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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549**

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**FORM 10-Q**

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(Mark One)

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

For the quarterly period ended March 31, 2019

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_.

Commission File Number: 001-38869

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**HOOKIPA PHARMA INC.**

(Exact Name of Registrant as Specified in its Charter)

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Delaware  
(State or other jurisdiction of  
incorporation or organization)

81-5395687  
(I.R.S. Employer  
Identification No.)

350 Fifth Avenue, 72nd Floor, Suite 7240  
New York, New York  
(Address of principal executive offices)

10118  
(Zip Code)

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes  No

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Small reporting company	<input checked="" type="checkbox"/>
Emerging growth Company	<input checked="" type="checkbox"/>		

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	HOOK	The Nasdaq Global Select Market

As of May 20, 2019, the registrant had 21,588,756 shares of common stock and 3,819,732 shares of Class A common stock outstanding, each \$0.0001 par value per share.

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## FORWARD-LOOKING STATEMENTS

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

- the success, cost and timing of our product development activities and clinical trials;
  - the timing, scope or likelihood of regulatory filings and approvals, including timing of Investigational New Drug Application and Biological Licensing Application filings for our current and future product candidates, and final U.S. Food and Drug Administration, European Medicines Agency or other foreign regulatory authority approval of our current and future product candidates;
  - our ability to develop and advance our current product candidates and programs into, and successfully complete, clinical studies;
  - our manufacturing, commercialization and marketing capabilities and strategy;
  - the potential benefits of and our ability to maintain our collaboration with Gilead Sciences, Inc., and establish or maintain future collaborations or strategic relationships or obtain additional funding;
  - the rate and degree of market acceptance and clinical utility of our current and future product candidates;
  - our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering our VaxWave and TheraT technologies and the product candidates based on these technologies, the validity of intellectual property rights held by third parties, and our ability not to infringe, misappropriate or otherwise violate any third-party intellectual property rights;
  - future agreements with third parties in connection with the commercialization of our product candidates and any other approved product;
  - regulatory developments in the United States and foreign countries;
  - competitive companies, technologies and our industry and the success of competing therapies that are or may become available;
  - our ability to attract and retain key scientific or management personnel;
  - our ability to obtain funding for our operations, including funding necessary to complete further development and commercialization of our product candidates;
  - the accuracy of our estimates of our annual total addressable market, future revenue, expenses, capital requirements and needs for additional financing;
  - our expectations about market trends; and
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- our expectations regarding the period during which we qualify as an emerging growth company under the Jumpstart Our Business Startups Act of 2012, as amended.

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

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

HOOKIPA PHARMA INC.

CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

(In thousands, except share amounts)

	<u>March 31,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 70,508	\$ 48,580
Accounts receivable	1,328	4,919
Prepaid expenses and other current assets	13,067	8,812
Total current assets	<u>84,903</u>	<u>62,311</u>
Non-current assets:		
Property and equipment, net	4,512	4,337
Operating lease assets	8,920	—
Other non-current assets	3,645	1,603
Total non-current assets	<u>17,077</u>	<u>5,940</u>
Total assets	<u>\$ 101,980</u>	<u>\$ 68,251</u>
<b>Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)</b>		
Current liabilities		
Accounts payable	\$ 3,298	\$ 3,656
Deferred revenues	6,368	6,619
Accrued expenses and other current liabilities	5,428	4,420
Total current liabilities	<u>15,094</u>	<u>14,695</u>
Non-current liabilities		
Loans payable, non-current	4,499	4,392
Operating lease liabilities, non-current	6,311	—
Deferred revenues, non-current	823	1,663
Other non-current liabilities	3,262	3,102
Total non-current liabilities	<u>14,895</u>	<u>9,157</u>
Total liabilities	<u>29,989</u>	<u>23,852</u>
Commitments and contingencies (Note 11)		
Redeemable convertible preferred stock (series A, B, C and D), \$0.0001 par value; 1,666,961 shares and 1,323,506 shares authorized, issued and outstanding at March 31, 2019 and December 31, 2018, respectively; aggregate liquidation preference of \$137.1 million and \$99.7 million at March 31, 2019 and December 31, 2018, respectively	142,048	104,774
Stockholders' equity (deficit):		
Common stock, \$0.0001 par value; 25,614,706 and 18,454,860 shares authorized at March 31, 2019 and December 31, 2018, respectively; 1,006,595 shares issued and outstanding at March 31, 2019 and December 31, 2018	0	0
Class A common stock, \$0.0001 par value; 19,006,880 and 0 shares authorized at March 31, 2019 and December 31, 2018, respectively; 0 shares issued and outstanding at March 31, 2019 and December 31, 2018	—	—
Additional paid-in capital	3,710	3,327
Accumulated other comprehensive loss	(4,457)	(3,720)
Accumulated deficit	(69,310)	(59,982)
Total stockholders' equity (deficit)	<u>(70,057)</u>	<u>(60,375)</u>
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	<u>\$ 101,980</u>	<u>\$ 68,251</u>

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

**HOOKIPA PHARMA INC.****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (UNAUDITED)****(In thousands, except share and per share amounts)**

	<b>Three months ended March 31,</b>	
	<b>2019</b>	<b>2018</b>
Revenue from collaboration and licensing	\$ 2,235	\$ —
Operating expenses:		
Research and development	(10,179)	(4,969)
General and administrative	(2,711)	(1,480)
Total operating expenses	<u>(12,890)</u>	<u>(6,449)</u>
Loss from operations	<u>(10,655)</u>	<u>(6,449)</u>
Other income (expense):		
Grant income	\$ 1,192	\$ 2,071
Interest income	64	—
Interest expense	(213)	(193)
Other income and expenses, net	<u>283</u>	<u>22</u>
Total other income (expense), net	<u>1,326</u>	<u>1,900</u>
Net loss before tax	(9,329)	(4,549)
Income tax expense	<u>(0)</u>	<u>(24)</u>
Net loss	<u>(9,329)</u>	<u>(4,573)</u>
Other comprehensive loss:		
Foreign currency translation (loss) gain, net of tax	<u>(736)</u>	<u>1,539</u>
Comprehensive loss	<u>\$ (10,065)</u>	<u>\$ (3,034)</u>
Net loss per share—basic and diluted	<u>\$ (9.27)</u>	<u>\$ (5.02)</u>
Weighted average common shares outstanding — basic and diluted	<u>1,006,595</u>	<u>911,777</u>

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

HOOKIPA PHARMA INC.

CONDENSED CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT (UNAUDITED)

(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 December 31, 2018</b>	1,323,506	104,774	1,006,595	0	3,327	(3,720)	(59,982)	(60,375)
Issuance of Series D preferred stock, net of issuance costs of \$158	257,000	37,274	—	—	—	—	—	—
Foreign currency translation adjustment, net of tax	—	—	—	—	—	(736)	—	(736)
Stock-based compensation expense	—	—	—	—	383	—	—	383
Net loss	—	—	—	—	—	—	(9,329)	(9,329)
<b>Balances as of March 31, 2019</b>	<u>1,580,506</u>	<u>\$ 142,048</u>	<u>1,006,595</u>	<u>\$ 0</u>	<u>\$ 3,710</u>	<u>\$ (4,456)</u>	<u>\$ (69,311)</u>	<u>\$ (70,057)</u>
	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 December 31, 2017</b>	1,323,506	104,774	911,777	0	2,451	(1,362)	(43,745)	(42,656)
Foreign currency translation adjustment, net of tax	—	—	—	—	—	1,539	—	1,539
Stock-based compensation expense	—	—	—	—	206	—	—	206
Net loss	—	—	—	—	—	—	(4,573)	(4,573)
<b>Balances as of March 31, 2018</b>	<u>1,323,506</u>	<u>\$ 104,774</u>	<u>911,777</u>	<u>\$ 0</u>	<u>\$ 2,657</u>	<u>\$ 177</u>	<u>\$ (48,318)</u>	<u>\$ (45,484)</u>

