following address:

HOOKIPA Pharma Inc.  
350 Fifth Avenue, 72nd Floor, Suite 7240  
New York, New York 10118  
+43 1 890 63 60



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## Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of HOOKIPA Pharma Inc.

### ***Opinion on the Financial Statements***

We have audited the accompanying consolidated balance sheets of HOOKIPA Pharma Inc. and its subsidiaries (the "Company") as of December 31, 2018 and 2017, and the related consolidated statements of operations and comprehensive loss, of redeemable convertible preferred stock and stockholders' deficit and of cash flows for the years then ended, 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, 2018 and 2017, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

### ***Basis for Opinion***

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

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

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

February 25, 2019, except for the effects of the stock split discussed in Note 2 to the consolidated financial statements, as to which the date is April 8, 2019

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

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

**HOOKIPA PHARMA INC.**  
**CONSOLIDATED BALANCE SHEETS**

(In thousands, except share amounts)

|   | As of<br>December 31, |                  | Pro Forma<br>December 31, |
|---|-----------------------|------------------|---------------------------|
|   | 2017                  | 2018             | 2018<br>(unaudited)       |
| <b>Assets</b>   |                       |                  |                           |
| Current assets:   |                       |                  |                           |
| Cash and cash equivalents   | \$ 61,362             | \$ 48,580        | \$ 48,580                 |
| Accounts receivable   | —                     | 4,919            | 4,919                     |
| Prepaid expenses and other current assets   | 2,076                 | 8,812            | 8,812                     |
| Due from shareholder  | 6,520                 | —                | —                         |
| Total current assets  | <u>69,958</u>         | <u>62,311</u>    | <u>62,311</u>             |
| Non-current assets:   |                       |                  |                           |
| Property and equipment, net   | 3,575                 | 4,337            | 4,337                     |
| Other non-current assets  | 199                   | 1,603            | 1,603                     |
| Total non-current assets  | <u>3,774</u>          | <u>5,940</u>     | <u>5,940</u>              |
| Total assets  | <u>\$ 73,732</u>      | <u>\$ 68,251</u> | <u>\$ 68,251</u>          |
| <b>Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)</b>   |                       |                  |                           |
| Current liabilities   |                       |                  |                           |
| Accounts payable  | \$ 1,477              | \$ 3,656         | \$ 3,656                  |
| Deferred revenues   | —                     | 6,619            | 6,619                     |
| Accrued expenses and other current liabilities  | 2,558                 | 4,420            | 4,420                     |
| Total current liabilities   | <u>4,035</u>          | <u>14,695</u>    | <u>14,695</u>             |
| Non-current liabilities   |                       |                  |                           |
| Loans payable, non-current  | 3,738                 | 4,392            | 4,392                     |
| Deferred revenues, non-current  | —                     | 1,663            | 1,663                     |
| Other non-current liabilities   | 3,841                 | 3,102            | 3,102                     |
| Total non-current liabilities   | <u>7,579</u>          | <u>9,157</u>     | <u>9,157</u>              |
| Total liabilities   | <u>11,614</u>         | <u>23,852</u>    | <u>23,852</u>             |
| Commitments and contingencies (Note 12)   |                       |                  |                           |
| Redeemable convertible preferred stock (series A, B and C), \$0.0001 par value; 1,323,506 shares authorized, issued and outstanding at December 31, 2017 and 2018; aggregate liquidation preference of \$104.6 million and \$99.7 million at December 31, 2017 and 2018, respectively; no shares issued and outstanding, pro forma at December 31, 2018 (unaudited) | 104,774               | 104,774          | —                         |
| Stockholders' equity (deficit):   |                       |                  |                           |
| Common stock, \$0.0001 par value; 18,454,860 shares authorized at December 31, 2017 and 2018; 911,777 shares and 1,006,595 shares issued and outstanding at December 31, 2017 and 2018, respectively; 16,416,228 shares issued and outstanding, pro forma at December 31, 2018 (unaudited)  | 0                     | 0                | 2                         |
| Additional paid-in capital  | 2,451                 | 3,327            | 108,099                   |
| Accumulated other comprehensive loss  | (1,362)               | (3,720)          | (3,720)                   |
| Accumulated deficit   | <u>(43,745)</u>       | <u>(59,982)</u>  | <u>(59,982)</u>           |
| Total stockholders' equity (deficit)  | <u>(42,656)</u>       | <u>(60,375)</u>  | <u>44,399</u>             |
| Total liabilities, convertible preferred stock and stockholders' equity (deficit)   | <u>\$ 73,732</u>      | <u>\$ 68,251</u> | <u>\$ 68,251</u>          |

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

## HOOKIPA PHARMA INC.

## CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share amounts)

|  | Year ended December 31, |             |
|--|-------------------------|-------------|
|  | 2017                    | 2018        |
| Revenue from collaboration and licensing   | \$ —                    | \$ 7,629    |
| Operating expenses:  |                         |             |
| Research and development   | (9,772)                 | (21,965)    |
| General and administrative   | (4,385)                 | (6,844)     |
| Total operating expenses   | (14,157)                | (28,809)    |
| Loss from operations   | (14,157)                | (21,180)    |
| Other income (expense):  |                         |             |
| Grant income   | \$ 2,069                | \$ 5,612    |
| Interest expense   | (606)                   | (778)       |
| Other income and expenses, net   | (25)                    | 133         |
| Total other income (expense), net  | 1,438                   | 4,967       |
| Net loss before tax  | (12,719)                | (16,213)    |
| Income tax expense   | (4)                     | (24)        |
| Net loss   | (12,723)                | (16,237)    |
| Other comprehensive loss:  |                         |             |
| Foreign currency translation (loss) gain, net of tax                               | 1,764                   | (2,358)     |
| Comprehensive loss   | \$ (10,959)             | \$ (18,595) |
| Net loss per share—basic and diluted   | \$ (13.95)              | \$ (17.76)  |
| Weighted average common shares outstanding—basic and diluted                       | 911,777                 | 914,375     |
| Pro forma net loss per share—basic and diluted (unaudited)                         |                         | \$ (0.99)   |
| Pro forma weighted average common shares outstanding—basic and diluted (unaudited) |                         | 16,324,008  |

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

**HOOKIPA PHARMA INC.**
**CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT**

(In thousands, except share amounts)

|   | Convertible Preferred Stock |                   | Common Stock     |             | Additional Paid-in Capital | Accumulated Other Comprehensive Income (Loss) | Accumulated Deficit | Total Stockholders' Deficit |
|---|-----------------------------|-------------------|------------------|-------------|----------------------------|---|---------------------|-----------------------------|
|   | Shares                      | Amount            | Shares           | Amount      |                            |   |                     |                             |
| <b>Balances as of January 1, 2017</b>   | 547,974                     | \$ 40,189         | 911,777          | \$ 0        | \$ 1,682                   | \$ (3,126)                                    | \$ (31,022)         | \$ (32,466)                 |
| Issuance of Series B preferred stock, net of issuance costs of \$0              | 82,032                      | 5,315             | —                | —           | —                          | —   | —                   | —                           |
| Issuance of Series C convertible preferred stock, net of issuance costs of \$93 | 693,500                     | 59,270            | —                | —           | —                          | —   | —                   | —                           |
| Foreign currency translation adjustment   | —                           | —                 | —                | —           | —                          | 1,764   | —                   | 1,764                       |
| Stock-based compensation expense  | —                           | —                 | —                | —           | 769                        | —   | —                   | 769                         |
| Net loss  | —                           | —                 | —                | —           | —                          | —   | (12,723)            | (12,723)                    |
| <b>Balances as of December 31, 2017</b>   | 1,323,506                   | 104,774           | 911,777          | 0           | 2,451                      | (1,362)                                       | (43,745)            | (42,656)                    |
| Issuance of common stock upon exercise of stock options                         | —                           | —                 | 94,818           | 0           | 9                          | —   | —                   | 9                           |
| Foreign currency translation adjustment (unaudited)                             | —                           | —                 | —                | —           | —                          | (2,358)                                       | —                   | (2,358)                     |
| Stock-based compensation expense  | —                           | —                 | —                | —           | 867                        | —   | —                   | 867                         |
| Net loss  | —                           | —                 | —                | —           | —                          | —   | (16,237)            | (16,237)                    |
| <b>Balances as of December 31, 2018</b>   | <u>1,323,506</u>            | <u>\$ 104,774</u> | <u>1,006,595</u> | <u>\$ 0</u> | <u>\$ 3,327</u>            | <u>\$ (3,720)</u>                             | <u>\$ (59,982)</u>  | <u>\$ (60,375)</u>          |

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

## HOOKIPA PHARMA INC.

## CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

|   | Year ended<br>December 31, |                  |
|---|----------------------------|------------------|
|   | 2017                       | 2018             |
| <b>Operating activities:</b>  |                            |                  |
| Net loss  | \$ (12,723)                | \$ (16,237)      |
| Adjustments to reconcile net loss to net cash used in operating activities: |                            |                  |
| Stock-based compensation expense  | 770                        | 867              |
| Depreciation expense  | 398                        | 640              |
| Other non-cash items  | (45)                       | 7                |
| Changes in operating assets and liabilities:                                |                            |                  |
| Accounts receivable   | —                          | (4,991)          |
| Prepaid expenses and other current assets                                   | (67)                       | (7,049)          |
| Other non-current assets  | (83)                       | (1,465)          |
| Accounts payable  | (1,172)                    | 3,413            |
| Deferred revenues   | —                          | 8,587            |
| Accrued expenses and other liabilities                                      | 1,009                      | 1,230            |
| Net cash used in operating activities                                       | <u>(11,913)</u>            | <u>(14,998)</u>  |
| <b>Investing activities:</b>  |                            |                  |
| Purchases of property and equipment   | <u>(1,297)</u>             | <u>(2,150)</u>   |
| Net cash used in investing activities                                       | <u>(1,297)</u>             | <u>(2,150)</u>   |
| <b>Financing activities:</b>  |                            |                  |
| Proceeds from issuance of redeemable convertible preferred stock            | 58,145                     | 6,439            |
| Proceeds from issuance of common stock                                      | —                          | 9                |
| Proceeds from borrowings  | <u>747</u>                 | <u>425</u>       |
| Net cash provided by financing activities                                   | <u>58,892</u>              | <u>6,873</u>     |
| <b>Net decrease / increase in cash and cash equivalents</b>                 | <b>45,682</b>              | <b>(10,275)</b>  |
| Cash and cash equivalents at beginning of period                            | 13,186                     | 61,362           |
| Effect of exchange rate changes on cash and cash equivalents                | <u>2,494</u>               | <u>(2,507)</u>   |
| Cash and cash equivalents at end of period                                  | <u>\$ 61,362</u>           | <u>\$ 48,580</u> |
| <b>Supplemental disclosure of cash flow information:</b>                    |                            |                  |
| Cash paid for interest  | \$ (60)                    | \$ (71)          |
| Cash paid for income taxes  | \$ (4)                     | \$ (24)          |
| <b>Supplemental disclosure of non-cash financing activities:</b>            |                            |                  |
| Due from shareholder for issuance of redeemable convertible preferred stock | \$ 6,520                   | \$ —             |

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

## HOOKIPA PHARMA INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### 1. Nature of the business and basis of presentation

HOOKIPA Pharma Inc. ("HOOKIPA" or the "Company") is a clinical stage biopharmaceutical company developing a new class of immunotherapeutics targeting infectious diseases and cancers based on its proprietary arenavirus platform that is designed to reprogram the body's immune system.

The Company was incorporated under the name of Hookipa Biotech, Inc. under the laws of the State of Delaware in February 2017 as a fully-owned subsidiary of Hookipa Biotech AG. In June 2018, the Company changed its name from Hookipa Biotech, Inc. to HOOKIPA Pharma Inc. and in order to effectuate the change of the jurisdiction of incorporation, the Company acquired all of the shares of Hookipa Biotech AG, now Hookipa Biotech GmbH. HOOKIPA is headquartered in New York, with European research and preclinical development operations headquartered in Vienna, Austria.

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.

##### *Transaction between entities under common control*

In June 2018, the Company acquired all of the shares of its parent company, Hookipa Biotech AG, against issuance of 911,777 shares of common stock and 1,323,506 shares of redeemable convertible preferred stock to the shareholders of Hookipa Biotech AG, who became the sole shareholders of the Company. The transaction was recorded as a transaction between entities under common control that led to a change in the reporting entity. In the accompanying consolidated financial statements, the assets and liabilities and relating operations of the transferring entity are retrospectively presented at their carrying amounts without a change in the basis for all periods during which the transferring entity was under common control. The share capital as well as the share and per share information included in the accompanying consolidated financial statements have been retrospectively adjusted to reflect the share capital of the Company after the transaction. Differences in the par value of common stock between the transferring and the receiving entity were reflected by adjustments to redeemable convertible preferred stock and additional paid-in capital.

**HOOKIPA PHARMA INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****2. Summary of significant accounting policies (Continued)*****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, 2018, the Company has funded its operations with proceeds from 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 \$12.7 million and \$16.2 million for the years ended December 31, 2017 and 2018, respectively. As of December 31, 2018, the Company had an accumulated deficit of \$60.0 million. The Company expects to continue to generate operating losses in the foreseeable future. As of February 25, 2019, the issuance date of the consolidated financial statements for the year ended December 31, 2018, the Company expected that its cash and cash equivalents would be sufficient to fund its operating expenses, capital expenditure requirements and debt service payments through at least 12 months from the issuance date of the consolidated financial statements.

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

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The consolidated financial statements do not reflect any adjustments relating to the recoverability and classification of assets or the amounts and classification of liabilities that might be necessary if the Company is unable to continue as a going concern.

***Use of estimates***

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue, income and expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the recognition of revenue and income, the accrual of research and development expenses, the valuation of common and preferred stock, the valuation of stock-based awards and the valuation of liabilities. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates as there are changes in circumstances, facts and experience. Actual results may differ from those estimates or assumptions.



**HOOKIPA PHARMA INC.**

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

**2. Summary of significant accounting policies (Continued)**

***Unaudited pro forma information***

The accompanying unaudited pro forma Consolidated Balance Sheet as of December 31, 2018 has been prepared to give effect, upon the closing of an initial public offering, to the automatic conversion of all outstanding shares of redeemable convertible preferred stock as of December 31, 2018 into 15,409,633 shares of common stock as if the proposed initial public offering had occurred on December 31, 2018.

In the accompanying Consolidated Statements of Operations and Comprehensive Loss, unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2018 has been prepared to give effect, upon the closing of an initial public offering, to the automatic conversion of all outstanding shares of redeemable convertible preferred stock as of December 31, 2018 into 15,409,633 shares of common stock as if the proposed initial public offering had occurred on January 1, 2018 or the issuance date of the redeemable convertible preferred stock.

***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. The Company's cash and cash equivalents as of December 31, 2017 and 2018 consisted primarily of cash balances held by Hookipa Biotech GmbH in euros.

Assets and liabilities of Hookipa Biotech GmbH are translated into United States dollars at the exchange rate in effect on the balance sheet date. Income items and expenses are translated at the average exchange rate in effect during the period. Unrealized translation gains and losses are recorded as a cumulative translation adjustment, which is included in the Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit as a component of Accumulated other comprehensive loss. Adjustments that arise from exchange rate changes on transactions denominated in a currency other than the local currency are included in Other income and expenses, net in the Consolidated Statements of Operations and Comprehensive Loss as incurred.

***Stock split***

In April 2019, the Company's board of directors and stockholders approved the split of every one issued and outstanding share of the Company's common stock into 11.643 shares of common stock, which was effected on April 5, 2019. The par value of the Common stock was not adjusted as a result of the split. All issued and outstanding share and per share amounts of Common stock and options included in the accompanying consolidated financial statements have been adjusted to reflect this stock split for all periods presented. The conversion ratios for each series of the Company's Redeemable convertible preferred stock (see Note 8) has been adjusted proportionally.

***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. As of December 31, 2017 and 2018, the Company's cash and cash equivalents consisted primarily of cash balances held in euros on accounts with European banks in excess of publicly insured limits. The Company does not believe that

**HOOKIPA PHARMA INC.**

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

**2. Summary of significant accounting policies (Continued)**

it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

Amounts due from related party consist of payments due from a shareholder in connection with the issuance of Series C convertible preferred stock (the "Series C Preferred Stock"). The Company monitors economic conditions to identify facts or circumstances that may indicate if such amount due is at risk of collection. There was no allowance for doubtful accounts recorded at December 31, 2017 and 2018.