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

## HOOKIPA PHARMA INC.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

(In thousands)

	Three months ended March 31,	
	2019	2018
<b>Operating activities:</b>		
Net loss	\$ (9,329)	\$ (4,573)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	383	206
Depreciation expense	566	140
Other non-cash items	54	7
Changes in operating assets and liabilities:		
Accounts receivable	3,509	(1)
Prepaid expenses and other current assets	(3,711)	(889)
Other non-current assets	(6,069)	(1)
Accounts payable	(958)	622
Deferred revenues	(935)	(0)
Accrued expenses and other liabilities	4,434	(483)
Net cash used in operating activities	(12,056)	(4,972)
<b>Investing activities:</b>		
Purchases of property and equipment	(400)	(262)
Net cash used in investing activities	(400)	(262)
<b>Financing activities:</b>		
Payments related to finance leases	(1,395)	—
Proceeds from issuance of redeemable convertible preferred stock	37,274	6,439
Payments of deferred offering costs	(722)	—
Proceeds from borrowings	—	440
Net cash provided by financing activities	35,157	6,879
<b>Net decrease / increase in cash and cash equivalents</b>	<b>22,701</b>	<b>1,645</b>
Cash and cash equivalents at beginning of period	48,580	61,362
Effect of exchange rate changes on cash and cash equivalents	(773)	1,750
Cash and cash equivalents at end of period	<u>\$ 70,508</u>	<u>\$ 64,757</u>
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid for interest	\$ —	\$ —
Cash paid for income taxes	\$ (0)	\$ (1)

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



**HOOKIPA PHARMA INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**

**1. Nature of the business and organization**

HOOKIPA Pharma Inc. ("HOOKIPA" or the "Company") is a clinical stage biopharmaceutical company developing a new class of immunotherapeutics targeting infectious diseases and cancers based on its proprietary arenavirus platform that is designed to reprogram the body's immune system.

The Company was incorporated under the name of Hookipa Biotech, Inc. under the laws of the State of Delaware in February 2017 as a fully-owned subsidiary of Hookipa Biotech AG. In June 2018, the Company changed its name from Hookipa Biotech, Inc. to HOOKIPA Pharma Inc. and in order to effectuate the change of the jurisdiction of incorporation, the Company acquired all of the shares of Hookipa Biotech AG, now Hookipa Biotech GmbH. HOOKIPA is headquartered in New York, with European research and preclinical development operations headquartered in Vienna, Austria. In April 2019, the Company closed its initial public offering ("IPO") and its shares started trading on the Nasdaq Global Select Market under the ticker symbol "HOOK".

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, the ability to establish clinical- and commercial-scale manufacturing processes and the ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities and may not ultimately lead to a marketing approval and commercialization of a product. Even if the Company's drug development efforts are successful, it is uncertain if and when the Company will realize significant revenue from product sales.

**2. Summary of significant accounting policies**

***Basis of presentation***

The Company's condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiary. All intercompany accounts and transactions have been eliminated in consolidation.

The accompanying condensed consolidated balance sheets as of March 31, 2019, the condensed consolidated statements of operations and comprehensive loss and of cash flows for the three months ended March 31, 2019 and 2018, and the condensed consolidated statement of redeemable convertible preferred stock and stockholders' deficit for the three months ended March 31, 2019 are unaudited.

The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited annual consolidated financial statements, except for the accounting of lease agreements that have been reported in accordance with ASC 842 and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement for interim reporting. Certain information and footnote disclosures typically included in annual financial statements prepared in accordance with GAAP have been condensed or omitted. Accordingly, these unaudited interim condensed consolidated financial statements should be read in conjunction with the Company's consolidated financial statements as of and for the year ended December 31, 2018, which are included in the Company's prospectus related to the Company's IPO, filed April 19, 2019 (File No. 333-230451) with the Securities and Exchange Commission ("SEC"), pursuant to Rule 424 (b) under the Securities Act of 1933, as amended. The results for any interim period are not necessarily indicative of results for any future period.

**HOOKIPA PHARMA INC.**

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

***Stock split***

On April 5, 2019, the Company effected a 11.643-for-one stock split of its issued and outstanding shares of common stock. The par value of the common stock was not adjusted as a result of the split. All issued and outstanding share and per share amounts of common stock and options included in the accompanying condensed 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 7) have been adjusted proportionally.

***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 March 31, 2019, 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 \$9.3 million and \$4.6 million for the three months ended March 31, 2019 and 2018, respectively. As of March 31, 2019, the Company had an accumulated deficit of \$69.3 million. The Company expects to continue to generate operating losses in the foreseeable future. As of May 20, 2019, the filing date of this Quarterly Report on Form 10-Q, 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 condensed consolidated financial statements.

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

The accompanying condensed 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 condensed 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 condensed 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 CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (continued)**

***Concentrations of credit risk and of significant suppliers***

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents and short-term bank deposits. As of December 31, 2018 and March 31, 2019, the Company's cash and cash equivalents included substantial amounts of cash balances held in euros on accounts with European banks in excess of publicly insured limits. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

The Company relies, and expects to continue to rely, on a small number of vendors to manufacture supplies and raw materials for its development programs. These programs could be adversely affected by a significant interruption in these manufacturing services or the availability of raw materials.

***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 would be expensed immediately as a charge to operating expenses in the condensed consolidated statements of operations and comprehensive loss. As of March 31, 2019 and December 31, 2018, the Company recorded deferred offering costs of \$2.3 million and \$1.5 million, respectively, in prepaid expenses and other current assets.

***Property and equipment***

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation and amortization expense is recognized using the straight-line method over the estimated useful life of each asset as follows:

	<u>Estimated useful life</u>
Leasehold improvements (1)	5 years
Laboratory equipment	3 - 10 years
Furniture and fixtures	3 - 10 years
Computer equipment and software	3 - 4 years

(1) In the course of the application of ASC 842, the economic useful lives of the leasehold improvements were adjusted to the lease terms.

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.

***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, Series C and Series D 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

**HOOKIPA PHARMA INC.**

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

carrying values of the redeemable convertible preferred stock to the liquidation preferences of such shares because of the uncertainty of whether or when such an event would occur.

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

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

The determination whether an arrangement was qualified as a lease was made at contract inception. Operating lease assets represent the Company's right to use an underlying asset for the lease term and operating lease liabilities represent its obligation to make lease payments arising from the lease. Operating lease assets and liabilities are recognized at the commencement date of the lease based upon the present value of lease payments over the lease term. When determining the lease term, the Company includes options to extend or terminate the lease when it is reasonably certain that the option will be exercised. The Company uses the implicit rate when readily determinable and uses its incremental borrowing rate when the implicit rate is not readily determinable based upon the information available at the commencement date in determining the present value of the lease payments. The incremental borrowing rate is determined using a secured borrowing rate for the same currency and term as the associated lease. The lease payments used to determine operating lease assets may include lease incentives, stated rent increases and escalation clauses linked to rates of inflation when determinable and are recognized as operating lease assets on the condensed consolidated balance sheets. In addition, certain of the Company's arrangements contain lease and non-lease components. The Company elected to generally separate lease payments from non-lease payments but applied an accounting choice to not separate lease payments from certain non-lease payments for its office and laboratory space leases and its car leases.

**HOOKIPA PHARMA INC.**

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

Operating leases are reflected in operating lease assets, in accrued expenses and other current liabilities and in non-current operating lease liabilities in the condensed consolidated balance sheets. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term.

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 ASC Topic 480 with a scope exception and does not impact the accounting for these mandatorily redeemable instruments. For public entities, this guidance is required to be adopted for annual periods beginning after December 15, 2018, including interim periods within those fiscal years. The Company adopted ASU 2018-11 as of January 1, 2019. The adoption of this ASU did not have a material impact on its consolidated loss from operations or cash flows.

*Recently Issued Accounting Pronouncements*

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

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

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

In June 2016, the FASB issued ASU No. 2016-13, "Financial Instruments-Credit Losses." The standard modifies the impairment model for most financial assets, including trade accounts receivables and loans, and will require the use of an "expected loss" model for instruments measured at amortized cost. Under this model, entities will be required to estimate the lifetime expected credit loss on such instruments and record an allowance to offset the amortized cost basis of the financial asset, resulting in a net presentation of the amount expected to be collected on the financial asset. The effective date of the standard is for fiscal years beginning after December 15, 2019 with early adoption

**HOOKIPA PHARMA INC.**

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

permitted. We are currently evaluating the potential impact of the adoption of this update on our consolidated financial statements.

**3. Collaboration and Licensing Agreements**

***Gilead Collaboration and License Agreement***

In June 2018, the Company has entered into a collaboration and license agreement (the “Gilead Agreement”) with Gilead Sciences, Inc. (“Gilead”) whereby the parties agreed to collaborate with respect to two preclinical research programs to evaluate potential vaccine products for the treatment, cure, diagnosis or prevention of the hepatitis B virus (HBV) and the human immunodeficiency virus (HIV).

Under the Gilead Agreement, the Company granted Gilead an exclusive, royalty-bearing license to the Company’s technology platforms. In June 2018, the Company has received a non-refundable \$10.0 million upfront payment from Gilead of which \$0.9 million was recorded as revenue from collaboration and licensing in the three months ended March 31, 2019 and \$6.1 million was included as a liability in deferred revenues, current and non-current, as of March 31, 2019. Approximately 91% of the upfront payment included in deferred revenue as of March 31, 2019 is expected to be recognized in the remainder of 2019, and the remaining 9% 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 days payment term. In addition to the \$0.9 million recognition of the upfront payment, the Company recognized \$1.3 million revenue from cost reimbursements for research and development services in the three months ended March 31, 2019.

Sublicense fees payable to certain licensors of technologies upon the receipt of the non-refundable upfront payment, were capitalized as a contract asset and will be amortized over the period in which the revenue from the triggering payment is recognized. As of March 31, 2019 and December 31, 2018, the contract asset relating to the sublicense payment was \$0.6 million and \$0.4 million, respectively.

**4. Leases**

The Company leases real estate, including office and laboratory space and has entered into various other agreements with respect to assets used in conducting its business. The Company’s leases have remaining lease terms ranging from 2 years to 5 years. Some of the lease agreements contain rent holidays and rent escalation clauses that were included in the calculation of the right of use assets and lease liabilities.

**HOOKIPA PHARMA INC.**

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

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

	<u>Balance sheet location</u>	<u>March 31,</u> <u>2019</u>
<b>Assets</b>		
Operating lease assets	Operating lease assets	\$ 8,920
Finance lease assets	Other non-current assets	1,879
Total lease assets		<u>10,799</u>
<b>Liabilities</b>		
Current operating lease liability	Accrued expenses and other current liabilities	1,643
Current finance lease liability	Accrued expenses and other current liabilities	145
Total current lease liabilities		<u>1,788</u>
Non-current operating lease liability	Operating lease liabilities, non-current	6,311
Non-current finance lease liability	Other non-current liabilities	460
Total non-current lease liabilities		<u>6,771</u>
Total lease liabilities		<u>\$ 8,559</u>

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

The following table summarizes the effect of lease costs in the Company's condensed consolidated statements of operations and comprehensive loss:

	<u>Income statement location</u>	<u>Three months ended</u> <u>March 31, 2019</u>
Operating lease expenses	Research and development expenses	\$ 202
	General and administrative expenses	111
Finance lease amortization expenses	Research and development expenses	62
	General and administrative expenses	3
Interest on finance lease liabilities	Interest expenses	3
Sublease income	Other income (expense)	(11)
Net lease expense		<u>\$ 370</u>

**HOOKIPA PHARMA INC.**

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

The minimum lease payments, net of income from subleases, for the next five years and thereafter are expected to be as follows:

	<b>March 31, 2019</b>		
	<b>Operating lease</b>	<b>Finance lease</b>	<b>Total</b>
2019 (remaining nine months)	\$ 1,244	\$ 107	\$ 1,351
2020	1,757	142	1,899
2021	1,762	129	1,891
2022	1,762	122	1,884
2023	1,749	120	1,869
2024	128	10	138
Thereafter	—	—	—
Total lease payments	8,402	630	9,032
Less: interest	(448)	(25)	(473)
Present value of lease liabilities	\$ 7,954	\$ 605	\$ 8,559

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

<b>Year ending December 31</b>	<b>Amount</b>
2019	\$ 520
2020	278
2021	43
2022	43
2023	11
Thereafter	—
Total	\$ 895

These annual minimum lease payments did not include the embedded lease obligations under an agreement with a contract manufacturing organization, which commenced in February 2019.

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

	<b>March 31, 2019</b>
Weighted average remaining lease term in years	4.8
Weighted average discount rate (1)	2.3 %

(1) The majority of the contracts are concluded in euros. The discount rate was determined on a currency-equivalent basis.



**HOOKIPA PHARMA INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (continued)**

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

	<u>March 31,</u> <u>2019</u>
Weighted average remaining lease term in years	4.7
Weighted average discount rate (1)	1.7 %

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

The Company subleases certain of its leased real estate that it does not currently utilize to a third party. The sublease has a remaining lease terms of 2 years without an option to renew and has been qualified as an operating lease. The Company recognizes sublease income as incurred in its condensed consolidated statements of operations and comprehensive loss. The Company continued to account for the head lease as it did before sublease commencement.

Supplemental disclosure of cash flow information related to our operating and finance leases included in cash flows provided by operating activities in our condensed consolidated statements of cash flows is as follows:

	<u>Three months ended</u> <u>March 31, 2019</u>	
Cash paid for amounts included in the measurement of operating lease liabilities (1)	\$	1,260
Cash paid for amounts included in the measurement of finance lease liabilities (1)		1,355
Operating lease assets obtained in exchange for lease obligations (2)		5,233
Finance lease assets obtained in exchange for lease obligations (2)		634

(1) The cash paid for amounts included in the measurement of lease liabilities includes upfront payments

(2) The lease assets reported in the cash flow information exclude upfront payments.

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

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

	<u>March 31,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
Consulting fees	\$ 1,267	\$ 1,764
Salaries and bonuses	1,009	1,404
Social security contributions	121	121
Unearned grant income (current)	856	833
Operating lease liabilities	1,643	—
Finance lease liabilities	145	—
Other accruals and liabilities	387	298
Total	<u>\$ 5,428</u>	<u>\$ 4,420</u>

**HOOKIPA PHARMA INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (continued)****6. Loans payable**

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

	<u>March 31,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
Loans from FFG	\$ 8,151	\$ 8,316
Unamortized debt discount	(3,652)	(3,924)
Total Loans payable, net	<u>\$ 4,499</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.