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.

***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 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. As of December 31, 2018 the Company recorded deferred offering costs of \$1.5 million.

***Cash equivalents***

The Company considers all highly liquid investments with original maturities of three months or less at the date of purchase to be cash equivalents.

***Fair value measurements***

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy:

- 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.

**HOOKIPA PHARMA INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****2. Summary of significant accounting policies (Continued)**

The Company's cash equivalents are carried at fair value, determined according to the fair value hierarchy described above. The carrying values of the Company's accounts payable and accrued expenses and other current liabilities approximate their fair values due to the short-term nature of these liabilities. The carrying value of the loans received under government funding agreements (see Note 7) approximates their fair value because the Company records imputed interest expense based on rates that approximate market rates of interest as of the issuance date of each loan.

***Property and equipment***

Property and equipment are stated at cost less accumulated depreciation. Depreciation expense is recognized using the straight-line method over the estimated useful life of each asset as follows:

|                                 | <u>Estimated useful life</u> |
|---------------------------------|------------------------------|
| Leasehold improvements          | 10 - 25 years                |
| Laboratory equipment            | 3 - 10 years                 |
| Furniture and fixtures          | 3 - 10 years                 |
| Computer equipment and software | 3 - 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.

***Impairment of long-lived assets***

Long-lived 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, 2017 and 2018.

***Segment information***

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company's singular focus is on developing pharmaceutical products to prevent and cure infectious diseases and cancer. The Chief Executive Officer is the chief operating decision maker, and regularly reviews the consolidated operating results to make decisions about the allocation of the Company's resources. Substantially all of the Company's tangible assets are held in Austria.

**HOOKIPA PHARMA INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****2. Summary of significant accounting policies (Continued)*****Revenue recognition from contracts with customers***

The Company has entered into a collaboration and license agreement (the "Gilead Agreement") with Gilead Sciences, Inc. ("Gilead") whereby the parties agreed to collaborate with respect to two preclinical research programs to evaluate potential vaccine products for the treatment, cure, diagnosis or prevention of the hepatitis B virus (HBV) and the human immunodeficiency virus (HIV). The Company's performance obligations under the terms of this agreement include one combined performance obligation for each research program (HBV and HIV) comprised of the transfer of intellectual property rights (licenses) and providing research and development services. The licenses do not represent distinct performance obligations, because they cannot be used without the research and development services. Payments to the Company under this agreement include a non-refundable up-front payment, payments for research and development activities, payments based upon the achievement of defined milestones, and if certain future conditions are met, payments for manufacturing services, commercial milestones and royalties on product sales.

The Company evaluates its collaboration and licensing arrangements pursuant to Accounting Standards Codification (ASC) 606. To determine the recognition of revenue from arrangements that fall within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation.

Under ASC 606, the Company applies significant judgement to evaluate whether the obligations under the collaboration and licensing arrangement, represent separate or one or more combined performance obligations, the allocation of the transaction price to identified performance obligations, and the determination of when milestone payments are probable of being received.

***Upfront payment***

The non-refundable upfront-payment received by the Company under the Gilead agreement is recorded as deferred revenue and allocated between the two research program performance obligations. Such amounts are recognized as revenue over the performance period of the respective services on a percent of completion basis using total estimated research and development labor hours (input method) for each of the obligations. The percent of completion basis using labor hours was considered the best measure of progress in which control of the combined performance obligations transfers to the customer, due to the short time intervals in which research results are shared with the collaboration partner and the nature of the work being performed.

***Reimbursement for services***

Under the collaboration and licensing agreement, the Company incurs employee expenses as well as external costs for research and manufacturing activities presented as operating expenses or prepaid expenses. Based on the nature of the Company's responsibilities under the collaboration arrangement, reimbursement of those costs are presented as revenue and not deducted from expenses, as the Company controls the research activities. Amounts of consideration allocated to the performance of research or manufacturing services are recognized over the period in which services are performed. Reimbursements for external costs are recognized as revenues in the period in which the goods or

**HOOKIPA PHARMA INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****2. Summary of significant accounting policies (Continued)**

services are received and external costs are recognized. Unpaid reimbursement amounts are presented as Accounts receivable.

*Research and development milestones*

The collaboration and license agreement includes contingent milestone payments related to specified preclinical and clinical development milestones. These milestone payments represent variable consideration that are not initially recognized within the transaction price as they are fully constrained under the guidance in ASC 606, due to the scientific uncertainties and the required commitment from Gilead. The Company will continue to assess the probability of significant reversals for any amounts that become likely to be realized prior to recognizing the variable consideration associated with these payments within the transaction price.

*Sales-based milestones and royalty payments*

The collaboration and licensing arrangement also includes certain sales-based milestone and royalty payments upon successful commercialization of a licensed product. In accordance with ASC 606-10-55-65, the Company recognizes revenues from sales-based milestone and royalty payments at the later of (i) the occurrence of the subsequent sale; or (ii) the performance obligation to which some or all of the sales-based milestone or royalty payments has been allocated has been satisfied. The Company anticipates recognizing these milestones and royalty payments if and when subsequent sales are generated from a licensed product by the collaboration partner.

*Cost to fulfill contracts*

The Company incurs costs for personnel, supplies and other costs related to its laboratory operations as well as fees from third parties and license expenses in connection with its research and development obligations under the collaboration and licensing agreement. These costs are recognized as research and development expenses over the period in which services are performed. Sublicense fees triggered by the receipt of payments are capitalized as an asset when the obligation to pay the fee arises. The capitalized asset is amortized over the period in which the revenue from the triggering payment is recognized.

***Research and development costs***

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including salaries and bonuses, stock-based compensation, employee benefits, facilities costs, laboratory supplies, depreciation, manufacturing expenses and external costs of vendors engaged to conduct preclinical development activities and clinical trials as well as the cost of licensing technology. Advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed.

All patent-related costs incurred in connection with filing and prosecuting patent applications are classified as research and development expenses and expensed as incurred due to the uncertainty about the recovery of the expenditure. Upfront payments, milestone payments and annual payments made for the licensing of technology are generally expensed as research and development in the period in which they are incurred. Incremental sublicense fees triggered by contracts with customers are capitalized and expensed as research and development expenses over the period in which the related revenue is recognized.

**HOOKIPA PHARMA INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****2. Summary of significant accounting policies (Continued)*****Research and manufacturing contract costs and accruals***

The Company has entered into various research and development and manufacturing contracts. Related payments are recorded as the corresponding expenses are incurred. The Company records accruals for estimated ongoing costs and prepaid expenses for advance payments. When evaluating the adequacy of the accrued liabilities and prepaid expenses, the Company analyzes progress of the research studies or clinical trials and manufacturing activities, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

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

The Company recognizes funding from grants and research incentives received from Austrian government agencies as other income. Income from grants and incentives is recognized in the period during which the related qualifying expenses are incurred, provided that the conditions under which the grants or incentives were provided have been met. For grants under funding agreements and for proceeds under research incentive programs, the Company recognizes grant and incentive income in an amount equal to the estimated qualifying expenses incurred in each period multiplied by the applicable reimbursement percentage.

Grant funding that has been received by the Company in advance of incurring qualifying expenses is recorded as deferred income. Grant and incentive income recognized upon incurring qualifying expenses in advance of receipt of grant funding or proceeds from research and development incentives is recorded in the consolidated balance sheets as prepaid expenses and other current assets.

The Company has received loans under funding agreements that bear interest at rates that are below market rates of interest. The Company accounts for the imputed benefit arising from the difference between a market rate of interest and the rate of interest charged as additional grant funding, and records interest expense for the loans at a market rate of interest. On the date that loan proceeds are received, the Company recognizes the portion of the loan proceeds allocated to grant funding as a discount to the carrying value of the loan and as other liability, which is subsequently recognized as additional grant income over the term of the funding agreement.