**7. 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"), Series C redeemable convertible preferred stock (the "Series C Preferred Stock") and Series D redeemable convertible preferred stock (the "Series D Preferred Stock"). Series D Preferred Stock was issued in February 2019. 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 December 2017 the Company issued and sold 693,500 shares of Series C Preferred Stock at an average price of \$85.60 per share for gross proceeds of \$59.4 million. An amount of \$6.5 million of the gross proceeds from the issuance of Series C Preferred Stock was received on January 4, 2018. The Company incurred issuance costs in connection with the Series C Preferred Stock of \$0.1 million.

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

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

**HOOKIPA PHARMA INC.**

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

As of March 31, 2019, the Preferred Stock consisted of the following (in thousands, except share amounts):

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

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

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

*Conversion*

Each share of Preferred Stock was convertible, at the option of the holder, at any time, and without the payment of additional consideration, into 11.643 fully paid and non-assessable shares of common stock or non-voting Class A common stock as 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. Upon the closing of the Company's the IPO, on April 23, 2019, all outstanding redeemable convertible preferred stock converted into shares of common stock or Class A common stock, as per election of the respective holders of preferred stock.

*Liquidation*

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company or certain deemed liquidation events, the holders of Preferred Shares had a right to receive, certain amounts in preference to any distribution to the holders of common stock. The liquidation preferences of the Preferred Stock were as follows (in thousands):

	<u>March 31,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
Series A Preferred Stock	\$ 8,021	\$ 8,020
Series B Preferred Stock	34,365	34,367
Series C Preferred Stock	57,283	57,282
Series D Preferred Stock	37,432	—
	<u>\$ 137,101</u>	<u>\$ 99,669</u>

**HOOKIPA PHARMA INC.**

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

**8. Common stock**

In June 2018 the Company became the reporting entity in a transaction between entities under common control. In the accompanying condensed 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, 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. As of March 31, 2019, the Company had 1,006,595 shares of common stock outstanding and issued and was authorized to issue additional 24,608,111 shares of common stock.

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 the 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.

As of March 31, 2019 the Company was, in addition, authorized to issue 19,006,880 shares of a new class of non-voting Class A common Stock, convertible into one share of common stock for each share of Class A common stock at the election of its holder. As of March 31, 2019, the Company has not issued any shares of Class A common stock.

**9. 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 condensed 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 and 2,038,619 shares were still available as of March 31, 2019.

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

**HOOKIPA PHARMA INC.**

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

Options granted under the 2018 Stock Option and Grant Plan generally vest over four years, with 25% of the options vesting upon the first anniversary of the grant date and the remaining 75% of the options vesting in 12 equal quarterly installments following the first anniversary of the grant date, provided the option holder continues to have an employment or service relationship with the Company on each vesting date.

*2019 Stock Option and Incentive Plan*

On April 1, 2019, the Company's stockholders approved the 2019 Stock Option and Incentive Plan, which became effective as of the 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, which shall be cumulatively increased each year by up to 4.0% of the then outstanding number of shares.

*Stock option activity*

The following table summarizes the Company's stock option activity since January 1, 2019 (in thousands, except share and per share amounts):

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2018	1,606,325	\$ 1.95	8.0	\$ 13,466
Granted	—	—		
Exercised	—	—		
Forfeited	(8,687)	3.61		
Outstanding as of March 31, 2019	<u>1,597,638</u>	<u>\$ 1.94</u>	<u>7.8</u>	<u>\$ 13,410</u>
Options exercisable as of March 31, 2019	720,190	\$ 0.13	7.8	\$ 7,345
Options unvested as of March 31, 2019	877,448	\$ 3.42	7.8	\$ 6,065

The aggregate intrinsic value of stock options was calculated as the difference between the exercise price of the stock options and the estimated fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock. The estimated fair value per common stock used for calculating the intrinsic values as of March 31, 2019 and December 31, 2018, was \$10.33

No cash from option exercise was received in the three months ended March 31, 2019 and 2018, respectively.

*Stock-based compensation*

Stock-based compensation expense was classified in the condensed consolidated statements of operations and comprehensive loss as follows (in thousands):

	Three months ended March 31,	
	2019	2018
Research and development expenses	\$ 261	\$ 93
General and administrative expenses	122	113
	<u>\$ 383</u>	<u>\$ 206</u>

**HOOKIPA PHARMA INC.**

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

**10. Income taxes**

During the three months ended March 31, 2018 and 2019, the Company recorded no income tax benefits for the net operating losses incurred, 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. The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets resulting from its net operating loss carryforwards. Management has considered the Company's history of cumulative net losses incurred since inception and 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 March 31, 2019 and December 31, 2018. Management reevaluates the positive and negative evidence at each reporting period.

**11. Commitments and contingencies**

*Contract manufacturing arrangements*

The Company has entered into arrangements with contract manufacturing organizations ("CMOs") for manufacturing of materials for research and development purposes, including manufacturing of clinical trial materials. These contracts generally provide for non-cancellable obligations or cancellation penalties depending on the time of cancellation. As of March 31, 2019, the Company's total non-cancellable obligations under contracts with CMOs, excluding embedded lease liabilities, were \$14.6 million, of which \$5.9 million relate to 2019 (remaining nine months) deliverables \$6.7 million relate to 2020 deliverables and \$2.0 million relate to 2021 deliverables.

*Intellectual property licenses*

The Company has entered into certain license agreements under which it is obligated to make milestone payments upon the achievement of certain development and regulatory milestones, to pay royalties on net sales of licensed products, and to pay a percentage of the sublicense fees which the Company receives from its sublicensees.

In the three months ended March 31, 2019, the Company recorded \$0.4 million in licensing fees from intellectual property licenses as research and development expenses. These amounts mainly related to the upfront payment and a milestone payment received by the Company under the Gilead Agreement. The amounts recognized as expenses have been agreed to by the licensors but calculation of sublicensing fees on future payments may be subject to interpretation and may change until agreed to by the receiving party.

*Indemnification agreements*

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and senior management that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any claims under indemnification arrangements, and it has not accrued any liabilities related to such obligations in its condensed consolidated financial statements as of March 31, 2019 and December 31, 2019.

**HOOKIPA PHARMA INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (continued)***Legal proceedings*

At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. While it is not feasible to predict the outcome of these matters with certainty, and some lawsuits, claims or proceedings may be disposed or decided unfavorably, the Company does not expect that any asserted or un-asserted legal claims or proceedings, individually or in the aggregate, will have a material adverse effect on the Company. The Company expenses the costs related to such legal proceedings as incurred.

**12. 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):

	<b>Three months ended March 31,</b>	
	<b>2019</b>	<b>2018</b>
Numerator:		
Net loss	\$ (9,329)	\$ (4,573)
Denominator:		
Weighted-average common shares outstanding, basic and diluted	1,006,595	911,777
Net loss per share, basic and diluted	\$ (9.27)	\$ (5.02)

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 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:

	<b>Three months ended March 31,</b>	
	<b>2019</b>	<b>2018</b>
Series A Preferred Stock	1,604,574	1,604,574
Series B Preferred Stock	5,730,612	5,730,612
Series C Preferred Stock	8,074,447	8,074,447
Series D Preferred Stock	2,992,260	—
Options issued and outstanding	1,597,638	1,431,181
Total	<u>19,999,531</u>	<u>16,840,814</u>

**13. Related parties**

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

**HOOKIPA PHARMA INC.**

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

During the three months ended March 31, 2019, the Company issued 50,670 shares of Series D Preferred Stock for total proceeds of \$7.4 million to certain stockholders that were related parties.

**14. Subsequent events**

*Initial public offering*

On April 23, 2019, the Company closed its IPO of 6,000,000 shares of common stock, at an offering price to the public of \$14.00 per share. The Company received net proceeds of approximately \$74.8 million, after deducting underwriting discounts and commissions. Upon the closing of the IPO, the Company's outstanding redeemable convertible preferred stock automatically converted into shares of common stock or Class A common stock, per election of the respective holders of preferred stock. As of May 20, 2019, the Company had 21,588,756 shares of common stock and 3,819,732 shares of Class A common stock outstanding, each \$0.0001 par value per share. The related carrying value of \$142.0 million was reclassified to common stock and additional paid-in capital.