***Redeemable convertible preferred stock***

The Company has applied the guidance in ASC 480-10-S99-3A, *SEC Staff Announcement: Classification and Measurement of Redeemable Securities* and has therefore classified the Series A, Series B and Series C redeemable convertible preferred stock as mezzanine equity. The redeemable convertible preferred stock is recorded outside of stockholders' equity because, in the event of certain deemed liquidation events considered not solely within the Company's control, such as a merger, acquisition and sale of all or substantially all of the Company's assets, the convertible preferred stock will become redeemable at the option of the holders. In the event of a change of control of the Company, proceeds received from the sale of such shares will be distributed in accordance with the liquidation preferences set forth in the Company's Preferred Stock agreements. The Company has determined not to adjust the carrying values of the redeemable convertible preferred stock to the

**HOOKIPA PHARMA INC.**

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

**2. Summary of significant accounting policies (Continued)**

liquidation preferences of such shares because of the uncertainty of whether or when such an event would occur.

***Stock-based compensation***

The Company measures stock-based awards granted to employees and directors based on the fair value on the date of grant using the Black-Scholes option-pricing model for options or the difference between the purchase price per share of the award, if any, and the fair value of the Company's common stock for restricted common stock awards. Compensation expense for those awards is recognized over the requisite service period, which is generally the vesting period of the respective award. The Company uses the graded-vesting method to record the expense of awards with service-based vesting conditions.

The Company classifies stock-based compensation expense in its Consolidated Statements of Operations and Comprehensive Loss in the same manner in which the recipient's payroll costs are classified or in which the recipient's service payments are classified.

***Comprehensive loss***

Comprehensive loss includes net loss and foreign currency translation adjustments. For the years ended December 31, 2017 and 2018, comprehensive loss included \$1.8 million of foreign currency translation gain and \$2.4 million of foreign currency translation loss adjustments, respectively.

***Basic and diluted net loss per share***

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

***Income taxes***

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements or in the Company's tax returns. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date. Changes in deferred tax assets and liabilities are recorded in income tax expense. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

## HOOKIPA PHARMA INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**2. Summary of significant accounting policies (Continued)**

The Company accounts for uncertainty in income taxes recognized in the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

***Recent accounting pronouncements***

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies that the Company adopts as of the specified effective date.

***Adopted as of current period***

In May 2014, the FASB issued Accounting Standards Update (ASU) No. 2014-09 ("ASU 2014-09"), *Revenue from Contracts with Customers* (Topic 606), and further updated through ASU 2016-12 ("ASU 2016-12"), which amends the existing accounting standards for revenue recognition. Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity 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 entity satisfies a performance obligation. Topic 606 also impacts certain other areas, such as the accounting for costs to obtain or fulfill a contract. The standard also requires disclosure of the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. For public entities, this standard is effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period. Effective January 1, 2017, the Company early adopted Topic 606, using the full retrospective transition method. The adoption did not have any impact on the Company's consolidated financial statements as the Company did not have any revenue from contracts with customers before fiscal year 2018.

In May 2017, the FASB issued ASU 2017-09, *Compensation—Stock Compensation* (Topic 718): *Scope of Modification Accounting*, which clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. For all entities, this standard is effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted. Effective January 1, 2017, the Company early adopted this guidance. The adoption did not have any impact on the Company's consolidated financial statements as the Company had no changes to the terms or conditions of its share-based payment awards.



**HOOKIPA PHARMA INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****2. Summary of significant accounting policies (Continued)**

In June 2018, the FASB issued ASU 2018-07, *Compensation-Stock Compensation* (Topic 718): "Improvements to Nonemployee Share-Based Payment Accounting", which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. An entity should apply the requirements of Topic 718 to nonemployee awards except for specific guidance on inputs to an option pricing model and the attribution of cost (that is, the period of time over which share-based payment awards vest and the pattern of cost recognition over that period). The new guidance is effective for all public business entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. The Company has elected to early adopt this standard. The adoption of this ASU did not have a material impact on its consolidated loss from operations or cash flows.

*To be adopted in future periods:*

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (Topic 842) ("ASU 2016-02"), which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e., lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less may be accounted for similar to existing guidance for operating leases today. The Company will adopt ASU 2016-02 on January 1, 2019 and will elect the package of practical expedients, including the optional transition method that allows for the application of the new standard at its adoption date. The comparative financial information will not be restated and will continue to be reported under the previous lease standard in effect during those periods. The Company expects the adoption to result in recognition of operating lease assets and corresponding liabilities of approximately \$3.0 million to \$4.0 million on its Consolidated Balance Sheets. No material impacts are expected on the consolidated statements of operations or cash flows.

In July 2018, the FASB issued ASU No. 2018-11, *Earnings Per Share* (Topic 260), *Distinguishing Liabilities from Equity* (Topic 480), *Derivatives and Hedging* (Topic 815) I. Accounting for Certain Financial Instruments with Down Round Features II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception ("ASU 2018-11"). Part I applies to entities that issue financial instruments such as warrants, convertible debt or convertible preferred stock that contain down-round features. Part II replaces the indefinite deferral for certain mandatorily redeemable noncontrolling interests and mandatorily redeemable financial instruments of nonpublic entities contained within Accounting Standards Codification ("ASC") Topic 480 with a scope exception and does not impact the accounting for these mandatorily redeemable instruments. For public entities, this guidance is required to be adopted for annual periods beginning after December 15, 2018, including interim periods within those fiscal years. The Company expects that the adoption of ASU 2018-11 will have no impact on its consolidated financial statements.

## HOOKIPA PHARMA INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**3. Collaboration and Licensing Agreements*****Gilead Collaboration and License Agreement***

In June 2018, the Company and Gilead entered into the Gilead Agreement.

Under the Gilead Agreement, the Company granted Gilead an exclusive, royalty-bearing license to the Company's technology platforms. The Company has received a non-refundable \$10.0 million upfront payment from Gilead of which \$2.8 million was recorded as revenue from collaboration and licensing in the year ended December 31, 2018 and \$7.2 million was included as a liability in deferred revenues, current and non-current, as of December 31, 2018. Approximately 92% of the deferred revenue is expected to be recognized in 2019, and the remaining 8% in 2020. Gilead is also obligated to make additional payments to the Company upon the achievement of pre-clinical, development and commercial milestones. The development milestones amount to a total of \$280 million. The commercial milestones amount to a total of \$100 million. Additionally, Gilead is obligated to pay royalties on net sales for each program. All payments from Gilead have a 60 day payment term. In addition to the \$2.8 million recognition of the upfront payment, the Company recognized \$2.8 million in revenue for the achievement of the first pre-clinical milestone and \$2.0 million revenue from cost reimbursements for research and development services in the year ended December 31, 2018.

Upon the receipt of the non-refundable upfront payment, the Company recorded a liability of \$0.5 million, for a sublicense fee payable to certain licensors of technologies and capitalized a contract asset in the same amount which will be amortized over the period in which the revenue from the triggering payment is recognized. As of December 31, 2018 the liability and the contract asset relating to the sublicense payment were \$0.5 million and \$0.4 million, respectively.

**4. Cash and cash equivalents**

As of December 31, 2017 and 2018, the Company had cash and cash equivalents of \$61.4 million and \$48.6 million, respectively. The Company mostly holds its cash and cash equivalents in accounts with foreign banks.

**5. Property and equipment, net**

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

|                                 | December 31,    |                 |
|---------------------------------|-----------------|-----------------|
|                                 | 2017            | 2018            |
| Leasehold improvements          | \$ 926          | \$ 1,885        |
| Construction in progress        | 523             | —               |
| Laboratory equipment            | 2,821           | 3,443           |
| Furniture and fixtures          | 307             | 352             |
| Computer equipment and software | 539             | 723             |
| Property and equipment, gross   | 5,116           | 6,403           |
| Less: Accumulated depreciation  | (1,541)         | (2,066)         |
| Property and equipment, net     | <u>\$ 3,575</u> | <u>\$ 4,337</u> |

## HOOKIPA PHARMA INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**5. Property and equipment, net (Continued)**

Depreciation expense for the years ended December 31, 2017 and 2018 was \$0.4 million and \$0.6 million, respectively. Construction-in-progress as of December 31, 2017 related to leasehold improvements in connection with the expansion of laboratories in the Company's leased facilities.