*Amended and restated certificate of incorporation*

In March 2019 and April 2019, the Company's board of directors and stockholders, respectively, approved an amended and restated certificate of incorporation that, effective simultaneous with closing of the IPO, increased 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.



## **Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations**

*The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our audited consolidated financial statements and related notes for the year ended December 31, 2018 included in our final prospectus for our initial public offering of our common stock filed with the Securities and Exchange Commission, or the SEC, pursuant to Rule 424(b)(4) of the Securities Act on April 18, 2019, which we refer to as the 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 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. On April 23, 2019, we completed an initial public offering of our common stock by issuing 6.0 million shares of our common stock, at \$14.00 per share, for gross proceeds of \$84.0 million, or net proceeds of \$74.8 million.

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

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

We currently anticipate that we will seek to fund our operations through equity or debt financings or other sources, such as government grants and additional collaboration agreements with third parties. Adequate funding may not be available to us on acceptable terms, or at all. If sufficient funds on acceptable terms are not available when

needed, we will be required to significantly reduce our operating expenses and delay, reduce the scope of, or eliminate one or more of our development programs.

We have incurred net losses each year since our inception in 2011, including net losses of \$9.3 million for the three months ended March 31, 2019 and \$4.6 million for the three months ended March 31, 2018. As of March 31, 2019, we had an accumulated deficit of \$69.3 million and we do not expect positive cash flows from operations in the foreseeable future. We expect to continue to incur net operating losses for at least the next several years as we advance our product candidates through clinical development, seek regulatory approval, prepare for and, if approved, proceed to commercialization, continue our research and development efforts and invest to establish a commercial manufacturing facility.

## **Components of Our Results of Operations**

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

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

On June 4, 2018, we entered into a Research Collaboration and License Agreement, or the Collaboration Agreement, with Gilead to evaluate potential vaccine products using or incorporating our TheraT technology and VaxWave technology for the treatment, cure, diagnosis or prevention of 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 obligated to reimburse us for our costs, including all benefits, travel, overhead, and any other expenses, relating to performing research and development activities under the Collaboration Agreement. We are also eligible to receive up to \$140.0 million in developmental milestone payments for each of the HBV and HIV programs and up to \$50.0 million in commercialization milestone payments for each of the HBV and HIV programs. Additionally, Gilead is obligated to pay royalties of a high single-digit to low-teens percentage on the worldwide net sales of each HBV product, and royalties of a mid-single-digit to low-teens percentage of worldwide net sales of each HIV product.

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

Since entering into the Collaboration Agreement, we have received from Gilead the non-refundable upfront payment of \$10.0 million discussed above and we have recognized \$3.3 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. In May 2019 we achieved a further pre-clinical milestone under the HBV program, entitling us to an additional milestone payment of \$2.0 million. During the three months ended March 31, 2019, we recognized revenue of \$2.2 million under the Collaboration Agreement, which included recognition of \$0.9 million of the upfront payment from collaboration and licensing, and \$1.3 million in cost reimbursements for research and development.

### ***Operating Expenses***

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

### ***Research and Development Expenses***

Since our inception, we have focused significant resources on our research and development activities, including establishing our arenavirus platform, conducting preclinical studies, developing a manufacturing process, conducting a Phase 1 clinical trial and initiating a Phase 2 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;

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- 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 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 primary from the losses of our Austrian subsidiary. 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 March 31, 2019.

### **Results of Operations**

#### **Comparison of Three Months Ended March 31, 2019 and 2018**

The following table summarizes our results of operations for the three months ended March 31, 2019 and 2018:

	Three months ended March 31,	
	2019	2018
Revenue from collaboration and licensing	\$ 2,235	\$ —
Operating expenses:		
Research and development	(10,179)	(4,969)
General and administrative	(2,711)	(1,480)
Total operating expenses	(12,890)	(6,449)
Loss from operations	(10,655)	(6,449)
Other income (expense):		
Grant income	1,192	2,071
Interest income	64	—
Interest expense	(213)	(193)
Other income and expenses, net	283	22
Total other income (expense), net	1,326	1,900
Net loss before tax	(9,329)	(4,549)
Income tax expense	(0)	(24)
Net loss	\$ (9,329)	\$ (4,573)

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

Revenue was \$2.2 million for the three months ended March 31, 2019, with no revenue recognized for the three months ended March 31, 2018. The increase was due to recognition of revenue under the Collaboration Agreement with Gilead. This revenue included \$1.3 million from reimbursement of research and development expenses and \$0.9 million from partial recognition of revenue related to the upfront payment of \$10.0 million that we received in June 2018.

#### **Research and Development Expenses**

For the three months ended March 31, 2019, our research and development expenses were \$10.2 million, compared to \$5.0 million for the three months ended March 31, 2018. The primary driver of the increase was direct research and development expenses of \$7.5 million. Direct research and development expenses increased primarily due to the preparation costs of clinical trials for our HB-201 and HB-202 programs and the expansion of earlier stage programs. In addition, costs related to our collaboration with Gilead contributed to the increase in direct expenses.

Personnel related research and development expenses for the three months ended March 31, 2019 and 2018 were \$1.9 million and \$1.2 million, respectively. This increase of \$0.7 million was primarily a result of our increased

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research and development headcount. In addition, an increase in other internal costs by \$0.2 million contributed to the overall increase in internal research and development expenses of \$0.9 million for the three months ended March 31, 2019 compared to the three months ended March 31, 2018.

	Three months ended March 31,	
	2019	2018
Direct research and development expenses by program:		
HB-101	\$ 1,201	\$ 1,650
HB-201/202	3,066	1,107
Gilead partnered programs <sup>(1)</sup>	758	—
Other and earlier-stage programs	2,497	425
Sub-total direct expenses	7,522	3,182
Internal research and development expenses:		
Personnel related (including stock-based compensation)	1,851	1,231
Facility related	347	302
Other internal costs	459	254
Sub-total internal expenses	2,657	1,787
Total research and development expenses	\$ 10,179	\$ 4,969

(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 three months ended March 31, 2019 and 2018 were \$2.7 million and \$1.5 million, respectively. The increase in general and administrative expenses in the three months ended March 31, 2019 was primarily due to an increase in personnel related expenses of \$0.4 million and an increase in professional and consulting fees of \$1.0 million which were partially offset by a decrease in other general administrative expenses. 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 three months ended March 31, 2019 and 2018, we recorded grant income of \$1.2 million and \$2.1 million, respectively, from grants, research incentives and imputed benefits from below market interest rates on loans from governmental agencies. The decrease in grant income of \$0.9 million in the three months ended March 31, 2019 compared to the three months ended March 31, 2018 was primarily due to the expiry of a grant from the Austrian Research Promotion Agency, or FFG, which contributed \$1.5 million to the grant income in the three months ended March 31, 2018.

#### ***Interest Expense***

Interest expenses for loans from government agencies were \$0.2 million in both, the three months ended March 31, 2019 and 2018. Interest expense was recorded at the market rate of interest, which exceeded the contractual interest.

#### **Liquidity and Capital Resources**

Since our inception in 2011, we have funded our operations primarily through private placements of our convertible preferred stock 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 March 31, 2019, we had received gross proceeds of approximately \$142.5 million from the issuance of our convertible preferred stock and \$10.9 million pursuant to the Collaboration Agreement with Gilead. On April 23, 2019, we completed an initial public offering of our common stock by issuing 6.0

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million shares of our common stock, at \$14.00 per share, for gross proceeds of \$84.0 million, or net proceeds of \$74.8 million. As of March 31, 2019, the principal amount outstanding under loans from government agencies was \$8.2 million and we had cash and cash equivalents of \$70.5 million.