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

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

|                                 | December 31,    |                 |
|---------------------------------|-----------------|-----------------|
|                                 | 2017            | 2018            |
| Consulting fees                 | \$ 136          | \$ 1,764        |
| Salaries and bonuses            | 1,069           | 1,404           |
| Social security contributions   | 447             | 121             |
| Unearned grant income (current) | 725             | 833             |
| Other accruals and liabilities  | 181             | 298             |
|                                 | <u>\$ 2,558</u> | <u>\$ 4,420</u> |

**7. Loans payable**

As of December 31, 2017 and 2018, loans payable consisted of the following (in thousands):

|                           | December 31,    |                 |
|---------------------------|-----------------|-----------------|
|                           | 2017            | 2018            |
| Loans from FFG            | \$ 8,296        | \$ 8,316        |
| Unamortized debt discount | (4,558)         | (3,924)         |
| Total Loans payable, net  | <u>\$ 3,738</u> | <u>\$ 4,392</u> |

In connection with the funding agreements with the Austrian Research Promotion Agency, (*Österreichische Forschungs-förderungsgesellschaft*, or "FFG"), the Company has received various loans ("FFG Loans"). The FFG Loans were made on a project-by-project basis. Amounts due under the FFG Loans bear interest at rates ranging from 0.75% to 1.0% per annum and mature at various dates between March 2021 and March 2024. Interest on amounts due under the loans is payable semi-annually in arrears, with all principal and remaining accrued interest due upon maturity.

The FFG Loans bear interest at rates that are below market rates of interest. The Company accounts for the imputed benefit arising from the difference between an estimated market rate of interest and the rate of interest charged by FFG as grant income from FFG. On the date that FFG loan proceeds are received, the Company recognizes the portion of the loan proceeds allocated to grant funding as a discount to the carrying value of the loan and as unearned income, which is recognized as grant income over the term of the funding agreement.

The Company recognized grant income of \$0.5 million and \$0.7 million during the years ended December 31, 2017 and 2018, respectively, related to the recognition of the unearned income recorded for the imputed benefit of FFG Loans at below-market interest rates. Unearned income (current) related to the imputed benefit of FFG Loans at below-market interest rates was \$0.7 million and \$0.8 million as of December 31, 2017 and 2018, respectively, and unearned income (non-current)

**HOOKIPA PHARMA INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****7. Loans payable (Continued)**

related to such benefit was \$3.8 million and \$3.0 million as of December 31, 2017 and 2018, respectively.

In addition, the Company has recorded a discount to the carrying value of each FFG Loan for the portion of the loan proceeds allocated to grant funding, which is being amortized to interest expense over the term of the loan using the effective interest method. As of December 31, 2017 and 2018, the unamortized debt discount related to FFG Loans was \$4.6 million and \$3.9 million, respectively.

The Company recognized interest expense of \$0.6 million and \$0.8 million during the years ended December 31, 2017 and 2018, respectively, related to the FFG Loans, which included interest expense related to the amortization of debt discount of \$0.5 million and \$0.7 million during the years ended December 31, 2017 and 2018, respectively. There were no principal payments due or paid under the FFG Loans during the years ended December 31, 2017 and 2018.

The Company uses an estimated market rate of 20%, which was determined based on an average of the available interest rates on unsecured loans to comparable companies. A 10% increase or decrease in the estimated market rate of interest would have no material impact on grant income or liabilities.

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, 2018, the aggregate minimum future principal payments due in connection with the FFG Loans are summarized as follows (in thousands):

| <u>Year ending December 31,</u> | <u>Amount</u>          |
|---------------------------------|------------------------|
| 2019                            | —                      |
| 2020                            | —                      |
| 2021                            | 2,168                  |
| 2022                            | 3,091                  |
| 2023                            | 629                    |
| Thereafter                      | 2,428                  |
| <b>Total</b>                    | <b><u>\$ 8,316</u></b> |

**8. Redeemable convertible preferred stock***Redeemable convertible preferred stock*

The Company has issued Series A redeemable convertible preferred stock (the "Series A Preferred Stock"), Series B redeemable convertible preferred stock (the "Series B Preferred Stock") and Series C redeemable convertible preferred stock (the "Series C Preferred Stock"). The Series A Preferred Stock, the Series B Preferred Stock and the Series C Preferred Stock (collectively referred to as the "Preferred Stock") were issued in June 2018 in a transaction between entities under common control by which the Company became the reporting entity. In the accompanying consolidated financial statements and notes, the Preferred Stock is retrospectively presented as if the Company had been the reporting entity for all periods during which the previous reporting entity was under common control.

**HOOKIPA PHARMA INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****8. Redeemable convertible preferred stock (Continued)**

The Preferred Stock has certain contingent redemption features based upon the occurrence of events that are not solely within the control of the Company and is therefore classified as mezzanine equity.

In November 2011 the Company issued and sold 137,814 shares of Series A Preferred Stock at a price of \$68.73 per share for gross proceeds of \$9.5 million. The Company did not record any issuance costs in connection with this transaction.

Between November 2013 and June 2015 the Company issued and sold 328,128 shares of Series B Preferred Stock at an average price of \$78.02 per share for gross proceeds of \$25.6 million. The Company incurred issuance costs in connection with this first tranche of Series B Preferred Stock of \$0.1 million. In December 2016 the Company issued and sold 82,032 shares of Series B Preferred Stock at a price of \$63.71 per share for gross proceeds of \$5.2 million. In connection with this tranche of Series B Preferred Stock the Company incurred issuance costs of \$0.03 million. Subsequently, in March 2017, the Company issued and sold an additional 82,032 shares of Series B Preferred Stock at a price of \$64.79 per share for gross proceeds of \$5.3 million.

In December 2017 the Company issued and sold 693,500 shares of Series C Preferred Stock at an average price of \$85.60 per share for gross proceeds of \$59.4 million. An amount of \$6.5 million of the gross proceeds from the issuance of Series C Preferred Stock was still due for payment at December 31, 2017 and was subsequently received on January 4, 2018. This amount was included in redeemable convertible preferred stock and shown as receivable due from shareholder in the accompanying consolidated financial statements at December 31, 2017. The Company incurred issuance costs in connection with the Series C Preferred Stock of \$0.1 million.

Upon issuance, the Series A Preferred Stock and Series B Preferred Stock had a liquidation preference corresponding to the issue price and a cumulative return of 8.0%. In connection with the issuance and sale of Series C Preferred Stock, the terms and conditions of the Series A Preferred Stock and Series B Preferred Stock were modified to change the liquidation preferences, including the removal of the cumulative return. The change in the terms of the Series A Preferred Stock and Series B Preferred Stock was accounted for as a modification, which did not have an impact on Redeemable convertible preferred stock of Stockholders' equity.

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

As of December 31, 2017 and 2018, the Preferred Stock consisted of the following (in thousands, except share amounts):

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

**HOOKIPA PHARMA INC.**

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

**8. Redeemable convertible preferred stock (Continued)**

The rights, preferences, privileges and restrictions for the holders of Preferred Stock are as follows:

*Voting rights*

The holders of the Preferred Stock are entitled to vote, together with the holders of common stock, on all matters submitted to the stockholders for a vote and are entitled to cast the number of votes equal to the number of whole shares of common stock into which the shares of Preferred Stock are convertible. Holders of Preferred Stock shall vote together with the holders of common stock as a single class. Holders of Preferred Stock, acting exclusively and as a separate class, are entitled to elect three directors of the Company.

*Dividends*

The holders of Preferred Stock are entitled to receive noncumulative dividends of 6.0% per annum, if any, declared by the Company's board of directors. The Company may not declare, pay or set aside any dividends on shares of any other class or series of capital stock of the Company (other than dividends on shares of common stock payable in shares of common stock) unless the holders of the Preferred Stock first receive, or simultaneously receive, a dividend on each outstanding share of each class or series of Preferred Stock. No dividends were declared or paid during the years ended December 31, 2017 or 2018.

*Liquidation*

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company or certain deemed liquidation events, the holders of Preferred Shares will receive, in preference to any distribution to the holders of common stock, an amount per share equal to the greater of the original issue price paid for such Preferred Shares, plus any dividends declared but unpaid thereon, plus a preferred participation amount (as defined below), or (ii) such amount per share as would have been payable had all shares of such series of Preferred Stock been converted into common stock prior to a liquidation, dissolution or winding up of the Company or deemed liquidation event. After the payment of all preferential amounts required to be paid to holders of shares of Preferred Stock, the remaining assets of the Company available for distribution to its stockholders shall be distributed (i) until the holders of Preferred Stock receive an amount per share equal to the product of two times the original issue price paid for such Preferred Shares (the preferred participation amount), among the holders of the shares of Preferred Stock and common stock, pro rata based on the number of shares held by each such holder, treating for this purpose all such securities as if they had been converted to common stock and (ii), after the holders of Preferred Stock have received an amount per share equal to the product of two times the original issue price paid for such Preferred Shares, among the holders of the shares of common stock, pro rata based on the numbers of shares of common stock held by each such holder.