We entered into various funding agreements with the FFG. The loans by FFG, or the FFG Loans, were made on a project-by-project basis and bear interest at rates ranging from 0.75% to 1.0% per annum. In the event that the underlying program research results in a scientific or technical failure, the principal then outstanding under any loan may be forgiven by FFG and converted to non-repayable grant funding on a project-by-project basis. The FFG Loans contain no financial covenants and are not secured by any of our assets.

Because the FFG Loans bear interest at below market rates we account for the imputed benefit arising from the difference between an estimated market rate of interest and the contractual interest rate as grant funding from FFG, which is included in grant income. On the date that FFG Loan proceeds are received, we recognize the portion of the loan proceeds allocated to grant funding as a discount to the carrying value of the loan and as unearned income. As of March 31, 2019, the unamortized debt discount related to FFG Loans was \$3.7 million.

We do not expect positive cash flows from operations in the foreseeable future, if at all. Historically, we have incurred operating losses as a result of ongoing efforts to develop our arenavirus technology platform and our product candidates, including conducting ongoing research and development, preclinical studies, clinical trials, providing general and administrative support for these operations and developing our intellectual property portfolio. We expect to continue to incur net operating losses for at least the next several years as we progress clinical development, seek regulatory approval, prepare for 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 March 31, 2019, we had an accumulated deficit of \$69.3 million. We expect to continue to incur significant losses for the foreseeable future. We anticipate that our expenses will increase substantially as we:

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

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- 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.

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;



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

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

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

If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, 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):

	<b>Three months ended March 31,</b>	
	<b>2019</b>	<b>2018</b>
Net cash used in operating activities:	\$ (12,056)	\$ (4,972)
Net cash used in investing activities	(400)	(262)
Net cash provided by financing activities	35,157	6,879
Net increase (decrease) in cash and cash equivalents	<u>22,701</u>	<u>1,645</u>

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

During the three months ended March 31, 2019, cash used in operating activities was \$12.1 million, which consisted of a net loss of \$9.3 million, adjusted by non-cash charges of \$1.0 million and cash used due to changes in our operating assets and liabilities of \$3.8 million. The non-cash charges consisted primarily of depreciation and amortization expense of \$0.6 million and stock-based compensation of \$0.4 million. The change in our operating assets and liabilities was primarily due to an increase of \$3.7 million in prepaid expenses and other current assets, an increase in other non-current assets of \$6.1, including \$5.9 from increases in operating lease assets, and a decreases in accounts payable and deferred revenues, partially offset by a decrease in accounts receivable of \$3.5 million and an increase of operating lease liabilities included in accrued expenses and other liabilities of \$4.7 million.

During the three months ended March 31, 2018, cash used in operating activities was \$5.0 million, which consisted of a net loss of \$4.6 million, adjusted by non-cash charges of \$0.4 million and cash used due to changes in our

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operating assets and liabilities of \$0.8 million. The non-cash charges consisted primarily of depreciation and amortization expense of \$0.1 million and stock-based compensation of \$0.2 million. The change in our operating assets and liabilities was primarily due to an increase of \$0.9 million in prepaid expenses, an increase of \$0.6 million in accounts payable and a decrease in accrued expenses and other liabilities of \$0.5 million.

***Cash Used in Investing Activities***

During the three months ended March 31, 2019, cash used in investing activities was \$0.4 million and resulted from capital expenditures in connection with an expansion of our laboratory and office space and purchase of property and equipment.

During the three months ended March 31, 2018 cash used in investing activities was \$0.3 million, 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 three months ended March 31, 2019, cash provided by financing activities was \$35.2 million, which consisted of proceeds of \$37.3 million from the issuance of shares of our Series D convertible preferred stock in February 2019, partially offset by an upfront payment for embedded finance lease assets and payments of deferred offering costs in preparation for our IPO.

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

**Off-Balance Sheet Arrangements**

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

**Contractual Obligations and Commitments**

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

	Payments Due by Calendar Year				
	Total	Remainder of 2019	2020 - 2021	2022 - 2023	Thereafter
Lease commitments	\$ 9,032	\$ 1,351	\$ 3,790	\$ 3,753	\$ 138
CMO commitments	14,588	5,929	8,659	—	—
Debt obligations	8,151	—	2,125	3,646	2,380
Total	<u>\$ 31,771</u>	<u>\$ 7,280</u>	<u>\$ 14,574</u>	<u>\$ 7,399</u>	<u>\$ 2,518</u>

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

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

## **Critical Accounting Policies**

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which we have prepared in accordance with the rules and regulations of the SEC, and generally accepted accounting principles in the United States, or GAAP. The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

Our critical accounting policies and the methodologies and assumptions we apply under them have not materially changed since our Prospectus, except for our adoption of the new leasing standards which is discussed below.

### ***Leasing***

Effective January 1, 2019, we adopted ASU No. 2016-02, Leases (Topic 842) as amended from time to time (the new leasing standards) using the modified retrospective transition approach with no restatement of prior periods or cumulative adjustment to retained earnings. Upon adoption, we elected the package of transition practical expedients, which allowed us to carry forward prior conclusions related to whether any expired or existing contracts are or contain leases, the lease classification for any expired or existing leases and initial direct costs for existing leases. We also elected the practical expedient to not reassess certain land easements and made an accounting policy election to not recognize leases with an initial term of 12 months or less within the condensed consolidated balance sheets and to recognize those lease payments on a straight-line basis in the condensed consolidated statements of operations over the lease term. Upon adoption of the new leasing standards an operating lease asset of \$3.3 million and a corresponding operating lease liability of \$3.3 million were recorded in our condensed consolidated balance sheets. The adoption of the new leasing standards did not have an impact on our condensed consolidated statements of operations.

The determination whether an arrangement was qualified as a lease was made at contract inception. Operating lease assets and liabilities are recognized at the commencement date of the lease based upon the present value of lease payments over the lease term. When determining the lease term, we include options to extend or terminate the lease when it is reasonably certain that the option will be exercised. We use the implicit rate when readily determinable and our incremental borrowing rate when the implicit rate is not readily determinable based upon the information available at the commencement date in determining the present value of the lease payments. The incremental borrowing rate is determined using a secured borrowing rate for the same currency and term as the associated lease. The lease payments used to determine operating lease assets may include lease incentives, stated rent increases and escalation clauses linked to rates of inflation when determinable and are recognized as operating lease assets on the condensed consolidated balance sheets. Certain of our arrangements contain lease and non-lease components. We applied an accounting policy choice to separate or not to separate lease payments for the identified assets from any non-lease payments included in the contract by asset class. Operating leases are reflected in operating lease assets, in accrued expenses and other current liabilities and in non-current operating lease liabilities in our condensed consolidated balance sheets. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term.

### **Recently Issued Accounting Pronouncements**

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our condensed consolidated financial statements appearing in this Form 10-Q.

### **Emerging Growth Company Status**

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

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

We are subject to the risk of fluctuations in foreign currency exchange rates, specifically with respect to the euro. Our functional currency is the U.S. dollar and the functional currency of our wholly owned foreign subsidiary, Hookipa Biotech GmbH, is the euro. Our cash and cash equivalents as of March 31, 2019 included substantial amounts of cash balances held by Hookipa Biotech GmbH in euro. We are exposed to market risk related to changes in interest rates. We had cash and cash equivalents of \$70.5 million as of March 31, 2019, which included substantial account balances with foreign banks. Interest income is sensitive to changes in the general level of interest rates; however, due to the nature of these investments, we do not believe that we have any material exposure to changes in the fair value of our investment portfolio as a result of changes in interest rates.