## HOOKIPA PHARMA INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**8. Redeemable convertible preferred stock (Continued)**

The liquidation preference of the Preferred Stock is as follows (in thousands):

|                          | December 31,      |                  |
|--------------------------|-------------------|------------------|
|                          | 2017              | 2018             |
| Series A Preferred Stock | \$ 8,427          | \$ 8,020         |
| Series B Preferred Stock | 36,065            | 34,367           |
| Series C Preferred Stock | 60,112            | 57,282           |
|                          | <u>\$ 104,604</u> | <u>\$ 99,669</u> |

*Conversion*

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

The Preferred Stock will automatically convert into common stock upon the closing of an initial public offering on an internationally recognized share exchange or a regulated securities market at a price of at least €6.19 per share (\$7.09 as of December 31, 2018), resulting in at least \$60.0 million of gross proceeds to the Company. The Preferred Stock will also automatically convert to common stock if 60% or more of the holders of Preferred Stock require such a conversion, and the conversion is approval by the holders of the Series C Preferred Stock.

*Preferred Stock rights*

A majority of the holders of Series C Preferred Stock are required to approve a liquidation event, sell material assets, intellectual property or technology, issue debt, create, issue or redeem additional preferred or common stock, and pay or declare dividends. A majority of all Preferred Stock holders are required to approve a liquidation event, change the articles of incorporation, create or issue new classes of stock, alter or amend any class of existing stock, purchase or redeem any shares, pay or declare dividends, an initial public offering, adopt or amend any stock based compensation plans, and grant options to directors.

**9. Common stock**

In June 2018 the Company became the reporting entity in a transaction between entities under common control. In the accompanying consolidated financial statements and notes, the common stock is retrospectively presented as if the Company had been the reporting entity for all periods during which the previous reporting entity was under common control.

As of December 31, 2017, the Company had 911,777 shares of common stock outstanding and issued and was authorized to issue 2,133,437 additional shares of common stock upon exercise of stock options and 15,409,633 additional shares of common stock upon conversion of Preferred Stock. As of December 31, 2018, the Company had 1,006,595 shares of common stock outstanding and issued and was authorized to issue 2,038,619 additional shares of common stock upon exercise of stock options and 15,409,633 additional shares of common stock upon conversion of Preferred Stock.

**HOOKIPA PHARMA INC.**

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

**9. Common stock (Continued)**

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 common stock do not have any cumulative voting rights. Subject to any preferential dividend rights of any outstanding preferred stock, holders of common stock are entitled to receive ratably any dividends declared by our board of directors out of funds legally available for that purpose. Common stock has no preemptive rights, conversion rights, or other subscription rights or redemption or sinking fund provisions.

In the event of a liquidation, dissolution, or winding up of the Company, holders of common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock.

**10. Stock-based compensation**

*2018 Stock Option and Grant Plan*

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

Under the 2018 Stock Option and Grant Plan, 2,133,437 shares of common stock have been authorized and reserved for the issuance of incentive stock options or non-qualified stock options to employees, officers, directors, and consultants of the Company, of which 94,818 shares of common stock were issued upon exercise of stock options in the year ended December 31, 2018 and 2,038,619 shares were still available as of December 31, 2018.

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

Options granted under the 2018 Stock Option and Grant Plan generally vest over four years, with 25 percent of the options vesting upon the first anniversary of the grant date and the remaining 75 percent 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.

*2016 Stock Option Plan*

In December 2016, the Company adopted the 2016 Stock Option Plan, which replaced all of the options then outstanding under the 2012 Stock Option Plan and an additional 326,203 shares of common stock were authorized for the issuance of stock options to directors, officers, employees and consultants. In December 2017, an additional 1,324,431 shares of common stock were authorized for the issuance of stock options.



## HOOKIPA PHARMA INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**10. Stock-based compensation (Continued)**

In total, 2,637,709 shares of common stock were authorized for the issuance of stock options under the 2012 and 2016 Stock Option Plans, of which 504,272 stock options were exercised prior to June 2018. In June 2018, the remaining 2,133,437 authorized shares of common stock for the issuance of stock options under the 2016 Stock Option Plan were replaced by the authorization of 2,133,437 shares of common stock for issuance of stock options under the 2018 Stock Option and Grant Plan.

*Stock option valuation*

The Company estimates the option's fair value on the date of grant using the Black-Scholes option-pricing model. Black-Scholes utilizes assumptions related to expected term, volatility, the risk-free interest rate, the dividend and employee exercise behavior. Forfeitures are accounted for when they occur. Expected volatilities utilized in the Black-Scholes model are based on historical volatilities of a group of comparable companies. The group of representative companies have characteristics similar to the Company, including the stage of product development and focus of life science industry. Management believes that this represents the most accurate basis for estimating expected future volatilities under the current conditions. The risk-free interest rate is derived from the yields for U.S. Treasuries with a remaining term approximating the expected life of the options. The expected term represents the period of time that the options granted are expected to be outstanding. As there is no public market for the Company's common stock, estimated fair value of common stock at the option grant date has been determined by management with hindsight, considering both, objective and subjective factors deemed relevant for valuation purposes.

The assumptions used in the Black-Scholes model to determine fair value for the stock options granted in the years ended December 31, 2017 and 2018 were:

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

For option grants in 2017, the Company used AAA-rated euro area central government bond yields as the basis for the risk-free interest rate in the Black-Scholes model. For 2018 options grants, following the change of incorporation to the United States, the Company used a risk-free interest rate based on the U.S. Treasury yield curve in effect at the time of grant. For 2018 grants, the Company used the simplified method in developing an estimate of the expected term because of a lack of historical exercise data.

## HOOKIPA PHARMA INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 10. Stock-based compensation (Continued)

## Stock options

The following table summarizes the Company's stock option activity since January 1, 2017 (in thousands, except share and per share amounts):

|   | Number of<br>Shares | Weighted<br>Average<br>Exercise<br>Price | Weighted<br>Average<br>Remaining<br>Contractual<br>Term<br>(in years) | Aggregate<br>Intrinsic<br>Value |
|---|---------------------|--|---|---------------------------------|
| Outstanding as of January 1, 2017           | 920,514             | \$ 0.09                                  | 10.0  | \$ 1,407                        |
| Granted                                     | 546,412             | 0.10                                     |   |                                 |
| Exercised                                   | —                   | —  |   |                                 |
| Forfeited                                   | (32,776)            | 0.10                                     |   |                                 |
| Outstanding as of December 31, 2017         | <u>1,434,150</u>    | <u>\$ 0.10</u>                           | <u>9.0</u>  | <u>\$ 4,055</u>                 |
| Options exercisable as of December 31, 2017 | 402,148             | \$ 0.10                                  | 9.1   | \$ 1,137                        |
| Options unvested as of December 31, 2017    | 1,032,002           | \$ 0.10                                  | 9.0   | \$ 2,918                        |

|   | Number of<br>Shares | Weighted<br>Average<br>Exercise<br>Price | Weighted<br>Average<br>Remaining<br>Contractual<br>Term<br>(in years) | Aggregate<br>Intrinsic<br>Value |
|---|---------------------|--|---|---------------------------------|
| Outstanding as of December 31, 2017         | 1,434,150           | \$ 0.10                                  | 9.0   | \$ 4,055                        |
| Granted                                     | 283,305             | 10.33                                    |   |                                 |
| Exercised                                   | (94,818)            | 0.10                                     |   |                                 |
| Forfeited                                   | (16,312)            | 0.10                                     |   |                                 |
| Outstanding as of December 31, 2018         | <u>1,606,325</u>    | <u>\$ 1.95</u>                           | <u>8.0</u>  | <u>\$ 13,466</u>                |
| Options exercisable as of December 31, 2018 | 779,847             | \$ 0.12                                  | 8.0   | \$ 7,960                        |
| Options unvested as of December 31, 2018    | 826,478             | \$ 3.67                                  | 8.0   | \$ 5,506                        |

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, 2017 and 2018, were \$2.93, and \$10.33, respectively. The fair value of common stock has been determined by management with hindsight, considering third-party valuations of the Company's common stock with input from management of objective and subjective factors that it believed were relevant.

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

## HOOKIPA PHARMA INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**10. Stock-based compensation (Continued)***Stock-based compensation*

Stock-based compensation expense was classified in the consolidated statements of operations and comprehensive loss as follows (in thousands):

|                                     | Year ended<br>December 31, |               |
|-------------------------------------|----------------------------|---------------|
|                                     | 2017                       | 2018          |
| Research and development expenses   | \$ 295                     | \$ 399        |
| General and administrative expenses | 475                        | 468           |
|                                     | <u>\$ 770</u>              | <u>\$ 867</u> |

In the year ended December 31, 2018, the terms of 23,286 outstanding stock options were modified to increase the exercise price from \$0.10 to \$2.93. The Company determined that the fair value of the modified award on the effective date of the modification was smaller than the fair value of the original award immediately before the modification. Therefore, the modification did not lead to recognition of additional compensation cost or a change in unrecognized compensation cost.

As of December 31, 2017 and 2018, total unrecognized compensation cost related to the unvested stock-based awards was \$1.3 million and \$2.2 million, respectively, which is expected to be recognized over weighted average periods of 2.0 and 1.7 years, respectively.

**11. Income taxes**

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

|                     | Year ended<br>December 31, |                    |
|---------------------|----------------------------|--------------------|
|                     | 2017                       | 2018               |
| United States       | \$ (121)                   | \$ (604)           |
| Foreign (Austria)   | (12,598)                   | (15,609)           |
| Net loss before tax | <u>\$ (12,719)</u>         | <u>\$ (16,213)</u> |

The Company's worldwide effective tax rate for the years ended December 31, 2017 and 2018 was 0% and (0.1)% respectively. The tax rate is affected by recurring items, such as tax rates in foreign jurisdictions and the relative amounts of income earned in those jurisdictions, which is expected to be fairly consistent in the near term. It is also affected by discrete items that may occur in any given year, but are not consistent from year to year. The following items had the most significant impact on the

## HOOKIPA PHARMA INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 11. Income taxes (Continued)

difference between the statutory U.S. federal income tax rate of 35% and 21% for the years ended December 31, 2017 and 2018 and the effective tax rate:

|  | Year ended<br>December 31, |         |
|--|----------------------------|---------|
|  | 2017                       | 2018    |
| U.S. federal statutory income tax rate               | (35.0)%                    | (21.0)% |
| State income taxes, net of federal benefit           | —                          | —       |
| Foreign tax rate differential(i)                     | 10.0                       | (4.0)   |
| Not taxable government grants(ii)                    | (3.0)                      | (7.5)   |
| Stock-based compensation(iii)                        | (3.5)                      | (4.6)   |
| other  | —                          | (0.5)   |
| Change in deferred tax asset valuation allowance(iv) | 31.5                       | 37.5    |
| Effective income tax rate                            | —%                         | (0.1)%  |

- (i) The 10% reduction and the 4% increase for the years ended December 31, 2017 and 2018, respectively, resulted from rate differences between U.S. and non-U.S. jurisdictions. Net loss before tax was principally generated in Austria, where the statutory tax rate is 25%.
- (ii) For the years ended December 31, 2017 and 2018, 3.0% increase and 7.5% increase, respectively, resulted from non-taxable research subsidies received from Austrian government agencies.
- (iii) For the years ended December 31, 2017 and 2018, 3.5% increase and 4.6% increase, respectively, resulted from non-taxable Stock-based compensation expense.
- (iv) For the years ended December 31, 2017 and 2018, 31.5% reduction and 37.5% reduction, respectively, resulted from changes in valuation allowance on deferred tax assets. Deferred tax assets will only be recovered when the generation of future taxable income is more likely than not. Due to the nature of the Company's research activities and the inherent uncertainties the deferred tax assets have been fully impaired.

Components of the net deferred tax assets or liabilities as of December 31, 2017 and 2018 consisted of the following (in thousands):

|                                  | December 31, |           |
|----------------------------------|--------------|-----------|
|                                  | 2017         | 2018      |
| Net operating loss carryforwards | \$ 13,804    | \$ 19,011 |
| Accrued expenses and other       | (47)         | 94        |
| Stock-based compensation         | 32           | 51        |
| Total deferred tax assets        | 13,789       | 19,156    |
| Valuation allowance              | (13,789)     | (19,156)  |
| Net deferred tax assets          | \$ —         | \$ —      |

## HOOKIPA PHARMA INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**11. Income taxes (Continued)**

As of December 31, 2017 and 2018, the Company had Austrian net operating loss carryforwards of \$55.2 million and \$76.0 million, respectively, with no expiry date. The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. Management has considered the Company's history of cumulative net losses incurred since inception and its lack of commercialization of any products or generation of any revenue from product sales since inception and has concluded that it is more likely than not that the Company will not realize the benefits of its deferred tax assets. Accordingly, a full valuation allowance has been established against the deferred tax assets as of December 31, 2017 and 2018. Management reevaluates the positive and negative evidence at each reporting period.

The amount of the deferred tax asset considered realizable, however, could be adjusted if estimates of future taxable income during the carryforward period are reduced or increased or if objective negative evidence in the form of losses is no longer present and additional weight may be given to subjective evidence. The tax years in which the tax carryforwards were generated may still be adjusted upon examination by the tax authorities. As of December 31, 2018, there were no pending income tax examinations.

A court case is currently pending at the Austrian Administrative Court as to whether servicing granted options by issuing new shares results in an expense-related and deductible personnel expense. As of the date of these financial statements, the Austrian Administrative Court had not issued a decision on this issue. If the court should deny the deductibility, the Company's loss carryforwards will decrease by \$9.4 million as of December 31, 2018.

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

|  | Year ended         |                    |
|--|--------------------|--------------------|
|  | December 31,       |                    |
|  | 2017               | 2018               |
| Valuation allowance at beginning of period | \$ (8,378)         | \$ (13,789)        |
| Increases                                  | (5,411)            | (5,367)            |
| Valuation allowance at end of period       | <u>\$ (13,789)</u> | <u>\$ (19,156)</u> |

On December 22, 2017, the United States enacted the Tax Cuts and Jobs Act ("Tax Reform Legislation" or "TCJA"), which made significant changes to U.S. federal income tax code, including a reduction of the statutory corporate tax rate from 35% to 21%, effective on January 1, 2018. This new legislation also eliminated or reduced certain corporate income tax deductions as well as introduced new provisions that taxed certain foreign income not previously taxed in the United States. The TCJA also includes a provision for a tax on all previously undistributed earnings of U.S. companies located in foreign jurisdictions. Undistributed earnings in the form of cash and cash equivalents is taxed at a rate of 15.5% and all other earnings are taxed at a rate of 8%. This tax is payable over 8 years and will not accrue interest.

The Tax Reform Legislation introduced section 951A, a new tax on so-called "global intangible low-taxed income," or "GILTI". GILTI applies to income of a controlled foreign corporation ("CFC") that is not otherwise subpart F income, and consists of the excess "tested income" over a 10% return

## HOOKIPA PHARMA INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**11. Income taxes (Continued)**

on the CFC's "qualified business asset investment," or "QBAI". QBAI is the total tax basis of the CFC's depreciable, tangible property used in the production of tested income. The full amount of GILTI is included in taxable income. The GILTI inclusion is then reduced by 50% (reduced to 37.5% after 2025). However, that reduction in GILTI may be limited based on the level of U.S. taxable income. A limited allowance for foreign tax credits is allowed that would reduce the U.S. tax cost. GILTI foreign tax credits can only reduce U.S. taxes owed on GILTI and are not eligible for carryforward. The Company's Austrian subsidiary falls under the category of a CFC and due to the nature of its business model as a technology company, there may not be a material amount of tangible assets if this subsidiary starts to generate profits. GILTI taxation therefore may be applicable.

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

**12. Commitments and contingencies***Operating leases*

The Company leases office and laboratory facilities in Vienna, Austria under three operating leases. The Company can generally terminate the leases with three months' notice at the end of each calendar quarter. However, it has waived its termination rights for one of the three leases until March 31, 2023 and for the other two leases until June 30, 2020. Furthermore, the Company leases office equipment, a company car and animal rooms. Rent expense under the leases for the year ended December 31, 2017 and 2018 was \$0.7 million and \$1.2 million, respectively.