### **Item 4. Limitations on Effectiveness of Controls and Procedures**

The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

### **Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of our Principal Executive Officer and Principal Financial Officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act of 1934). Based on that evaluation, our Principal Executive Officer and Principal Financial Officer concluded that our disclosure controls and procedures were not effective at a reasonable assurance level as of March 31, 2019 due to the material weakness described below.

### **Material Weakness**

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.

We are in the process of implementing measures designed to improve our internal control over financial reporting to remediate these material weaknesses, including the hiring of additional qualified accounting personnel and segregating duties among accounting personnel, 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 to remediate the underlying causes of the material weaknesses.

**Changes in Internal Control Over Financial Reporting**

Other than as described above, no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) has occurred during the three months ended March 31, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II—OTHER INFORMATION

### Item 1. Legal Proceedings.

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

### Item 1A. Risk Factors

*Careful consideration should be given to the following risk factors, in addition to the other information set forth in this Quarterly Report on Form 10-Q and in other documents that we file with the SEC, in evaluating our company and our business. Investing in our common stock involves a high degree of risk. If any of the following risks actually occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.*

#### **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, and a net loss of \$9.3 million for the three months ended March 31, 2019. As of March 31, 2019, we had an accumulated deficit of \$69.3 million. We expect to continue to incur significant losses for the foreseeable future. We anticipate that our expenses will increase substantially if, and as, we:

- pursue the clinical and preclinical development of our current and future product candidates;
- leverage our technologies to advance product candidates into preclinical and clinical development;
- 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;

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- 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.

***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 March 31, 2019, we had approximately \$70.5 million in cash and cash equivalents. On April 23, 2019, we completed an initial public offering of our common stock by issuing 6.0 million shares of our common stock, at \$14.00 per share, for gross proceeds of \$84.0 million, or net proceeds of \$74.8 million. Based on our research and development plans, we expect our cash and cash equivalents at March 31, 2019, along with the proceeds from our initial public offering, 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;

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- 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;

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- 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;

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- 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 two groups of 20 patients each and future trials for HB-201 or other product candidates may similarly enroll a small number of patients. The preliminary results of trials with smaller sample sizes, such as our 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;

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- 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;

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

***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;



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- 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.

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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.

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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.

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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.

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



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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.

***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 directive 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, is involved with enforcement of the books and records provisions of the FCPA and may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions. Recently the SEC and DOJ have increased their FCPA enforcement activities with respect to pharmaceutical companies. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA.

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

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

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

our affiliates due to our loss making situation. You are urged to consult your tax adviser regarding the implications of the TCJA on an investment in our common stock.

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

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

**Risks Related to Our Intellectual Property**

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

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

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

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

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

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

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

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

Our success depends in large part on our ability to obtain and maintain patent protection with respect to our VaxWave technology, including our HB-101 product candidate, obtain patent protection with respect to our TheraT technology, including our HB-201, HB-202 and HB-301 product candidates, the vaccine product candidates we are developing with Gilead for HBV and HIV, and other proprietary product candidates. Although we own or license from others certain patent applications that cover the foregoing technologies and product candidates, we do not currently own or license from others issued patents covering all of the foregoing. Our reliance on patent applications carries certain risks associated with pending patent applications prior to the issuance of patents, as described below. If we do not adequately obtain and protect our intellectual property rights, competitors may be able to erode, negate or preempt any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we file patent applications in the United States and abroad related to our product candidates that are important to our business. The patent application and approval process is expensive and time-consuming and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We cannot predict:

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

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

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights may be uncertain. The patent applications that we own or in-

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

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

***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.

##### ***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 arrangements with the underwriters of our initial public offering.

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

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

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

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

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

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

assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

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

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

We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee 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 Ownership of Our Common Stock**

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

In April 2019, we closed our initial public offering. Prior to that offering, there was no public market for our common stock. Although we have completed our initial public offering and shares of our common stock are listed on The Nasdaq Global Select Market, an active trading market for our shares may not be sustained. You may not be able to sell your shares quickly or at the market price if trading in shares of our common stock is not active. As a result of these and other factors, it may be difficult for our stockholders to resell their shares of our common stock at or above the prices at which they acquired their shares or sell their shares at the time they would like to sell. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration.

***The price of our stock may be volatile.***

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

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

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

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

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

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



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

Our Class A common stock has no voting rights. As a result, all matters submitted to our stockholders are decided by the vote of holders of our common stock. Our executive officers, directors, and 5% stockholders beneficially owned approximately 70.0% of our outstanding voting stock immediately after our initial public 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.

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

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

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

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

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

Following the April 2019 closing of our initial public offering, we had outstanding 21,588,756 shares of common stock, of which 18,401,893 shares are subject to restrictions on transfer under 180-day lock-up arrangements with the underwriters of our initial public offering. These restrictions are due to expire on October 15, 2019, resulting in the majority of these shares becoming eligible for public sale on October 15, 2019 if they are registered under the Securities Act of 1933, as amended, or the Securities Act, or if they qualify for an exemption from registration under the

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Securities Act including under Rules 144 or 701. 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 arrangements and other legal restrictions on resale lapse, the trading price of our common stock could 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 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, and 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. In addition, new regulations and disclosure obligations may lead to additional compliance costs and may 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.

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

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

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

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

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by our board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of (i) not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action and (ii) the majority of the outstanding shares of our voting stock to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

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

directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

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

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

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

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

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

***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 the closing of our initial public offering in April 2019, we had 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.

As a public company, we are 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. 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.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.**

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, for gross proceeds of \$37.4 million. We have relied on the exemption from the registration requirements of the Securities Act by virtue of Section 4(a)(2) thereof and the rules and regulations promulgated thereunder relating to transactions not involving any public offering.

***Use of Proceeds from Initial Public Offering of Common Stock***

On April 23, 2019, we closed our initial public offering of 6,000,000 shares of our common stock at a public offering price of \$14.00 per share for an aggregate offering of \$84.0 million. The offer and sale of all of the shares in the offering were registered under the Securities Act of 1933, as amended, pursuant to registration statement on Form S-1 (File No. 333-230451), which was declared effective by the SEC on April 17, 2019. Merrill Lynch, Pierce, Fenner & Smith Incorporated, SVB Leerink LLC and RBC Capital Markets, LLC acted as joint book-running managers for the offering. The offering commenced on April 17, 2019 and did not terminate until the sale of all of the shares offered.

We received aggregate net proceeds from the offering of \$74.8 million, after deducting underwriting discounts and commissions of \$5.9 million and estimated offering expenses of \$3.3 million payable by us. None of the underwriting discounts and commissions or offering expenses were incurred or paid to directors or officers of ours or their associates or to persons owning 10% or more of our common stock or to any affiliates of ours.

We had not received any of the net offering proceeds as of March 31, 2019 and therefore, have not used any of the net proceeds from the offering. There has been no material change in our planned use of the net proceeds from the offering as described in our Prospectus dated April 17, 2019.

**Item 3. Defaults upon Senior Securities.**

None.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information.**

Not applicable.

**Item 6. Exhibits.**

The exhibits listed on the Exhibit Index immediately preceding such exhibits, which is incorporated herein by reference, are filed or furnished as part of this Quarterly Report on Form 10-Q.