Future annual minimum lease payments under non-cancellable operating leases are as follows (in thousands):

| <u>Year ending December 31,</u> | <u>Amount</u> |
|---------------------------------|---------------|
| 2019                            | 520           |
| 2020                            | 278           |
| 2021                            | 43            |
| 2022                            | 43            |
| 2023                            | 11            |
| Total                           | <u>\$ 895</u> |

Future annual minimum lease payments do not include future embedded lease obligations under an agreement with a contract manufacturing organization commencing in February 2019, which are included in the non-cancellable minimum obligations under contracts with CMOs (see below).

*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, 2018,

HOOKIPA PHARMA INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**12. Commitments and contingencies (Continued)**

the Company's total non-cancellable obligations under contracts with CMOs were \$19.6 million, of which \$9.2 million relate to 2019 deliverables, \$6.4 million relate to 2020 deliverables and \$4.0 million relate to 2021 deliverables.

In December 2018, the Company entered into an agreement with a contract manufacturing organization for the production of clinical trial material, including seed lots, drug substance for toxicology studies, stability studies and clinical studies as well as related technology transfer, quality control and process optimization activities to commence in February 2019. Under the financial terms of the agreement the Company is obliged to pay non-cancellable minimum service fees totaling \$15.7 million through 2021. The Company has determined that the agreement includes embedded leases which, upon effectiveness, will result in recognition of operating lease assets and corresponding liabilities under ASU 2014-09 on the Consolidated Balance Sheets.

*Intellectual property licenses*

In October 2011, the Company entered into a license agreement with University of Zurich ("Zurich") for an exclusive, worldwide, royalty-bearing license for a propagation-deficient arenavirus vector. The Company is obligated to pay royalties of low single digits on net sales of products licensed under the agreement, and to pay a percentage of the sublicense fees which the Company receives from its sublicensees.

In February 2017, the Company entered into a license agreement with Université de Genève ("Geneva") for an exclusive, worldwide, royalty-bearing licence for a tri-segmented Arenavirus vector. In consideration for these rights the Company is obligated to pay Geneva an annual fee which is fully deductible from any milestone, royalty or sublicense payments. The Company is also obligated to pay milestone nominal payments for each licensed product upon the achievement of certain development and regulatory milestones and to pay royalties of low single digits on net sales of licensed products. The Company is obligated to pay a percentage of the sublicense fees which the Company receives from its sublicensees.

In December 2016, the Company entered into a license agreement with University of Basel ("Basel") for an exclusive, worldwide, royalty-bearing licence for a tri-segmented Pichinde virus vector. The Company is required to use reasonable efforts to make commercially available licensed products. In consideration for these rights, the Company is 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 on net sales of licensed products. The Company is obligated to pay a percentage of the sublicense fees which the Company receives from its sublicensees.

In the year ended December 31, 2018, the Company recorded \$0.1 million in licensing fees from intellectual property licenses as research and development expenses. At December 31, 2018, \$0.5 million payable from sublicensing fees were included in accrued expenses and other current liabilities. These amounts mainly related to the upfront payment received by the Company under the Gilead collaboration. The calculation of the sublicensing fees according to the Company's intellectual property licenses is subject to interpretation and the amounts recognized as expenses or liability may therefore be subject to change until agreed to by the receiving party.

## HOOKIPA PHARMA INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**12. Commitments and contingencies (Continued)***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, 2017 and 2018.

*Legal proceedings*

At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. While it is not feasible to predict the outcome of these matters with certainty, and some lawsuits, claims or proceedings may be disposed or decided unfavorably, the Company does not expect that any asserted or un-asserted legal claims or proceedings, individually or in the aggregate, will have a material adverse effect on the Company. The Company expenses as incurred the costs related to such legal proceedings.

**13. 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, |                   |
|   | 2017               | 2018              |
| <b>Numerator:</b>   |                    |                   |
| Net loss  | \$ (12,723)        | \$ (16,237)       |
| <b>Denominator:</b>   |                    |                   |
| Weighted-average common shares outstanding, basic and diluted | 911,777            | 914,375           |
| <b>Net loss per share, basic and diluted</b>                  | <b>\$ (13.95)</b>  | <b>\$ (17.76)</b> |

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



## HOOKIPA PHARMA INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**13. Net loss per share (Continued)**

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, |                   |
|--------------------------------|-------------------------|-------------------|
|                                | 2017                    | 2018              |
| Series A Preferred Stock       | 1,604,574               | 1,604,574         |
| Series B Preferred Stock       | 5,730,612               | 5,730,612         |
| Series C Preferred Stock       | 8,074,447               | 8,074,447         |
| Options issued and outstanding | 1,434,150               | 1,606,325         |
| Total                          | <u>16,843,783</u>       | <u>17,015,958</u> |

**14. Related parties**

The Company is party to research and service arrangements with the University of Basel. The Company's Chief Scientific Officer and his spouse are employees of the University of Basel and both are involved in providing services under these arrangements. In the years ended December 31, 2017 and 2018 the Company recorded \$0.3 million and \$0.4 million, respectively, in research and development expenses for service fees paid to the University of Basel. The University of Basel is also entitled to receive de minimis royalties on the net sales of any product that is based on a patent created by the Company's Chief Scientific Officer in the course of his consulting services to the Company. In the years ended December 31, 2017 and 2018 no royalties were paid pursuant to the terms of this arrangement.

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

**15. Subsequent events**

For the consolidated financial statements as of December 31, 2017 and 2018, the Company evaluated subsequent events through February 25, 2019, the date on which those consolidated financial statements were available to be issued.

In February 2019, the Company issued and sold 257,000 shares of Series D redeemable convertible preferred stock (the "Series D Preferred Stock") at a price of \$145.65 per share for gross proceeds of \$37.4 million, and incurred issuance costs of \$0.2 million in connection with Series D Preferred Stock. 50,670 shares of Series D Preferred Stock for total proceeds of \$7.4 million were issued to certain stockholders that were related parties. Rights, preferences, privileges and restrictions of the Series D Preferred Stock are similar to those of the holders of other Series of Preferred Stock and include, amongst others, preferred dividend and liquidation rights as well as certain approval rights. Shares of Series D Preferred Stock convert into shares of Common Stock or Class A Common Stock at the same terms as shares of other Series of Preferred Stock.

In connection with the Series D financing, the stockholders approved to amend and restate the Company's certificate of incorporation to, amongst other changes, increase the authorized number of shares of common stock to 25,614,706, create Series D Preferred Stock consisting of 308,960 authorized

**HOOKIPA PHARMA INC.**

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

**15. Subsequent events (Continued)**

shares, and create a new class of non-voting stock (the "Class A Common Stock"), consisting of 19,006,880 authorized shares.

**Events subsequent to original issuance of Consolidated Financial Statements (unaudited)**

*Amended and restated certificate of incorporation*

In March 2019 and April 2019, the Company's board of directors and stockholders, respectively, approved that prior to the consummation of the Company's IPO, the Company will file an amended and restated certificate of incorporation that, effective simultaneous with closing of the IPO, increases the total number of shares of capital stock which the Company shall have authority to issue to 113,900,000 shares, par value \$0.0001 per share, of which 100,000,000 shares shall be shares of Common stock, 3,900,000 shares shall be Class A common stock and 10,000,000 shares shall be undesignated preferred stock.

*2019 Stock Option and Incentive Plan*

On April 1, 2019, the Company's stockholders approved the 2019 Stock Option and Incentive Plan, which will become effective as of the effectiveness of the registration statement in connection with the Company's IPO. The maximum number of shares of the Company's Common stock that may be issued under the Company's 2019 Stock Option and Incentive Plan is 2,608,042, after giving effect to the stock split, with automatic increases.

On April 1, 2019, the Company's stockholders approved the 2019 Employee Stock Purchase Plan, which will become effective as of the effectiveness of the registration statement in connection with the Company's IPO. The number of shares of the Company's Common stock available for grant and issuance under the 2019 Stock Purchase Plan shall be 260,804, after giving effect to the stock split, with automatic increases.

Through and including May 12, 2019, (the 25th day after the date of this prospectus), all dealers effecting transactions in the Common Stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

**6,000,000 Shares**



**Common Stock**

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**PROSPECTUS**

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**BofA Merrill Lynch**

**SVB Leerink**

**RBC Capital Markets**

**Kempen**

**April 17, 2019**

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