<b>Exhibit Number</b>	<b>Description</b>
3.1	<a href="#">Amended and Restated Certificate of Incorporation of HOOKIPA Pharma Inc. (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K (File No. 001-38869) filed with the SEC on April 23, 2019)</a>
3.2	<a href="#">Amended and Restated By-laws of HOOKIPA Pharma Inc. (incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K (File No. 001-38869) filed with the SEC on April 23, 2019)</a>
4.1	<a href="#">Shareholders Agreement among HOOKIPA Pharma Inc. and certain of its shareholders, dated February 15, 2019 (incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K (File No. 001-38869) filed with the SEC on April 23, 2019)</a>
10.1#	<a href="#">Senior Executive Cash Incentive Bonus Plan</a>
31.1	<a href="#">Certificate of Principal Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</a>
31.2	<a href="#">Certificate of Principal Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</a>
32.1*	<a href="#">Certificate of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes Oxley Act of 2002</a>
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

# Indicates a management contract or any compensatory plan, contract or arrangement.

\* The certification furnished in Exhibit 32.1 hereto is deemed to accompany this Quarterly Report on Form 10-Q and will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference. Such certification will not be deemed to be incorporated by reference into any filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

HOOKIPA Pharma Inc.

Date: May 20, 2019

By: /s/ Joern Aldag  
Joern Aldag  
Chief Executive Officer (Principal Executive Officer)

By: /s/ Reinhard Kandra  
Reinhard Kandra  
Chief Financial Officer (Principal Financial Officer)



**HOOKIPA PHARMA INC.**  
**SENIOR EXECUTIVE CASH INCENTIVE BONUS PLAN**

1. Purpose

This Senior Executive Cash Incentive Bonus Plan (the “*Incentive Plan*”) is intended to provide an incentive for superior work and to motivate eligible executives of HOOKIPA Pharma Inc. (the “*Company*”) and its subsidiaries toward even higher achievement and business results, to tie their goals and interests to those of the Company and its stockholders and to enable the Company to attract and retain highly qualified executives. The Incentive Plan is for the benefit of Covered Executives (as defined below).

2. Covered Executives

From time to time, the Compensation Committee of the Board of Directors of the Company (the “*Compensation Committee*”) may select certain key executives (the “*Covered Executives*”) to be eligible to receive bonuses hereunder. Participation in this Plan does not change the “at will” nature of a Covered Executive’s employment with the Company.

3. Administration

The Compensation Committee shall have the sole discretion and authority to administer and interpret the Incentive Plan.

4. Bonus Determinations

(a) Corporate Performance Goals. A Covered Executive may receive a bonus payment under the Incentive Plan based upon the attainment of one or more performance objectives that are established by the Compensation Committee and relate to financial and operational metrics with respect to the Company or any of its subsidiaries (the “*Corporate Performance Goals*”), including 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 the Company’s 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 the Company’s 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 (A) measured in absolute terms or compared to any incremental increase, (B) measured in terms of growth, (C) compared to another company or companies or to results of a peer group, (D) measured against the market as a whole and/or as compared to applicable market indices and/or (E) measured on a pre-tax or post-tax basis (if applicable). Further, any Corporate Performance Goals may be used to measure the performance

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of the Company as a whole or a business unit or other segment of the Company, or one or more product lines or specific markets. The Corporate Performance Goals may differ from Covered Executive to Covered Executive.

(b) Calculation of Corporate Performance Goals. At the beginning of each applicable performance period, the Compensation Committee will determine whether any significant element(s) will be included in or excluded from the calculation of any Corporate Performance Goal with respect to any Covered Executive. In all other respects, Corporate Performance Goals will be calculated in accordance with the Company's financial statements, generally accepted accounting principles, or under a methodology established by the Compensation Committee at the beginning of the performance period and which is consistently applied with respect to a Corporate Performance Goal in the relevant performance period.

(c) Target; Minimum; Maximum. Each Corporate Performance Goal shall have a "target" (100 percent attainment of the Corporate Performance Goal) and may also have a "minimum" hurdle and/or a "maximum" amount.

(d) Bonus Requirements; Individual Goals. Except as otherwise set forth in this Section 4(d): (i) any bonuses paid to Covered Executives under the Incentive Plan shall be based upon objectively determinable bonus formulas that tie such bonuses to one or more performance targets relating to the Corporate Performance Goals, (ii) bonus formulas for Covered Executives shall be adopted in each performance period by the Compensation Committee and communicated to each Covered Executive at the beginning of each performance period and (iii) no bonuses shall be paid to Covered Executives unless and until the Compensation Committee makes a determination with respect to the attainment of the performance targets relating to the Corporate Performance Goals. Notwithstanding the foregoing, the Compensation Committee may adjust bonuses payable under the Incentive Plan based on achievement of one or more individual performance objectives or pay bonuses (including, without limitation, discretionary bonuses) to Covered Executives under the Incentive Plan based on individual performance goals and/or upon such other terms and conditions as the Compensation Committee may in its discretion determine.

(e) Individual Target Bonuses. The Compensation Committee shall establish a target bonus opportunity for each Covered Executive for each performance period. For each Covered Executive, the Compensation Committee shall have the authority to apportion the target award so that a portion of the target award shall be tied to attainment of Corporate Performance Goals and a portion of the target award shall be tied to attainment of individual performance objectives.

(f) Employment Requirement. Subject to any additional terms contained in a written agreement between the Covered Executive and the Company, the payment of a bonus to a Covered Executive with respect to a performance period shall be conditioned upon the Covered Executive's employment by the Company on the bonus payment date. If a Covered Executive was not employed for an entire performance period, the Compensation Committee may pro rate the bonus based on the number of days employed during such period.

5. Timing of Payment

(a) With respect to Corporate Performance Goals established and measured on a basis more frequently than annually (e.g., quarterly or semi-annually), the Corporate Performance Goals will be measured at the end of each performance period after the Company's financial reports with respect to such period(s) have been published. If the Corporate Performance Goals and/or individual goals for such period are met, payments will be made as soon as practicable following the end of such period, but not later 74 days after the end of the fiscal year in which such performance period ends.

(b) With respect to Corporate Performance Goals established and measured on an annual or multi-year basis, Corporate Performance Goals will be measured as of the end of each such performance period (e.g., the end of each fiscal year) after the Company's financial reports with respect to such period(s) have been published. If the Corporate Performance Goals and/or individual goals for any such period are met, bonus payments will be made as soon as practicable, but not later than 74 days after the end of the relevant fiscal year.

(c) For the avoidance of doubt, bonuses earned at any time in a fiscal year must be paid no later than 74 days after the last day of such fiscal year.

6. Amendment and Termination

The Company reserves the right to amend or terminate the Incentive Plan at any time in its sole discretion.

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO RULES 13A-14(A) AND 15D-14(A) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF SARBANES-OXLEY ACT OF 2002**

I, Joern Aldag, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of HOOKIPA Pharma Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report), that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: May 20, 2019

/s/ Joern Aldag

Joern Aldag  
Chief Executive Officer  
(Principal Executive Officer)

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**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO RULES 13A-14(A) AND 15D-14(A) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF SARBANES-OXLEY ACT OF 2002**

I, Reinhard Kandra, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of HOOKIPA Pharma Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report), that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: May 20, 2019

/s/ Reinhard Kandra

Reinhard Kandra  
Chief Financial Officer  
(Principal Financial Officer)

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**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of HOOKIPA Pharma Inc. (the "Company") for the quarterly period ended March 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Joern Aldag and Reinhard Kandra, Chief Executive Officer of the Company and Chief Financial Officer of the Company, respectively, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to their knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 20, 2019

/s/ Joern Aldag

Joern Aldag  
Chief Executive Officer  
(Principal Executive Officer)

Dated: May 20, 2019

/s/ Reinhard Kandra

Reinhard Kandra  
Chief Financial Officer  
(Principal Financial Officer)

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